AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

April 8, 2019

VIA ELECTRONIC MAIL
http://www.regulations.gov

Daniel Levinson
Office of the 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

Dear Mr. Levinson,

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to provide the following comments on the Office of Inspector General's proposed rule to remove the safe harbor protection for rebates involving prescription pharmaceuticals and to create a new safe harbor. Our organization of five Seventh-day Adventist affiliated health systems includes 84 hospitals and more than 300 other health facilities in 17 states and the District of Columbia. AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California.

Below, please find AHPA's comments on the proposed rule. Specifically, we comment on the following issues:

- Amendment to the Safe Harbor
- Timeline for Implementation

Amendment to the Discount Safe Harbor

The rule proposes to amend an existing safe harbor under the federal Anti-Kickback Statute (AKS) that protects from liability price reductions from manufacturers to plan sponsors under Medicare Part D, Medicaid Managed Care Organizations (MCOs) or Pharmacy Benefit Managers (PBMs). The OIG argues that the objective of such amendment is to "curb list price increases, reduce financial burdens on beneficiaries, lower or increase Federal expenditures, improve transparency, and reduce the likelihood

that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid MCOs." The rule also proposes to 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.

While AHPA commends the Agency's effort to reduce drug prices, we believe that the proposed policy would run counter to its desired objective. AHPA is concerned that removing the discount safe harbor would inadvertently lead to higher costs for beneficiaries, PBMs, dispensing pharmacies and the federal government. Moreover, the proposed policy may not result in significant reductions to the cost of drugs. As noted in the rule, an analysis from the Centers for Medicare and Medicaid Services' (CMS) Office of the Actuary (OACT) assumed that pharmaceutical manufacturers would retain 15 percent of the existing Medicare Part D rebates and would only apply 25 percent of the remaining rebates to lower list prices. OACT based this assumption on the belief that consumer discounts provide less return on investment to drug manufacturers than rebates.[1] While removing the discount safe harbor may result in some beneficiary savings at the pharmacy counter, the costs would likely be shifted in the form of higher premiums.

Below we provide further details on the potential impact of the proposed policy to different stakeholders.

Impact to Beneficiaries

The proposed policy will likely cause PBMs and plan sponsors to make up for any lost revenues by increasing premiums and patient co-payments. Patients may also experience changes to their formulary coverage as drugs that previously had a lower cost due to the rebates may no longer be covered or could be more expensive to obtain. These premium increases could reduce enrollment among seniors in Medicare Part D or Managed Care and increase their out-of-pocket costs if they are unable to obtain drug coverage. This would jeopardize beneficiary access to needed medications and adversely impact patient outcomes.

The OIG projects that the amendment of the safe harbor will result in lower Medicare Part D beneficiary spending because the reduced out-of-pocket costs on drugs are expected to outweigh the potential premium increases. However, such assumption is still uncertain and we recommend that the Agency abstain from implementing any policy that increases premiums and consequently limits access to medical

[1] See page 17 of the proposed rule. Analysis is posted as supplementary material in the docket for this rule.

treatment. As noted by the Milliman study, the impact of the proposal would vary depending on their drug spending and other characteristics.[2]

Impact to Dispensing Pharmacies

AHPA is concerned that the proposed policy may drive PBMs to compensate for any lost rebates by charging higher fees to dispensing pharmacies. If a consumer discount is provided at the point of service, dispensing pharmacies will likely have to pay fees for bolt on software or pay a fee to the switch company.

Impact to the Federal Government

The removal of the discount safe harbor could also be costly for the federal government. The OACT concluded that the federal government would likely spend between $34.8 billion to $196.1 billion in the next decade implementing the rule.[3] While this impact may change depending on the behavior of PBMs, manufacturers and plan sponsors, it is still important to factor in when considering whether to finalize the proposed rule.

Timeline for Implementation

The OIG proposes for the amendment to the safe harbor, if finalized, to become effective on January 1, 2020. The Agency seeks comments on whether the proposed effective date gives affected entities a sufficient transition period to restructure any arrangements that could implicate the Anti-Kickback Statute and no longer be protected by a safe harbor.

If the proposed safe harbor amendment is finalized, AHPA strongly recommends extending the effective deadline. We believe that this is needed to allow plan sponsors and drug manufacturers to make any needed contractual changes or adjustments to value-based arrangements. Additionally, we recommend that the OIG examines the rule's impact on a regular basis to evaluate whether any changes are needed. As recognized by the OIG in the rule, it is difficult to accurately determine the impact of the proposed rule because it is largely dependent on the response of PBMs, manufacturers and health plan sponsors. Therefore, an impact analysis would be needed if the proposed safe harbor amendment is finalized.

[2] Milliman. Impact of Potential Changes to the Treatment of Manufacturer and Pharmacy Rebates. September 2018.
[3] See page 20 of proposed rule

Conclusion

AHPA commends the OIG for its efforts to reduce drug prices and we encourage the Agency to continue working with stakeholders to develop policies that advance such goal. We welcome the opportunity to further discuss any of the comments above. If you have any questions, please do not hesitate to contact Carlyle Walton, President of AHPA, at Carlyle.Walton@AdventHealth.com or Julie Zaiback-Aldinger, Director of Public Policy and Community Benefit, at Julie.Zaiback@AHPA.com.

Sincerely,

Carlyle Walton, FACHE
President
Adventist Health Policy Association