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December 20, 2024

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) Information Collection Request-[Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form](#)

Docket Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to 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 A: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment 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.

Preliminary Roadmap of Comments/Concerns

Before addressing the specific questions on the proposed enrollment form, we request clarity on who will have access to the information in the MTF enrollment form, and how CMS will be protecting the confidentiality of this data.

Additionally, we argue that the Medicare Transaction Facilitator (MTF) should not require or collect redundant data. Pharmacies have already addressed ownership and related issues during their enrollment with Part D plans, making it unnecessary to revisit these details in the MTF enrollment process. Instead, the MTF enrollment should focus on collecting only the essential fields needed to accurately identify the pharmacy and ensure proper routing of payments and EDI 835s. We believe the process could be streamlined by relying, to the maximum extent possible, on the NCPDP Registry and the successful enrollment of pharmacies with Part D plans.

Page 1

On page one of the Enrollment form, CMS states that CMS intends to propose in future rulemaking a requirement that Part D plan sponsors include in their pharmacy agreements provisions requiring dispensing entities to be enrolled in the MTF DM. CMS has already proposed this in its proposed rule, [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](#). **NCPA strongly opposes this mandatory requirement, as the impact of the Medicare Drug Price Negotiation (MDPN) Program, as it currently stands, will be devastating for independent pharmacies.** Based on CMS guidance implementing the MDPN Program released to date, we are not seeing anything from CMS to protect pharmacies from facing below cost reimbursements from PBM's for MPF drugs, including pharmacy price concessions being withdrawn due to CMS's unwillingness to "interfere" with PBM/pharmacy contracts -- even though Congress has provided CMS a specific exemption to do so [and CMS's own prior interpretation agreed that it can]. At the same time, we are seeing CMS interfere in PBM/pharmacy contracts when it dictates that any contract between the sponsor or its PBM and a pharmacy must include a provision requiring the pharmacy to be enrolled in the Medicare Transaction Facilitator Data Module (MTF DM). So, while CMS is willing to interfere with contracts concerning the data module, it is not willing to interfere in contracts that make certain pharmacies are paid fairly. For those reasons, we think this program has a high likelihood of failure and opens CMS up to potential legal claims that it can in fact interfere in PBM/pharmacy contracts but chooses not to do so.

Page 2

On page 2, CMS mandates that pharmacies need to maintain the accuracy of the information in the MTF DM: "The dispensing entity is responsible for determining and acquiring information necessary to complete Part I, and for maintaining the completeness and accuracy of the requested information in the MTF DM as long as the dispensing entity is enrolled in the MTF DM." **NCPA opposes this requirement, given the high administrative burden that updating this information would entail.**

PSAO/Pharmacy Relations, and Importance of NCPDP Registry

Establishing and accurately managing pharmacy-to-PSAO relationships is a dynamic and intricate process. Pharmacies use PSAO services, and every month, hundreds of them switch affiliations—often due to changes in distributors or buying groups. When payer records contain outdated or inaccurate relationship information, payments and remittance details may be sent

to the wrong PSAO, delaying fund transfers to pharmacies and complicating payment tracking and reconciliation.

The NCPDP Registry has since been enhanced and refined, providing much-needed clarity in managing pharmacy-PSAO connections. The Registry serves as a centralized, authoritative source for pharmacy profiles—covering chains, independents, and mail-order pharmacies—and is trusted by commercial, Medicaid, and Medicare payers alike. Each pharmacy maintains control over its profile with robust security measures, ensuring that only the pharmacy or its authorized proxy can make modifications.

This trusted system underpins the multi-step approval process for pharmacy-to-PSAO relationships. The process begins when a pharmacy submits an enrollment request to a PSAO. The PSAO, as part of its due diligence, thoroughly evaluates the request before formalizing the relationship through a contract—a process that typically takes 30 to 60 days. Once complete, the PSAO updates the NCPDP Registry to initiate its approval and sets a start date for the relationship. The final step requires the pharmacy to acknowledge the approval, completing the process.

If CMS does not adopt this proven industry solution, the MTF must establish similar systems and processes to accommodate joint approvals and future start dates. Without a centralized system like the NCPDP Registry, CMS will be required to build comparable capabilities to ensure the accuracy and efficiency of pharmacy-to-PSAO connections. This would include creating and maintaining an authoritative source for pharmacy profiles, which would be a complex and resource-intensive process. By leveraging the NCPDP Registry, CMS can avoid the duplication of efforts, reduce the burden on pharmacies, and streamline the implementation of the MTF.

We strongly urge CMS to adopt the NCPDP Registry as the primary authoritative source for maintaining pharmacy-to-PSAO connections. Pharmacies are currently in control of their profiles and they are required to be up to date to participate in Part D plans, so it does not make sense for CMS to require pharmacies to create another type of profile to put in this information.

Although we encourage CMS to adopt the NCPDP Registry as the sole mechanism for managing PSAO relationships, the MTF enrollment process should include an option for pharmacies to opt out of having their PSAOs manage payments. Pharmacies should still be able to direct their 835s to their PSAOs to facilitate refund reconciliation.

Pharmacy Profiles

We strongly recommend that the MTF adopt and integrate the NCPDP Registry as the authoritative source for pharmacy profiles. As the foundation for pharmacy enrollment in Part D plans, the NCPDP Registry already serves as a trusted and centralized resource for accurate and up-to-date pharmacy information. Ensuring alignment between the NCPDP Registry, Part D plans, and the Medicare Transaction Facilitator (MTF) is essential for maintaining consistency and streamlining processes.

Pharmacies are accountable for their profiles in the NCPDP Registry. When applicable, pharmacies must provide supporting documentation for validation and complete their profile. The Medicare Transaction Facilitator (MTF) should subscribe to and receive updates from the NCPDP Registry. These updates should populate profile fields within MTF systems and be displayed to the pharmacy. It is critical that these fields remain consistent and cannot be altered independently, as discrepancies would undermine the reliability and integrity of the enrollment process.

The NCPDP Registry serves as the definitive source for the fields it provides, ensuring that all stakeholders operate with a single, consistent set of data. Allowing mismatched profile fields across systems would lead to inefficiencies, increased administrative burden, and potential confusion for pharmacies. By leveraging the NCPDP Registry as the authoritative source, the MTF can enhance accuracy, reduce errors, and support a more seamless experience for pharmacies and other industry stakeholders. **The NCPDP Registry should be integrated as the authoritative source for pharmacy profiles to ensure consistency across systems.**

On page 2, the form also states that “dispensing entities...should only complete part 1 [while]...entities such as a PSAO...should only complete part 2.” **NCPA has the following clarification questions:**

- What means/mechanisms to enroll are available – is this electronic only or can pharmacies submit via paper application?
- Who has access to this information? How can independent pharmacies know with whom this sensitive information will be shared? What privacy protections are available?
- Can PSAOs fill out these forms for independents?
- Do chain pharmacies submit part 1?
- Do independents under PSAOs have the PSAO submit part 2?
- What about independent pharmacies that do not have PSAOs, such as regional chain pharmacies? Are those payments coming directly to pharmacies in electronic or check payment? When pharmacies receive these payments, do they have access to the 835 files for reconciliation purposes? Do the independent pharmacies have to fill out part 1?
- Do refund payments go directly to PSAOs? For PSAOs that require payments to go through them, can CMS ensure that PSAOs will pass through these payments to pharmacies?
- Do PSAOs have the option to get payments in aggregate or to pass them through to individual pharmacies?

Page 3

Under “Section 1: MTF DM User Roles,” **NCPA seeks clarification if the three required roles of 1) authorized signatory official, 2) access manager; and 3) staff end user each require a separate staff member, or if these roles can be combined in staff members, and if so, how.**

Page 4

Page 4, Section 2 refers to the type of dispensing entity enrolling, specifying that it can be a

CHO or a “dispensing entity under common ownership.” However, the concept of ownership is not always straightforward, as many pharmacies share administrative functions but have different owners, making the classification of “common ownership” difficult to apply. Additionally, pharmacies have already addressed ownership questions when contracting with Part D plans, so it seems redundant for the MTF to require the same information. This question could cause unnecessary confusion and may not add value to the enrollment process. It would be more efficient to streamline the process by removing this question altogether, particularly given that the enrollment of non-common ownership entities, such as those with shared administrative functions, may raise further complexities regarding EIN requirements.

Page 5

The categories listed in Section 2, Question 2 of the CMS form are unclear and could lead to confusion. Many independent pharmacies operate under franchise agreements, which blur the distinction between 'Franchise Pharmacy' and 'Independent Pharmacy.' Additionally, many independent pharmacies service long-term care facilities, raising the question of whether they should be categorized as 'Long-Term Care Pharmacy.' Furthermore, some independent owners manage multiple locations—which might classify them as a 'Chain Pharmacy' despite being independently owned. These overlaps create ambiguity, and selecting the wrong category could result in misclassification, leading to unnecessary complications.

We contend that this classification question is unnecessary and could generate more confusion than clarity. If CMS needs to gather information about specific pharmacy types, it would be more effective to include separate checkboxes for those scenarios rather than forcing pharmacies to navigate overlapping or vague categories. This would allow for more accurate data and better serve both the pharmacies and the MTF system.

Page 6

On page 6, question 3 discusses “material cashflow concerns”:

Question 3 provides an opportunity for dispensing entities to self-identify as having **material cashflow concerns** at the start of the initial price applicability year due to the shift from payment by the Part D plan sponsor to a combination of Part D plan sponsor payment plus a potentially lagged MFP refund. For example, CMS expects that **certain types** of dispensing entities—such as **sole proprietor rural and urban pharmacies with high volume of Medicare Part D prescriptions dispensed; pharmacies who predominantly rely on prescription revenue to maintain business operations; long-term care pharmacies; 340B covered entities with in-house pharmacies;** and Indian Health Service, Tribal, and Urban Indian (I/T/U) pharmacies—may have material concerns about cashflow related to the effectuation of MFP. [NCPA emphasis]

NCPA argues that all pharmacies, not just the types that CMS has stated, have “material cashflow concerns” under the Medicare Drug Price Negotiation Program. Under this model, each community pharmacy would need to float on average [\\$27,000 per month](#), 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 pharmacies: according to the 2024 NCPA Digest, nearly all revenue (90 percent) of our membership comes from behind the counter.

Requiring pharmacies to state they are distressed due to cash flow concerns could have unintended negative consequences. Such a declaration may impact their banking relationships and loan agreements, as financial institutions may view this as a sign of financial instability. This could jeopardize the pharmacy’s ability to secure future financing or loans, potentially restricting their access to necessary capital for operations, expansion, or unforeseen expenses.

Additionally, NCPA is concerned with manufacturer discretion of 1) sharing eligibility criteria for mitigation and 2) mitigation itself. Both are problematic for pharmacy protections under this program:

As stated in section 90.2.1 of the Final Guidance, CMS will make the list of the self-identified dispensing entities available to Primary Manufacturers in the MTF DM prior to Primary Manufacturers’ submission of MFP effectuation plans for 2026 and 2027 and will provide updates to the list on an ongoing basis as other dispensing entities enroll in the MTF DM and self-identify as having material cashflow concerns or dispensing entities update their self-identification over time. **CMS views sharing this list as informational and recognizes a Primary Manufacturer may establish its own eligibility criteria for determining which dispensing entities are included in its mitigation approach.** Any such eligibility criteria should be outlined in the Primary Manufacturer’s mitigation process in their MFP Effectuation Plan. **The Primary Manufacturer has discretion for dispensing entity inclusion criteria for any alternative approach; selecting “Yes” does not guarantee the dispensing entity will gain access to a Primary Manufacturer’s mitigation process.**

On Section 3, question 1, regarding “NCPDP ‘Parent Organization ID’” and “NCPDP ‘Chain Relationship ID’”, can CMS clarify what these numbers mean? Do the pharmacies need to enter a chain code for the PSAOs that they participate in? We do not fully understand the purpose of these fields but recommend that they have the same purpose as those used by Part D plans, and that the NCPDP Registry be considered the authoritative source for this field and all data fields that pertain to the pharmacy profile. This will ensure consistency across systems and reduce the burden on pharmacies having to maintain separate profiles.

Page 7

For the chart at the top of the page, do pharmacies need to submit this information for each location?

Page 8

On page 8, the form states the following:

Dispensing Entity CHO: If the entity completing this section is a Dispensing Entity CHO, please indicate whether the Dispensing Entity CHO will accept MFP refund payments from Primary Manufacturers on behalf of all pharmacies under the Dispensing Entity CHO provided in response to Section 3, Question 2. **By selecting “Yes” in response to Question 1, of this section, the Dispensing Entity CHO authorizes the MTF PM to pass through MFP refund payments in an aggregated, single amount on a recurring basis from Primary Manufacturers directly to the payment address or bank account provided.** The Dispensing Entity CHO shall be responsible for disbursing MFP refund payment amounts to its chain pharmacies as applicable from the single payment passed through by the MTF PM. [NCPA emphasis]

NCPA asks CMS if it can further define what it means by “aggregated, single amount on a recurring basis.”

Page 9

On page 9, the form states:

Non-Chain Dispensing Entities or Dispensing Entity CHOs are responsible for maintaining the accuracy of information in this section and reporting any changes over time. Upon any change to the information in this section, the information in this form should be updated via the MTF DM user interface. Failure to promptly update information may cause delays or interruptions in processing of MFP refunds.

NCPA opposes this provision due to the significant administrative burden this would cause pharmacies. Alternatively, our third-party support entities could be responsible for this.

Page 10

On page 10, Section 4, Question 2A reads the following:

Section 4, Question 2A. If “Yes” was selected in response to Question 2, please provide the name of the dispensing entity’s third-party support entity and the MTF-related services that the third-party support entity is authorized to provide to the dispensing entity for purposes of the MTF. Please add a new row to enter more than one third-party support entity .

Third-party Support Entity	Third-party Support Entity Service	Third-Party Support Entity Service Effective Dates	NCPDP Payment Center ID	NCPDP Remit and Reconciliation ID
Text	[Service: Drop-down menu]	Text	Text or Enter “Not Applicable”	Text or Enter “Not Applicable”

Drop-down Menu Options

1	Central payment(i.e., receive MFP refunds on behalf of a dispensing entity)
2	Remittance (i.e., receive ERAs or remittance advice on behalf of dispensing entity)
3	Reconciliation (i.e., submit complaints/disputes on behalf of a dispensing entity)
4	Audit assistance (i.e., assist a dispensing entity or produce records during an investigation or audit)
5	Other

NCPA requests clarification if the dispenser selects option 1 (central payment), does this include electronic remittance advice as well? Can a dispenser choose more than one option in this drop-down menu? How do independent pharmacies know which function to select?

Section 4, Question 2C states “If applicable, please confirm the third-party support entity that will receive MFP refunds on the dispensing entity’s behalf by entering the name of the third-party support entity in the text box.” **NCPA asks if this can be more than one entity.**

Page 11

On page 11, CMS states:

Note: With respect to payments passed through the MTF PM, the MTF PM’s transfer of the Primary Manufacturer’s authorized MFP refund payment to a dispensing entity shall not in any way indicate or imply that CMS or its MTF Contractors have evaluated or determined that the amount paid by the Primary Manufacturer is sufficient to make the MFP available to the dispensing entity and shall not otherwise discharge the Primary Manufacturer’s statutory obligation to make the MFP available. Neither CMS nor its MTF Contractors will assert independent control over the disposition of deposited payment amounts or direct payment transfers; instead, the MTF Contractors will perform a ministerial

function at the behest and direction of the participating Primary Manufacturer with respect to the pass through of the Primary Manufacturer's funds in the amounts and to the dispensing entities identified by the Primary Manufacturer in its claim-level payment elements.

NCPA opposes this, as CMS is not protecting pharmacies from making sure that they are paid sufficiently to make the MFP available.

Additionally, CMS has stated that it will not pay for this program nor will it assume any responsibility for payment:

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. [NCPA emphasis]

NCPA re-iterates that independent pharmacies cannot and should not, nor was it the intent of Congress for pharmacy to pre-fund the MDPN program. Without CMS making the necessary changes outlined above, including CMS pre-funding the program, pharmacies will not be able to afford to dispense these drugs and the MDPN program will fail.

EDI 835 Remittance Advice

As CMS works with the X12 standard to develop its specific implementation of the remittance advice to be used by the payment module, we would like to make two key points.

The first is that the implementation layout be made available early in 2025 so that industry stakeholders who offer reconciliation services can initiate development efforts and be ready for the January 2026 kickoff. Sample data should also be made available to assist in the testing process.

The second is that the layout should include one or more fields that can be used for cross-reference. For example, if a manufacturer claws back a previously paid refund because it has subsequently been identified as a 340B claim, the 835 could contain the HRSA identifier for the covered entity, as many pharmacies serve as contract pharmacies for multiple covered entities. Another example might be an invoice number where the discount was prospectively paid.

Page 14

On page 14, for the instruction in 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 (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). [NCPA emphasis]

NCPA is seeking clarification as to if CMS needs proof of the person having authority equivalent to CEO or CFO of the organization, or an individual with the directly delegated authority to perform the certification. NCPA is also wondering how CMS seeks to prevent fraudulent filing, especially bad actors who are not pharmacies who are filling out forms with fake accounts to fraudulently get money.

Page 15

For the third-party support questionnaire, NCPA seeks clarification that for PSAOs enrolling pharmacies, if the pharmacies are designating a PSAO, does the PSAO just need to fill out one form? We reiterate that the MTF should rely on the NCPDP Registry as the authoritative source for pharmacy-to-PSAO relationships, which would help eliminate redundant forms and reduce administrative burdens for both pharmacies and PSAOs.

Page 16

Regarding the NCPDP “Payment Center ID” and NCPDP “Remit and Reconciliation ID” fields, is this a chain code? Will the third-party support entities have to enter every dispensing entity’s information? This would be a significant administrative burden for PSAOs. We reiterate that the MTF should rely on the NCPDP Registry as the authoritative source for pharmacy profiles. This would eliminate redundant forms and reduce administrative burdens. As noted earlier in our comments, we request that the new system allow pharmacies the option to opt out of having payments directed to their PSAO.

Page 17

On Page 17, the last column of the chart – this information is a significant burden for PSAOs, as effective dates are different, as pharmacies are joining and leaving PSAOs at all times. This could also impact manufacturer payments going to the wrong PSAOs. We reiterate that the MTF should rely on the NCPDP Registry as the authoritative source for pharmacy-to-PSAO relationships,

which would help eliminate redundant forms and reduce administrative burdens for both pharmacies and PSAOs.

Additional comments

No fees. CMS stated in the [final guidance](#) that “...Primary Manufacturers and dispensing entities will not have to pay any fees to enroll in the MTF DM, and Primary Manufacturers will not have to pay any fees to participate in the MTF PM, including but not limited to user fees or transaction fees, as CMS will bear the cost of operationalizing the MTF. In addition, and regardless of whether the MFP refund is passed through the MTF PM or made outside of the MTF PM, neither Primary Manufacturers nor their third-party vendors shall charge dispensing entities any transaction or other fees for the pass through of the MFP refund to the dispensing entity.” We support CMS’ re-iteration in the final guidance that pharmacies cannot be charged any fees to participate as CMS would bear the cost of operationalizing the MTF. **CMS must ensure that plans, PBMs, manufacturers, wholesalers, CMS nor any other entity be allowed to assess any fee on pharmacies to effectuate the MTF or any aspect of the Medicare Drug Price Negotiation Program whatsoever. Any EFT fees should be borne by the manufacturer and not the pharmacy.**

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,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a long horizontal line extending to the right.

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