American Pharmacists Association

April 25, 2025

Stephanie Carlton
Deputy Administrator and Chief of Staff
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10912).

Dear Deputy Administrator Carlton,

The American Pharmacists Association (APhA) appreciates the opportunity to provide comments to CMS under the notice "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the IRA." APhA shares CMS's goal of ensuring patients have affordable access to medications. However, APhA has significant concerns regarding the financial and operational challenges pharmacies will face following the implementation of the Medicare Drug Price Negotiation Program and the Medicare Transaction Facilitator (MTF) system. The current framework mandates that plan sponsors require pharmacies to be enrolled in the MTF Data Module (DM), subjecting pharmacies to significant financial losses and forcing them to float the costs of the program's operation while waiting for reimbursements that may also be lower than their acquisition costs. These two aspects, along with the others raised in our comments, if not addressed, will contribute to more pharmacies closing across the country, making it more difficult for patients to access the medications within the confines of this program and the essential care and services that pharmacists provide to their communities.

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.

Medicare Prescription Payment Plan

Basis, Scope, and General Rule

CMS's "proposed regulatory changes to codify agency guidance implementing section 11202 of the IRA, which establishes the Medicare Prescription Payment Plan and requires each PDP [prescription drug plan] sponsor offering a prescription drug plan and each MA [Medicare Advantage] organization offering an MA–PD [Medicare Advantage prescription drug] plan to provide any enrollee of such plan, including an enrollee who is subsidy eligible, the option to elect with respect to a plan year to pay cost sharing under the plan in monthly amounts that are capped."[1] In this final rule, CMS is moving forward with "codify[ing], with limited modifications, agency guidance implementing section 11202 of the IRA, which establishes the Medicare Prescription Payment Plan and requires Part D sponsors to provide all Part D enrollees the option to pay their out-of-pocket (OOP) prescription drug costs in monthly amounts over the course of the plan year, instead of paying OOP costs at the point of sale (POS)."[2] During the initial comment period of this rule, APhA raised concerns about the unpaid balances of this program being collected at the pharmacy counter following the grace period and urged CMS to clarify the complaint process if a pharmacist or patient suspects inappropriate cost-sharing calculations after a patient is involuntarily removed from Medicare Prescription Payment Plan for missing the grace period. CMS noted in its final rule "that pharmacies cannot be held responsible for any unsettled balances of a participant or for collecting unpaid balances from the participant on the Part D plan sponsor's behalf."[3] Additionally, CMS acknowledged APhA's comment and provided that "Part D sponsors must use their existing coverage determination, appeals, and grievance procedures for the Medicare Prescription Payment Plan to ensure that Part D enrollees have the ability to contest copay amounts and any adverse decisions related to participation in the Medicare Prescription Payment Plan."[4] APhA appreciates CMS providing these clarifications.

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[1] Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 90 Fed. Reg. 15792 (Apr. 15, 2025). Available at: https://www.federalregister.gov/d/2025-06008/p-24.

[2] *Id.* at 15794. Available at: https://www.federalregister.gov/d/2025-06008/p-37.

[3] *Id.* at 15823. Available at: https://www.federalregister.gov/d/2025-06008/p-388.

[4] *Id.* at 15817. Available at: https://www.federalregister.gov/d/2025-06008/p-305.

Pharmacy Payment Obligations

Under section 1860D-12(b)(4) of the Social Security Act and § 423.502, CMS proposed that "Part D plan sponsors must reimburse a network pharmacy the total of a participant's OOP costs for the Medicare Prescription Payment Plan and the Part D plan sponsor portion of the payment for a covered Part D drug no later than 14 calendar days after the date on which the claim is received for an electronic claim or no later than 30 calendar days after the date on which the claim is received for any other claim."[5] APhA's initial comments strongly recommended that CMS require payments to pharmacies not to exceed the 14-day prompt pay requirement under Medicare Part D to minimize the time pharmacies are floating these reimbursement costs. The final rule notes that "Part D plan sponsors must reimburse a network pharmacy the total of a participant's OOP costs for the Medicare Prescription Payment Plan and the Part D plan sponsor portion of the payment for a covered Part D drug no later than 14 calendar days after the date on which the claim is received for an electronic claim or no later than 30 calendar days after the date on which the claim is received for any other claim."[6] 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 imposed on pharmacies by this rule. CMS also notes that it "recognizes the important role that pharmacies will play in the implementation of this program and strongly encourages Part D plan sponsors to ensure that pharmacies receive adequate reimbursement for services provided to Part D enrollees related to participation in the Medicare Prescription Payment Plan."[7] As such, APhA urges CMS to utilize its full authority to ensure that pharmacies do not receive underwater reimbursements that will result in pharmacy closures, further decreasing access to care nationwide.

Timely Submission Requirements for Prescription Drug Event (PDE) Records (§ 423.325)

CMS originally "proposed to codify the existing 30-day and 90-day general PDE submission timeframes, with two slight modifications."[8] Those two proposed modifications were to change "the 30-day and 90-day requirements [to] refer to calendar days, as opposed to business days" and "modify the timing of the initial PDE records submission, which currently begins from the date the claim is received by the Part D sponsor or the date of service, whichever is greater."[9] CMS also "proposed to clarify that the initial PDE records must be submitted within 30 calendar days of when the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim" because that "claim cannot be received by the Part D sponsor (or its contracted first tier, downstream, or related entity (for example, pharmacy benefit manager

[5] *Id.* at 15823. Available at: https://www.federalregister.gov/d/2025-06008/p-375.
[6] *Id.* Available at: https://www.federalregister.gov/d/2025-06008/p-375.
[7] *Id.* Available at: https://www.federalregister.gov/d/2025-06008/p-379.
[8] *Id.* at 15830. Available at: https://www.federalregister.gov/d/2025-06008/p-456.
[9] *Id.* Available at: https://www.federalregister.gov/d/2025-06008/p-456.

(PBM))) until on or after the date of service."[10] During that initial comment period, APhA recommended CMS shorten the 30-day window for Part D plan sponsors to submit complete Part D PDE records to CMS's Drug Data Processing System (DPPS) to 7 days. Additionally, APhA asked CMS to prefund the MTF. If CMS could not prefund the program, APhA alternatively asked CMS to shorten the PDE reporting period from 30 days to 1 day and require the MTF to provide the requisite data to the Primary Manufacturers daily.

Regarding PDE submission timeliness requirements in the notice, "CMS is codifying timeframes at § 423.325(a) to require that—(1) initial PDE records be submitted within 30 calendar days following the date the claim is received by the Part D sponsor (or its contracted first tier, downstream, or related entity); (2) adjustment and deletion PDE records are due within 90 calendar days following discovery of the issue requiring a change to the PDE; and (3) resolution of rejected PDE records are due within 90 calendar days following the receipt of rejected record status from CMS."[11] At § 423.325(b), CMS also states the agency is "establish[ing] a distinct PDE submission timeliness requirement for selected drugs, in which CMS requires that a Part D sponsor must submit initial PDE records for selected drugs (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim."[12]

CMS acknowledged APhA's comments regarding prefunding the MTF and shortening the PDE reporting period from 30 days to 1 day. Although CMS stated while the agency "recognizes the critical importance of ensuring timely payment of MFP refunds to dispensing entities," it found that prefunding the MTF is outside the scope of this rule and "shortening the PDE submission timeframe for selected drugs to 1 day would not be operationally feasible for Part D sponsors."[13] While APhA appreciates CMS's efforts in shortening the timeliness requirement to 7 days for retrospective MFP refunds to help dispensing entities obtain timely payment, APhA strongly urges CMS to do more to address the financial concerns of pharmacies related to the MTF. Studies have shown 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 IRA.[14] Other studies have estimated 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 to be between $40,279.04 and $46,475.82 per pharmacy per year.[15]

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[10] *Id.* Available at: https://www.federalregister.gov/d/2025-06008/p-456.
[11] *Id.* at 15794. Available at: https://www.federalregister.gov/d/2025-06008/p-37.
[12] *Id.* Available at: https://www.federalregister.gov/d/2025-06008/p-37.
[13] *Id.* at 15833. Available at: https://www.federalregister.gov/d/2025-06008/p-489.
[14] *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.
[15] 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-

Without pharmacies, the Medicare Drug Price Negotiation Program will fail to expand Americans' access to these medications. Accordingly, APhA urges CMS to implement protocols and safeguards that protect pharmacies from further financial harm, including reconsidering mechanisms for prefunding the program.

Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

CMS initially "proposed to require Part D sponsors (or first tier, downstream, or related entities, such as PBMs, acting on the sponsors' behalf) to include in their network participation agreements with contracting pharmacies a provision that requires the pharmacy to be enrolled in the MTF DM (or any successor to the MTF DM) in a form and manner to be determined by CMS."[16] During the last comment period, APhA expressed concern that requiring plan sponsors, including PBMs, to include in their pharmacy contracts a requirement for pharmacies to be enrolled in the MTF DM would force pharmacies to take unsustainable financial losses. APhA drew CMS's attention to our previous meeting with CMS regarding underwater pharmacy reimbursements and noted that PBMs are reimbursing pharmacies at unsustainable rates far below the cost to dispense these medications, often at a minimum of 3% below the cost of dispensing brand medications. APhA strongly recommended that CMS require that MTF payments to pharmacies do not exceed the 14-day prompt pay requirement under Medicare Part D to minimize the time pharmacies are floating these reimbursement costs. Additionally, APhA noted CMS has stated the agency cannot act to protect pharmacies from underwater reimbursements made by PBMs due to the noninterference clause in section 1860D-11(i) of the Social Security Act. However, CMS is "interfering" here by requiring that any contract between the sponsor or its PBM and a pharmacy include a provision requiring a pharmacy to be enrolled in the MTF DM. Accordingly, pharmacy participation in the MTF DM should be voluntary to avoid confusion and alignment with other policies or this same discretion should be utilized to prohibit PBMs from paying pharmacies below their acquisition costs under the Medicare Part D program.

01/January2025-ThreeAxisAdvisors-Unpacking-the-Financial-Impacts-of-Medicare-Drug-Price-Negotiation.pdf.

[16] Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 90 Fed. Reg. 15836 (Apr. 15, 2025). Available at: https://www.federalregister.gov/d/2025-06008/p-510

In the notice, CMS states the agency is "finalizing as proposed our proposal to amend § 423.505 by adding paragraph (q), requiring that Part D sponsors' network participation agreements with contracting pharmacies, including any contracts with any first tier, downstream, and related entities require such pharmacies to be enrolled in the Medicare Drug Price Negotiation Program's [MTF DM] and that such pharmacies certify the accuracy and completeness of their enrollment information in the MTF DM."[17]

While CMS acknowledged comments by APhA and others opposing codifying network pharmacy participation in the MTF DM, CMS provided that, without an enrollment requirement, participation would be variable, leading to "uneven access to selected drugs that are covered Part D drugs by an MFP-eligible individual."[18] APhA emphasized that mandatory participation without further intervention by CMS will lead to significant and unsustainable financial hardship for many pharmacies, leading to additional pharmacy closures, which will decrease seniors' access to health care as well as federal pharmacy access standards under § 423.120 for the entire Part D program. The uneven access issues CMS is trying to avoid by mandating pharmacy enrollment will be vastly overshadowed by the access issues caused by the closure of additional pharmacies following the implementation of this rule. As such, APhA again strongly reiterates our previous comments urging CMS to reconsider mandating pharmacy participation in the MTF DM.

CMS also recognized APhA's comments that cited the noninterference clause in section 1860D-11(i) of the Social Security Act, contending that CMS is interfering with pharmacy network agreements despite its previous inability to utilize this authority to protect pharmacies from underwater PBM reimbursements.[19] CMS responded to these comments stating the agency" consider[s][] the issue of Part D sponsors' reimbursement rates out of scope for this rulemaking" and disagrees "that the requirement on Part D sponsors to include a contractual provision in its network pharmacy agreements is in violation of the noninterference clause," citing "the final rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29874 and 29875)."[20] APhA fails to see the nuance between the two actions and again strongly encourages CMS not to require pharmacy participation in the MTF DM.

[17] *Id.* at 15793. Available at: https://www.federalregister.gov/d/2025-06008/p-35.
[18] *Id.* at 15838. Available at: https://www.federalregister.gov/d/2025-06008/p-525.
[19] *Id.* Available at: https://www.federalregister.gov/d/2025-06008/p-527.
[20] *Id.* Available at: https://www.federalregister.gov/d/2025-06008/p-528.

Regarding reimbursement, APhA is concerned that this rule's framework will exacerbate many of the problems leading to the closure of more pharmacies nationwide. Within the final comments, CMS notes the agency considers many of the previous comments related to the financial burdens this rule would place on pharmacies out of scope.[21] While APhA appreciates CMS's awareness of this issue and its efforts "to implement policies that will mitigate any potential adverse impact,"[22] APhA urges CMS to issue rulemaking addressing the scope of these critical issues to the success of the Medicare Drug Price Negotiation Program and use any applicable authority to ensure that pharmacies are paid no less than the MFP plus a commensurate dispensing fee and that payment is prompt to ensure that already struggling pharmacies are not left carrying the financial burden of this program.

APhA's previous comments to the proposed rule addressed two provisions related to transparency requirements and protecting beneficiaries from disruptions, which are not included in the final rule. Regarding transparency requirements, in the proposed rule, CMS proposed requiring "Part D sponsors (or first tier, downstream, or related entities (FDRs), such as pharmacy benefit managers (PBMs), on the sponsors' behalf) to notify network pharmacies which plans the pharmacies will be in-network for in a given plan year by October 1 of the year prior to that plan year and to require sponsors to provide pharmacies a list of these plans to network pharmacies on request after October 1."[23] Additionally, CMS proposed "requir[ing] contracts with pharmacies for participation in Part D networks that allow the Part D sponsor or FDR [first tier, downstream, or related entities] to terminate the contract without cause to also allow pharmacies to terminate the contracts without cause after providing the same notice that the contract requires the sponsor or FDR to provide the pharmacy."[24] These proposals and CMS's responses to comments related to these topics appear absent from the final rule. APhA urges CMS to review and reassess the exclusion of these provisions from the final rule, as both ensure that pharmacies can effectively operate within the confines of this rule's framework rather than yielding to the large PBMs that are driving independent pharmacies out of business and jeopardizing access to care for thousands of seniors.

APhA appreciates the opportunity to provide CMS with additional insight into how implementing the Medicare Drug Price Negotiation Program will impact pharmacists and our patients. APhA recommends CMS use its applicable authority to minimize the financial and operational burdens this rule imposes on pharmacies. Pharmacies are already struggling to stay

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[21] *Id.* at 15839. Available at: https://www.federalregister.gov/d/2025-06008/p-536.
[22] *Id.* Available at: https://www.federalregister.gov/d/2025-06008/p-537.
[23] Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 89 Fed. Reg. 99342 (Dec. 10, 2024). Available at: https://www.federalregister.gov/d/2024-27939/p-36.
[24] *Id.* Available at: https://www.federalregister.gov/d/2024-27939/p-36.

open and continue serving the communities that depend on them. CMS should work to ensure that a program designed to increase patient access to affordable medications does not unintentionally close the most accessible, and often only, health care provider in many rural and underserved communities. If you have any questions or would like to meet with APhA to discuss our comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,

Michael Baxter
Vice President, Government Affairs

Cc: The Honorable Mehmet Oz, M.D., M.B.A., Administrator, CMS