PCMA

May 1, 2025

Filed electronically via www.reginfo.gov/public/do/PRAMain
William Parham
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Information Collection Request (ICR); Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act [Document Identifier: CMS-10912]

Dear Mr. Parham:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments to the White House Office of Management and Budget (OMB) on the Centers for Medicare & Medicaid Services' (CMS) information collection request (ICR) for the Medicare Drug Price Negotiation Program ("Negotiation Program")[1], specifically Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form, which would be used for initial price applicability year (IPAY) 2026. The 30-day notice of review was posted in the *Federal Register* on April 1, 2025.[2]

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 289 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and plans offered for sale on the Exchanges established by the Affordable Care Act. PBMs negotiate price concessions with manufacturers on their brand medications to improve the value of the Part D program. These price concessions reduce premiums for all beneficiaries and provide access to preferred drugs with reduced cost sharing.

We want to reiterate our concerns regarding CMS's approach to one aspect of the effectuation plans that Primary Manufacturers must provide to CMS. Below, we have repeated most of our comments on Medicare Transaction Facilitator (MTF) for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act submitted to CMS on its 60-day PRA notice on December 27, 2025, with additional context where necessary.

Background: The MTF was created by CMS to facilitate the exchange of claims and payment data between dispensing entities and drug Primary Manufacturers to facilitate the effectuation of

[1] https://www.regulations.gov/docket/CMS-2024-0198/document.
[2] 90 Fed. Reg. 14373, April 1, 2025.

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the Maximum Fair Price (MFP), in furtherance of the statutory mandate created by the Inflation Reduction Act (IRA). PCMA has previously raised significant concerns about the design of the MTF and its financial impact on dispensing entities, particularly independent and rural pharmacies, as well as the negative impacts on payment delays and pharmacy financial health.

For IPAY 2026 and 2027, CMS has proposed new forms and reporting requirements to effectuate the MFP. While these forms aim to standardize and streamline the MFP effectuation process, PCMA has several concerns about the impact on dispensing entities, especially on independent and rural pharmacies.[3] We have specific comments on Appendix A, Section: Part I: Dispensing Entity Enrollment Questionnaire, below.

The proposed forms place significant reporting obligations on pharmacies and other dispensing entities requiring detailed data submissions to support price adjustments and payments. Pharmacies are already concerned about potential delays in payment, and the complexity and likely errors in these forms could further exacerbate payment delays, leaving pharmacies vulnerable to cashflow issues. There is a legitimate concern that these forms will shift the financial risk from Primary Manufacturers to dispensing entities.

CMS is proposing to include one form question (Section 2, Question 3 & 3A) for dispensing entities to self-identify as anticipating material cashflow concerns at the start of the IPAY due to the shift from payment by the Part D sponsor to a combination of Part D sponsor payment plus a potentially lagged MFP refund from Primary Manufacturers. CMS expects certain types of dispensing entities, such as sole proprietor rural and urban pharmacies, long-term care pharmacies, 340B covered entities with in-house pharmacy, and Indian Health Services and Urban Indian (I/T/U) pharmacies, may have material concerns about cash flow. CMS states responses to this question are optional and will be treated as confidential and shared with Primary Manufacturers to inform the Primary Manufacturers' development of their MFP Effectuation Plan only.

While the dispensing entity will make a self-identification of having material cashflow problems, CMS proposes to allow Primary Manufacturers to make the unilateral determination as to whether a dispensing entity actually has material cashflow concerns under the new IRA framework and, thus, whether the dispensing entity will have access to the yet-to-be-defined Primary Manufacturer MFP Effectuation Plan. This approach is highly problematic for several reasons. First, permitting Primary Manufacturers to determine whether a dispensing entity has material cashflow concerns is a direct conflict of interest, as the Primary Manufacturers have a direct financial stake in minimizing their costs, including avoiding making available any alternative mitigation process that is likely to be more burdensome on the Primary Manufacturer. Allowing Primary Manufacturers to assess a pharmacy's cashflow concerns could lead to biased decisions aimed at protecting their own financial interests rather than supporting the pharmacy's stability when effectuating the MFP. In addition, independent pharmacies are already operating at low margins, and granting Primary Manufacturers the authority to determine whether a pharmacy faces material cashflow problems leaves pharmacies vulnerable to exploitation and/or arbitrary decisions.

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[3] Separately, CMS proposed and finalized a requirement that Part D plan sponsors require pharmacies participating in their networks to enroll in the MTF. 90 *Fed. Reg.* 15837, April 15, 2025. In this final rule CMS adequately responded to PCMA's concerns about enforcement of the provision.

The proposed forms do not guarantee that Primary Manufacturers will use consistent or transparent criteria to evaluate dispensing entity cashflow issues. This will create uncertainty and potential inequities in how a dispensing entity is assessed, further undermining trust in the program MFP effectuation process. There is also concern that dispensing entities that challenge Primary Manufacturers and/or report problems to CMS could face retaliatory actions, such as delayed payments or unfavorable terms. These risks will be particularly acute for small, rural, or independent pharmacies that lack bargaining power against manufacturers.

Lastly, CMS has not provided any guidance on what mitigation processes will be approved as part of its review of Primary Manufacturers' MFP Effectuation Plans. Even if Primary Manufacturers choose to exercise the discretion of permitting a dispensing entity to participate in such a mitigation process, CMS has provided no clarity on what type of process will be deemed acceptable to accommodate the needs of pharmacies facing cashflow concerns.

Dispensing entities serve as the frontline providers of Medicare Part D prescription medications to beneficiaries. If Primary Manufacturers make arbitrary and incorrect decisions about the financial stability of dispensing entities or fail to make a meaningful mitigation process available, many pharmacies could struggle to maintain inventory, particularly for expensive MFP-selected drugs. This will lead to medication shortages and reduced beneficiary access to medically necessary prescription medications, undermining the goals of the Medicare Drug Negotiation Program.

The Trump Administration has recently gone so far as to acknowledge the existing problems with the current guidance for the Medicare Drug Price Negotiation Program in its April 15, 2025, **Executive Order titled *"Lowering Drug Prices by Once Again Putting Americans First"***. In Section 3(a), the order requires (within 60 days) the Secretary of Health and Human Services (Secretary) to propose and seek comments on the Primary Manufacturer's effectuation of the MFP. This order underscores the Administration's view that the current guidance for the Primary Manufacturers' effectuation of the MFP is insufficient and requires further evaluation.

While the Administration, policymakers, and stakeholders have recognized these potential problems, CMS released proposed forms for the MTF under IPAY 2026 and 2027 that could create significant cashflow problems for dispensing entities, especially rural and independent pharmacies.

PCMA Recommendations: To alleviate these issues, PCMA recommends specific considerations to address these concerns and ensure a transparent, fair, and functional program.

- **CMS should maintain oversight and develop standards** for dispensing entity cashflow determinations. Primary Manufacturers should not have a role in arbitrarily assessing dispensing entity cashflow concerns.
- **CMS should develop standards for appropriate mitigation processes** so that dispensing entities that avail themselves of this process are materially protected.
- **Prompt payment protections** should be codified, including an enforceable payment timeline and mechanisms to resolve disputes quickly.
- **Independent audits** should be conducted regularly to monitor compliance and ensure fair treatment of dispensing entities.

- **Technical and financial support** should be provided to independent and rural pharmacies to assist them in navigating the new MTF reporting and payment system.

Conclusion

We thank OMB for the opportunity to comment on these important concerns and we look forward to the opportunity to discuss our concerns and share our proposed recommendations. If you have any questions, please contact Emilia Clements at eclements@pcmanet.org.

Sincerely,

Timothy Dube, Senior Vice President, Policy & Regulatory Insights, PCMA