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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 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 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. NCPA thanks CMS for incorporating its past comments on the importance of the NCPDP registry; we believe that MTF enrollment should be streamlined by relying, to the maximum extent possible, on the NCPDP Registry and the successful enrollment of pharmacies with Part D plans. Finally, we ask that the strictest of privacy and security protections be in place to make sure this information is secure and only shared with the manufacturers when needed to effectuate the MFP.

Page 1

On page one of the Enrollment form, CMS states that CMS has proposed in 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 finalized this in its final 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 negatively impact independent pharmacies. Based on CMS guidance implementing the MDPN Program released to date, CMS has not protected pharmacies from facing below cost reimbursements from PBMs for MFP drugs, including the imposition of pharmacy price concessions. CMS's claims it is unwilling 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].

Yet, CMS is requiring that the Part D plans and its PBM contractors 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 understands the need to maintain the accuracy of information in the NCPDP file as well as additional information, such as banking information, necessary for pharmacies to be paid on time.

On page 2, the form also states that "[t]he dispensing entity is responsible for determining and acquiring information necessary to complete Part I…[while]…Third-party support entities that contract with a dispensing entity to provide prescription-related, administrative, or intermediary services to a dispensing entity, such as a pharmacy services administrative organization (PSAO)

or reconciliation vendor, should complete only Part II." NCPA requests that the following be considered:

- A paper means to enroll in the MTF-DM be made available as well as an electronic method;
- 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 and 835s in aggregate to pass them through to individual pharmacies?

Page 3

Under "Section 1: MTF DM User Roles," the form states that "The dispensing entity should determine how many user roles are appropriate depending on the dispensing entity's staffing resources and business practices. Additional information on assigning user roles and user management will be detailed in upcoming technical instructions." 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 3 discusses "common ownership":

> Dispensing entities under common ownership should be enrolled by their parent organization or chain home office. The parent organization or dispensing entity "chain home office" (hereinafter "dispensing entity CHO") is responsible for completing this form on behalf of all associated locations. If a parent organization is organized into multiple dispensing entity CHOs (e.g., regionally) with claims reimbursement directed to different bank accounts for each sub-component, each dispensing entity CHO may enroll in order to align MFP refund payment with the appropriate payment destination; however, individual locations (e.g., stores under the CHO) should not enroll independently under these circumstances. Note that each MTF DM enrollment will be associated with a single payment destination for MFP refunds.

NCPA appreciates CMS providing additional clarity on 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, and enrollment of non-common ownership entities, such as those with shared administrative functions, may raise further complexities regarding EIN requirements.

Page 5

On page 5, 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. Responses to this question are optional and will be treated as confidential and shared with Primary Manufacturers for purposes of informing Primary Manufacturer's development of their MFP Effectuation Plan only. 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 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 $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 pharmacies: according to the 2024 NCPA Digest, nearly all revenue (90 percent) of our membership results from prescription sales.

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.

Furthermore, as the cash flow of pharmacies can change dramatically from year to year, NCPA requests that CMS provide a mechanism where pharmacies can easily inform manufacturers and change their status regarding having "material cashflow concerns." That is, if in year one a pharmacy has not self-identified as having "material cashflow concerns," that pharmacy should be able to easily inform the manufacturers that it now has cash flow issues, and either in the next year, or mid-year, be able to easily change its status as now having "material cashflow concerns."

Additionally, NCPA is concerned with manufacturer discretion of granting mitigation to dispensing entities, as it is 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 reflect changes to the list of dispensing entities that self-identify as having material cashflow concerns. CMS views sharing this list as informational; Each Primary Manufacturer may establish its own mitigation approach, which must be described in the Primary Manufacturer's MFP Effectuation Plan; selecting "Yes" does not guarantee the dispensing entity will gain access to any Primary Manufacturer's mitigation process.

NCPA further states that under no circumstances should the manufacturer share any of the information provided by the pharmacy to the MTF-DM.

Section 2, Question 1 gives pharmacies the option to authorize the MTF to use and rely on the dispensing entity's information as reported to NCPDP:

> Section 2, Question 1. Please indicate below if you authorize the MTF to use and rely on the dispensing entity's information as reported to NCPDP dataQ Pharmacy Database. Your response does not affect your ability to designate the dispensing entity as the direct recipient of MFP refund payments or to designate the third-party support entity listed in the database as the recipient (see Section 3, Questions 1-1A). Your response will guide how we collect your identifying information and optimize enrollment procedures in the MTF Data Module. Accordingly, please ensure that your information in NCPDP dataQ Pharmacy Database is correct and up to date prior to completing this enrollment form. Selecting "Yes" means a copy of the most recent information from NCPDP dataQ Pharmacy Database will be displayed in Question 2 for your verification.

NCPA thanks CMS for incorporating its past comments on the importance of the NCPDP registry. We re-iterate that we strongly urge CMS to adopt the NCPDP Registry as the primary authoritative source for maintaining pharmacy-to-PSAO connections. 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. The NCPDP Registry should be integrated as the authoritative source for pharmacy profiles to ensure consistency across systems.

<u>Page 6</u>

On Section 2, question 2, 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.

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

Page 8

On Page 8:

> Section 3, Question 1. Irrespective of your decision to authorize the MTF to rely on your information in the NCPDP dataQ™ Pharmacy Database, you retain the option to have MFP refund payments sent either to a third-party support entity listed in that database or to yourself. Please confirm whether the dispensing entity is using a third-party support entity for purposes of the MTF:

Field	Response Format
Are you using a third-party support entity to process your MFP refund payments?	☐ Yes ☐ No

> To ensure MFP refund payments are directed appropriately, please confirm where MFP refunds should be sent (i.e., directly to you or to a third-party support entity you work with).

Field	Response Format
Name of entity to which MFP refund payments should be sent	Text

> Section 3, Question 1A. Irrespective of your decision to authorize the MTF to rely on your information in the NCPDP dataQ™ Pharmacy Database, you retain the option to make ERAs or remittance advice available either to a third-party support entity listed in that database or to yourself.

NCPA asks CMS to provide more options for receiving MFP payments, that is, in scenarios where: 1) there is more than one third-party support entity (or PSAO); 2) the dispenser has some refund payments going from the manufacturer directly to itself, and some refund payments going from the manufacturer to the third-party support entity/entities. For example, a dispenser may work with more than one PSAO, or work with a PSAO for 75 percent of its contracts, while directly contracting for the remaining 25 percent. Moreover, the TPSE support entity is identified by the pharmacy in Part I of the form. The TPSE is not expected to complete Part II of the same form. That is, the TPSE is completing its own form as part of the enrollment process so that it can collect refunds as well as process 835 forms on behalf of all pharmacies and dispensing entities that identified it in Part I. NCPA is wondering how the MTF will match the pharmacies with the TPSEs if the pharmacies sign up for the TPSE functions but the TPSE does not sign up for the same functions, i.e., if there is not an exact match between these assignments.

Regarding the format of Section 3, Questions 1 and 1A, NCPA is concerned that allowing pharmacies to list their third-party support entities in a free text response may create some administrative burden for CMS. For example, if the names do not match what CMS has on file

exactly, there could be issues that need to be resolved creating additional delays. For example, if pharmacies list “EPIC,” “EPN,” “EPIC Pharmacy Network,” etc., this may create discrepancies that may prove problematic for CMS to map pharmacies to the right PSAO. NCPA advises that CMS use NCPDP to provide a list of all PSAOs and reconciliation companies and then have these two fields be populated via a drop-down selection rather than a free text response.

Page 9

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 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.

Page 13

On page 13, 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 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).

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 concerned about the possibility of fraudulent filings, 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 15 states the following: "Only third-party support entities responsible for central pay and reconciliation services for their contracted dispensing entities, or those selected by a dispensing entity to receive MFP refunds and/or ERAs/remittance advice on their behalf, as indicated by the dispensing entity in Part I of this form, should complete Part II." NCPA requests clarification if "central payment" includes electronic remittance advice as well?

Additionally, NCPA asks CMS to clarify how pharmacies will be able to cross-reference and reconcile manufacturer refund payments against specific claims, such as with an Rx number and date of service. Pharmacies need a process that can be standardized to reconcile claims and identify missing and under/overpayments. Importantly, a process that can be standardized allows pharmacies to leverage automation and reduce the administrative burden of dispensing MFP drugs. know that a certain payment goes to a certain claim; will pharmacies need software to walk the claim to their pharmacy software system, perhaps through BIN (saying it is a claim that has an MFP payment) and PCN (assigned to the drug name) numbers that could assist the pharmacy in getting the reconciliation into their system?

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.

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." Additionally, in CMS' final 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*, CMS stated that "The MTF will not charge dispensing entities any fees to use the system." We support CMS' re-iteration in the final guidance and the final rule 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.

Request for MTF Service-Level Expectations and Processing Timelines

Given the essential role of the Medicare Transaction Facilitator (MTF) in managing enrollment data and processing manufacturer refund payments, NCPA strongly recommends that CMS publish clear service-level expectations for the MTF and its contractors. This should include defined timelines for processing new enrollment forms and updates, confirming receipt of data corrections, and responding to inquiries or data discrepancies.

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 beyond the publication of the CARC/RARC codes.

The first is that the implementation layout be made available as soon as possible 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 field that could be used for relating a payment to a specific claim. 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.

Request for Pilot Testing of the MTF Payment Module and 835 Transactions

In addition to early publication of the 835 implementation layout and sample data, NCPA urges CMS to support coordinated pilot testing of the MTF Payment Module and EDI 835 processes with PSAOs, reconciliation vendors, and pharmacy system stakeholders. A structured testing window—conducted well in advance of the January 2026 launch—will help identify and resolve technical issues, minimize disruption, and ensure dispensing entities are able to reconcile MFP refunds accurately. Pharmacy systems and third-party support entities will require adequate time

for system integration, validation, and staff training. A collaborative pilot will strengthen readiness across the ecosystem and reduce the risk of failure when the MTF goes live.

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
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National Community Pharmacists Association