APhA
American Pharmacists Association

March 7, 2022

Jennifer Shapiro, Director of the Medicare Plan Payment Group
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-4192-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, Proposed Rule

Submitted via www.regulations.gov to Docket Number: CMS-4192-P

Dear Director Shapiro:

The American Pharmacists Association (APhA) is pleased to submit comments on the Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, Proposed Rule.

APhA is the only organization advancing the entire pharmacy profession. Our expert staff and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians find success and satisfaction in their work while advocating for changes that benefit them, their patients, and their communities.

Background
For years, APhA, its pharmacy partners, and community pharmacies have submitted comments to CMS regarding the harmful impact of retroactive "clawbacks," from pharmacy benefit managers (PBMs) operating as a standalone Part D plan sponsor or contracted to provide the prescription benefit for a health plan that serves as the plan sponsor. PBMs use retroactive direct and indirect remuneration (DIR) fees to increase out-of-pocket costs for Part D beneficiaries, resulting in pharmacies closing their doors and endangering access to pharmacist-provided care.

As CMS notes in the preamble, retroactive DIR fees imposed on pharmacies have exploded in recent years, where "[t]he data show that pharmacy price concessions, net of all pharmacy

incentive payments, grew **more than 107,400 percent between 2010 and 2020**." This is unsustainable.

PBMs extract retroactive DIR fees from pharmacies weeks or months after they dispense prescriptions to Medicare Part D patients. The fees are based on PBM and Medicare Part D plan "savings," generated by requiring price concessions for pharmacies to be part of their networks. However, since beneficiaries' point-of-sale prices or copays at the pharmacy counter are based on the contracted price before retroactive DIR is extracted, beneficiaries end up paying higher out-of-pocket costs for their prescription drugs.

As CMS states in the background of the proposed rule, numerous research studies suggest higher cost-sharing can impede patient access to necessary medications, which can lead to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.[1]

Furthermore, the retroactive nature of the fees prevents pharmacies from determining whether they can afford to stay open—and many cannot. Community pharmacies, which are vital to the Administration's health equity efforts and operate in underserved areas, bore the brunt of the closures (one in eight pharmacies closed between 2009 and 2015), but retroactive DIR fees affect pharmacies of all sizes.[2] This is an additional harm to seniors and millions of other Americans who need access to local health care providers.

APhA has four primary recommendations for CMS, as described within these comments:[3]

- **Finalize the definition of "negotiated price" in proposed § 423.100.**
- **Ensure that the lowest possible reimbursement guarantees payment for a pharmacy's cost for purchasing and dispensing medications.**
- **Apply the same definition of "negotiated price" uniformly across Part D plan phases.**
- **End the remaining devastating business practices of PBMs.**

[1] See, page 736. Michele Heisler et al., "The Health Effects of Restricting Prescription Medication Use Because of Cost," Med Care, 2004 Jul;42(7):626-634, available at https://www.ncbi.nlm.nih.gov/pubmed/15213486. Also, see Peter Bach, "Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs," New England Journal of Medicine 2009, 360:626-633, available at https://www.nejm.org/doi/full/10.1056/NEJMhpr0807774. Also, see Sonya Blesser Streeter et al, "Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions," Journal of Oncology Practice 2011, 7(3S):46s-51s, available at: http://ascopubs.org/doi/full/10.1200/jop.2011.000316.

[2] Guadamez, J et al., Assessment of Pharmacy Closures in the United States From 2009 Through 2015. JAMA Intern Med. 2020;180(1):157-160. doi:10.1001/jamainternmed.2019.4588, available at: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2753258

[3] APhA offers these comments on the proposed rule without commenting on CMS' statutory authority to modify the definition of "negotiated prices." APhA is presently a plaintiff in a lawsuit challenging CMS' existing regulatory definition of "negotiated prices," *see NCPA et al. v. Becerra*, No. 1:21-cv-131 (D.D.C.), and nothing in this letter should be construed as a waiver of the arguments that APhA and the other plaintiffs have made in the litigation challenging the existing regulatory definition.

APhA provides the following comments on the specific provisions in the proposed rule:

Comments re: Introduction (pg. 1909)

As explained in the introduction to the proposed rule, to address concerns about the lack of transparency in the performance measures used to evaluate pharmacy performance, CMS finalized a proposed amendment to § 423.514(a), requiring Part D sponsors to disclose to CMS their pharmacy performance measures used to evaluate pharmacy performance, starting January 1, 2022, as established in their network pharmacy agreements. This is an essential first step toward building equitable pharmacy performance programs that are based on standardized quality measures with technical specifications appropriate for use in pharmacies.

The performance measures that health plans and their PBMs use to determine DIR fees are arbitrary, lack transparency, and are not subject to oversight. While PBMs contend such DIR fees are based on "pharmacy performance," the metrics used by PBMs in assessing performance are not standardized nor appropriately incentivized like in other CMS performance programs, and therefore, offer pharmacies little opportunity to actually influence their "quality" scores. PBM agreements may also assess "pharmacy performance," based primarily on certain types of maintenance medications—such as those for diabetes or statins—but assess DIR fees against the gross reimbursement for all prescriptions received by pharmacies, not just maintenance medications. This results in an inappropriate performance program design for pharmacies across the board. For example, in community oncology clinics with integrated on-site pharmacies or dispensing facilities, which dispense few maintenance medications, application of this approach provides a significant windfall for PBMs. In this case, a 5% DIR Fee on a $2,000 oral cancer drug provides a $100 profit to the PBM each time the drug is dispensed.[4]

APhA strongly urges CMS to publicly release Part D sponsor pharmacy performance data in a comprehensive form to allow analysis by all pharmacy stakeholders and to examine whether these "metrics" actually evaluate pharmacists' ability to improve health care outcomes or measure pharmacy "quality."

[4] Freir Levitt, LLC. PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues. January 2017, available at: https://communityoncology.org/wp-content/uploads/2017/01/COA_White_Paper_on_DIR-Final.pdf

Comments re: Cost-Sharing (pg. 1913)

As CMS explains, "when pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point-of-sale (that is, are applied instead as DIR at the end of the coverage year), beneficiary cost-sharing increases, covering a larger share of the actual cost of a drug."

However, CMS states in the proposed rule that applying price concessions to the point-of-sale provides "$33.1 billion savings to beneficiaries over 10 years (2023-2032)," without application to the coverage gap.

CMS also states the agency "anticipate[s] that beneficiaries would see *lower prices at the pharmacy point-of-sale* [emphasis added] and on Plan Finder for most drugs, beginning immediately in the year the proposed change would take effect (2023)."

CMS' proposed rule will unquestionably lower patients' out-of-pocket costs. Since patients' point-of-sale prices or copays at the pharmacy counter are based on the contracted price before retroactive DIR is extracted, retroactive DIR fees hide the true cost of patients' prescriptions and unnecessarily increase their out-of-pocket costs for their prescription drugs and their cost-sharing obligations.

APhA strongly agrees with CMS' analysis that "lower point-of-sale prices would result directly in lower cost-sharing costs for non-low-income beneficiaries, and *on average we expect these cost-sharing decreases would exceed the premium increases* [emphasis added]."

To ensure transparency and predictability for pharmacists and our patients, APhA requests CMS clarify that prices net of DIR will be available on the pharmacy receipt, as well as on the Explanation of Benefits, and displayed in Plan Finder.

Comments re: Transparency and Competition (pg. 1914)

CMS states, "[t]he significant growth in pharmacy price concessions in recent years and inconsistency in how pharmacy price concessions are treated by different Part D sponsors (that is, they are applied to the point-of-sale price to differing degrees or estimated and factored into plan bids with varying degrees of accuracy) has resulted in plans that are not consistent with each other with respect to the aggregate share of drug costs covered by the plan versus the beneficiary."

CMS' proposal for all price concessions to be included in the negotiated price at the pharmacy counter will increase consistency for Part D plans, increase transparency for patents and help pharmacies better determine whether they can afford to stay open.

To ensure transparency, APhA strongly urges CMS to make clear in the final rule that this "negotiated price," from Part D plans is visible to pharmacies for each individual claim at the point-of-sale on the adjudicated claim response to ensure profit or loss of a transaction at the pharmacy counter. APhA also requests CMS confirm that the "negotiated price," equals the amount on a pharmacy's remittance advice that is paid within the prompt pay rules of 14 calendar days.

APhA is also concerned that PBMs will restructure pharmacy fees to sources other than claim-level fees to circumvent the proposed rule. Accordingly, APhA urges CMS to also ensure PBMs make all pharmacy price concessions attributable at the claim level for increased transparency for pharmacies and our patients.

Comments re: Proposed Changes to the Definition of Negotiated Price (§ 423.100) (pg. 1914)

In essence, CMS is eliminating PBMs' and Part D plans' use of retroactive DIR fees. APhA strongly supports CMS' proposal to adopt a new definition of "negotiated price" at § 423.100 that would include all pharmacy price concessions received by the plan sponsor for a covered Part D drug at the point-of-sale. We commend CMS for closing the regulatory loophole created under the 2014 final rule[5] where the "exception" to other types of PBM-negotiated price concessions reflected at the pharmacy counter has proven to be anything but "narrow." Instead, PBMs have exploited the loophole to use retroactive DIR "clawbacks," as a new revenue stream for themselves by destabilizing pharmacy businesses, pocketing savings that rightly belong to Part D patients, and endangering access to pharmacist-provided patient care.

APhA believes Congress' plain language and intent in the legislation that established the Medicare Part D program[6] is that beneficiaries have access to negotiated prices, and negotiated price concessions including, but not limited to, DIR, discounts, and rebates, be taken into account in determining the negotiated price available for the beneficiary. The loophole created by excluding price concessions that cannot be reasonably determined at the point of sale from

[5] CMS. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. Final Rule. 79 FR 29843. 5/23/2014, available at: https://www.federalregister.gov/documents/2014/05/23/2014-11734/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the

[6] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).

the definition of negotiated prices is counter to this legislative intent. As a result, as CMS clearly explains in the proposed rule, beneficiaries pay higher costs at the counter due to inflated costs at the point of sale.

We appreciate CMS' recognition that pharmacy price concessions can be included in the negotiated price and implemented in a manner that provides meaningful price transparency, consistent application of all pharmacy payment concessions by all Part D sponsors and preventing cost-shifting to beneficiaries and taxpayers. Plans argue that performance-contingent pharmacy payment arrangements are variable and can only be determined after the sale. However, experience demonstrates that contract arrangements between pharmacies and plans leaves little leeway for pharmacies to be considered "high" performing and are often assessed maximal DIR fees retroactively. Although we disagree with the non-transparent, unfair, and unstandardized means of determining pharmacy performance, there is no reason to believe that plans cannot account for this at the point of sale.

Comments re: Lowest Possible Reimbursement (pg. 1915)

CMS states that "[r]equiring the negotiated price to reflect the lowest possible pharmacy reimbursement as proposed would move the negotiated price closer to the final reimbursement for most network pharmacies under current pharmacy payment arrangements, and thus closer to the actual cost of the drug for the Part D sponsor."

We also appreciate CMS' exclusion of additional contingent amounts, such as incentive fees, in order to allow pharmacies to receive increased reimbursements without increasing patients' costs at the pharmacy counter. This should be maintained in the final rule.

However, APhA strongly recommends CMS add safeguards that the reimbursement rate to network pharmacies, at a minimum, covers the pharmacy's costs of purchasing and dispensing covered items and providing covered services even when all pharmacy price concessions are applied at the point of sale. Pharmacies should never be forced to dispense medications at a loss below the cost to acquire these medications from wholesalers. Such guardrails are necessary to protect pharmacies from any unintended consequences.

Comments re: Negotiated Prices of Applicable Drugs in the Coverage Gap (pg. 1916)

CMS' proposed rule also states "[i]n contrast, for applicable drugs during the coverage gap, plans would have the flexibility to determine how much of the pharmacy price concessions to pass through at the point-of-sale, and beneficiary, plan, and manufacturer liability in the coverage gap would be calculated using this alternate negotiated price."

In essence, CMS is setting up a dual track where all pharmacy price concessions have to be passed through to patients at the point of sale except for drugs in the coverage gap. APhA strongly disagrees with this approach.

CMS knows very well that whenever such "flexibility" is permitted, Part D plans have a scant track-record of passing through these savings to beneficiaries. As CMS states in the proposed rule, "actual Part D program experience has not matched expectations in this regard. In recent years, less than 2 percent of plans have passed through any price concessions to beneficiaries at the point-of-sale." In 2018, CMS previously estimated "less than 1 percent of plans have passed through any price concessions…the amount that is passed through is less than 1 percent of the total price concessions those plans receive."[7]

Based on comments, CMS states the agency "will need to provide technical or operational guidance to Part D sponsors regarding the calculation of the gap discount, PDE reporting, and straddle claim processing." CMS requested comments on concerns "about the feasibility of sponsors having two different rules for applying pharmacy price concessions to applicable drugs in the coverage gap versus other phases of the Part D benefit." APhA believes that such complexity is unnecessary and appears to be based around maintaining premium "savings." Furthermore, this action conflicts with CMS' own estimation that "on average we expect *these cost-sharing decreases would exceed the premium increases* [emphasis added]."

APhA believes CMS should apply the same approach for pharmacy price concessions regardless of whether a beneficiary is in the Part D coverage gap. The definition of "negotiated price" should be revised to require Part D sponsors to apply all pharmacy price concessions at the point of sale regardless of type of drug or whether the beneficiary is inside or outside the Part D coverage gap. Having different and inconsistent standards perpetuates a lack of transparency, higher prices, and confusion at the point-of-sale and continues the retroactive uncertainty that CMS is otherwise addressing in another phase of Part D coverage.

Alternatively, CMS also states that applying pharmacy prices concessions to the point of sale in the coverage gap "shows the *increased savings* [emphasis added] to enrollees. Ten-year total savings to enrollees increase 37 percent from $21.3 billion…to $29.1 billion," with application of the new "negotiated price," to applicable drugs in the coverage gap," where "the total savings to enrollees accounts for both cost-sharing savings and expected premium increases."

[7] CMS. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. Proposed Rule. 11/30/2018. 83 FR 62152, available at: https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses

Comments re: Non-pharmacy Price Concessions/Manufacturer Rebates

CMS also states in the proposed rule that the agency is focusing its policy proposals on "pharmacy price concessions, and not non-pharmacy price concessions [manufacturer rebates]," which CMS notes "account for the largest category of DIR." APhA agrees that CMS has clear, independent statutory authority, pursuant to section 1860D-2(d)(1)(B) of the Social Security Act, to regulate the application of non-pharmacy price concessions to negotiated price. APhA also appreciates that CMS is "following an incremental approach and only proposing policies related to pharmacy price concessions at this time." However, the proposed rule would reduce the negotiated price along with "non-pharmacy price concessions [manufacturer rebates] and other [DIR] that the Part D sponsor passes through to Part D enrollees at the point of sale." APhA is concerned that this provision could be read to mean that pharmacies are accountable for "non-pharmacy" price concessions and asks for clarification in the final rule. There is simply no connection between nonpharmacy price concessions given by manufacturers to PBMs and the prices paid by pharmacies to their wholesalers. Accordingly, APhA asks CMS to expressly clarify that "nonpharmacy price concessions," as used in this provision, are not intended to be associated with pharmacy payments.

As CMS understands from estimates in previous final and proposed rules, today, many cost-sharing amounts are tied to the list price of medicines, even if insurers are charged less. Moving "non-pharmacy price concessions [manufacturer rebates], under the delayed "rebate rule"[8] to the point-of-sale would begin to put an end to this practice by insurers, which results in sick patients subsidizing insurers and healthy patients. Rather, it would ensure that Part D works how insurance is supposed to work, with everyone paying in and the healthy subsidizing the sick.

As "non-pharmacy price concessions" are mentioned in this proposed rule, APhA reminds CMS that certain classes of medicines – diabetes, rheumatoid arthritis, and others – have historically significant high manufacturer rebates and have not passed those rebates onto patients to help with their out-of-pocket costs. Previous analyses shows that patient cost-sharing savings under such a proposal would *outweigh* the small ($3-$6) increase in average monthly premiums that HHS had predicted for beneficiaries who do not qualify for the low-income subsidy – on average, a dime a day. For example, actuaries have estimated that a

[8] See, CMS. 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. Final Rule. (85 FR 76666).

beneficiary taking a $400 brand medicine with a 30% manufacturer rebate could save $120 in the deductible and then $30 monthly on coinsurance.[9]

Comments re: Impact on Prescription Drug Costs for Government, Beneficiaries, Part D Sponsors, and Manufacturers (pg. 1944)

In the proposed rule, CMS "estimates assume that pharmacies will seek to retain 2 percent of the existing pharmacy price concessions they negotiate with plan sponsors and other third parties to compensate for pricing risk and differences in cash flow and we assume that these business decisions will result in a slight increase in pharmacy payments of 0.1-0.2 percent of Part D gross drug cost." CMS is also soliciting comment on the potential indirect impact estimates of the pharmacy price concessions provision included in this rule.

APhA members, across all sites of care, believe CMS' estimate of a "slight increase in pharmacy payments" is overly optimistic, even at 0.1-0.2 percent of gross drug cost, and that without sufficient guardrails in the final rule to ensure pharmacies do not have to dispense medications below acquisition cost, PBMs will use existing practices to further decrease pharmacy revenues.

In order to provide applicable and comprehensive comments, APhA requests CMS provide the complete context and analysis made to provide these estimates of the amount that pharmacies will seek to retain. More specifically, CMS should make available the determination of the "slight increase in pharmacy payments" of Part D gross drug cost in a publicly viewable format with a new, formal notice and comment period for pharmacy stakeholders to provide accurate and informed feedback on these estimates to the agency.

Conclusion

APhA urges CMS not to leave PBMs the opportunity to find other loopholes to squeeze patients and pharmacies. Without additional clarifications to the proposed rule, PBMs will still be able to use DIR fees to extract arbitrary fees, merely moving them to the point-of-sale, in addition to extracting other unreasonable concessions from pharmacies. APhA remains concerned about other abuses by PBMs, including negative reimbursements (through which the PBM reimburses the pharmacy less than it costs to acquire the drug) and "patient steering" for brand, generic, and specialty drugs to PBM-affiliated pharmacies. As such, it is important for CMS to finalize the definition of "negotiated price" to address at least one of these harmful tactics used by PBMs.

[9] Klaisner J, Holcomb K, Filipek T. "Impact of Potential Changes to the Treatment of Manufacturer Rebates." Milliman, January 2019, available at: https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf

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As you finalize the proposed rule and deliberate on other relevant CMS policies, please separately consider the reimbursement of the product cost (which is fixed for pharmacists) from the cost of dispensing and any related patient care service or performance incentive payment. This would provide adequate reimbursement under a sustainable business model that improves—and does not disrupt—Medicare beneficiaries' access to pharmacy care.

Keeping the doors to our nation's community pharmacies open is vital for achieving the Administration's health equity goals where the anticompetitive actions of the vertically-merged PBMs are putting pharmacies out of business and creating "pharmacy deserts" in minority and underserved communities.[10] Pharmacists have demonstrated during the COVID-19 pandemic that we are a vital part of health care infrastructure to advance health equity in underserved and minority communities, whether rural or urban, where the local community pharmacy may be the only health care provider for miles.

APhA urges CMS to finalize the proposed rule in a uniform manner and build on this first step of eliminating retroactive DIR fees by taking action to end the remaining devastating business practices of PBMs, which only increase costs for patients, pharmacies, and the federal government. We also highly recommend that you review the new report "Deserving of Better: How American Seniors Are Paying for Misaligned Incentives Within Medicare Part D,"[11] which provides additional data and information about Medicare Part D payment and identifies new approaches that would save money for beneficiaries and the government.

Thank you for your efforts to end Part D plans' and PBMs' harmful use of retroactive DIR fees. If you have any questions or require additional information, please contact Michael Baxter, Senior Director, Regulatory Policy at mbaxter@aphanet.org.

Sincerely,

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[10] Wisseh, Cheryl. Et. al. Social Determinants of Pharmacy Deserts in Los Angeles County. Journal of Racial and Ethnic Health Disparities volume 8, pages1424–1434 (2021), available at: https://link.springer.com/article/10.1007/s40615-020-00904-6
[11]Three Axis Advisors. Deserving Of Better: How American Seniors Are Paying for Misaligned Incentives Within Medicare Part D. March 2022, available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=WsZuUr4MMAw%3d