

April 8, 2019

Daniel Levinson
Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building
330 Independence Avenue S.W., Room 5527
Washington, DC 20201

Re: RIN 0936-AA08, 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; Proposed Rule (Vol. 84, No. 25), February 6, 2019.

Dear Mr. Levinson:

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 Department of Health and Human Services' (HHS) Office of Inspector General's (OIG) proposed rule that would change drug discount safe harbors.

Specifically, the agency proposes to amend an existing safe harbor under the federal anti-kickback statute (AKS) that protects from liability certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D and Medicaid managed care organizations (MCOs), or pharmacy benefit managers (PBMs) under contract with those programs. Additionally, the proposal would create two new safe harbors. The first would protect price reductions that are provided at the point-of-sale and the second would protect certain fees paid by pharmaceutical manufacturers for PBM services provided to them.

The AHA appreciates the administration's continued efforts to lower prescription drug prices. The high price of prescription drugs creates significant challenges for patients and the providers who care for them. **While we are supportive of the intent of OIG's**



proposed rule to lower drug prices, we cannot support the specific provisions set forth in the proposal. Rebates are an important negotiating tool for PBMs and plan sponsors, and the removal of the safe harbor protection that currently exists is likely to negatively impact Medicare Part D beneficiaries and the providers who care for them. **In addition, the proposed rule fails to address the core issue at play – high and rising drug prices.** If finalized, it also is likely to result in adverse impacts to patient access to affordable health care as a result of premium increases, and we are concerned with the potential implications for other federal programs, like the Medicaid rebate program. Finally, this proposal fails to provide the necessary mechanisms to hold drug manufacturers accountable for their primary role as the entity setting the high price of drugs. In fact, the entire structure of PBM pricing negotiation is a direct result of excessively high prices and the need for purchasers – insurers and providers – to have some mechanism to lower them. **We urge the agency instead to consider alternative, market-based solutions aimed directly at lowering drug prices.**

Our specific comments follow.

THE PROPOSED RULE FAILS TO ADDRESS HIGH DRUG PRICES

Although this proposal has the stated goal of decreasing costs for beneficiaries at the pharmacy counter, it fails to appropriately take aim at the root issue responsible for these policy proposals – high and rising drug prices set by pharmaceutical manufacturers. None of the provisions in this rule actually address high list prices, rather the agency is trusting pharmaceutical companies to independently lower list prices, a scenario that is unlikely to occur given the recent and continued actions of those very companies. In fact, the safe harbor amendments in the proposed rule may lead to price increases as manufacturers would move to reduce or eliminate price concessions once negotiated pricing information becomes public. Without including provisions requiring or incentivizing drug manufacturers to lower list prices, those same companies stand to see increased profit margins if rebates are removed. Specifically, drug companies are likely to have less coverage gap responsibility for Part D beneficiaries and are likely to retain a portion of the money that would have otherwise been directed toward rebates.

Not only do the provisions included in this proposal threaten PBM and plan sponsor negotiating power, but these changes also could undermine the progress being made through the utilization of outcomes-based and indication-specific contracts and arrangements. Since these types of agreements typically rely on retroactive rebates, they are likely to disappear if the rebate safe harbor is eliminated. **Rather than targeting the current rebate and price reduction system, we urge HHS to examine and pursue market-based solutions that would increase competition, such as by incentivizing biosimilar interchangeability applications and curtailing the anti-competitive practices employed by pharmaceutical companies to extend patents and/or market exclusivity periods. These actions would further our shared objective of reducing drug prices.**

THE PROPOSED RULE WOULD LEAD TO HIGHER PREMIUMS

The agency's proposal to eliminate the rebate safe harbor for PBMs likely would result in increased premiums for beneficiaries. Rebates are one of the most important negotiating tools that purchasers have to keep premiums and drug costs down. In fact, according to an analysis by Altarum, PBMs passed on \$55 billion to Medicare Part D and private health plans in the form of rebates.¹ Altarum notes, "if half of PBM profits were deemed to be excess, this would represent only about 10 percent of rebates passed along to health plans."² In other words, the Altarum study finds that the vast majority of rebates are being used to lower beneficiary premiums.

Removing the rebate safe harbor protection also likely would be costly. The Centers for Medicare & Medicaid Services' Office of the Actuary (OACT) concluded that the federal government likely would have to spend an additional \$196.1 billion over 10 years to pay for the changes in this rule. If finalized, this would be the most expensive regulation in United States rulemaking history, and it is unlikely to translate into a real solution to the nation's drug pricing crisis, which is negatively impacting both patients and the providers who care for them. Further, according to OACT, "the majority of beneficiaries would see an increase in their total out-of-pocket premium costs" likely leading to only a minority of beneficiaries who utilize drugs with significant manufacturer rebates experiencing a substantial decrease in cost. While the AHA supports efforts to lower drug prices for individuals at the pharmacy counter, we cannot support doing so in a way that simply shifts costs into premiums. In effect, the provisions of this rule are asking beneficiaries to finance the agency's policy changes through increased premium payments with only the potential for savings at the pharmacy counter. As noted by OACT, only a subset of the beneficiary population is likely to see savings. These premium increases could have a chilling effect on enrollment among seniors with fixed incomes, potentially giving them greater financial exposure if they opt to forego Medicare Part D drug coverage.

Finally, the rule as structured could enable brand name pharmaceutical manufacturers to benefit from fewer and lower rebates without having to make any commitment to lower drug prices. Specifically, OACT estimates that drug companies stand to gain significant profits as a result of this proposal, stating that its "analysis assumed manufacturers would retain 15 percent of the existing Medicare Part D rebates," effectively estimating a financial windfall for drug companies. We urge the agency to shift its focus to policies like curbing drug manufacturer discount coupons, which artificially reduce prices for select individuals, but, in reality, increase premiums and drive drug prices higher.

THE RULE'S EFFECTIVE DATE IS IMPRACTICAL

¹ https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf

²*Id.*

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In its proposal, OIG states an effective date of Jan. 1, 2020. This timeline for such significant change is impractical and could cause disruption and confusion for beneficiaries, particularly if plan sponsors must make significant changes to premium prices as a result.

Should OIG decide to move forward with this flawed proposal, it should, at the very least, provide the appropriate amount of time for stakeholders to make the necessary decisions and changes to adapt and effectively implement such necessary changes.

Again, the AHA appreciates the administration's continued focus on drug prices, and urges consideration of policy solutions that will effectively address the issue of high and rising drug prices. Please contact me if you have questions or feel free to have a member of your team contact Mark Howell, senior associate director of policy, at mhowell@aha.org or (202)-626-2274.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President