



April 2, 2019

Department of Health and Human Services
Office of Inspector General
Attention: OIG-0936-P
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 New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees" (RIN 0936-AA08; OIG-0936-P)

To Whom It May Concern:

The Alliance for Transparent and Affordable Prescriptions (ATAP) consists of twenty-three patient and provider groups who are concerned about the role pharmacy benefit managers (PBMs) play in the rising cost of drugs and reduced patient access. As providers and patients, we know firsthand how increasing out-of-pocket costs are putting needed treatments out of reach for many Americans. We appreciate the Administration's various efforts to reduce the cost of drugs for patients who need them.

Summary

Currently, rebate payments by pharmaceutical manufacturers to PBMs and plans are not considered "kickbacks." The proposed regulation seeks to change that. Specifically, the regulation, if finalized, would eliminate safe harbor protection from antikickback law for rebates paid on prescription drugs by manufacturers to plan sponsors under Medicare Part D and Medicaid Managed Care Organizations. Thus, going forward, these payments would be considered kickbacks. Further, the proposed rule would add two new safe harbors. The first would protect discounts given at the point of sale to beneficiaries. The second would protect certain flat fees pharmaceutical manufacturers pay to PBMs for services.

As we have expressed in comment letters on other proposals, ATAP is deeply concerned about the incentives inherent in our current pharmaceutical supply chain. First, we are concerned that the rebates paid by pharmaceutical manufacturers to PBMs are resulting in formulary design decisions that are based on the potential size of the rebate rather than the clinical value of a product. Second, our current system encourages high list prices, as those maximize rebate potential for the PBM. Finally, we are concerned that patients' cost-sharing is based on those artificially high list prices, which do not reflect rebates. As such, we strongly support the Office of the Inspector General's proposal to outlaw these arrangements. Further detail is below.

I. Formulary Design

Ideally, formularies would be designed based on the latest medical and scientific information, encouraging patients and their providers to use the covered product that is most clinically effective and cost-effective. By contrast, our current system is such that the patient is encouraged to use the product that provides the most rebate potential to the PBM. Throughout the proposed rule, OIG highlights that the current rebate structure may actually result in PBMs placing more expensive products in a preferred formulary position over less expensive equivalents. This is because a more expensive product generates a higher rebate. This system benefits no one but the PBM.

Eliminating the rebates would go a long way to solving this issue. In a system without rebates, pharmaceutical companies would compete on the actual price and clinical value of the product rather than the product's potential profitability for the middlemen. Formularies are often the basis for other utilization management techniques. Thus, ensuring they are sensibly designed may lead to more rational utilization management as a downstream benefit. While additional reforms are needed to correct our supply chain, eliminating rebates and their detrimental impact on formulary design would result in a simplified, more transparent, and streamlined system.

II. High List Prices

The current rebate system encourages pharmaceutical manufacturers to set high list prices, as these prices are just the starting point of negotiations with the PBM. OIG notes that this system is a "potential barrier to lowering drug costs." Given the well-documented problems that patients across this country are experiencing with prescription drug affordability, any barrier to the lowering of costs must be eliminated.

The Senate Finance Committee recently held a hearing that was instructive on the issue of list versus net prices.¹ The hearing featured seven pharmaceutical company executives as witnesses. Across the board, these individuals testified that the rebates and discounts provided across their portfolios of products have risen in recent years. A sample of quotes from three of their statements illustrates this point:

- The CEO of AstraZeneca testified that the company's "average rebate is nearly 50% of our gross revenues in the U.S."²

¹ Senate Finance Committee, "Drug Pricing in America: A Prescription for Change, Part II" (February 26, 2019).

² Testimony of Pascal Soriot, Executive Director and CEO, AstraZeneca, <https://www.finance.senate.gov/imo/media/doc/26FEB2019SORIOT-ASTRAZENECA.pdf>.

- The CEO of Bristol-Myers Squibb testified that, in 2018, the average net pricing across the company's U.S. portfolio "did not increase and we anticipate the same in 2019."³
- The CEO of Merck testified that, "[O]ur average net price declined in 2017 by almost 2 percent. In 2017, the average discount for our medicines and vaccines was more than 45 percent lower than the list price."⁴

If net prices are flat or even declining, why do patients have more trouble than ever affording the medicines they need? The answer is that little of these savings make it to patients, because the "savings" are absorbed by the middlemen as revenue. Rebates are not savings for patients; they are income for PBMs. Solving this requires elimination of the current rebate structure.

III. Cost-Sharing

Perhaps the most offensive aspect of the entire system is that the artificially high list prices are fictional numbers for everyone except the patient, whose coinsurances are based on those prices. The higher the list price, the higher the coinsurance. And, as noted above, the current structure creates an incentive for high list prices. There is little evidence that patients benefit from the rebates and discounts negotiated between PBMs and manufacturers. For these reasons, as the rule correctly states: this system "works to the disadvantage of beneficiaries[.]"

The proposed rule seeks to eliminate rebates and instead encourage direct discounts to beneficiaries. While we have always supported a mandatory pass-through of rebates, such a pass-through is only necessary if one assumes the rebate structure continues to exist. With the proposed elimination of manufacturer-to-PBM rebates, it is our hope that manufacturers will compete based on their prices and direct discounts to patients and thus reduce prices and out-of-pocket costs to patients. We do not rule out the need for a requirement on manufacturers in the future, but understand this is outside the scope of the proposed regulation.

Impact

We would be remiss if we did not acknowledge the varying estimates of the financial impact on beneficiaries contained in the proposed rule. As the OIG states, it is difficult to accurately predict the behavioral response by stakeholders. Thus, the proposed rule provides different scenarios with varying impacts on both beneficiaries and the federal government, assuming no behavioral response. Overall, it appears that premiums would rise, but cost-sharing reductions will more than offset that increase. The OIG notes that: "the amount saved by reducing cost-sharing exceeds the cost of increasing premiums for beneficiaries overall." Further, the proposed regulation states that "out-of-pocket impacts are likely to vary by individual and the greatest benefit of these transfers accrues to sicker beneficiaries (e.g., those with more drug spending and/or those using high-cost drugs)."

³ Testimony of Giovanni Caforio, M.D., Chairman and CEO, Bristol-Myers Squibb, <https://www.finance.senate.gov/imo/media/doc/26FEB2019CAFORIO-BRISTOLMYERSQUIBB.pdf>.

⁴ Testimony of Kenneth Frazier, Chairman and CEO, Merck, <https://www.finance.senate.gov/imo/media/doc/26FEB2019FRAZIER-MERCKCO.pdf>.

In other words: the proposed regulation would cause a small increase in premiums across the program for all beneficiaries so that beneficiaries with high drug costs can experience significant out-of-pocket savings. This is the very concept of health insurance.

Closing

ATAP thanks the Administration for beginning to correct the perverse incentives in our drug supply chain that have caused sharply increasing list prices and ever-climbing out-of-pocket burdens for patients. We support elimination of the antikickback safe harbor for rebate payments from pharmaceutical manufacturers to PBMs. We also encourage the Administration's vigilance to ensure that arrangements mimicking rebates do not crop up in their place. ATAP supports allowing manufacturers to provide discounts directly to patients at the point-of-sale and notes that this reform will remove barriers to manufacturers lowering drug prices.

While we acknowledge the OIG's jurisdictional limitations, we urge the Administration to find a way to extend these reforms to commercial markets as well. The perverse incentives outlined herein exist outside federal programs as well. Holistically fixing our drug supply chain will require reform of all markets.

Thank you for consideration of these comments. Should you have any questions, please do not hesitate to contact any of the undersigned organizations.

Sincerely,

American Association of Clinical Urologists
American College of Rheumatology
Association of Women in Rheumatology
California Rheumatology Alliance
Coalition of State Rheumatology Organizations
Florida Society of Rheumatology
Global Healthy Living Foundation
International Foundation for Autoimmune & Autoinflammatory Arthritis
Lupus and Allied Diseases Association, Inc.
National Infusion Center Association
National Organization of Rheumatology Managers
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Rheumatology Alliance of Louisiana
Rheumatology Nurses Society
South Carolina Rheumatism Society
Tennessee Rheumatology Society
U.S. Pain Foundation