



Academy of
Managed Care
Pharmacy®

April 8, 2019

Aaron Zajic
Office of Inspector General
U.S. Department of Health & Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201

Re: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of a New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees [OIG-0936-P]

Dear Mr. Zajic:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services Office of Inspector General (HHS-OIG) for the opportunity to provide comments in response to the proposed rule titled “[Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of a New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees \[OIG-0936-P\]](#)” published in the *Federal Register* on February 6, 2019.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, AMCP’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP supports the Administration’s goals to reduce prescription drug spending for consumers and to encourage drug pricing transparency within the health care system. As the Administration continues to work to encourage system transformation that promotes affordable health care, AMCP recognizes that the need to address the rising cost of prescription medications remains critical and supports competitive marketplace solutions to lower costs for Americans. AMCP continues its efforts and work with the Administration and Congress to find solutions and support proposals that achieve the goals of optimizing medication use at affordable costs. To this end, AMCP has concerns with the proposed rule to eliminate the safe harbor protections for

rebates that currently exist in the federal Anti-Kickback Statute (AKS) and replace these protections with proposed new safe harbors allowing for point-of-sale discounts to beneficiaries and for manufacturer-paid service fees to PBMs. In July 2018, AMCP provided recommendations to the Department of Health and Human Services (HHS) in response to its *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*.¹ In our comments, AMCP cautioned HHS and other agencies to proceed cautiously before making substantial changes to existing programs, including the elimination of the ability of Medicare Part D plans to collect rebates.

AMCP is concerned that the Administration's proposal to remove the safe harbor protection for rebates may result in unintended consequences for patients, payers, and providers. We generally caution HHS that focusing only on rebates is a diversion from the issues facing Medicare beneficiaries on list price of medications. The rebate system is currently an important lever to ensuring affordability of prescription medications and health care premiums for Americans, and it is unclear what would replace this important lever that payers now use to manage overall beneficiary costs. Additionally, AMCP is concerned that the Administration chose to address one single provision in the Federal AKS that has the potential to produce widespread implications on the entire health care system. AMCP also recommends that the Administration and Congress consider reforms in other regulations and laws that result in higher beneficiary costs, such as Medicaid best price provisions.

The proposal suggests that list prices would likely fall in the absence of rebates; however, there is uncertainty regarding how manufacturers will alter drug pricing should this proposal be implemented. Prior to finalizing any changes to the AKS, the full implications of this proposal must be carefully examined and tested, including the effects on beneficiary premium payments and medication costs for those who do not receive the benefit of rebates. This review is especially important considering when various analysis models within the proposal lack consistency in showing the impact on lowering of overall costs. AMCP offers additional comments and recommendations below.

HHS Should Consider the Full Implications on Cost to Beneficiaries and Taxpayers

Despite the HHS rhetoric, it is unclear how the savings could really add up without further reforms and clarification. HHS' own analyses included in the proposal suggest that net savings or costs to the Medicare Part D program and the Medicaid program at both the federal and state levels are uncertain and various models do not show consistency with lowering overall costs. HHS actuaries suggest that the impact on the federal budget could range anywhere from a savings of \$100 billion to a cost of \$35 billion. Additionally, implementation of this rule could

¹ AMCP Blueprint Comments. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=23723>. Accessed April 3, 2019.

result in premium increases in Medicare Part D by approximately \$3-\$5/month (12% - 22%)² but the potential for savings is not clearly defined in the proposal and may not benefit all patients consistently, including those who may receive single source expensive products or products in the Medicare Part D clinically protected classes, for example cancer medications. To this end, a Milliman report on prescription drug rebates and Part D drug costs found that for brand drugs with rebates, protected class drugs had the lowest average rebate at 14% of gross cost while drugs in classes with brand competition had the highest average manufacturer rebate at 39% of gross cost.³

In its proposal, HHS notes that “the effect of this rule on individual beneficiaries depends on whether they use medications, and whether the manufacturers of the drugs in their regimen are paying rebates.”⁴ AMCP recognizes that beneficiaries with high copays for prescription medications where rebates are offered could stand to experience some relief in out-of-pocket costs from the proposal; however, patients with no prescriptions or those utilizing cost-saving generics or prescription medications that are not tied to rebates could run the risk of higher out of pocket costs in premiums. The previously referenced Milliman report on prescription drug rebates and Part D drugs costs found that 81% of Part D prescriptions written in 2016 did not have manufacturer rebates.⁵ Additionally, a recent article in the *New York Times* noted that patients whose medications cost thousands of dollars may not experience significant relief from skyrocketing costs.⁶ Furthermore, the overall impact has the potential to go beyond beneficiaries as HHS actuaries suggest that federal expenditures might increase as much as \$200 billion over the next 10 years due to premium increases, affecting federal taxpayers. Overall, while this proposal has the potential to redirect dollars flowing through the Part D program to reduce costs, HHS itself notes that the actual impact from these changes is difficult to predict.

While this proposal seeks to provide beneficiaries with discounts at the point of sale, it may be a disincentive to the use of generic and more affordable alternatives. For example, if a beneficiary

² Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. [Vol. 84] Federal Register [No. 25] February 6, 2019. Table 2.A. Pg. 2357.

³ Johnson NJ, Mills CM, Kridgen M. Milliman Report. Prescription Drug rebates and Part D drug costs. July 16, 2018. Available at: <https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf>. Accessed on April 4, 2019.

⁴ Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. [Vol. 84] Federal Register [No. 25] February 6, 2019. Table 2.A. Pg. 2357.

⁵ Johnson NJ, Mills CM, Kridgen M. Milliman Report. Prescription Drug rebates and Part D drug costs. July 16, 2018. Available at: <https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf>. Accessed on April 4, 2019.

⁶ Abelson R, Thomas K. How Trump’s latest plan to cut drug prices will affect you. *New York Times*. February 5, 2019. Available at: <https://www.nytimes.com/2019/02/05/health/drug-prices-rebates-sotu.html>. Accessed February 6, 2019.

is aware that a high cost medication is associated with a steep discount to them, it may be a disincentive to use a more affordable medication and the overall net cost paid by a plan sponsor and the pharmacy may be greater than using the lower cost agent. Overall, the impact could be increased Medicare spending by beneficiaries and the government.

HHS Should Not Eliminate Rebates Used in Value-Based Contracting

AMCP supports the Administration's commitment to move the health care system towards value-based care as it is a primary strategy for improving patient care while managing costs. Implementation of effective, outcomes-driven, value-based contracting strategies remains a key focus area for AMCP and its members. In its proposal, HHS indicates that "The Department does not intend for this proposal to have any effect on existing protections for value-based arrangements between manufacturers and plan sponsors under Medicare Part D and Medicaid MCOs."

However, as proposed, the rule would significantly curtail PBM flexibility in administering rebates and, therefore, restrict the use of and growth of value-based arrangements. If finalized as currently drafted, the rule would appear to implicate most outcomes-based payments given that they are not (1) a flat fee paid to a PBM; nor (2) passed through at the point-of-sale. Despite numerous initiatives signaling an intention to increase the use and scope of value-based arrangements, the Administration is proposing to curtail a tool (rebates) that has shown essential in promoting and recognizing value. To safeguard the Administration's intent to advance value-based care, AMCP urges HHS OIG to propose and adopt a safe harbor that provides protection for value-based arrangements, including those that rely on rebates to recognize value.

Value-based contracts (VBCs) have emerged as a mechanism that payers may use to better align their contracting structures with broader changes in the health care system. Establishing a safe harbor for VBCs would help to remove the regulatory uncertainty that currently stands as an obstacle to broader adoption of VBCs. The safe harbor should include a wide range of services to not only address the current construct of VBCs, but also to encourage best practices for future innovation as new advancements in health care are introduced. Examples include but are not limited to: interventions that improve medication utilization to promote better outcomes, mobile health products provided to the patient, and analytics related to the potential impact on outcomes and costs for certain patient populations. As another solution, the OIG could issue an opinion or guidance that VBCs do not invoke the Federal Anti-Kickback Statute or clarification of the requirements of the discount safe harbor that would help address this barrier.

HHS Should Provide Clarification on Chargeback Process and Allow Longer Timeline for Implementation

HHS proposes to implement a discount safe harbor under the Federal Anti-Kickback Statute that would allow for discounts to be provided to beneficiaries at the point of sale through a chargeback or series of chargebacks at the pharmacy counter. The new proposal would require an entire re-working of the current drug supply chain system that has been in place for over thirty years and the full implications and responsibilities of each party in this section, including manufacturers, pharmacies, and plans have not been fully considered. Further guidance, including technical guidance for Medicare Part D plans from CMS, is necessary for stakeholders to test a new system for successful implementation. CMS would also have to change the Part D rules related to pharmacy payment and benefit design.

If fully implemented, the proposed rule would take effect beginning on January 1, 2020, but HHS notes that manufacturers may even make changes sooner than that date. The proposal would require manufacturer, pharmacy, and client contracts to be opened and renegotiated with very little time between the issuance of a final rule and the implementation date. Additionally, Part D 2020 bids are due to CMS on June 3, 2019. On April 5, 2019, CMS issued a memo on guidance regarding Part D bids should the proposal be finalized to include a change in the safe harbor rules effective in 2020.⁷ According to this guidance, CMS will conduct a voluntary two-year demonstration that would test an efficient transition for beneficiaries and plans to such a change in the Part D program. The guidance notes that under the demonstration, further guidance regarding the application process would be provided later. AMCP strongly recommends that if the proposal is finalized, the implementation date should be delayed, at the very least, until after CMS testing through the demonstration model has been completed and further guidance on preparing for the bid process has been provided to Part D plans by CMS.

It is highly unlikely that the short implementation timeline will allow for adequate preparation to successfully implement a chargeback transaction and allow for any possible technology and workflow changes by manufacturers, plans, and pharmacies that may be needed for seamless implementation by January 1, 2020. This is concerning as unintentional administrative burdens could result in delays for beneficiaries at the pharmacy counter.

HHS Should Not Promote Congressional Action to Eliminate Rebates in Commercial Markets Until the Concerns about the Proposed Rule are Considered

⁷ Centers for Medicare and Medicaid Services. Guidance regarding Part D bids. April 5, 2019. Available at: file:///C:/Users/awagner/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/EIDMGDSI/HPMS_Memo_Providing_Bidding_Guidance_04052019_final_v2.pdf. Accessed on April 5, 2019.

During a recent speech before the Bipartisan Policy Center, HHS Secretary Alex Azar noted that expansion to commercial insurance markets will require Congress to pass a law.⁸ Congress has introduced legislation to expand these provisions to the commercial market. However, AMCP cautions against HHS further promoting this option until it fully considers comments on the proposed rebate changes for federal government programs and makes changes based on these comments.

HHS Should Remove Medicaid Managed Care from Inclusion in its Proposed Rule

The HHS proposal, as written, would apply to both Medicare Part D plans and Medicaid managed care plans – two considerably different markets. Medicaid beneficiaries largely have zero dollar or low-cost sharing for prescription medications, and it is unclear how the proposal would benefit this population who does not have cost sharing on prescription medications. Rather, elimination of rebates for Medicaid managed care organizations could result in increased administrative costs for Medicaid managed care plans that states and the federal government would have to subsidize. In fact, the Center for Medicare & Medicaid (CMS) Office of the Actuary (OACT) estimated a net increase in Medicaid drug spending of \$200 million over 10 years if the proposal is finalized.⁹

Furthermore, under the provisions in the proposed rule, states may still negotiate supplemental rebates in Medicaid fee-for-service. This situation could result in a disincentive for Medicaid managed care organizations to manage total cost of care, including prescription drug costs, by shifting management to states. This situation would be contrary to the goals of promoting value-based care because directly managing medication costs are an integral component of whole person care.

Conclusion

While AMCP remains a strong proponent of developing solutions to reduce patients' out-of-pocket costs, we are concerned that this proposal is not the right approach. Instead, we urge HHS to consider reforms in other regulations and laws that result in higher beneficiary costs, such as Medicaid best price provisions and a comprehensive examination of the AKS, that would lead to its goal of lowering out-of-pocket costs for beneficiaries. AMCP also suggests that CMS publish

⁸ Alonso-Zaldivar R. Trump health chief asks congress to pass drug discount plan. US News & World Report. February 1, 2019. Available at: <https://www.usnews.com/news/politics/articles/2019-02-01/prescriptiondiscounts-channeled-to-patients-in-trump-plan>. Accessed on February 6, 2019.

⁹ Centers for Medicare and Medicaid Services. Proposed Safe Harbor Regulation. August 30, 2018. Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>. Accessed on April 5, 2019.

the results of its demonstration model prior to implementing any changes to the rebate provisions.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer