July 15, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Meeting Request—Pharmacy Community Comments to CMS on Negotiated Price Reforms Included in Final Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-F)

Dear Administrator Brooks-LaSure:

The undersigned organizations thank the Centers for Medicare and Medicaid Services ("CMS") for finalizing the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4192-F) (hereinafter the "final rule") as a meaningful first step to reform Medicare Part D price concessions, also known as "pharmacy direct and indirect remuneration" or "pharmacy DIR fees" at the point of sale.

We support CMS' effort to reduce prescription drug prices for Medicare Part D beneficiaries by removing the reasonably determined regulatory exception and adopting a revised definition of "negotiated price" for a covered Part D drug that includes all pharmacy price concessions, requiring them to be applied at the point of sale. Doing so should better align marketplace competition with the interests of Medicare beneficiaries and lead to lower out-of-pocket costs. We also appreciate that the final rule may provide enhanced transparency for pharmacies operating in the program. However, we have a number of concerns with the final rule for which we would appreciate further conversation with, and action by CMS. The undersigned organizations respectfully request a timely meeting to discuss these issues further and to collaborate and identify where regulatory action can occur to address these issues. Our concerns are outlined below.

We thank you in advance for consideration of these comments and again request that a timely meeting be held with the signatories of the letter to address these issues. Please contact any of the following individuals to schedule a meeting.

Sincerely,
American Pharmacists Association: Michael Baxter (mbaxter@aphanet.org)
FMI - The Food Industry Association: Jennifer Hatcher (jhatcher@fmi.org)
National Association of Chain Drug Stores: Christie Boutte (cboutte@nacds.org)
National Association of Specialty Pharmacy: Julie Allen (julie.allen@powerslaw.com)
National Community Pharmacists Association: Ronna Hauser (ronna.hauser@ncpa.org)
National Grocers Association: Stephanie Johnson (sjohnson@nationalgrocers.org)

Cc: Jonathan Blum; CMS Principal Deputy Administrator & Chief Operating Officer
Cheri Rice; Center for Medicare Deputy Director, Parts C and D
Amy Larrick; Director, Medicare Drug Benefit and C and D Data Group

Pharmacy Community Concerns for Discussion with CMS

Reasonable Pharmacy Reimbursement and Impact on Beneficiary Access to Pharmacies

Immediate Pharmacy Reimbursement Concerns: Calendar Year 2023

Although pharmacies are generally supportive of the final rule as a first step toward needed pharmacy DIR reform, we want to collectively reiterate to CMS the anticipated significant 2023 reimbursement concerns that are expected from its implementation. Pharmacies are in receipt of calendar year 2023 agreements that we understand will represent major upfront reimbursement reductions, and we expect these pharmacies will also be subjected to significant retroactive DIR claw backs (from 2022 agreements) that are applied during the 2023 calendar year. Pharmacies may be forced to restructure their operations in anticipation of significant reimbursement concerns, and we collectively share concerns about the impact this may have on beneficiary access to pharmacies for their medications and services.

Reasonable Pharmacy Reimbursement and Impact on Beneficiary Access to Pharmacies

Once the final rule goes into effect in 2024, we remain very concerned about the prospect of continued post-sale pharmacy price concessions in addition to significant reductions in upfront reimbursement. Despite the rule's revisions to negotiated price, the rule continues to permit plans and their PBMs to charge pharmacies post-sale price concessions, which we believe will compromise a fair, competitive, and transparent Part D pharmacy marketplace by reimbursing pharmacies below their cost, and therefore, undermining their participation in plan networks.

CMS previously recognized that any willing provider requirements permit the agency to regulate reasonable reimbursement provisions.[1] In the final rule, CMS states that the agency is considering rulemaking to "establish safeguards to guarantee that pharmacies participating in Medicare Part D receive a reasonable rate of reimbursement."[2] Considering that the final rule does not address the impacts that retroactive DIR fees have had on pharmacy viability and beneficiary access to pharmacies, we are pleased that CMS is considering this long-overdue rulemaking and urge the agency to begin the rulemaking process immediately.

CMS has recognized that pharmacy DIR fees have increased significantly, growing more than 107,400 percent between 2010 and 2020.[3] We are concerned that the exponentially increasing downward push on pharmacy reimbursement will lead to continued pharmacy closures, limiting beneficiary access to their pharmacies.

Nationwide, pharmacies of all types have reported that pharmacy DIR fees often result in pharmacy reimbursement that is below a pharmacy's costs to dispense drugs to Medicare beneficiaries. Some pharmacies have reported publicly that such deep concessions have made their participation in preferred pharmacy networks unsustainable. This structure puts pharmacies in an untenable situation with respect to providing needed care for the beneficiaries and communities they serve.

[1] 79 Fed. Reg. 1918, 1970 (January 2014).
[2] 87 Fed. Reg. 27704, 27845 (May 2022).
[3] 87 Fed. Reg. 1842, 1910 (January 2022).

We have long advocated for the end of retroactive pharmacy DIR fees on pharmacies. We implore CMS to assess the impact that the final rule has on pharmacy reimbursement on an ongoing basis and to continue to assess any use of retroactive pharmacy DIR fees and whether such fees violate the terms of the final rule or ultimately result in unreasonable reimbursement in violation of the any willing provider statute, so immediate action can be taken by CMS.

Pharmacy Performance Evaluations and Possible Incentive Payments

The final rule continues to permit contract agreements between pharmacies and plans that allow for positive incentive payment adjustments (e.g., performance-based agreements) outside of the negotiated price. However, as CMS noted in the final rule, pharmacies rarely receive these types of payments, and the final rule provided no incentives for plans/PBMs to offer such incentive-based opportunities to pharmacies. CMS also did not establish any parameters in the final rule to ensure pharmacy performance evaluations for any such incentive payment terms are appropriate, fair, and relevant based on the drugs a pharmacy dispenses and the services a pharmacy provides. In the absence of these important issues being addressed by CMS, pharmacy cannot expect or rely on incentive payment opportunities to address reimbursement concerns.

Our organizations continue to advocate for comprehensive pharmacy DIR reform, with such reform including the standardization of performance-based pharmacy price concessions, CMS requirements for fair pharmacy performance evaluation, and regulatory incentives for plans to offer pharmacy performance-based agreements to pharmacies. We believe it is important that CMS immediately work with pharmacy stakeholders to conduct a review to ensure pharmacy performance evaluations are fair and are associated with Part D plans' Star Ratings, thus aligning incentives for Part D plans and pharmacies toward better quality, equity, and reductions in preventable spending for beneficiaries.

Specifically related to action we believe CMS can and must take immediately, in the final rule, CMS stated the following:

> We addressed reporting of pharmacy performance measures to CMS in the January 2021 final rule (86 FR 5864). In the January 2021 final rule, we finalized a proposal to give CMS the authority to establish a Part D reporting requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements. This authority to establish a reporting requirement is effective January 2022; however, the actual data elements must be proposed through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process in a future package.[4]

CMS' delay in exercising its authority to establish a Part D reporting requirement for Part D sponsors to disclose the pharmacy performance measures they use is especially disconcerting, given the concerns expressed by the pharmacy community and CMS' reporting that such measures have directly resulted in the substantial growth of pharmacy DIR fees. We continue to encourage CMS to undertake and enforce collection of these measures and to conduct a review with pharmacy stakeholders, as we highlight above. We also urge CMS to work in collaboration with the Federal Trade Commission on this review, as the FTC considers anticompetitive market practices impacting pharmacies that are not affiliated with plans or PBMs.

[4] 87 Fed. Reg. 27704, 27844 (May 2022).

Impact on Pharmacy Viability

CMS estimated that the final rule could result in a slight increase in pharmacy payments of 0.1 - 0.2 percent of Part D gross drug cost.[5] We question the basis of these assumptions and request CMS provide the numbers or calculations upon with they relied. We are very concerned most pharmacies will instead see significant reductions in payments; and we seek CMS' calculations to better understand the agency's assumptions.

Further, we are concerned that CMS' Regulatory Flexibility Act ("RFA") analysis does not fully contemplate the proposal's impact on smaller pharmacy businesses.[6] It is well established that an agency must conduct an RFA analysis or certify that a proposed rule will have a significant impact on a substantial number of small entities.[7] If the agency does the latter certification, the agency must provide a factual basis, including[8] a description of the number of affected entities and the size of the economic impact on those small businesses, including revenue.

Additionally, CMS should consider the unintended consequences of its 2014 rule, which inadvertently produced the dramatic pharmacy DIR fees seen today by PBMs. Being mindful that it is entirely possible that similar unintended consequences could result from this final rule, CMS should carefully monitor novel PBM activities that run counter to CMS' intent. We again encourage CMS to engage with FTC as its inquiry into the business practices of PBMs proceeds, but also CMS should continue to study and report on PBM industry trends and practices that change noticeably as a result of the final rule that do not have beneficiaries' best interests in mind.

Proper Reporting of Pharmacy Administrative Service Fees

To ensure that "pharmacy administrative service fees" are properly reported either in a plan's bid or as a price concession in the "negotiated price," as required in the final rule, we urge CMS to require plans to certify or attest that any administrative fees, regardless of what the plan or PBM calls them, are actually utilized for administrative services and that such services are relevant and applicable to the pharmacy against which the fee is applied. Fees that the plans collect from pharmacies should either be accounted for in the plan bid as a cost of administering the benefit or they must be acknowledged as part of the "negotiated price" so they may be included in the calculation under the final rule that lowers beneficiaries' out-of-pocket costs. CMS has required such a certification or attestation process from the Chief Executive Officer, Chief Financial Officer, Chief Operating Officer or other delegated individual for other programs under Medicare to ensure compliance with program requirements.[9]

Part D Bidding Process

As the final rule is being implemented, CMS must closely review plan bid estimations and reporting of DIR and other fees. CMS must disincentivize plans from underestimating prospective DIR during their bid submissions, and given CMS' acknowledgements in the rule, should be overseeing this process to

[5] 87 Fed. Reg. 1842, at 1944.
[6] 5 U.S.C. § 601-612.
[7] *Id.*
[8] 70 Fed. Reg. 4194, 4497 (January 2005) ("HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.").
[9] 81 Fed. Reg. 41099 (June 2016).

understand to what extent plans are retaining overpayments obtained from DIR and administrative fees that are in excess of their DIR bid estimates. Eliminating this practice should be a priority focus for the agency.

Clarity Needed Regarding Pharmacy Claims Processes

We request that CMS address the lack of clarity in the final rule regarding pharmacy claims processes and information transparency to pharmacies. First, to ensure full transparency for pharmacies at the point-of-sale, we request that CMS clarify that Part D plans must provide a mechanism for pharmacies to know the lowest possible reimbursement at the point-of-sale. Part D plans must ensure that the appropriate fields are included and populated in the claims response so that this information is provided to the pharmacy.

Second, we request that CMS provide clarity for situations when a Part D plan reimburses the pharmacy at the point-of-sale in an amount that is greater than the lowest possible reimbursement and the timeframe for when a plan may adjust that reimbursement to a different amount. We ask that CMS ensure that a plan that makes any such adjustment does so in accordance with Part D prompt payment requirements.

Conclusion

On behalf of the pharmacy community, we reiterate our thanks for CMS taking an initial step forward toward addressing pharmacy DIR concerns and reducing beneficiary drug cost. We now want to work with CMS to achieve needed comprehensive pharmacy DIR reform that will support the viability of our pharmacies and allow for beneficiary access to the pharmacy of their choice. We urge CMS to put in place additional regulatory protections as detailed above to ensure other incentives within the Medicare program are not exploited by plans or their partners before and after the final rule goes into effect.