

April 8, 2019

SUBMITTED ELECTRONICALLY VIA
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Daniel R. Levinson
Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue SW
Washington, DC 20201

RE: 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; OIG–0936–P

Dear Mr. Levinson:

The American Geriatrics Society (“AGS”) appreciates the opportunity to submit comments on the Department of Health and Human Services (HHS) proposed rule entitled 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 (“Proposed Rule”).¹

Founded in 1942, the American Geriatrics Society (AGS) is a nationwide, not-for-profit society of geriatrics healthcare professionals dedicated to improving the health, independence, and quality of life of older people. Our nearly 6,000 members include geriatricians, geriatric nurses, social workers, family practitioners, physician assistants, pharmacists, and internists who are pioneers in advanced-illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons. The Society provides leadership to healthcare professionals, policymakers, and the public by implementing and advocating for programs in clinical care, research, professional and public education, and public policy that can support us all as we age.

In the Proposed Rule, HHS sets forth three proposals:

1. To exclude from the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a prescription pharmaceutical product manufacturer to Part D plan sponsors, Medicaid managed care organizations (MCOs), or their pharmacy benefit managers (PBMs);

¹ 84 Fed. Reg. 2340 (Feb. 6, 2019).

2. To adopt a new safe harbor that would protect point-of-sale price reductions offered by manufacturers on certain prescription pharmaceutical products payable under Medicare Part D or by Medicaid MCOs (“point-of-sale price reduction safe harbor”); and
3. To adopt a new safe harbor that would protect fixed fees that manufacturers pay to PBMs for services rendered to manufacturers that meet specified criteria (“PBM service fees safe harbor”).

We appreciate the Administration’s focus on lowering out-of-pocket costs for prescriptions, and hope that this proposal represents a step toward ensuring that patients are the direct beneficiaries of at least some of the more than \$16 billion rebate dollars paid by manufacturers into the Federal market each year.² We strongly believe that the current rebate system for medicines is not working in the best interest of patients, and we welcome a change that is meant to focus the benefits of competition within the healthcare industry on patients. However, we urge HHS to be thoughtful about implementing the Proposed Rule, and to be cautious about making changes that might inadvertently raise patient costs or lead to decreased patient access to medically necessary medicines.

We urge HHS to consider the following comments and recommendations in the final rule:

- AGS recommends that HHS monitor any finalized changes to ensure that patient cost sharing does not increase.
- AGS recommends that HHS work with Congress to extend the changes proposed to the commercial market.
- AGS recommends that HHS monitor any finalized changes to ensure that as a result of system changes, Part D plans, Medicaid MCOs, and their PBMs do not impose additional utilization management on prescription drugs and further restrict patient access to medicines.
- AGS recommends that HHS communicate any finalized changes to beneficiaries in a patient-friendly manner.
- AGS urges HHS to clarify how point-of-sale price reductions would apply during each phase of a beneficiary’s cost sharing obligation, including during periods of 100% beneficiary cost sharing.
- AGS recommends that HHS require that additional information regarding patient cost sharing be communicated to the patient in order to increase transparency.

I. HHS Monitoring to Ensure No Patient Harm Occurs as a Result of Any Changes

While AGS supports HHS’s efforts to reduce out-of-pocket costs, we recognize that there are a multitude of unknowns about both the practical implementation of the Proposed Rule and the reaction of market factors to HHS finalizing the Proposed Rule. In particular, AGS is concerned that higher premiums resulting from the proposed changes could have a detrimental effect on beneficiaries’ access to medically necessary medicines.³ Despite HHS’s statement that “lower out-of-pocket costs may lead to

² CMS, 2014 Part D Rebate Summary for All Brand Name Drugs, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2014_PartD_Rebates.html (finding that the total brand name drug rebates in 2014 was \$16,268,249,791).

³ See 84 Fed. Reg. at 2358 (stating that “[a]ll analyses that assumed no behavioral changes that would reduce net prices below current net prices saw Part D premiums increase in 2020 and beyond. The increase in 2020 Part D premiums ranged from \$3.20 per beneficiary per month to \$5.64 per beneficiary per month (PBPM).”).

fewer enrollees abandoning prescription drugs,”⁴ we urge HHS to monitor patient access and patient care to ensure that there are no detrimental effects on patient health as a result of the proposed changes.

II. Increased Transparency at the Pharmacy Counter

AGS is pleased to hear that HHS anticipates that “the enhanced transparency of premiums, out-of-pocket costs and improved formulary designs will help beneficiaries make more actuarially favorable decisions.”⁵ However, we urge HHS to monitor whether its prediction comes to fruition. Additionally, to help patients make actuarially favorable decisions, we urge HHS to facilitate increased transparency at the pharmacy counter. It would benefit patients to have additional information about the cost of their medicines. For example, a patient is informed of his or her out-of-pocket cost for a given prescription at the time the patient picks up a prescription. But additional information provided to the patient about the costs of his or her medicine could help the patient make better-informed financial decisions.

III. Communicating Changes to Beneficiaries

AGS acknowledges that the Proposed Rule may have a substantial impact on Federal beneficiaries, and we encourage HHS to communicate the finalized changes to patients in an easy-to-understand format. The Proposed Rule would directly affect beneficiary out-of-pocket costs, and so the beneficiaries themselves should have access to explanatory material about those changes that will help them make informed decisions about their health care.

IV. Extension of the Proposed Changes to the Commercial Market

HHS requests comments on the potential effects that the proposed amendments to the current discount safe harbor and the proposed safe harbor for point-of-sale price reductions might have on commercial markets.⁶ AGS believes that the changes proposed in the Proposed Rule should apply not only to Medicare and Medicaid plans, but to other Federal program plans as well as to health plans in the commercial market. Limiting the proposed changes to only certain sectors would prolong the incentives in all other sectors and could prevent manufacturers from lowering list prices and/or providing point-of-sale price reductions. Eliminating the current rebate incentives in all market sectors will help reduce patient out-of-pocket costs, which in turn will improve patient access, adherence, and overall health outcomes.

V. Monitoring the Increased Use of Utilization Management

In the Proposed Rule, HHS explains that one analysis, conducted by Milliman, found that it is possible that Part D plan sponsors or their PBMs will choose to increase utilization management as a result of the changes contemplated in the Proposed Rule.⁷ This analysis concerns AGS, and we therefore urge HHS to

⁴ 84 Fed. Reg. at 2355.

⁵ 84 Fed. Reg. at 2355.

⁶ 84 Fed. Reg. at 2344.

⁷ 84 Fed. Reg. at 2360.

monitor the ongoing implementation of the Proposed Rule to ensure that Part D plan sponsors or their PBMs do not impose additional, and unnecessary, utilization management.

The burden and potential barriers to access imposed on vulnerable older adults caused by utilization management, such as prior authorization, cannot be emphasized enough. Vulnerable, older adults with limited cognition, health literacy, and physical abilities can be negatively impacted by utilization management. For example, it could be especially difficult for these adults to navigate a long and complicated prior authorization process. Additionally, imposing utilization management on medically necessary medicines could prevent older patients from accessing those medicines in a timely manner, which could result in treatment interruptions, decreased adherence, and worse patient outcomes.

Furthermore, AGS recognizes that the use of utilization management is often motivated not by clinically appropriate decision-making, but as a mechanism for plan sponsors and PBMs to leverage higher discounts from drug manufacturers. Under the proposed safe harbor for point-of-sale price reductions, if manufacturers are able to condition point-of-sale price reductions on formulary placement, the incentives for plan sponsors and their PBMs to employ utilization management as a tool to negotiate higher discounts remain intact. Although AGS does not oppose the negotiation of price reductions contingent on formulary placement, for the reasons above, we urge HHS to monitor the implementation of the Proposed Rule to ensure there is not increased use of utilization management.

VI. Clarifying the Application of the Proposed Rule on Patient Cost Sharing Obligations

In the Proposed Rule, HHS does not clarify how manufacturer point-of-sale price reductions would be applied to patient cost sharing obligations (*e.g.*, during periods of 100% patient cost sharing or when the patient cost sharing amount is less than the applicable price reduction). To facilitate clarity regarding the application of point-of-sale price reductions to patient cost sharing, we recommend that HHS describe such application in the final rule, either in regulatory text or in preamble language.

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Thank you for your attention to these comments. Please contact Alanna Goldstein at (212) 308-1414 or agoldstein@americangeriatrics.org if you have any questions.

Sincerely,



Laurie Jacobs, MD, AGSF
President



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