NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

April 30, 2025

Centers for Medicare and Medicaid Services
Attention: CMS–10912
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Submitted via: https://www.reginfo.gov/public/do/PRAMain

Re: Agency Information Collection Activities: Submission for OMB Review; Document Identifier CMS–10912

Docket Management Staff:

The National Association of Chain Drug Stores (NACDS) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on its docket: Agency Information Collection Activities: Submission for OMB Review; 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).

1. **Appendix A: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form**

As a threshold matter, we seek clarification on who will have access to the information contained in the MTF enrollment form and how CMS plans to ensure the confidentiality of this data.

We recommend that the Medicare Transaction Facilitator (MTF) not collect redundant data. Pharmacies have already provided ownership and related information during their enrollment with Part D plans, so it is unnecessary to repeat these details in the MTF enrollment process. The focus of the MTF enrollment should be on gathering only the essential fields needed to accurately identify the pharmacy and ensure proper routing of payments and EDI 835s. NACDS appreciates CMS for acknowledging its previous comments on the importance of the National Council for Prescription Drug Programs (NCPDP) registry. MTF enrollment can be streamlined by relying on the NCPDP registry and the successful enrollment of pharmacies with Part D plans.

On page 3, under Section 1: MTF DM User Roles, NACDS seeks clarification whether the three required roles of 1) Authorized Signatory Official, 2) Access Manager, and 3) Staff End User each must be a different individual or if these roles may be combined among one or two staff members, and if so, how?

On pages 9-10, CMS has stated that federal funds will not be used for the Medicare Drug Price Negotiation program:

> Because the MTF PM will only pass payments between Primary Manufacturers and dispensing entities, **under no circumstances will federal funds be used for these transactions or to resolve or make payment related to disputes that may arise between parties when the MTF PM is utilized, including with respect to nonpayment or insufficient payment by a particular party. Neither CMS nor the MTF Contractors will be responsible for funding or paying the refund amounts owed by the Primary Manufacturer in instances where the Primary Manufacturer does not pay an MFP refund owed to a dispensing entity**, including in cases where the Primary Manufacturer may be unable to pay (e.g., bankruptcy, insolvency, etc.). Neither CMS nor its MTF Contractors will accrue any interest on funds held by the MTF PM during the period before the funds are transferred to the dispensing entity (or returned to the Primary Manufacturer in the event of unclaimed funds). The MTF PM will serve only as a mechanism to transfer funds of the Primary Manufacturer to dispensing entities as directed by the Primary Manufacturer in the amounts authorized by the claim-level payment elements transmitted by the Primary Manufacturer and will not collect funds for any other use. (emphasis added)

NACDS would like to reinforce to CMS that pharmacies cannot and should not be forced to pre-fund the MDPN program, nor was it the intent of Congress. Pharmacies will face significant financial hardship unless CMS pre-funds the program.

On pages 13-14, under the instruction for Section 6, CMS states:

> An individual eligible to certify this submission on behalf of the dispensing entity must be one of the following: (1) the chief executive officer (CEO) of the organization, (2) the chief financial officer 14 (CFO) of the organization, (3) an individual other than a CEO or CFO, **who has authority equivalent to a CEO or CFO of the organization**, or (4) **an individual with the directly delegated authority to perform the certification** on behalf of one of the individuals mentioned in (1) through (3). (emphasis added)

NACDS seeks clarification from CMS as to the type of proof or documentation that CMS will require to verify that a person has authority equivalent to the CEO or CFO of the organization, or is an individual with the directly delegated authority to perform the certification.

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

We understand that CMS has provided very little guidance to manufacturers regarding this process, nor sample Effectuation Plans. On January 1st, 2026, ten MFP Effectuation Plans will enter effect. On January 1st, 2027, there will be twenty-five different Effectuation Plans with that number growing in future years of the program. We believe that manufacturers, whenever possible, should coalesce around a unified Effectuation Plan to reduce the burden on pharmacies and manufacturers.

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 122 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.

Throughout the draft form, CMS mentions that manufacturers have the option to provide retrospective payments to pharmacies outside of the MTF PM. NACDS is concerned that manufacturers have the option not to provide the retrospective payments through the MTF PM. We believe that manufacturer participation in the MTF PM should be mandatory. Otherwise, pharmacies could be placed in a predicament of having some of their MFP refunds come from the MTF PM and other payments come from multiple other sources. This type of arrangement would be infeasible and would essentially negate the main benefit of the second option—having payment come from one source.

On page 8, Q6., CMS requests a description of the manufacturers process for effectuating nonduplication of claims that are 340B eligible and not subject to MFP availability. NACDS reminds CMS that pharmacies typically do not know whether a claim is a 340B claim at the point of sale and thus, would not be able to report this information for use by the MTF.

We support the need for the deduplication of claims; however, the current lack of system integration between pharmacy claims receivable systems and 340B systems poses a significant challenge. For instance, if a pharmacy were to have a previously paid MFP payment clawed back due to a duplicate 340B discount, it would be extraordinarily difficult to reconcile that transaction against the current 340B accounting systems. The administrative burden and financial strain of such clawbacks could jeopardize the operational viability of many contract pharmacies.

Therefore, we urge CMS to influence the industry design by prohibiting the clawback of previously paid MFP refunds for 340B deduplication purposes. Preventing clawbacks will provide incentives for covered entities and manufacturers to develop effective means to make covered entities whole without involving contract pharmacies. This approach ensures that the responsibility for resolving duplication issues rests with the parties best equipped to manage them, thereby protecting contract pharmacies from undue administrative and financial burdens. Until such time that covered entities and manufacturers develop this effective means, any 340B adjustments or resolution(s) related to a 340B claim should be handled outside of the MFP process and as appropriate through the dispute resolution process that currently is in place.

On page 8, Q7., CMS mentions that manufacturers are required to transmit claim-level payment elements within 14 days of receiving claim-level data elements from the MTF DM. As NACDS has commented previously to CMS, we are deeply concerned about pharmacies having to pre-fund, or provide a financial float for the MDPN program. As we have urged in the past, CMS should pre-fund the program, similar to how CMS pre-funds the Coverage Gap Discount Program, or require manufacturers to pre-fund the program.

However, in the alternative, should CMS not agree with us that it has the authority to pre-fund the MDPN program or to require manufacturers to pre-fund the program, then we urge CMS to shorten the PDE reporting period from 30 days to one calendar day, and to require MTFs to provide the requisite data to manufacturers on a daily (calendar) basis. Unless the reporting time frames are reduced to daily

reporting, pharmacies will not be fully reimbursed for up to 30 days or more. This would be tantamount to CMS requiring pharmacies to pre-fund the program, which it does not have the authority to do.

As a further alternative, should it be absolutely infeasible to shorten PDE reporting to one calendar day and/or infeasible for MTFs to report to manufacturers on a daily (calendar) basis, then we would urge CMS to require a percentage of claims be reported through the PDE within one calendar day and/or reported by the MTF to manufacturers on a daily (calendar) basis.

On page 13, Q23., 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. 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 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.

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

CMS is proposing to require complaints and disputes to be submitted no later than 120 calendar days from the date of the subject of the complaint or dispute. However, CMS is not proposing a requirement for response time or for resolution of the complaint or dispute. We ask that CMS provide an estimated response time for complaints and disputes, or at a minimum, ensure that acknowledgement of receipt of complaints and disputes will be provided in a timely manner.

With respect to "Question 5: Supporting Documentation," we thank CMS for addressing our concern about the five-document limit on the supporting documentation upload by increasing the document limit to 10 documents. As we have mentioned previously, it is possible that a chain pharmacy could submit complaints and disputes on a similar issue among multiple pharmacies and that more than 5 supporting documents would be necessary for proper documentation.

With respect to dispute resolution, to help prevent delays in patient access to medications and continued pharmacy operation, we recommend that manufacturers do not interrupt payment to pharmacies during a dispute and all claims be paid. As CMS has indicated, the credit/debit ledger system will exist as a mechanism for manufacturers to recoup or correct any incorrect payments.

4. **Additional Concerns**

- No Fees: We appreciate that CMS has stated a number of times that pharmacies cannot be charged any fees to participate in the MDPN program as CMS would bear the cost of operationalizing the MTF. We would like to reiterate that CMS must ensure that plans, PBMs, manufacturers, wholesalers, CMS, nor any other entity assess any fees on pharmacies to effectuate the MTF or any other aspect of the MDPN program. Any electronic fund transfer (EFT) fees should be borne by the manufacturer and not by the pharmacy.

- EDI 835 Remittance Advice: As CMS works with X12 on implementation of the pharmacy remittance advice to be used by the MTF PM, we ask that the implementation layout be made as

soon as possible so that industry stakeholders can initiate development efforts and be ready for January 2026. Sample data should also be made available to assist in pre-launch testing. In addition, the layout should include one or more fields that can be used for cross-reference. For example, if a manufacturer claws back payment because of a 340B claim, the 835 could include the HRSA identifier for the covered entity, as pharmacies typically serve as contract pharmacies for multiple covered entities. Another example would be an invoice in which the discount was prospectively applied.

- Technical Issues: CMS must ensure that all Medicare Part D processors, including the MTF, DDPS, PBMs and plans, and manufacturers comply with and validate their technical and security infrastructure before implementation, or they cannot participate in the MTF payment process. Inadequate technical infrastructure and implementation by these entities may impact and delay payment to pharmacies.

- Pharmacy Portal: CMS should establish a portal for pharmacies to monitor the status of MTF payments at the claim level. This portal could be read-only, allowing pharmacies to log in with the MTF to research claims. For example, it could outline the following statuses: claim received, claim under review by the manufacturer, claim paid, or claim rejected along with the reason for rejection.

5. Conclusion

In conclusion, NACDS extends its gratitude to CMS for the opportunity to submit comments and for considering our recommendations aimed at reducing the burdens on pharmacies. We anticipate continued collaboration with CMS's IRA team to ensure beneficiary access, a seamless transition, and sustainable reimbursement for the pharmacy sector. If we can provide any additional information, please do not hesitate to contact Dr. Christie Boutte, Senior Vice President, Reimbursement, Innovation, and Advocacy, at cboutte@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer