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William Parham
Director
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Information Collections and Regulatory Impacts
Attention: CMS-10912

Re: Information Collection Request: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear Director Parham:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS, the Agency) on the second round Information Collection Request (ICR) for the *Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)*, which CMS released on April 1, 2025. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.[1]

Below, PhRMA provides comments and requests for clarity across Appendix B (the Primary Manufacturer MFP Effectuation Plan Form), Appendix C (the Primary Manufacturer Payment Elements Form), and the Complaint Information Request Form for Non-MTF Users. In addition to this feedback, we have attached our comments from December 2024 on the first round MTF ICR forms, including comments on the required mitigation plans for pharmacies identifying as having material cashflow concerns and comments on the Agency holding Primary Manufacturers responsible for other distinct corporate entities ("Secondary" manufacturers) to make discounts available, as PhRMA continues to have concerns with many of the MTF ICR forms and requirements.

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[1] PhRMA. (August 16, 2024). 2024 PhRMA Annual Membership Survey. Available at: https://phrma.org/resource-center/Topics/Research-and-Development/2024-PhRMA-Annual-Membership-Survey

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I. Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

PhRMA appreciates the clarity CMS has added to the MFP Effectuation Plan form on which responses will be non-public versus made available to MTF DM users (including in a redacted form). It is important for manufacturers to understand how proprietary information will be protected. However, we encourage CMS to continue to engage with manufacturers of selected drugs on protections for proprietary information as manufacturers develop and submit effectuation plans. For example, despite CMS' clarity that responses to questions in Section 2 will be made available to dispensing entities without redactions, manufacturers may find that to fully address questions raised in Section 2 they need to include some proprietary information. We ask that CMS maintain flexibility in this scenario for IPAY 2026 and work with manufacturers to understand if portions of responses need to be redacted.

PhRMA also appreciates the clarification made by CMS that the MFP Effectuation Plan Form can cover all of a manufacturer's selected drugs as opposed to needing to separately respond for each selected drug. This helps to reduce the burden on manufacturers.

Additional comments on specific elements of the MFP Effectuation Plan Form are included below.

Q2C: Confirmation of Bank Account Information.

PhRMA recommends that CMS adopt a simplified approach to verifying bank account information for manufacturers that elect to participate in the MTF PM. Specifically, for other programs such as the Part D Coverage Gap Discount Program, manufacturers have historically filled out an electronic funds transfer (EFT) authorization form as opposed to supplying a voided check or bank letter. We recommend that CMS adopt a similar approach for MFP effectuation.

Section 2: Managing Relationships with Dispensing Entities.

In the lead-in to Question 4, PhRMA assumes that CMS meant to convey that Primary Manufacturers will be provided with a list of dispensing entities that have self-identified as having material cashflow concerns with those cashflow concerns occurring at the beginning of the price applicability period. As written, we believe this lead-in statement could be interpreted as Primary Manufacturers not receiving this list until the start of the price applicability year, which would be too late for manufacturers to take the dispenser status into account. PhRMA recommends that CMS clarify this statement.

II. Appendix C: Drug Price Negotiation Program Primary Manufacturer Payment Elements Form

PhRMA asks that CMS provide clarity on whether manufacturers could submit batched payment element forms. For example, could payment element form information be batched by dispensing entity such as through a common ownership or chain code?

PhRMA also asks that CMS provide additional information in a timely manner on the operations of the credit/debit ledger system that will be maintained by the MTF PM for participating manufacturers. There is significant confusion about the credit/debit ledger system, in particular how the ledger will interface with the payment elements reported by manufacturers. We ask that the Agency provide additional details, such as examples involving illustrative claims.

Additional questions and comments on individual payment elements are included below.

Payment Element 3: Method for Determining MFP Refund Amount.

PhRMA requests that CMS clarify the statement in the description of this field that "[c]odes should be based on the final disposition of a refund." Did CMS mean to indicate that the code a manufacturer enters should account for any credits or debits?

In addition, PhRMA also asks that CMS clarify the statement that "Code 7 should be used when the refund amount transmitted was adjusted by a credit amount on a manufacturer-maintained credit ledger." Is this statement referring to the debit/credit ledger that will be maintained by the MTF PM? If not, would manufacturers utilize Code 2 for refund amounts that have been adjusted based on the MTF PM-maintained credit/debit ledger?

Payment Element 3 Code 4: No Refund Transmitted – Section 1193(d)(1) Exception.

Under current CMS guidance, Code 4 only addresses scenarios where a selected drug's 340B ceiling price is lower than the MFP. However, a drug's 340B ceiling price can also be equal to the MFP or, under certain circumstances, higher than the MFP. PhRMA strongly urges CMS to:

- Expand Code 4 to include the scenario where the 340B ceiling price equals the MFP;
- Add an additional payment element code to address the scenario where the 340B ceiling price is higher than the MFP by allowing manufacturers to pay the difference between the 340B ceiling price and the MFP as the MFP refund amount; and
- Manufacturers utilizing the MTF PM should also be able to use the credit/debit ledger system to make these adjustments for claims identified as 340B outside of the 14-day prompt MFP payment window.

PhRMA remains highly concerned about the continued lack of a role for CMS in identifying and deduplicating 340B claims, with CMS stating in the Final Guidance for the Medicare Drug Price

Negotiation Program[2] that the Agency "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[3] Under the current 340B replenishment model used by covered entities, manufacturers in many cases have very limited insight into which Part D units are subject to 340B pricing, which creates a significant risk of duplicate 340B and MFP discounts despite the IRA's statutory prohibition.[4]

Under the 340B replenishment model, the pharmacy or provider will track, typically with a computerized system, units of medicines dispensed or administered to eligible 340B patients. When a certain threshold of units is reached, the pharmacy or provider places an order to replenish that stock at the discounted price.[5] A manufacturer will provide access to the 340B price on the replenishment order through a wholesaler chargeback. However, requests for chargebacks are at the package level, and typically do not contain information about the individual prescriptions underlying the replenishment request. As an example, a 340B covered entity could seek to replenish a 900-tablet bottle of a selected drug at the 340B price. Underlying that request are prescriptions filled for 340B patients with a variety of insurance coverage, but the manufacturer will not know which, if any, of those prescriptions were filled by Part D beneficiaries. Indeed, legislation in at least two states[6] purports to prevent manufacturers from requiring claims-level data from 340B covered entities as a condition of providing access to the 340B price. This makes it extremely difficult, if not impossible, for manufacturers to avoid providing access to the 340B price on prescriptions dispensed to Part D beneficiaries, significantly increasing the risk of 340B/MFP duplicate discounts, unless CMS requires that units dispensed or administered under the 340B program be identified by a modifier, reported to a repository, or otherwise identified as 340B-acquired drugs.

While we continue to urge CMS to play a role in deduplicating 340B/MFP claims, such as through a claims repository with mandatory reporting, in the interim, we ask that CMS allow manufacturers to have a clear way to address 340B/MFP duplicate discounts that the manufacturer has been able to identify by taking several steps, including expanding the existing guidance and payment codes to cover situations where the 340B ceiling price is equal to the MFP or higher than the MFP.

Specifically, as noted above, we ask that Code 4 be expanded to include the scenario where the 340B ceiling price is equal to the MFP. If a manufacturer can utilize Code 4 both where the 340B ceiling price is equal to or lower than the MFP refund, the manufacturer can continue to provide access to the 340B price while avoiding a duplicate 340B/MFP discount. We believe the expansion of Code 4 to include the scenario of the 340B ceiling price being equal to the MFP would be

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[2] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. *See* https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

[3] Final Guidance, p. 55.

[4] By discussing the replenishment model used buy covered entities, we do not mean to imply that that the model is consistent with the 340B statute.

[5] For an overview of the replenishment model, as utilized by contract pharmacies in the 340B program, please see: OIG. Memorandum Report: Contract Pharmacy Arrangements in the 340B Program. February 4, 2014. Available at: https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf

[6] Missouri and West Virginia.

consistent with the combined meaning of sections 1193(d)(1) and 1193(d)(2) of the Social Security Act (the Act).

PhRMA also asks that CMS amend its existing guidance to add a new payment element code to address the scenario where the 340B ceiling price is higher than the MFP by allowing manufacturers to calculate the MFP refund as the difference between the higher 340B ceiling price and the MFP (this could also be addressed by amending the existing Code 2). Section 1193(d)(2) of the Act states that a manufacturer of a selected drug "shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals… at such ceiling price in a *nonduplicated amount to the ceiling price* if such maximum fair price is below the ceiling price for such selected drug" (emphasis added). But the existing payment element codes established by CMS do not seem to contemplate this scenario. And again, because manufacturers typically lack the information necessary to exclude individual prescriptions from a replenishment chargeback request, there is a high likelihood that a manufacturer will pay both an MFP refund and provide access to the 340B ceiling price on the same claim. If manufacturers can provide access to the MFP by paying the difference between the higher 340B ceiling price and a lower MFP, while still providing the 340B covered entity with access to the 340B price, this will prevent a duplicate discount.

In addition, for claims identified as 340B outside of the 14-day prompt MFP payment window, CMS should clarify that manufacturers utilizing the MTF PM may adjust the credit/debit ledger to account for scenarios where the 340B ceiling price is equal to the MFP and where the 340B ceiling price is higher than the MFP.

Payment Element 4: Quantity of Selected Drug.

In the description of this payment element, CMS notes that in cases "where the payment elements represent a claim that was adjusted or reversed, the Primary Manufacturer will indicate the new number of units of the selected drug included in the adjusted MFP refund paid or reversed as a *positive value*" (emphasis added). PhRMA believes there could be scenarios where the new number of units is zero, and zero is neither a positive nor negative value. As such, we ask that CMS clarify this statement to allow for zero values.

III. Appendix D: Drug Price Negotiation Program Complaint and Dispute Intake Form

In future guidance, PhRMA recommends that CMS provide more clarity on the complaints and disputes process, including more specificity on the timeline for the complaints and disputes processes and more clarity about CMS' role.

IV. Drug Price Negotiation Program Complaint Information Collection Request (ICR) Form for Non-MTF Users

CMS has included an information collection form for non-MTF users stating that CMS will engage a "compliance contractor" that will "support the successful administration of the Negotiation Program by collecting and investigating (as needed) complaints and disputes from dispensers, pharmacies, mail order services, manufacturers and other interested parties," including complaints "related to lack of access to the maximum fair price, or lack of access to accurate cost-sharing." Without more detail as to how a contractor will perform such functions and the authority of such contractor, it is difficult to comment on how such a contract will operate. CMS should provide greater detail to allow stakeholders to properly comment.

In addition, to comply with federal acquisition regulations prohibiting contractors from performing inherently governmental functions, CMS should ensure that the contractor does not have final decision-making authority over the outcome or final fact-finding of any investigation.

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Should you have any questions, please feel free to reach out to us at the email addresses below.

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