



April 8, 2019

[Submitted electronically via www.regulations.gov]

The Honorable Daniel R. Levinson, Inspector General
c/o Mr. Aaron Zajic, Supervisory Project Manager
Office of Inspector General (OIG)
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 (PBM) Service Fees (OIG-0936- P) (RIN 0936-AA08) (ID: HHSIG-2019-0001-0001)

Dear Inspector General Levinson:

The American Pharmacists Association (APhA) is pleased to submit these comments regarding the Department of Health and Human Services (“HHS”) proposed rule “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,” (hereinafter the “Proposed Rule”). APhA, founded in 1852 as the American Pharmaceutical Association, represents 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, specialty pharmacies, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

A. Amendment to the Discount Safe Harbor (Pgs. 2347-2348)

OIG is proposing “...to amend the existing discount safe harbor so that it would no longer protect price reductions from manufacturers to plan sponsors under Medicare Part D or Medicaid Managed Care Organizations (MCOs).” These price reductions are extended either directly or through pharmaceutical benefit manager (“PBMs”) acting under contract with plan sponsors. Price reductions are made in connection with the sale or purchase of prescription

pharmaceutical products, unless the reduction in price is required by law. APhA appreciates that OIG intends for the "...discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities, including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payors in other Federal health care programs." Accordingly, APhA asks OIG to confirm pharmacies will be able to continue to use these amounts to provide innovative and other patient care services to meet patient needs and improve health outcomes.¹

APhA also requests OIG clarify the term "price reductions" in the Proposed Rule. Will this definition align with the term "price concessions," recently included in the separate HHS proposed rule that specifically addresses direct and indirect remuneration ("DIR") fees between pharmacies and prescription drug plan sponsors ("PDPs") or their PBMs?² Will the modifications to the term "rebate" under 42 CFR 1001.952(h) of the safe harbor statute include retroactive DIR fees? To ensure consistency, APhA strongly recommends OIG clarify that the term "price reductions" no longer protects the use of retroactive DIR fees and /or similar policies /terminology, such as "true up" practices under the discount safe harbor when the "negotiated price" is made available at the time a medication is dispensed at the point-of-sale.³

In addition, APhA still has serious concerns regarding "pharmacy price concessions" based on performance under the separate proposed rule "Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses,"⁴ where any negative contingent amounts would be included in the "negotiated price," at the point-of-sale, but any positive contingent amounts could be applied retroactively. While eliminating the retroactive nature of the negative concessions will make it possible for pharmacists to understand their cash flow up front, it creates scenarios where pharmacies could potentially still be forced to sell medications below actual cost which could limit patient access to necessary medications and negatively impact the pharmacy's ability to serve patients. As such, this proposal may have the potential to unintentionally squeeze margins for community pharmacies (particularly independent pharmacies with little leverage). If pharmacy total reimbursement is a calculation dependent on the lowest possible amount specified in the contract at the point-of-sale, a lower "net price" will potentially also lower the total dollar amount going to the pharmacy necessary to cover pharmacy acquisition and inventory management costs, patient services, etc. Under this proposal, negative DIR fees would still be taken, just up-front, and while more transparent,

¹ APhA also requests OIG confirm that pharmacies will continue to be able to receive manufacturer discounts for providing de-identified data. Pharmacies should also receive appropriate wholesaler discounts for meeting established purchasing and payment terms (e.g., minimum purchase of a percentage of generics, etc.). These discounts allow a number of pharmacies to provide necessary medications (including specialty medications), clinical patient care services and other services (e.g., delivery, mail, refrigeration, etc.) required by patients, without going below cost.

² See, CMS. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. Proposed Rule. CMS-4180-P. November 30, 2018, available at: <https://www.regulations.gov/document?D=CMS-2018-0149-0002>. Also, See, Milliman. "Impact of Potential Changes to the Treatment of Manufacturer Rebates," January 31, 2019, available at: <https://www.regulations.gov/document?D=HHSIG-2019-0001-0002> - which states "This rule change would eliminate all DIR payments from pharmacies to plans, requiring these discounts to be reflected at POS. Only negative DIR, or payments from plans to pharmacies would be permitted. For example, a pharmacy would be paid the lowest amount specified in the contract at the POS, but negative DIR could later be paid if the pharmacy met performance guarantees associated with higher reimbursement."

³ See, CMS. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. Proposed Rule. CMS-4180-P. November 30, 2018, available at: <https://www.regulations.gov/document?D=CMS-2018-0149-0002>.

⁴ Ibid.

would still force pharmacies to dispense below cost. Thus, APhA requests OIG clarify “net price” from “negotiated price.” In short, APhA maintains that pharmacies should never be required to dispense products for reimbursements lower than their cost of acquisition.

To illustrate our concerns and to emphasize that OIG/ HHS needs to ensure that total pharmacy reimbursement does not decrease as these rules are adjusted, based on OIG’s list price example of \$100 with a pharmacy reimbursement calculation of “ $1.20 \times \text{WAC}/\text{list price}$ minus 15 percent plus a \$2 dispensing fee,”⁵ we are including the following basic table to demonstrate how a \$4 margin shrinks to a \$3.40 margin by moving the rebate (assuming that PBMs will apply new net prices to calculate pharmacy reimbursement):

Example pre- and post-rule change moving rebates from the equation and reduction in net pharmacy reimbursement

Transaction	Brand (Current)	Brand (Proposed)	Difference	Notes
List Price	\$100	\$70	(\$30)	POS rebate reduces the total price at the counter
Pharmacy Reimbursement	\$104	\$73.40	(\$30.60)	$1.2 * (\text{Price}) - 15\% + \2 dispensing fee
Pharmacy Gross Margin	\$4	\$3.40	(\$0.60)	This is based on the assumption that pharmacy reimbursements negotiated by PBMs will now reflect their net price

APhA agrees performance measures can be effective in measuring the quality of health care services and placing risk on health care providers when appropriate. However, pharmacies are in no position to assume risk for product cost over which they have no control. In addition, the price concessions given by manufacturers to plans are not enjoyed by pharmacies. Thus, PBM efforts to “recover” those price concessions from pharmacies are illogical. Any performance-based risk and payment mechanisms must be based on what pharmacies do or don’t do to affect patient care, not on what the product costs that pharmacy to purchase for beneficiaries. Therefore, APhA strongly urges OIG to add clarifying language protecting/ensuring pharmacies are reimbursed for full medication cost to them as well as costs to acquire, handle, and dispense medications. HHS must also cover necessary or appropriate clinical services separate from the cost of dispensing medications, including if/ when rebates move to point-of-sale. Below cost reimbursements negatively impact patient access and pharmacies’ ability to provide the scope of patient care activities that the literature has shown to improve patient outcomes and value from the pharmaceuticals being purchased.

APhA also continues to share OIG’s concern regarding “...unintended loopholes...” where “...such price reductions could be used to funnel remuneration to parties that otherwise

⁵ See, FR Vol. 84, No. 25. Pgs.2341-2342. Wednesday, February 6, 2019, available at: <https://www.regulations.gov/document?D=HHSIG-2019-0001-0001>

would have been in the form of rebates where such rebates, under this proposed rule, would no longer qualify for safe harbor protection.” As OIG/ HHS understands, DIR was originally designed to capture rebates and other mechanisms extended to plans and PBMs by manufacturers and not included at the point-of-sale. However, DIR by PBMs are now being used beyond their original purpose to retroactively adjust pharmacies’ payments months after the sale, often below the price paid by the pharmacy. There is simply no connection between price concessions given by manufacturers to PBMs and the prices paid by pharmacies to their wholesalers. Thus, DIR fees “recovered” from pharmacies by PBMs are totally irrational (i.e., recovering money from pharmacies that pharmacies did not “receive” in the first place). Many pharmacies are struggling to stay open and cutting back hours due to the current DIR fee structure, which also challenges their ability to provide quality and meaningful patient care services. In addition, because current point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before DIR is extracted, many beneficiaries actually pay higher out-of-pocket costs. HHS and OIG have cited numerous research that further suggests higher cost-sharing can impede beneficiary access to necessary medications, which leads to poorer medication adherence and health outcomes, and higher medical care costs for beneficiaries and Medicare. Therefore, APhA strongly urges OIG close this potential “loophole” by clarifying that pharmacy DIR fees are not protected under the discount safe harbor at 42 CFR 1001.952(h).⁶

B. New Safe Harbor for Certain Price Reductions on Prescription Pharmaceutical Products (Pgs. 2348-2349)

This new safe harbor would include discounts negotiated by PBMs passed onto beneficiaries at the point-of-sale for those enrolled in health plans electing to use the proposed new safe harbor as long as “...the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or a series of chargebacks, or the rebate required by law.” However, APhA has serious concerns whether the secondary “chargeback” transaction would account for the pharmacy’s acquisition and handling costs, patient care services, etc. As the Proposed Rule states the “full value” of the reduction in price is provided to the dispensing pharmacy through a “chargeback.”⁷ However, the Proposed Rule does not ensure that pharmacies would not be forced to dispense products below cost or take a loss, which would only hinder patient access to necessary medications. As stated in one recent analysis “...additional clarity may be necessary as part of the rule-making process to ensure that pharmacies are reimbursed at levels that exceed their acquisition costs, rather than based on the discounted price of medications.”⁸ Therefore, APhA strongly urges OIG/ HHS lay out a specific system with clear guardrails under which the “chargeback” will account for pharmacy costs without detrimental flaws. We also ask OIG to clarify the definition of “chargeback” in the Proposed Rule to include a payment agreed upon by the “pharmacy,” and not just Part D issuers and/ or their PBMs. Currently, pharmacies have to agree to “take it or leave it” terms in their

⁶ APhA’s House of Delegates passed a resolution stating “APhA opposes retroactive direct and indirect remuneration (DIR) fees and supports initiatives to prohibit such fees on pharmacies.” 2018. Pg. 115, available at:

https://media.pharmacist.com/hod/APhA_Policy_and_Procedures_2018.pdf

⁷ OIG proposes to define a “chargeback” as “...a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product.”

⁸ Avalere Health. Drug Rebate Proposal Fundamentally Changes Current System, Raises Critical Questions. February 11, 2019, available at: <https://avalere.com/insights/drug-rebate-proposal-fundamentally-changes-current-system-raises-critical-questions>

contracts with the PBMs, which highlights that pharmacies have little negotiating power with PBMs and payment should be under formulas that include pharmacies' actual acquisition cost, and the associated costs for inventory management, dispensing, patient counseling, etc. Administratively, the pharmacy will have to know at point of purchase what the ultimate product and service payment will be, how much to collect from the patient, and if payments will cover pharmacy costs.

APhA continues to remind HHS when developing mechanisms to lower drug costs, OIG and HHS need to separately consider the reimbursement of the product, which is fixed for pharmacists, from the cost of dispensing and any related patient care service or performance incentive payment to provide adequate reimbursement under a sustainable business model that improves and does not disrupt our nation's pharmacy distribution system. Unfortunately, this current system still fails to provide coverage for the true cost of the medication and any payment for pharmacies to provide needed patient care services.

APhA does appreciate that the new proposed safe harbor is "...intended to exclude from its protection conduct that mimics rebates but are referenced in other ways in the contracts between a manufacturer and a PBM..." Thus, as previously stated, APhA requests HHS apply this same tenet to retroactive DIR fees or other similar policies /terminology/ practices used by PBMs/ Part D issuers (such as "true up," etc.).

C. New Safe Harbor for Certain PBM Service Fees (Pgs. 2349-2350)

As previously stated, APhA shares OIG's concerns regarding "unintended loopholes" where price reductions could be used to funnel remuneration to parties. In multiple proposals, HHS has pointed out PBM practices in the Medicare program negatively impact patient costs, care and access.⁹ Accordingly, OIG/ HHS may want to consider restricting PBM "services" to adjudicating claims, which should be a minimal flat-fee and a commodity. Any additional "service" or "feature" may only serve to create loopholes which are exploited to the detriment of patients, the federal government and the health care system in general. Additional proposals from the Administration have pointed out PBMs operate in a consolidated, opaque space and pose a barrier to pharmaceutical companies lowering their prices¹⁰ and have spent a significant amount of effort trying to rectify the negative impact certain PBM practices have had on patients and pharmacies. Therefore, we are against creating another safe harbor for "(PBM Service Fees) that would protect fixed fees that manufacturers pay to PBMs for services rendered to the manufacturer," particularly "...when those services relate in some way to the PBMs' arrangements to provide pharmacy benefit management services to health plans." Such language directly contrasts the clear statement in the Proposed Rule that "[t]his safe harbor would protect only a pharmaceutical manufacturer's payment for those services that a PBM furnishes to the pharmaceutical manufacturer, and *not [emphasis added]* for any services that the PBM may be

⁹ CMS. Medicare Program; Contract Year (CY) 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Proposed Rule. November 27, 2017, available at: <https://www.regulations.gov/document?D=CMS-2017-0156-0046>. Also, *See* CMS. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses. Proposed Rule. November 30, 2018, available at: <https://www.regulations.gov/document?D=CMS-2018-0149-0002>.

¹⁰ HHS. American Patients First - The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 2018, available at: <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>

providing to a health plan.” Specifically, we are concerned the Proposed Rule’s open-ended definition of “pharmacy benefit management services,” and examples (below), which conflate PBM services provided to manufacturers and plans would allow many of these PBM practices, including “rebates” (retroactive DIR fees, etc.) to likely continue. For example, the Proposed Rule states OIG/ HHS would:

*“[C]onsider ‘pharmacy benefit management services’ to be services such as contracting with a network of pharmacies; establishing payment levels for network pharmacies; **negotiating rebate arrangements [emphasis added]**; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs. We do not propose to create a definition for ‘pharmacy benefit management services’ as these services could evolve over time.”*

Indeed, many of these “pharmacy benefit management services” are provided by PBMs to health plans,¹¹ not manufacturers. In addition, “...performing drug utilization review; and operating disease management programs...” are services pharmacists provide. Therefore, APhA strongly recommends HHS/ OIG clarify these “services” listed in the Proposed Rule are not protected under a new PBM safe harbor¹² and HHS should ensure PBMs and plans provide adequate compensation to pharmacists providing these drug utilization reviews, disease state management services, formulary management, etc., where applicable, beyond the cost of simply purchasing medications. Furthermore, as many of these services will be provided to health plans, APhA also recommends OIG reference our previous concerns shared with HHS regarding PBMs’/ plans’ use of limited distribution networks¹³ and prior authorization¹⁴ which often limit patient access to necessary medications.

Finally, this second safe harbor would also require PBMs to “...disclose in writing to each health plan with which it contracts at least annually, and to the Secretary upon request, the services it rendered each pharmaceutical manufacturer that are related to the PBM’s arrangements with that health plan and the associated costs for such services.” However, the Proposed Rule does not require PBMs disclose this information to beneficiaries, pharmacies or other stakeholders which hinders OIG’s efforts to increase transparency.

Thank you for the opportunity to provide feedback on the Proposed Rule and consideration of our comments. As HHS understands, APhA supports patient access to affordable and cost-effective medications and appreciates your continued efforts to look at ways to reduce patients’ rising prescription drug costs. APhA welcomes the opportunity to serve as a

¹¹ APhA also asks OIG remove and correct references to the term “health insurance providers” (see, Pgs. 2354, 2363) as health plans do not meet any definition of clinical health care “providers,” under current statute or regulations.

¹²Ibid.

¹³ APhA/NASPA. Joint comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. July 16, 2018, available at: https://www.pharmacist.com/sites/default/files/audience/Submitted%20-%20%20Joint%20APhA%20NASPA%20Comments%20-%20Trump%20Drug%20Pricing%20Blueprint%20July%2016%202018_0.pdf

¹⁴ APhA comments on CMS’s Proposed Rule Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. January 25, 2019, available at: <https://www.pharmacist.com/sites/default/files/audience/APhA%20Comments%20to%20CMS%20on%20Part%20D%20Drug%20Pricing%201%202025%2019%20FINAL.pdf>

resource to HHS and can provide access to pharmacists who are experiencing the effects of these pricing policies. If you have any questions or require additional information, please contact, Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Mitchel C. Rothholz, RPh, MBA, APhA Chief Strategy Officer
Principal Deputy Inspector General Joanne Chiedi
The Honorable Alex Azar II, Secretary, HHS