Submitted electronically to: https://www.reginfo.gov/public/do/PRAMain

May 1, 2025

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10912
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: Agency Information Collection Activities: Proposed Collection; Comment Request [Docket No. CMS–10912] - CMS–10912 Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

Docket Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) to its docket: Agency Information Collection Activities: Proposed Collection; Comment Request [Docket No. CMS–10912] regarding the Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA). Our comments are limited to the Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

Overview

CMS has provided very little guidance to manufacturers regarding this process, nor sample Effectuation Plans. However, on January 1st, 2026, ten MFP Effectuation Plans will become operational. On January 1st, 2027, there will be possibly up to twenty-five different Effectuation Plans with that number growing in future years of the program. We believe that Manufacturers, whenever possible, should coalesce around single format, single approach Effectuation Plans to reduce the burden on pharmacies and Manufacturers.

Further, Appendix B is unclear as to when and at which levels a manufacturer can have an alternate effectuation plan for the same drug. NCPA recommends that CMS limit variability in the effectuation plan, where manufacturers can only use one effectuation plan per selected drug/per dispensing entity.

Additionally, NCPA recommends that the manufacturer effectuation plans need to identify effective dates, any changes to the effectuation plan have to have a future effective date and the MTF-DM has to notify all dispensing entities before the effective date. Additionally, NCPA recommends that the manufacturer effectuation plans have the following details:

- Primary Manufacturer Payer ID (to be returned in REF01/REF02 of the 835);
- Selected Drug(s) Name subject to this effectuation plan;
- MFP Effectuation Plan Effective Date;
- NDC-11 IDs for all selected products associated to the primary manufacturer's labeler code and subject to this effectuation plan;
- Secondary Manufacturer Name; and
- NDC-11 IDs for all selected products associated to the secondary manufacturer's labeler code and subject to this effectuation plan.

To reduce confusion and improve consistency across the industry, NCPA recommends that CMS require all Primary Manufacturers to submit their Effectuation Plans using a standardized format with clearly defined core elements. This template should outline required content areas such as refund methodology, payment timing, communication protocols, dispute resolution processes, and pharmacy support resources. Establishing a uniform plan structure will help ensure pharmacies and PSAOs can review, compare, and prepare for manufacturer-specific requirements more effectively—without needing to interpret 25+ unique plan formats each year.

While CMS requires Manufacturers to submit their Effectuation Plans by September 1st of the year before the negotiated MFP takes effect, pharmacies and technology providers need more than 120 days to establish systems, procedures and protocols to effectively participate in the Effectuation Plan. Manufacturers should publish their Effectuation Plans, in whole or in part, as early as feasible.

Pharmacies and Manufacturers do not currently have established financial relationships as the U.S. drug supply chain leverages wholesalers and other mechanisms to ensure access to needed medications. Independent pharmacies do not have established direct relationships with manufacturers for purposes of procuring drugs.

<u>Specific Comments/Concerns</u>
We have the following concerns with Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form:

<u>Page 3</u>
"Q1. Respond to the following regarding the use of the MTF PM.

NCPA is concerned that CMS has chosen to allow manufacturers to voluntarily effectuate the MFP via the MTF PM. This leads to greater uncertainty and potential administrative burden on independent pharmacies. The Primary Manufacturer will use the MTF PM to provide retrospective reimbursements to dispensing entities. Selecting 'Yes' indicates that the Primary Manufacturer intends to use the MTF PM to pass through MFP refunds as part of its approach to MFP access for any of its MFP-eligible claims; selecting 'Yes' does not preclude the Primary Manufacturer from also engaging in alternative arrangements to process MFP refunds without the MTF PM as described in Q11 – Q15 of this Form."

NCPA emphasizes that the high degree of discretion and variability allowed for manufacturers in this model creates an insurmountable administrative burden for pharmacies, which could potentially be facing up to 25 different effectuation plans by 2027.

Making use of an MTF-PM payment facilitation functionality voluntary for Primary Manufacturers could result in many manufacturers electing not to use the MTF PM, which could impact access to certain drugs for pharmacies that do not have a direct relationship with that drug's manufacturer.

Page 5

Q3. "Describe the Primary Manufacturer's process for contacting, receiving, and responding to communications from dispensing entities regarding MFP effectuation. The response should describe any proactive outreach to dispensing entities related to the Primary Manufacturer's MFP Effectuation Plan and its related policies and procedures, plans for disseminating or publishing key information, and the approach the Primary Manufacturer intends to establish for intaking and responding to communications initiated by dispensing entities as the program continues."

NCPA emphasizes that the high degree of discretion and variability allowed for manufacturers in this model creates an insurmountable administrative burden for pharmacies, which could potentially be facing up to 25 separate effectuation plans by 2027. Having said that, this information should be centralized in the MTF-DM so pharmacies know where to find it and presented in a standardized format. This would include the information required from the manufacturers with respect to how to contact them for information relating to disputes and complaints outside the formal process established by CMS.

Q3 & Q4: Dispensing Entities with "Material Cash Flow Concerns"

To mitigate cashflow for pharmacies, NCPA provides ideas for alternative mechanisms to mitigate pharmacy cashflow issues and to support continued, efficient pharmacy operations. We encourage CMS to work with manufacturers to consider these options as they develop their plans and as CMS reviews the plans.

Preferred Option: Advanced Payment of Expected Maximum Fair Price (MFP) Refund to Pharmacies at the Beginning of the Month
Using claims-level data, pharmacies will communicate to manufacturers the expected number of price-negotiated medications likely to be dispensed to MFP-eligible individuals during a specific month. At the start of the month, the manufacturer would issue a payment for all expected MFP refunds and any additional fees for the given month to the pharmacy.

To ensure manufacturers are not over or underpaying refunds, we recommend use of the credit-debt ledger, through the MFP DM, on a quarterly basis to review payments and adjust for overpayment and underpayment in preceding months and to adjust monthly payments for the forthcoming quarter.

Early Access to Cashflow Mitigation Mechanism
Given the nature of the pharmaceutical supply chain and necessity for many pharmacies to stock medications for immediate dispensing, we believe Manufacturers should initiate their material cashflow mitigation plans by at least October 31 of the year before the negotiated Maximum Fair Price (MFP) takes effect as many products that will be dispensed at the MFP beginning in January will be purchased by pharmacies in the fourth quarter of the preceding year.

Generally, we argue that all pharmacies, not just the types that CMS has stated, have "material cashflow concerns" under the Medicare Drug Price Negotiation Program. Under this proposed MTF-DM model, each community pharmacy would need to float on average $11,000 per week, so all pharmacies should qualify as having "material cashflow concerns" by default, or should be exempt from the MDPN program.

Additionally, CMS' category of "pharmacies who predominantly rely on prescription revenue to maintain business operations" encompasses most independent pharmacies: according to the 2024 NCPA Digest, nearly all revenue (90 percent) earned by the businesses of our membership results from prescription sales. Additionally, pharmacies need to pay wholesalers at least twice per month, with some paying wholesalers every seven days. Pharmacies are critically strapped in their abilities to pay wholesalers, and often wholesalers are unwilling to allow for flexibility of payment from pharmacies.

Page 6
Q5D. "Describe any additional mechanisms the Primary Manufacturer intends to implement to effectuate the MFP to each dispensing entity within the 14-day prompt MFP payment window, if applicable."
Q5F. "Describe the Primary Manufacturer's process for ensuring the 14-day prompt payment window is met for both its electronic and paper options."

Please see our comments below regarding the 14-day window.

Page 8

Q6. […] "Describe the Primary Manufacturer's process for effectuating nonduplication of claims that are 340B eligible and not subject to MFP availability."

NCPA supports CMS policy to not require pharmacies to identify 340B claims, as CMS stated in October 2024 *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 in 2026 and 2027*. NCPA re-emphasizes the infeasibility of pharmacies identifying those claims either proactively or retroactively. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems. For NCPA's full comments on this matter, see our March 2023 feedback on CMS' *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.

We recognize that it is rarely possible for pharmacies to identify 340B eligible patients at the point-of-sale; therefore, we believe only claims with a paid response from a Part D Plan – a signal of MFP-eligibility – should be forwarded to manufacturers for Maximum Fair Price (MFP) refund. Additionally, we encourage pharmacies and manufacturers to use the dispute resolution mechanism proposed below to address disagreements over specific claims.

"Q7. As described in the final guidance, Primary Manufacturers are required to transmit their claim-level payment elements within 14 days of receiving claim-level data elements from the MTF DM." NCPA stresses that pharmacies need to be paid timely, within 14 days of adjudicating the claim. As CMS acknowledges, under 42 C.F.R. § 423.520 (Prompt Payment by Part D Sponsors), Part D sponsors are required to pay pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.[1] At the outset of the Part D program and before this provision was put in place, independent pharmacies were closing rapidly due to delays in payment that caused significant impacts on cashflow. Independent pharmacies operate on small margins and are presently closing at the rate of over 1 per day, decreasing beneficiary access to care in their local communities. While NCPA appreciates CMS's effort to incorporate a 14-day prompt payment requirement for Primary Manufacturers, the proposed trigger for that window can vary widely depending on when data is transmitted to the Primary Manufacturer. NCPA stresses that pharmacies need to be paid amounts owed for the MFP within 14 days of adjudicating the claim. This policy would not pay pharmacies within 14 days, it would just require the transmission of the data within 14 days to the MTF-DM.

We highly encourage CMS to continue searching for ways to reduce the cycle until it is within 14 days from the dispense date. To help achieve this, CMS could require Part D plans to send data to the MTF-DM daily rather than weekly, which would deliver claims earlier to the MTF DM and the manufacturers. Additionally, perhaps manufacturers could be incentivized or rewarded in some manner paying refunds within 14 days of the dispense date. We encourage CMS to explore

[1]See 42 C.F.R. § 423.520, available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.520.

these and other ideas until pharmacies are receiving their refunds within 14 days of the dispense date.

Page 9
Q8. […]

1. The Primary Manufacturer primarily plans to use the Standard Default Refund Amount (SDRA) set forth in the final guidance to calculate and make the retrospective MFP refund payments to a dispensing entity OR
2. The Primary Manufacturer generally plans to contact dispensing entities to obtain their actual acquisition cost to calculate the MFP refund. OR
3. The Primary Manufacturer generally plans to use a proxy for acquisition cost other than WAC to calculate and make the retrospective MFP refund payments to a dispensing entity. OR
4. The Primary Manufacturer does not intend to use one of the methods listed above as its primary approach and instead intends to use a variety of approaches (e.g., using the SDRA for some dispensing entities while using actual acquisition costs for others) to calculate MFP refunds. OR
5. The Primary Manufacturer does not intend to use retrospective reimbursements to effectuate the MFP.

NCPA seeks further clarification as to what Option #4 above means. Does this mean that manufacturers can change their approach on how they will calculate the MFP refund, and how will CMS monitor such changes? Will manufacturers be able to negotiate different types of refunds with certain pharmacies that would be acceptable to CMS?

NCPA strongly recommends that manufacturers use WAC to calculate the Maximum Fair Price (MFP) refund amount; as an equation: WAC – negotiated MFP = MFP Refund. NCPA believes that pharmacies need protection from manufacturers arbitrarily imposing refund amounts other than the Standard Default Refund Amount (WAC minus MFP) that do not appropriately effectuate the MFP. NCPA thanks CMS for stipulating in the guidance that the claim-level data elements that the Primary Manufacturer will receive from the MTF will include a Standard Default Refund Amount that will reflect the difference between the WAC and the MFP of the selected drug at time of dispensing based on the quantity dispensed. NCPA prefers using WAC as the standardized metric. The WAC price should reflect the date of adjudication, not the date of the refund.

We have concerns that it is voluntary for manufacturers to adopt WAC, given that manufacturers and dispensing entities can "use a proxy for acquisition cost other than WAC to calculate and make the retrospective MFP refund payments to a dispensing entity," and therefore agree to a different benchmark. In other words, the MTF sends the amount as part of the minimum data elements to the manufacturer, which is WAC-MFP. If the pharmacy and the manufacturer have agreed on a different amount other than WAC, then when the manufacturer sends the data elements back to the MTF, the MTF would send a different amount because that is the indicator that the standardized refund was paid. NCPA strongly urges CMS to require the use of WAC as

the standardized metric and that any difference between WAC and MFP is the Standard Default Refund Amount.

The voluntary nature of WAC as a benchmark is especially concerning for dispensers, considering that pharmacies need to be reasonably compensated for these MFP drugs. NCPA advises CMS to require that the manufacturer provide the MFP using the Standard Default Refund Amount and that dispensers have sufficient protections for reasonable reimbursement.

Q9. […] "Describe the Primary Manufacturer's methodology for determining the amounts it will reimburse dispensing entities when the Primary Manufacturer is not calculating an MFP refund using the SDRA. Include a description of the documentation the manufacturer intends to retain to support any MFP refund calculations that do not use the SDRA."

NCPA thanks CMS for granting NCPA's previous ask that manufacturers include a description of this documentation.

Page 13

Q23: Amendments to Effectuation Plans

While CMS allows 90-days for the Manufacturer to submit copies of any new agreements that memorialize any substantive changes to alternative arrangements with dispensing entities within 90 days of the change, we strongly encourage manufacturers to refrain from making amendments to their effectuation plans until the start of a new calendar year and that plan changes be submitted through the annualized process of submitting plans to CMS on September 1st for the forthcoming year. Additionally, we strongly encourage CMS to require Manufacturers to make their effectuation plans available prior to September 1 each year as pharmacies need to make decisions on PBM/plan contracts earlier.

Miscellaneous Comments

Establishment of a Reasonable "Handling Fee" Associated with Dispensing Products at the Maximum Fair Price (MFP)

The current models that ensure access to needed medications for individuals covered by Medicare Part D have been dependent on revenue from branded medications, especially for long-term care (LTC) pharmacies. While CMS has pledged to monitor program implementation and potentially take immediate corrective action, pharmacies are deeply concerned by CMS' "hands off approach" to addressing the worst behaviors of insurers/PBM's and how delays in federal action will undermine patient access to needed medications.

We recommend that manufacturers, as part of the Effectuation Plans, provide a handling fee as part of the Maximum Fair Price (MFP) refund provided to a pharmacy or other dispensing entity. We believe this professional fee should be a percentage of the MFP refund instead of a flat fee for each dispensed prescription. We believe in cases for very expensive medications with a large difference between WAC and MFP, it would be reasonable for the Manufacturer to cap this handling fee at a specific dollar amount or restrict it to the set number of dispensed prescriptions.

Trade Association Access to MTF Effectuation Plans

We also request from CMS that pharmacy trade associations such as NCPA, and PSAOs, can access the MTF effectuation plans in addition to the pharmacies themselves.

Dispute Resolution

As disputes will arise, we recommend that both parties submit any disputes using the specific X12 835 claim number. We appreciate CMS adding to its revised version of Appendix D the "MTF Internal Claim Number(s) or Reference ID(s) on X12 835" with an optional text field to Question 3: Selected Drug & Claim Information as information that can be provided if known.

To facilitate continued pharmacy operation and access to medications by patients, we recommend that manufacturers do not interrupt payments to pharmacies during a dispute and that all claims be paid as the credit/debt ledger exists as a mechanism for manufacturers to recoup any over or incorrect payments. To ensure disputes are rapidly addressed, we believe manufacturers and pharmacies should agree to binding arbitration if they are unable or unwilling to resolve the dispute within 30 days on the initial complaint by one party. Finally, we recommend that both parties identify a singular point of contact for all disputes.

NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association