April 8, 2019

Submitted electronically via http://www.regulations.gov

Aaron Zajic
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-P
Room 5527, Cohen Building
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

Dear Sir:


The rule proposes changes to the safe harbor regulation concerning discounts, which defines certain conduct as protected from liability under the federal anti-kickback statute under Section 1128B(b) of the Social Security Act. The Proposed Rule would revise the “discount safe harbor” to explicitly exclude from safe harbor protection certain reductions in price or other remuneration from a drug manufacturer to plan sponsors under Medicare Part D and Medicaid managed care organizations (“Medicaid MCOs”), or pharmacy benefit managers (PBMs) under contract with them. The OIG is also proposing two new safe harbors: one to protect certain point-of-sale reductions in price on prescription drugs; and the second to protect certain PBM service fees.
The American Benefits Council is a Washington D.C.-based employee benefits public policy organization. The Council advocates for employers dedicated to the achievement of best-in-class solutions that protect and encourage the health and financial well-being of their workers, retirees and families. Council members include over 220 of the world’s largest corporations and collectively either directly sponsor or administer health and retirement benefits for virtually all Americans covered by employer-sponsored plans.

Pharmaceutical drug therapies have played a significant role in treating and curing injury, illness and disease. They allow millions of Americans to overcome debilitating conditions, return to work after injury, illness or disease and live longer, healthier, more productive lives.

Although the benefits of pharmaceutical drug therapies are substantial, these benefits often come with significant financial costs – to both participants and to payers in the health care system, including employer-sponsored plans. As evidenced in 2016 alone, private health plans spent more than $142 billion on prescription drug coverage – more than ever before.\(^1\) From 2013 to 2016, spending on prescription drug coverage grew more than any other category of health care expenses for individuals with employer-sponsored health coverage.\(^2\) These costs continue to increase across plans. Of note, among employers with 500 or more employees, prescription drug costs increased by 7.6% in 2017 and were projected to rise by another 7.8% in 2018.\(^3\)

The Council supports the Administration’s goal of lowering prescription drug costs, as noted in the Council’s comments to the “HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs” issued last year.\(^4\) As a general matter, employers do not support the current rebate structure as it is complex and opaque, hiding the true prices of drugs and the true value of how the rebate is calculated. The Council is concerned, however, that the Proposed Rule will not do enough to change the incentives for entities in the drug delivery chain that lead to higher list prices and larger rebates. Thus, the Council supports the Administration’s consideration of additional strategies to help

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\(^1\) See Peterson-Kaiser Health System Tracker, *Health Spending Explorer*, [https://tinyurl.com/y9moy7qq](https://tinyurl.com/y9moy7qq)


\(^4\) See the American Benefits Council’s July 16, 2018, comment letter to the U.S. Department of Health and Human Services, [https://www.americanbenefitscouncil.org/pub/?id=9460ea0-a95e-7eef-cc02-81b549ce389f](https://www.americanbenefitscouncil.org/pub/?id=9460ea0-a95e-7eef-cc02-81b549ce389f)
lower drug prices. In this regard, the Council also supports efforts for increased transparency for plans and issuers, as well as strategies that will continue to allow employers and health plans the necessary flexibility to innovate in plan design. These efforts by federal regulators are important initial steps and should be part of a broader, collaborative effort among all stakeholders to help lower drug costs, while ensuring continued access to clinically effective – and cost-effective – pharmaceutical drug therapies.

The Council notes PBMs can serve as important partners to employer plan sponsors in negotiating lower costs and implementing strategies to bring better value to employers and employees. The Council encourages PBMs to increase their focus on the implementation and operation of programs and strategies designed to help employer-sponsored plans manage drug costs, while ensuring access by employees to clinically necessary drugs.

Our specific comments are set forth below.

I. Terminology in the Proposed Rule and Use of Explanatory Examples

The Council is concerned that stakeholders may not be construing the Proposed Rule in the same manner because of confusion around the meaning of the terms “reductions,” “rebates” and “discounts.” The Council encourages HHS to clarify the specific terminology used throughout the Proposed Rule. Moreover, there appears to be continued confusion regarding what specific types of discount/rebate arrangements remain permissible under the Proposed Rule. Accordingly, we encourage HHS to consider, where appropriate, including specific examples regarding what constitute permissible and impermissible arrangements under the Proposed Rule, as contemplated.

II. Proposal to Exclude from the Discount Safe Harbor Reductions in Price or Other Remuneration from Drug Manufacturer

The current rebate structure used in the marketplace is complex and opaque for many employers, making it hard for these employers as well as plan participants and beneficiaries to understand the true prices of drugs and the true value of how the rebate is calculated. While some PBMs may disclose the nature and extent of specific drug rebates, this practice varies by PBM and does not appear to be the norm across the industry. For employers with significant bargaining power (for example, because of their plans’ number of covered lives), such employers may have greater success in gaining access to information regarding the extent and nature of rebates paid to their PBM by drug manufacturers.

Moreover, when PBM compensation is tied to a percentage of the list price of the
drug, this can create a market incentive that encourages higher list prices and larger rebates, specifically where the PBM compensation is factored into the cost of the drug by the drug manufacturer (and gets reflected in the list price set by the drug manufacturer). This can have a particularly negative impact on consumers enrolled in high deductible health plans that pay the list price of the drug rather than a lower price that reflects the rebate. As a result, a small but growing number of Council member employers pass rebates through to plan enrollees at the point of sale.

The Proposed Rule would, in part, exclude from safe harbor protection reductions in price or other remuneration from a drug manufacturer to plan sponsors under Medicare Part D and Medicaid MCOs, or PBMs under contract with them. As noted above, the Council supports the efforts by HHS and this Administration to seek to bring down drug costs, and as a general matter, employers do not support rebates under the current structure. The Council is concerned, however, that elimination of the current discount safe harbor would have potentially adverse effects on Medicare Part D plan beneficiaries in the form of increased premiums. The Council cautions that, according to the Centers for Medicare and Medicaid Office of the Actuary (CMS OACT), the Proposed Rule is expected to increase premiums for Medicare Part D enrollees, noting that “[o]ver the 10-year period 2020-2029, overall drug spending net of rebates and the new chargeback discounts would increase by approximately $137 billion, and Federal spending would increase by $196 billion,” and while, “overall spending by households would decrease by $43 billion due to a $93-billion reduction in out-of-pocket (OOP) spending (defined as spending paid directly by the consumer at the point-of-sale), . . . premiums for households would increase by $50 billion—an expense that would be borne by Medicare Part D enrollees.” The Council requests OIG seriously consider the unintended consequences of this proposal and delay the proposal until it has more information about the potential impact to Part D plan premiums.

Even more important to employers than excluding rebates from the discount safe harbor is the need for increased transparency by the PBM regarding the extent of discount pricing, including but not limited to, volume-based rebates that the PBM is receiving so that plans can bargain in good faith with the PBM over the PBM’s retention of these amounts. This has been a desire for some in the employer community with respect to ERISA-covered plans for years. While retirement plan service providers are generally subject to upfront disclosure of the revenue they will earn with respect to a given plan pursuant to ERISA Section 408(b)(2), as well as back-end reporting to the plan on an annual basis regarding actual revenue earned, these rules do not apply to

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5 As a general comment, the Council believes Medicaid MCOs should be excluded from the Proposed Rule because point-of-sale discounts do not function the same in Medicaid MCOs where beneficiaries do not have cost-sharing responsibilities and the MCO rebates are already passed back to the State.

Many employers believe increased transparency with respect to PBM rebates will help enable plan sponsors to work to recoup or otherwise retain some of these rebates for the benefit of plan participants and beneficiaries.

With respect to the preceding point, we note that many of our employer members have worked to identify, as well as recoup, these PBM rebates for the benefit of plan participants and beneficiaries. In this regard, many employers currently use these recouped rebates in numerous ways – such as through reduced premiums and reduced coinsurance. In fact, in an informal poll of our members (likely for active employee coverage) during a recent webinar regarding the Proposed Rule, a significant percentage indicated that they currently use the rebates to provide reduced cost-sharing for participants and beneficiaries. Thus, the Council is supportive of efforts by this Administration to increase the visibility by plan sponsors and carriers of the rebates paid to PBMs by drug manufacturers.

III. PROPOSAL TO CREATE POINT-OF-SALE SAFE HARBOR (“POS SAFE HARBOR”)

The Proposed Rule would create a new POS Safe Harbor under which: (1) any “reduction in price” must be set in advance, (2) the sale must not involve a rebate unless the dispensing pharmacy receives the full value of the reduction in price through a chargeback and (3) the reduction in price must be completely applied to the price of the prescription drug charged to the beneficiary at the point of sale.

Per the above discussion, our employer members generally support the OIG’s efforts to use its authority to increase transparency regarding the extent of any price reductions that the PBM is receiving from drug manufacturers with respect to the plan’s drug benefits, regardless of what these reductions are called (e.g., price reductions, discounts, rebates, etc.), and regardless of whether they are based on express volume-related metrics. The POS Safe Harbor would seem to provide increased transparency regarding the extent of “reductions” and “rebates” in that it appears it would require that these amounts be completely applied to the price of the drug charged to the beneficiary at the point of sale.

While employers support increased transparency regarding PBM drug pricing, the Council is concerned that the proposed POS Safe Harbor could have potentially adverse effects on plan participants and beneficiaries in the form of increased premiums and/or

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7 https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/supplemental-2009-schedule-c.pdf (confirming in Q 27 that compensation received by a PBM directly from an ERISA plan is reportable on Schedule C as “direct compensation” and explaining in Q 27 that “discount and rebate revenue” paid to PBMs by drug manufacturers need not be reported on a plan’s Schedule C as indirect compensation pending further guidance while the DOL considers the extent to which they should be reported).
increased cost-sharing. Even a small increase in premiums could have a significant impact on individuals who already are struggling to afford health insurance through their employer. In addition, with respect to employer-sponsored plans, this change could increase plan costs on Employer Group Waiver Plans and Part D plans and result in employers reaching the Affordable Care Act’s “Cadillac Tax” threshold sooner. Any reforms must, therefore, carefully consider implications and the potential for unintended consequences.

To the extent the OIG believes it is necessary to finalize a POS Safe Harbor, the Council notes the following with respect to the Proposed Rule:

**Setting forth reductions/discounts in writing**

Our employer members generally support rules that would require reductions/discounts be set forth in writing, in advance of the drug being available under the plan. Under the current structure, many employers may not be aware of the extent of a rebate on a given drug. Even if the employer is aware of the rebate, the rebates are typically based on volume and, therefore, rebates may be provided/paid to the PBM by the manufacturer long after the drug has been sold (and the plan has been initially charged). Moreover, not all employers may have the ability to audit or account for rebates adequately.

With respect to the Proposed Rule, we recommend adding language to the definition of “set in advance” to make clear that not only must any reduction be a fixed amount, but that such reduction must also not be determined based on volume or referrals (similar to requirement in PBM Fee Transparency Safe Harbor). This would help eliminate the complex reconciliation that currently takes place in order for the plan sponsor to receive any rebate.

**Clarification that POS Safe Harbor does not undercut plans’ drug utilization management strategies**

As noted above, the Proposed Rule provides that “the reduction in price must be completely applied to the price of the prescription pharmaceutical product charged to the beneficiary at the point of sale.” Based on the Council’s conversations with our employer members, there is a fair amount of concern and confusion regarding the extent to which the POS Safe Harbor could in effect undercut a plan’s carefully structured drug utilization management strategies – specifically in the form of reducing or eliminating a participant’s fixed copayment or coinsurance obligation.

With respect to plans that use a coinsurance strategy, we believe the intention of the rule is not to affect the participant’s coinsurance rate, but rather to have the rebate applied at point-of-sale to reduce the cost of the drug to which this coinsurance rate is applied.
For example, assume a drug has a cost of $200 to the plan, and the plan, by its terms, imposes a participant coinsurance obligation of 10%. Also, assume the PBM has contracted for a rebate of $20. Under the current rules whereby the PBM is permitted to retain the rebate, the participant’s coinsurance obligation would be $20. Under the Proposed Rule, assuming a preserved coinsurance rate of 10%, the participant’s coinsurance obligation would be reduced ratably to $18 (i.e., 10% x ($200 minus $20 rebate) = $18). To the extent this is not the case, further clarification is needed.\(^8\)

For those plans that use a fixed copayment strategy (such as $20 per fill for a given drug regardless of the plan’s actual drug cost), clarification is needed regarding how the POS Safe Harbor would apply. It is imperative that plans continue to be able to use a fixed copayment amount as part of their utilization management. Thus, further guidance is needed.

Lastly, the Council does not support a rule that would result in the payment of point-of-sale rebates that exceed a participant’s out-of-pocket costs for the drug. Such a result would increase system waste. Rather, any excess amounts should be returned to the plan for the benefit of plan participants and beneficiaries more generally.\(^9\)

**Final Rule should permit plans to distribute rebates ratably to participants and beneficiaries**

As drafted, the Proposed Rule would appear to require that any rebate be reflected in the amount of the specific prescription drug “charged to the beneficiary at the point of sale.” If this provision of the Proposed Rule prompts drug manufacturers and in turn PBMs to lower drug prices because new market forces are at work once PBM compensation is no longer tied to a percent of the list price, most stakeholders would agree this is a positive step. However, if this rule merely memorializes the status quo of large list prices coupled with large rebates that are now required to be passed to consumers at the point of sale, employers would strongly prefer to maintain the flexibility to determine the best use of the drug rebate dollars. Moreover, because the

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8 A similar issue arises with respect to high-deductible health plans offered outside of the Medicare context. Assume for example that a drug has a cost of $200 to the plan and the PBM has contracted for a rebate of $20. To the extent the Proposed Rule or the like is made applicable to these HDHPs, the participant would pay $180 (versus the $200).

9 The Council is aware of legislative proposals that would enact a similar proposal with respect to the commercial marketplace. If a similar proposal was enacted in the commercial market, the Council is concerned about how point-of-sale rebates would work where a participant is utilizing a “coupon” or other third party financial assistance to purchase the drug. It would appear that such a rule would effectively benefit solely the drug manufacturer by requiring that a lesser amount of the coupon’s face value be redeemed at point-of-sale.
costs of these drugs are being borne in the aggregate by all plan participants in the form of increased plan costs and resulting premiums, a plan should be allowed to retain the full value of the rebates for the benefit of the plan, i.e., all of its participants and beneficiaries, as opposed to limiting the benefit to those that actually utilize the drug. A plan could then elect to apply the rebates at “point of sale” for the benefit of all participants regardless of whether a given drug is itself subject to a rebate by the manufacturer. Alternatively a plan could elect to apply the aggregate rebates to reduce plan costs and, in turn, reduce overall premiums. The plan should maintain the ability to determine what is best for the plan and their enrollees.

Need for plans to be permitted to retain the portion of the rebate not otherwise remitted to the participant at point of sale by the dispensing pharmacy

As noted above, many employers seek to identify and retain drug manufacturer rebates for the benefit of plan participants and beneficiaries. Thus, using the example set forth above, many plans seek to retain as much as possible of the $20 rebate and then use the rebate for the benefit of plan participants and beneficiaries.

Under the Proposed Rule’s POS Safe Harbor, $2 of the $20 rebate would be paid to the participant who is being prescribed the drug in the form of a $2 reduction to the coinsurance amount charged at point-of-sale. But what happens to the remaining $18 of the rebate?

The Council is very concerned about a rule that would effectively require that plans be prohibited from accessing rebates that are otherwise being made available on a given drug by a drug manufacturer. As mentioned above, many employers have sought to retain drug rebates for the benefit of plan participants and beneficiaries. Unless the Proposed Rule is as effective in bringing down overall drug costs (e.g., as measured by the drug’s actual wholesale acquisition cost), a plan’s inability to access continued rebates should be expected to increase overall plan costs. This is perhaps most easily evidenced by referring to our example above. Under current rules, the plan has the potential to access the full $20 of rebate to bring down a plan’s drug costs. If the plan can no longer retain some or all of that remaining $18 of rebate, plan costs will most certainly increase to the detriment of plan participants and beneficiaries. The retention of the rebate becomes increasingly important when the dynamics of the prescription drug marketplace are considered, with varying classes of drugs being subject to different levels of, or no, rebate. By permitting the plan to retain the value of the non-beneficiary portion of the rebate, the overall benefit of the POS Safe Harbor will accrue to the benefit of all beneficiaries, and eliminate the potential for waste under Medicare and Medicaid. Accordingly, we urge the OIG to permit plans to contract with PBMs to retain the portion of the rebate not otherwise distributed to the participant at point-of-sale. This will ensure that all participants and beneficiaries are not harmed by the rule.
IV. PROPOSAL TO CREATE A PBM SERVICE FEES SAFE HARBOR (“SERVICE FEES SAFE HARBOR”)

The Proposed Rule would also create a PBM Service Fees Safe Harbor that would protect payments pharmaceuticals manufacturers make to PBMs for services the PBMs provide to pharmaceutical manufacturers that relate to health plans. The safe harbor requires that the (1) PBM and pharmaceutical manufacturer have a written agreement that covers the services the PBM provides to the manufacturer in connection with the PBM’s arrangement with health plans and the compensation associated with the services, (2) compensation paid to the PBM must be consistent with fair market value, a fixed payment, not based on a percentage of sales, and not determined based on volume or referrals and (3) PBM discloses in writing at least annually to each contracting health plan, and to the Secretary upon request, the services it rendered to each pharmaceutical manufacturer related to the PBM’s arrangements with the health plan and the associated cost for such services.

As noted above, the Council supports increased transparency by PBMs for services that relate to contracting health plans. Thus, the Council supports this proposal to require PBMs to provide an annual disclosure of the services it provides to pharmaceutical manufacturer and the costs associated with those services in order to satisfy the safe harbor. As agents of the health plans with which they contract, the Council believes this PBM transparency requirement is important to ensure that the PBMs’ arrangements with pharmaceutical manufacturers are aligned with the services the PBMs provide to the health plans.

V. PROPOSED RULE EFFECTIVE DATES

The Proposed Rule’s exclusion from the “discount safe harbor” for certain reductions in price or other remuneration from a drug manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D and Medicaid MCOs, or PBMs under contract with them, would be effective January 1, 2020. The two new safe harbors would be effective 60 days from date of publication of the final rule. Employer plan sponsors and carriers of Medicare Advantage and Medicare Part D plans need a reasonable implementation timeline to modify PBM contracts and account for any changes as a result of this rulemaking. The Council is concerned that this proposed effective date would not give affected entities a sufficient transition period to restructure arrangements that could implicate the anti-kickback statute and no longer be protected under the safe harbor. Additionally, we encourage HHS to keep in mind that bids from Medicare Part D sponsors are due each June for the subsequent calendar year. Thus, the Council urges the OIG to provide additional time for stakeholders to take the necessary actions following the issuance of any final rule to comply with the exclusion of the current safe harbor and to reflect any related economic and substantive
changes in their plans/benefits (including as part of the Medicare Part D sponsor bid process). For example, the applicability date could be for new or renewed PBM contracts with plan sponsors under Medicare Part D and Medicaid MCOs beginning after January 1, 2021 (or a future date depending on when the rule is finalized). This would give plans the opportunity to contract with PBMs and modify benefits and plan terms consistent with any final rule.

VI. Transparency

As mentioned above, the Council believes approaches focused specifically on transparency (versus point-of-sale delivery of rebates/reductions, etc.) may be more beneficial to plans, as well as participants and beneficiaries, because it would allow plans to better negotiate with PBMs for the plan’s retention and use of the reductions/rebates for the benefit of the plans and participants and beneficiaries.

As such, the Council recently submitted a letter to the Senate Health, Education, Labor and Pension (HELP) Committee leadership offering specific recommendations lawmakers should take to lower health care costs. In conjunction with a series of hearings dating back to the previous Congress, HELP Committee Chairman Lamar Alexander asked the Council and other stakeholders for suggestions to reduce the growing burden of health care costs on “taxpayers, employers and family budgets.”

One of the recommendations offered by the Council is to increase access to data. The Council noted that most employers that have had success decreasing the rate of health care spending have started by taking deep dives into their data. They do this to better understand how much they are spending for various services delivered in different settings and, ultimately, to steer their enrollees to higher-value providers operating in higher-value settings. Thus increased access to data will enable competitive and healthy market forces to work more effectively and efficiently, ultimately leading to better cost and quality outcomes.

While not directly pertinent to Medicare and Medicaid arrangements, as part of the broader policy discussion around drug prices and the rules with respect to rebates, the Council has put forth the following recommendations.

First, the Administration should consider using existing authority to increase transparency. In 2014, the U.S. Department of Labor (“DOL”) ERISA Advisory Council recommended applying ERISA Section 408(b)(2) to health and welfare plans. Under this potential approach, service providers to an ERISA plan, including PBMs, would

10 https://www.americanbenefitscouncil.org/pub/?ID=432ee9de-d448-3701-9bc9-2aecc50b16f5
11 https://www.americanbenefitscouncil.org/pub/?id=497eeb87-c285-5e9c-f6ec-3913f64f96c
disclose to employers at the time of contracting the fees and compensation (both direct and indirect) the service provider would earn as a result of providing services to the plan. This transparency would help ensure the service providers only receive reasonable compensation for the goods and services provided to the ERISA plan. If the DOL pursues this regulatory approach, this disclosure requirement should be crafted such that it does not increase liability for plan sponsors.

Second, the Council encourages DOL to revise its frequently asked question (FAQ) guidance regarding Schedule C reporting (i.e., “back-end disclosure”) of PBM compensation to require a PBM’s “discount and rebate revenue” to be reported as indirect compensation. In 2010, DOL issued FAQs regarding Schedule C Reporting of PBM Compensation. FAQ 26 confirms that compensation received by a PBM directly from an ERISA plan is reportable on Schedule C as “direct compensation.” However, FAQ 27 provides that “discount and rebate revenue” paid to PBMs by drug manufacturers need not be reported on a plan’s Schedule C as indirect compensation pending further guidance. Requiring at least Schedule C reporting by PBMs to plan sponsors of this “discount and rebate revenue” would provide more complete information to plan sponsors to ensure that PBMs receive no more than reasonable compensation for services rendered to the plan. This disclosure requirement should be crafted such that it does not trigger additional liability for plan sponsors.

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The Council looks forward to working with the Administration and other stakeholders to bring the voice of employer plan sponsors to this all-important effort to lower drug prices. Thank you for considering these comments. If you have any questions or would like to discuss these comments further, please contact us at (202) 289-6700.

Sincerely,

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