APhA
American Pharmacists Association

October 30, 2025

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

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
7500 Security Boulevard
Baltimore, MD 21244-1859

RE: Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Dear Administrator Oz,

The American Pharmacists Association (APhA) appreciates the opportunity to provide CMS comments on the September 30, 2025, "Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028."

APhA is the only organization advancing the entire pharmacy profession. It 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.

As CMS works towards "supplement[ing] this guidance with further program instruction to explain how these policies will be implemented for initial price applicability year 2028 and during 2026, 2027, and 2028,"[1] APhA reemphasizes its concerns about the final guidance.

[1] Chris Klomp, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, Centers for Medicare & Medicaid Services, 1 (Sept. 30, 2025). Available at: https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

Providing Access to the MFP in 2026, 2027, and 2028 (Sections 40.4 and 90.2)

APhA has stated, and CMS has acknowledged, that a significant concern for pharmacies and pharmacists is that they will be reimbursed by Part D plan sponsors and pharmacy benefit managers (PBMs) at a rate below the cost of acquiring the medication.[2] Economics shows that a business cannot stay open if it sells products for less than the cost of acquiring them. While the closure of any business is tragic, the loss of a pharmacy can have a detrimental effect on the health and access to health care of individuals in a community. While CMS states in its final guidance that it "expects plans and PBMs to engage in sustainable and fair reimbursement practices with all pharmacies to ensure access to selected drugs … for individuals with Part D,"[3] a recent survey found that "96.5 percent of independent pharmacists said PBM and plan reimbursement for Medicare Part D threatened the viability of their business."[4] Taking this into consideration, given the rate at which pharmacies are closing and the already low plan and PBM reimbursement rates for medications, access to these medications for Medicare beneficiaries is in serious jeopardy. As CMS continues to move forward with its approach to ensuring pharmacies are adequately reimbursed, APhA asks CMS to include metrics on pharmacy financial health and stocking of the selected drugs as part of its monitoring for plan reimbursement of the selected drugs and to take subsequent action to correct problems that result in pharmacists being under-reimbursed for providing these medications. APhA reiterates to CMS that pharmacies must be reimbursed at a rate that accounts for the acquisition cost of the medication and a professional dispensing fee or patient access will be limited, as that same survey indicated that "93.2 percent of independent pharmacists are considering not stocking, or have already decided not to stock, one or more of the first 10 drugs listed in the Medicare Drug Price Negotiation Program."[5]

Within the final guidance, CMS notes that "commenters recommended that CMS should maintain and invest in the MTF infrastructure during the initial years of implementation to

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[2] *See* APhA Comments on Medicare Drug Price Negotiation Program Draft Guidance, APhA (June 24, 2024). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=OdXeJyyLtHw%3d. *See also* APhA Comments on Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA), APhA (April 25, 2025). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=FhUCsGiE6nw%3d. *See also* APhA Comments on Medicare Drug Price Negotiation Program Draft Guidance, APhA (June 26, 2025). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=yijpw7jX3j8%3d. *See also* Chris Klomp, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, Centers for Medicare & Medicaid Services, 47 (Sept. 30, 2025). Available at: https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

[3] *Id.* at 47.

[4] *Report for January 2025 Survey of Independent Pharmacy Owners/Managers*, National Community Pharmacists Association (Jan. 2025). Available at: https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf.

[5] *Id.*

avoid unnecessary administrative burden for manufacturers, pharmacies, and plans, with one commenter citing the potential cost and complexity of developing independent systems."[6] Following these remarks, CMS stated that another "commenter requested that CMS ensure that dispensing entities are not financially burdened through additional fees if a private market alternative is developed and leveraged in place of the MTF."[7] As CMS continues with the rollout of the MTF infrastructure, APhA asks CMS to ensure that pharmacy operations are not substantially burdened by the enrollment process or any subsequent changes to the system. Additionally, APhA asks that CMS consider the limited financial resources many pharmacies have and assess the additional strain that the costs of services or products used to verify or route MFP refund payments would place on their operations if they are not made available at no cost.

With respect to the MTF DM and PM rollout, CMS noted that at least "[o]ne commenter requested CMS publicly report metrics on pharmacy enrollment and other aspects of the MTF DM and PM rollout before initial price applicability year 2026 and publish more detailed information on the MTF testing scope and timeline process."[8] CMS responded by stating it "is committed to continued stakeholder engagement as preparations for MFP effectuation in 2026 continue, including providing information and support for stakeholders during enrollment, onboarding, and testing of the MTF."[9] APhA encourages CMS to continue providing these resources and to create additional opportunities for pharmacists and pharmacies to learn more about and ask questions about this rollout. APhA can communicate additional updates and the availability of new resources with our members and the over 330,000 pharmacists and pharmacy teams nationwide.

The final guidance provides that "[a] few of commenters state that, if required by a manufacturer to purchase retrospectively, pharmacies would have to purchase the drugs at a higher price and be exposed to financial shortfalls until receiving the MFP refund retrospectively."[10] Some "asserted that this process would lead to more independent pharmacies going out of business."[11] Other commenters pointed out that CMS should explore other options that "do[] not place financial constraints on pharmacies."[12] Addressing these concerns, CMS noted that "[i]n section 40.4 of this final guidance, CMS maintains that a Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP;

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[6] Chris Klomp, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, Centers for Medicare & Medicaid Services, 48 (Sept. 30, 2025). Available at: https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

[7] *Id.*

[8] *Id.* at 50.

[9] *Id.*

[10] *Id.* at 49.

[11] *Id.*

[12] *Id.*

or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP."[13] CMS then acknowledges "that there may be advantages and disadvantages to both approaches … [and] encourages Primary Manufacturers and dispensing entities to work together to reach agreements as to whether the dispensing entity will access the MFP prospectively or retrospectively for a given MFP-eligible claim."[14] APhA appreciates the efforts CMS has made to help alleviate some of the financial burden on pharmacies resulting from this program's implementation. If CMS continues not to prefund the program, APhA urges CMS to ensure that payment is promptly and easily made to pharmacies, that manufacturers work with pharmacies to resolve material cash flow concerns, and that future solutions are rolled out as CMS learns about the impact of this program on pharmacies.

CMS also states that "section 40.4.2.2 of this final guidance describes a process for dispensing entities to self-identify as dispensing entities that anticipate material cashflow challenges because of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window, and section 90.2.1 of this final guidance describes a requirement for Primary Manufacturers to include their process for mitigating cashflow concerns for such dispensing entities in their MFP effectuation plans."[15] APhA supports mechanisms that alleviate the financial burdens of pharmacies associated with implementing this program, but reiterates its previous concerns about the unknown consequences of such mitigation strategies. APhA is concerned that such arrangements could impose a cost or administrative burden on the pharmacy at a time when its financial and operational resources are already being strained. As such, APhA requests that CMS evaluate the successes and shortcomings of these mitigation strategies to recommend improvements for future iterations of these mechanisms, ensuring that pharmacies facing cash flow concerns can access these medications for their patients.

Retrospective Refund (Section 40.4.1)

Within the final guidance, CMS noted that several commenters stated that they opposed "the retrospective refund model discussed in section 40.4.1 of the draft guidance for initial price applicability year 2028, noting that they preferred a prospective MFP purchase model, where a dispensing entity would acquire the drug at the MFP cost, as opposed to a retrospective refund model, citing the potential financial strain that a retrospective refund model placed on dispensing entities."[16] In its response, CMS noted "that a Primary Manufacturer may provide access to the MFP prospectively or retrospectively."[17] APhA discusses its concerns in the above section. CMS also provided that some commentors "recommended changes to the 14-day prompt MFP payment window and considerations for providing the dispensing entities with access to the MFP more quickly."[18] Addressing the comments regarding the 14-day prompt

[13] *Id.*
[14] *Id.*
[15] *Id.* at 50.
[16] *Id.* at 55.
[17] *Id.*
[18] *Id.*

MFP payment window, CMS stated that it "will apply the standards set forth in current Part D prompt pay reimbursement regulations regarding payment by plan sponsors to pharmacies to Primary Manufacturers for their transmission of MFP refunds for selected drugs."[19] CMS goes on to provide that "[t]he 14-day prompt MFP payment window provides Primary Manufacturers with the same 14-day timeframe to transmit payment as applies for Part D plan sponsors under existing Part D prompt pay rules" and "section 40.4.2.2 of this final guidance describes a process for dispensing entities to self-identify as dispensing entities that anticipate material cashflow challenges because of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window."[20] APhA appreciates CMS's efforts to require prompt payment for these reimbursements, as timely payment will help alleviate some of the financial and operational burdens. APhA encourages CMS to continue reviewing whether payment could be facilitated more quickly for pharmacies, anticipating material cash flow concerns, if the mitigation strategies with manufacturers are insufficient or not working as designed.

MTF Data Facilitation (Section 40.4.2)

Commenters also "expressed concern with the 14-day prompt MFP payment window, … stat[ing] that the 14-day prompt MFP payment window is too long and could cause cash flow concerns for dispensing entities."[21] In its response, CMS stated that it "will require that a Primary Manufacturer transmit payment of an amount that provides access to the MFP to pharmacies, mail order services, and other dispensing entities within 14 days."[22] APhA reiterates its previous points about the need for prompt payment to pharmacies. APhA asks CMS not to create additional hurdles or barriers to pharmacies' reimbursement and to resolve any claim disputes or technical errors expeditiously.

Within this section, "commenters [also] expressed appreciation for the ability of dispensing entities to indicate that they expect to experience material cashflow concerns."[23] CMS provided that "[o]ne commenter suggested criteria for dispensing entities to qualify for having material cashflow concerns."[24] CMS responded to this comment by stating that they "did not specify other criteria by which dispensing entities qualify for such designation."[25] CMS explicitly provides that it "agrees that timely movement of funds is important and appreciates that prefunding would offer advantages." Accordingly, APhA supports not specifying criteria for pharmacies to qualify for programs that alleviate material cashflow concerns; any additional criteria could make it harder for pharmacies to stock these medications and threaten patient access.

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[19] *Id.*
[20] *Id.*
[21] *Id.* at 57.
[22] *Id.* at 58.
[23] *Id.*
[24] *Id.*
[25] *Id.* at 59.

MTF Payment Facilitation (Section 40.4.3)

CMS noted that "[s]ome commenters expressed concern or provided comment related to the financial burdens of the MFP effectuation process on dispensing entities, with a couple of commenters expressing concerns with how MFP refund payments are effectuated."[26] CMS also provided that "[c]ommenters requested that CMS work collaboratively with the pharmacy and provider community to establish mitigation strategies to avoid cash flow disruptions."[27] In response, CMS stated that "the IRA did not include an appropriation to 'prefund' MFP refund payments."[28] However, CMS mentions the 14-day prompt MFP payment window and the ability for pharmacies to self-identify as anticipating material cashflow concerns as solutions to this problem. While APhA supports the prefunding option, APhA appreciates that CMS is providing these other solutions to ensure that pharmacies are paid quickly and can access these medications if they are struggling to afford the upfront costs. APhA reiterates its request to CMS to promote the development of additional solutions as CMS begins to receive data following the program's implementation in 2026.

CMS provides within the final guidance that they are "requir[ing] Part D plan sponsors to include in their network pharmacy agreements a provision requiring dispensing entities to be enrolled in the MTF DM."[29] CMS has also stated that "[e]nrolling in and using the MTF is free for pharmacies and does not place any requirement on them to actually dispense selected drugs under the Part D program."[30] As such, APhA urges CMS to continue ensuring that pharmacies can enroll in and use the MTF free of charge and that enrollment does not impose any dispensing requirement, especially when dispensing could result in underwater reimbursements for the pharmacy.

Manufacturer Plans for Effectuating MFP (Section 90.2.1)

CMS indicated that "[m]any commenters provided feedback related to CMS' decision to allow dispensing entities to identify themselves as anticipating material cashflow concerns at the start of an initial price applicability year with respect to a selected drug as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window, and requiring that a Primary Manufacturer include a process for mitigating material cashflow concerns for dispensing entities in its MFP Effectuation Plan."[31] CMS also noted that

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[26] *Id.*

[27] *Id.* at 59-60.

[28] *Id.*

[29] *Id.* at 64.

[30] Mehmet Oz, *Letter to the Honorable Earl L. "Buddy" Carter*, Centers for Medicare & Medicaid (June 23, 2025). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=Pu5zcdIsSlU%3d/.

[31] Chris Klomp, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the*

some "commenters worried about the effectiveness of this effort and whether this policy may actually create additional burden for pharmacies, for example, in the types of information Primary Manufacturers might request related to material cashflow concerns."[32] As discussed above, APhA has concerns about the effectiveness of these mitigation strategies and the additional burdens they may impose on pharmacies, but urges CMS to evaluate them as they are implemented and make appropriate changes to how they operate to aid pharmacies that self-identify as anticipating or experiencing material cash flow concerns.

40.4.2.2 Dispensing Entity Enrollment in the MTF DM

With this final guidance, "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."[33] APhA addresses its concern related to this requirement above.

Thank you for the opportunity to provide feedback on the final guidance and for considering our comments. If you have any questions or would like to meet with APhA and our nation's pharmacists, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Government Affairs

CC: Chris Klomp, CMS Deputy Administrator and Director of the Center for Medicare

Maximum Fair Price in 2026, 2027, and 2028, Centers for Medicare & Medicaid Services, 118 (Sept. 30, 2025). Available at: https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

[32] *Id.*

[33] *Id.* at 227-228.