APhA
American Pharmacists Association

June 26, 2025

[Submitted electronically to IRARebateandNegotiation@cms.hhs.gov]

Chris Klomp
Deputy Administrator of the Center for Medicare
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, Maryland 21244-1859

RE: Medicare Drug Price Negotiation Program Draft Guidance

Dear Deputy Administrator Klomp,

The American Pharmacists Association (APhA) appreciates the opportunity to provide CMS comments on the May 12, 2025, Medicare Drug Price Negotiation Program Draft Guidance. APhA commends CMS for recognizing the vital role pharmacies will play in the success of the Medicare Drug Price Negotiation Program. However, APhA recommends that pharmacies, especially those anticipating material cash flow problems, be able to continue serving the patients within their communities. More specifically, APhA urges CMS to reconsider mandating pharmacy participation and ensure pharmacies are paid promptly and adequately.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

40.4.2.2 Dispensing Entity Enrollment in the MTF DM

Previously, "CMS finalized in rulemaking a requirement that Part D plan sponsors, starting in contract year 2026, include in their pharmacy agreements provisions requiring the pharmacy to

be enrolled in the MTF DM."[1] CMS reasoned that "[d]ispensing entity enrollment in the MTF DM [(Medicare Transaction Facilitator Data Module)] is needed for necessary operations related to administration of the [Medicare Drug Price] Negotiation Program and the Part D program, including creating and making available remittances or ERAs [(Electronic Remittance Advices)], maintaining access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are drugs covered under Part D, and ensuring accurate Part D claims information and payment."[2] CMS noted that commenters responding to the "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027"… "noted that small pharmacies that rely primarily on prescription revenue to maintain business operations would face material cashflow pressures due to the shift from payment by the Part D plan sponsor to a combination of Part D plan sponsor payment plus a potentially lagged MFP refund."[3] CMS is "concerned" following the receipt of these comments, but that "this challenge will be most acute in the transition period when MFPs for selected drugs first become effective in January 2026 and at the start of each subsequent initial price applicability year when MFPs for new selected drugs first become effective," and CMS "does not anticipate this challenge to continue with respect to a selected drug once MFP [(maximum fair price)] refunds for that selected drug are flowing and dispensing entities become accustomed to the 14-day prompt MFP payment window."[4]

APhA raised its concerns to CMS in its previous comments that mandating plan sponsors, including pharmacy benefit managers (PBMs), include in their pharmacy contracts a requirement for pharmacies to be enrolled in the MTF DM will force pharmacies to take unsustainable financial losses. APhA also echoed these concerns more recently in response to CMS's request for information regarding President Trump's Executive Order 14192, "Unleashing Prosperity Through Deregulation." Pharmacies are already struggling due to unsustainable reimbursement rates from PBMs, often far below the cost of dispensing these medications, including a minimum of 3% below the cost of dispensing brand medications. This mandate further hurts pharmacies and will likely result in more pharmacy closures.[5] As such, APhA recommends that pharmacy participation be voluntary to avoid being subject to underpayment reimbursements from PBMs. If CMS continues to mandate pharmacy participation, CMS should explore avenues that do not run afoul of the noninterference clause

[1] Chris Klomp, *Draft Guidance on the Medicare Drug Price Negotiation Program*, Centers for Medicare & Medicaid Services, 71 (2025). Available at: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.
[2] *Id.* at 71-72.
[3] *Id.* at 73.
[4] *Id.*
[5] Ruichen Xu, et al., *Mapping U.S. Pharmacy Closures January 2014 to March 2024*, University of Pittsburgh (May 14, 2024). Available at: https://storymaps.arcgis.com/stories/21620f1e07c14d7f81adc4503faaf51e.

in section 1860D-11(i) of the Social Security Act. APhA notes that CMS in the past has cited this clause as the reason for their inability to protect pharmacies from underwater reimbursements made by the PBMs but points out that CMS is likely "interfering" here by requiring that any contract between the plan sponsor or its PBM and a pharmacy include a provision requiring a pharmacy to be enrolled in the MTF DM.

In this draft guidance, CMS stated that "[c]ommenters particularly noted that small pharmacies that rely primarily on prescription revenue to maintain business operations would face material cashflow pressures due to the shift from payment by the Part D plan sponsor to a combination of Part D plan sponsor payment plus a potentially lagged MFP refund."[6] In response, CMS plans to ask pharmacies to self-identify during enrollment if they "anticipate[] having material cashflow concerns at the start of the initial price applicability year due to the reliance on retrospective MFP refunds within the 14-day MFP payment window."[7] CMS then plans to share that information with Primary Manufacturers.[8] Primary Manufacturers will be required to include an approach to mitigate such cash flow concerns within their MFP Effectuation Plans, as described in Section 90.2.1 of the draft guidance.[9] In creating this requirement, CMS expects primary manufacturers to be better situated to address the material cash flow concerns that some pharmacies may face so that beneficiaries do not lose access to these drugs.[10]

APhA has concerns regarding the effectiveness of the Primary Manufacturers' MFP Effectuation Plans in ensuring that pharmacies facing material cash flow concerns can survive financially during this transition and under this program. As noted by CMS within this draft guidance, types of pharmacies expected to experience this problem include "sole proprietor rural and urban pharmacies with [a] high volume of Medicare Part D prescriptions dispensed, pharmacies who predominantly rely on prescription revenue to maintain business operations, long-term care pharmacies, 340B covered entities with in-house pharmacies, and Indian Health Service, Tribal, and Urban Indian (I/T/U) pharmacies."[11] Closing pharmacies, especially those listed above, as they often serve rural and underserved communities, or making it financially impossible for these pharmacies to stock these medications, will cause patient access issues. In this draft guidance, CMS notes that it "recognizes that the success of the Negotiation Program is, in part, dependent on Medicare beneficiaries' access to selected drugs through dispensing entities, which in turn necessitates that dispensing entities—particularly those that rely primarily on prescription revenue to maintain business operations—are able to timely access

---

[6] Chris Klomp, *Draft Guidance on the Medicare Drug Price Negotiation Program*, Centers for Medicare & Medicaid Services, 73 (2025). Available at: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.* at 73-74.

the MFP."[12] Accordingly, CMS should do more to ensure pharmacies remain open, allowing patients to access their necessary medications. APhA recommends that CMS prioritize efforts in its final guidance that require prompt payment and adequate reimbursement for the services pharmacists provide to Part D enrollees.

This draft guidance also provides that "CMS will evaluate the degree to which this pharmacy self-identification process provides useful data for Primary Manufacturers in developing MFP Effectuation Plans."[13] APhA appreciates CMS taking steps to evaluate the effectiveness of this process and how it will impact the development of the MFP Effectuation Plans. APhA encourages CMS to use this data to ensure that pharmacies facing material cash flow concerns are appropriately supported and that reimbursement never falls below a product's acquisition cost.

40.4.3 MTF Payment Facilitation

During its previous comment request period, CMS received many requests for CMS "to support the facilitation of MFP refund payments between Primary Manufacturers and dispensing entities."[14] Within this draft guidance, CMS has clarified that it "will not float or issue funds to a dispensing entity on the Primary Manufacturer's behalf in anticipation of a future MFP refund payment from the Primary Manufacturer to the dispensing entity."[15] The draft guidance mentions "the following approaches [that] might be pursued by interested parties to provide timely payment, potentially focused on dispensing entities that self-identify as anticipating having material cash flow concerns at the start of the initial price applicability year, and all of which could be paired with retrospective reconciliation once the Primary Manufacturer receives claim-level data elements from the MTF DM: (1) Primary Manufacturers could make prospective sales of selected drugs to dispensing entities at the MFP while leveraging virtual inventory management systems and pharmaceutical wholesaler chargebacks where applicable; (2) Primary Manufacturers could establish pre-funded MFP refund payment accounts directly with dispensing entities; and/or (3) Primary Manufacturers could leverage established relationships between dispensing entities and PSAOs [(pharmacy services administrative organizations)] to establish accounts that are pre-funded by the Primary Manufacturer for the PSAOs to use to disburse MFP refund payments to dispensing entities, with the PSAOs facilitating any necessary financial, reconciliation, and administrative services for the dispensing entity, thus minimizing the number of point of contacts for the Primary Manufacturer."[16]

---

[12] *Id.* at 73.
[13] *Id.* at 74.
[14] *Id.* at 75.
[15] *Id.* at 77.
[16] *Id.*

APhA's previous comments urged CMS to reconsider mechanisms for prefunding the program to protect pharmacies from financial harm caused by its implementation. As CMS has made clear in this draft guidance that it will not prefund the program or float these costs, APhA stresses the importance of ensuring that pharmacies have viable ways to remain a part of the program because, without pharmacies, the program and CMS will fail to expand Americans' access to these medications. APhA again brings CMS's attention to studies it cited in its previous comments that show that pharmacies are considering or are already not stocking drugs with prices negotiated under Medicare Part D because of the cash flow problems and delays in payment due to the Inflation Reduction Act and that, on average, pharmacies will bear the burden of prefunding the program at the cost of almost $11,000 per week, with the estimated revenue loss between $40,279.04 and $46,475.82 per pharmacy per year.[17] As such, APhA urges CMS to implement protocols and safeguards that protect pharmacies from further financial harm, including prompt payment, adequate reimbursement, and appropriate education regarding the program.

While CMS provides three approaches for dispensing entities that anticipate having material cash flow concerns and Primary Manufacturers to take to resolve this issue, they are still inadequate. The first approach CMS recommends to solve material cash flows that dispensing entities may face is to have Primary Manufacturers "make prospective sales of selected drugs to dispensing entities at the MFP while leveraging virtual inventory management systems and pharmaceutical wholesaler chargebacks where applicable."[18] This approach fails to address the problem at hand and imposes an administrative burden on the pharmacy to track inventory and monitor chargebacks. The cost and labor burden of managing and operating the inventory in this manner, along with the unknowns surrounding pharmaceutical wholesaler chargebacks (e.g., reimbursement concerns), render this solution insufficient.

Another approach outlined in this draft guidance by CMS to solve this problem was that "Primary Manufacturers could establish pre-funded MFP refund payment accounts directly with dispensing entities."[19] This approach shifts prefunding away from CMS to Primary Manufacturers. Because this option to prefund would not be required, and the details

---

[17] *Report for January 2025 Survey of Independent Pharmacy Owners/Managers*, National Community Pharmacists Association (Jan. 27, 2025). Available at: https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf. *Unpacking the Financial Impacts of Medicare Drug Price Negotiation: Analysis of Pharmacy Cash Flows*, Three Axis Advisors (Jan. 2025). Available at: https://ncpa.org/sites/default/files/2025-01/January2025-ThreeAxisAdvisors-Unpacking-the-Financial-Impacts-of-Medicare-Drug-Price-Negotiation.pdf.

[18] Chris Klomp, *Draft Guidance on the Medicare Drug Price Negotiation Program*, Centers for Medicare & Medicaid Services, 77 (2025). Available at: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.

[19] *Id.*

surrounding any additional costs or burdens on pharmacies that have Primary Manufacturers prefund the program are unknown, this approach still falls short in ensuring that the implementation of this program does not overly burden all pharmacies, which may anticipate material cash flow concerns.

The last approach in this draft guidance from CMS related to dispensing entities having cash flow problems was that "Primary Manufacturers could leverage established relationships between dispensing entities and PSAOs to establish accounts that are pre-funded by the Primary Manufacturer for the PSAOs to use to disburse MFP refund payments to dispensing entities, with the PSAOs facilitating any necessary financial, reconciliation, and administrative services for the dispensing entity, thus minimizing the number of point of contacts for the Primary Manufacturer."[20] Again, this approach shifts the prefunding burden away from CMS to the Primary Manufacturers. The same concerns apply here as with the second option, as there is no guarantee that all Primary Manufacturers will pursue prefunding options. Thus, not many pharmacies will have access to a prefunded option.

In this section, CMS also states that "[n]either CMS nor the MTF Contractors will be responsible for funding or paying the refund amounts owed by the Primary Manufacturer in instances where the Primary Manufacturer does not pay an MFP refund owed to a dispensing entity, including in cases where the Primary Manufacturer may be unable to pay (e.g., bankruptcy, insolvency, etc.).[21] Additionally, "[n]either CMS nor its MTF Contractors will accrue any interest on funds held by the MTF PM [(Medicare Transaction Facilitator Payment Module)] during the period before the funds are transferred to the dispensing entity."[22] Further, CMS provides within the draft guidance that it intends the agency to bear the costs of operating the MTF PM.[23] As such, Primary Manufacturers and dispensing entities are not required to pay any fees associated with the MTF PM, including user and transaction fees.[24]

APhA supports CMS, not pharmacies, funding the costs associated with the MTF PM, as any additional financial burdens placed on pharmacies will lead to more pharmacy closures, further limiting patient access to their medications and pharmacist patient care services. Additionally, APhA encourages CMS to ensure the implementation process and related protocols and procedures work smoothly once required. Any problems with the rollout or administration of the MTF PM will cost pharmacies money, as they will have to divert staff time and financial resources to solve problems that arise during the transitional period. To achieve a smooth transition, APhA requests CMS continue to provide pharmacies, pharmacists, pharmacy

[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] *Id.* at 77-78.

technicians, and other pharmacy personnel with ample educational resources regarding best practices. APhA routinely updates its members regarding the implementation of this program and CMS resources available to them and extends an offer to CMS to collaborate on further disseminating new information to our nation's pharmacists.

90.2.1. Manufacturer Plans for Effectuating MFP

As mentioned above, CMS will share a list of dispensing entities that self-identify as anticipating material cash flow issues with Primary Manufacturers, which are required to have processes within their MFP Effectuation Plans to mitigate these concerns.[25] The draft guidance provides that prospective purchasing agreements and accelerated MFP refund timelines are examples of ways Primary Manufacturers can mitigate these concerns.[26] APhA supports mechanisms that alleviate the financial burdens associated with implementing this program. However, APhA is concerned about the unknown consequences of such mitigation strategies. Additionally, APhA is concerned that such arrangements might impose a cost or administrative burden on the pharmacy, which is already struggling to stay afloat. As such, APhA reiterates that pharmacy participation in the MTF DM should be voluntary, and CMS should prioritize policies and procedures that require prompt payment and adequate reimbursement for pharmacies.

APhA appreciates the opportunity to provide CMS with additional insight into how the Medicare Drug Price Negotiation Program Draft Guidance impacts pharmacies, pharmacists, and patients. APhA encourages CMS to utilize its authority to minimize the financial and operational burdens this guidance places on pharmacies, allowing them to stay open and continue providing access to these medications for patients nationwide. If you have any questions or would like to meet with APhA to discuss these comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Best,

Michael Baxter

Michael Baxter
Vice President, Government Affairs

[25] *Id.* at 170.
[26] *Id.* at 170-71.