



April 8, 2019

Daniel Levinson
Office of Inspector General
Department for Health and Human Services
Cohen Building, Room 5527
330 Independence Ave, 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,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Office of the Inspector General's (OIG) proposed rule regarding 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. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College commends the Administration for taking a continued interest in addressing the issue of prescription drug costs and expressing a willingness to consider a broad range of proposals in order to create a more sustainable marketplace and lower costs for our patients. The issue of rising prescription drug prices is of particular interest for physicians as prescription

drugs comprise one part of a physician's comprehensive toolkit and have been crucial in improving the health and lives of millions of our patients. As the rising cost of drugs increasingly pose a barrier to the adherence of recommended treatment plans, ACP is concerned that the status quo will result in patients developing more serious health conditions, and in turn, significantly impact a patient's quality of life and add additional financial strain to the nation's health care system.

Current fraud and abuse laws, like the Anti-Kickback Statute (AKS), are crucial in preserving the integrity of federal health care programs. AKS has been critical in protecting the integrity of the Medicare program by reducing fraud and abuse, preventing corrupt medical decision making, and ensuring taxpayers' resources are utilized effectively in the provision of necessary care. Under current law, AKS prohibits soliciting or receiving anything of value in return for the referral, recommendation, or arrangement of any item or service paid for in part by a federal health care program. However, OIG has previously issued safe harbor exceptions that protect the transmission of rebates between pharmaceutical companies and pharmacy benefit managers (PBMs) and prevents them from being considered a "remuneration" under AKS.

ACP appreciates the points of concern that OIG raises regarding the financial burden placed on federal health care programs and their beneficiaries as a result of the current safe harbor protecting rebates to PBMs. In the current system, these rebates are paid to PBMs after the point of sale. Since Medicare Part D beneficiary cost sharing is based on the up front list price, and not the lower negotiated price that accounts for the rebate, OIG asserts that beneficiaries are stuck with artificially high costs for drugs. Similarly, as rebates and discounts paid by manufacturers to PBMs are excluded from the average manufacturer price (AMP) and best price in the current formula that manufactures must pay in rebates to Medicaid, OIG contends the Medicaid program is deprived of lower costs or higher rebates.

The College also appreciates the Agency's concern that rebates to PBMs can create an environment ripe with perverse financial incentives for both PBMs and pharmaceutical companies. OIG argues that because PBMs are often paid by insurers based on discounts obtained, an incentive exists to increase list prices in order to realize a larger discount, in turn increasing revenue for the PBM. Further, pharmaceutical companies are also incentivized to use rebates as leverage to obtain favorable formulary placements. ACP strongly believes that decisions about which drugs are chosen for formulary inclusion should be based upon the drug's effectiveness, safety, and ease of administration, rather than solely based on cost or other financial arrangements, such as rebates.

OIG Proposals

In an attempt to address these concerns, OIG proposes three major provisions in this rule:

1. **Amend the Discount Safe Harbor:** The existing safe harbor that currently protects rebates would be amended so that it would not protect price reductions from manufacturers to plan sponsors under Part D or Medicaid MCOs either directly or through PBMs. The discount safe harbor would continue to protect discounts offered to other entities, including wholesalers, hospitals, physicians, pharmacies, and third-party payers in FHPs.
2. **Create New Safe Harbor for Certain Price Reductions on Prescription Pharmaceutical Products:** A new safe harbor would be created that protects point-of-sale price reductions offered by manufacturers either directly or through PBMs on certain drugs that are payable under Part D or Medicaid MCOs and meet certain criteria. The price reduction must be fixed and disclosed in writing to the plan sponsor by the time of initial purchase. Further, it may not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or series of chargebacks. Additionally, the reduction in price must be completely reflected in the price the pharmacy charges to the beneficiary at the point of sale.
3. **Create New Safe Harbor for Certain PBM Service Fees:** A new safe harbor would be created that protects fixed fees manufacturers pay to PBMs for services the PBMs provide to the manufacturers, for the manufacturers' benefit, when those services relate in some way to the PBMs' arrangements to provide pharmacy benefit management services to health plans. A written agreement would be required that covers specifics of services provided and compensation received. Compensation must be consistent with fair market value in an arm's-length transaction, be fixed and not a percentage of sales, and not take into account the volume or value of referrals or business generated between the parties. PBMs must also disclose in writing each health plan with which it contracts at least annually, and to the Secretary upon request, the services it rendered to manufacturers.

ACP Comments

The College supports the Administration's goals and intentions of lowering prescription drug prices and increasing access to vital prescription medications for federal health care program beneficiaries while acknowledging the need for a strong pharmaceutical market that fosters investment in and development of new treatments. **We believe that transparency in the pricing, cost, and comparative value of all pharmaceutical products, including disclosure of actual material and production costs to regulators, is a necessary principle in any policy**

solution to drug pricing. Specifically, ACP strongly advocates for stringent government regulation and industry self-regulation of PBMs and the public disclosure to patients, physicians, and insurers of the financial relationships between PBM companies and pharmaceutical manufacturers. The provisions in the proposed rule take a step towards increased price transparency.

With that in mind, we have concerns around the uncertain effects of the proposal as well as the feasibility of the implementation timeline as proposed. As the proposed rule itself acknowledged, it is difficult to predict the strategic behavior changes various stakeholders may make as a result of the provisions in the rule. Numerous analyses of the proposal conducted by the Centers for Medicare and Medicaid Services' (CMS) Office of the Actuary (OACT), as well as two independent actuarial firms, concluded that while beneficiary cost sharing would decrease, premiums would increase, and the two would more or less offset each other. So while those beneficiaries with high prescription drug costs, such as those on specialty medications or those with chronic conditions who take multiple medications, may see some relief, others who do not utilize the prescription drug benefit will be paying more for no additional benefit as all beneficiaries' premiums would go up since rebates could no longer be used to lower them. Further, while it may benefit Medicare beneficiaries on the whole, it does not give much consideration to how these changes would affect the private market, which is a larger share of plans than Medicare Part D.

There is even more uncertainty surrounding how the rule would impact aggregate federal spending. Given that the federal government directly subsidizes Part D premiums, actuary estimates predict government spending would rise en masse by shifting the rebate savings to the point of sale. However, after accounting for behavioral changes by pharmaceutical companies or Part D plans, these forecasts find conflicting results: between 2020 through 2029, one analysis projects a decrease of \$99.6 billion in federal spending while another projects an increase of \$139.9 billion in federal spending. Hence, without being able to predict how all the stakeholders will alter their behaviors as a result of these policies, it is impossible to predict whether these drastic measures will achieve the Administration's goal of reducing prescription drug list prices.

ACP is also worried that the aggressive implementation timeline may be impractical. As proposed, the elimination of the existing discount safe harbor for rebates and creation of the two new safe harbors would become effective beginning January 1, 2020. Implementing this rule will completely upend the pharmaceutical drug industry and will not be as easy as simply allowing the rebates to pass through. Given the tight turnaround times for this proposal, as well as other recently proposed prescription drug rules that, if finalized, may impact the industry around the same time, it may be infeasible for stakeholders to successfully and effectively implement these changes. **The College urges OIG to take the time to ensure that the policies they are proposing, and ultimately finalizing, are thoughtful and meticulous in how they are**

implemented to protect patient access to prescription drugs. Enough time must be given in implementing the rule to address any legal challenges and concerns and to address any major logistical issues that stakeholders may face as a result of these significant changes.

Conclusion

We appreciate the opportunity to provide comments on this proposed rule and urge OIG to take into account all of the effects that any finalized rule would have on federal health care programs and their beneficiaries' access to prescription drugs. Although manufacturers are solely responsible for setting their price, it is important to keep in mind that other factors (i.e. PBMs, payers, physicians, regulations, patents, etc.) play a role in how manufacturers set them, regardless of other motivations. Hence, any solution addressing the many issues surrounding prescription drug pricing cannot be as straightforward as unilateral action by a single actor—it will require concessions by all stakeholders. Please contact Brian Outland, PhD by phone at 202-261-4544 or email at boutland@acponline.org if you have any questions or need additional information.

Sincerely,

A handwritten signature in black ink that reads "Jacqueline W. Fincher MD". The signature is written in a cursive, flowing style.

Jacqueline W. Fincher, MD, MACP
Chair, Medical Practice and Quality Committee
American College of Physicians