# Medicare Transaction Facilitator: Frequently Asked Questions (FAQs) for Pharmacies and Other Dispensing Entities



This Frequently Asked Questions (FAQs) document contains operational details related to implementing the Medicare Drug Price Negotiation Program (Negotiation Program). Specifically, these FAQs offer guidance to pharmacies, mail order services, and other dispensing entities (hereafter collectively referred to as "dispensing entities") as they prepare to engage with the new Medicare Transaction Facilitator (MTF). To ensure the implementation of the maximum fair prices (MFPs) agreed upon by CMS and applicable manufacturers for drugs selected for negotiation, CMS will establish an MTF system composed of two modules: the MTF Data Module (MTF DM) and the MTF Payment Module (MTF PM).

The MTF DM will facilitate the exchange of data between CMS, manufacturers, and dispensing entities to support the effective and timely effectuation of the negotiated prices. Meanwhile, the MTF PM will offer manufacturers an optional service to assist in passing through their MFP refunds to the appropriate dispensing entities. Critically, dispensing entities only need to enroll in the MTF DM. Upon enrolling in the MTF DM, dispensing entities will indicate whether they prefer receiving MFP refund payments in the form of an electronic transfer of funds, which will be the default selection for dispensing entities at the time of enrollment or a paper check. Since participation in the MTF PM is optional for manufacturers, dispensing entities may receive MFP refunds via the MTF PM or via an alternative process established by a manufacturer.

For more information, please see the MTF Fact Sheet: https://www.cms.gov/files/document/pharmacy-and-dispensing-entity-mtf-fact-sheet.pdf. All detailed guidance on the Negotiation Program can be found on the IRA section of the CMS website. See links at the end of this document.

#### **MTF Enrollment**

### How will dispensing entities enroll in the MTF Data Module (MTF DM)?

Dispensing entities will enroll in the MTF DM by accessing an online web-based portal using a standardized enrollment form to provide information on MTF DM users, entity demographics, third-party support entity relationships, and preferences for how the entity will receive MFP refunds. Each dispensing entity will review and sign MTF-related user agreements during enrollment to finalize MTF DM user functionality access. The enrollment process will be designed to accommodate a variety of operational and business structures. For dispensing entities under common ownership, such as chain pharmacy organizations, the system will provide functionality for centralized enrollment by the parent organization (rather than requiring enrollment for each location), while independent pharmacies will enroll individually. CMS will provide detailed instructions on the enrollment processes and timelines well before dispensing entities need to take any action to enroll.

#### As a dispensing entity, do I have to enroll in the MTF DM?

In the Contract Year 2026 Medicare Advantage (MA) and Part D Proposed Rule, CMS has proposed requiring Part D plan sponsors to include in their network agreements provisions requiring dispensing entities to participate in the MTF DM for purposes of data exchange. Such a requirement, if finalized, would be announced in the Final Rule, which is expected in Spring 2025. Enrolling in the MTF DM will help dispensing entities receive MFP refunds and communicate other information that is helpful to manufacturers and CMS in effectuating the MFP.

#### When will the MTF DM be available to dispense entity enrollment?

CMS is planning for the MTF DM to begin dispensing entity enrollment starting in late Spring 2025 and will make information about enrollment and using the MTF DM available ahead of any need for dispensing entity action. CMS will continue to refine this timing and will keep dispensing entities informed. CMS anticipates that dispensing entity enrollment will be ongoing. While CMS encourages early enrollment to be fully prepared for January 1, 2026, when the first cycle of negotiated prices goes into effect, enrollment and onboarding will continue to be available even after MFP effectuation has begun.

#### Once enrolled, how do I access and use the MTF DM?

The MTF DM web-based platform will allow users to enroll and set up their accounts in order to access the various features that will be available within the MTF DM's user interface. The system will feature secure account access (e.g., multifactor authentication). All MTF functionality for dispensing entities will be centrally housed in the MTF DM and will be available on-demand following successful completion of the enrollment process. Dispensing entities can expect to receive a user guide with instructions for navigating the MTF DM. They will have support available via the MTF help desk to use the system.

#### What functionality will the MTF DM have for dispensing entities?

The MTF DM will provide a single point of access to assist dispensing entities with timely MFP payment tracking and reconciliation. The MTF DM will facilitate dispensing entities receiving MFP refund payment for the selected drug prescription from manufacturers choosing to effectuate the MFP through a retrospective refund of the difference between acquisition cost and MFP. The MTF DM will provide dispensing entities enrolled in the MTF DM with remittances (for dispensing entities not using X12 835 format) or electronic remittance advice (ERAs) (X12 835 standard format) to reconcile MFP refund payments when a manufacturer chooses to pass payment to the dispensing entity through the MTF PM.

Dispensing entities enrolled in the MTF DM will also have streamlined access to submit complaints and disputes within the MTF DM to alert CMS of issues with timely MFP refund payments.

The MTF DM will also serve as a central repository connecting manufacturers with information about dispensing entities needed to fulfill their program obligations. For example, during enrollment, a dispensing entity can self-identify if they anticipate material cashflow concerns due to the transition to retrospective MFP refunds within the 14-day prompt MFP payment window; CMS will share such selfidentifications with manufacturers for consideration in their approach to mitigating such cashflow concerns as required in their MFP Effectuation Plans. The MTF DM will also support MFP effectuation with information about where the manufacturer can direct MFP refunds to dispensing entities if the manufacturer chooses not to use the optional MTF PM services.

CMS intends for dispensing entities to view reports on the status of MFP refunds from manufacturers through the MTF DM user interface. The ability to track MFP refunds may help dispensing entities better manage their cash flow or aid their financial planning to meet other administrative burdens or operational costs. Dispensing entities will also receive an ERA or remittance within the MTF DM when they receive a refund payment so that they know the final disposition of MFP refund claims.

#### I use a third-party support entity, like a Pharmacy Services Administrative Organization (PSAO), to assist with processing payments to my pharmacy. Can they play a role in supporting MFP refunds in the MTF DM?

Yes, once a dispensing entity is enrolled, the MTF DM will provide functionality to allow them to continue leveraging the services of third-party support entities like PSAOs. As the MTF DM enrollment process moves forward, CMS will provide additional information about how these third parties will interact with the MTF DM and how they can support the dispensing entities that use their services.

## How can I give feedback to CMS about MTF DM enrollment processes and requirements?

CMS opened a public comment period between October 28, 2024, and December 27, 2024, on the MTF Information Collection Request (ICR), including an opportunity to provide feedback and comments on the ICR's Dispensing Entity and Third-party Support Entity Enrollment Form. CMS will reissue this form for a 30-day comment period in early 2025 and continue encouraging the dispensing entity community to engage in the public comment process and provide their input.

### What information will I need to provide during enrollment?

The draft dispensing entity enrollment form includes five categories of information, as described in the table below. Interested parties can view the details of the draft dispensing entity enrollment form that CMS released for a 60-day public comment period between October 28, 2024, and December 27, 2024, here: MTF DM Dispensing Entity Enrollment Form. Note that this form is not final and is subject to change as CMS reviews public comments received and finalizes the enrollment process.

MTF DM User Roles	Assign user roles for individuals needing access to the MTF DM.
Dispensing Entity Selection	Basic information about the type of dispensing entity enrolling in the MTF DM, e.g., chain pharmacy, independent pharmacy, and more specific business model classifications.
Dispensing Entity Identification Information	Identifying information about the dispensing entity, including federally issued identifying information and demographic, geographic, and relationship information for verification purposes and to enable enrollment in the MTF DM.
Dispensing Entity Financial Information	Financial and account information to facilitate the pass-through of the MFP refund payment from the manufacturer to the dispensing entity.
Dispensing Entity Contact Information	Points of contact within the Dispensing Entity to facilitate system operations.

#### **MTF Agreements**

### As a dispensing entity, what do I need to know about the MTF Agreements?

All dispensing entities must sign two user agreements upon enrolling in the MTF to gain access to the platform's full functionality. One is a general program agreement between the dispensing entity and CMS (the Dispensing Entity Program Agreement). This agreement outlines general responsibilities for CMS and the dispensing entity related to using the MTF, such as confidentiality and data use provisions. The other is a specific agreement between the dispensing entity and the MTF DM Contractor (the MTF DM Agreement), which outlines the responsibilities and obligations of each party to establish what a dispensing entity can expect from the contractor operating the MTF DM. These agreements will be made available within the MTF DM user interface during the enrollment process for each dispensing entity to review and sign to finalize enrollment.

Dispensing entities can review these agreements on the IRA website: https://www.cms.gov/inflationreduction-act-and-medicare/medicare-drugprice-negotiation.

In addition to revising these draft agreements in response to public feedback, the agreement provisions may also be updated to reflect input from the MTF DM contractor as the development and implementation process progresses.

### What are the details about the public feedback period for the MTF Agreements?

CMS released the draft MTF Agreements, both for the dispensing entities and the Primary Manufacturers, for public feedback on December 17, 2024. The public feedback period is open until January 31, 2025. Please submit your feedback to CMS via IRARebateandNegotiation@cms.hhs.gov using the subject line "MTF Agreements Feedback". Note that these draft MTF Agreements are not final and are subject to change as CMS reviews feedback, continues the MTF development process, and finalizes the MTF Agreements. In addition to making the final agreements available in the MTF DM for review and signature, CMS intends to publish the final versions online prior to initiating the enrollment process.

## Why do dispensing entities need to sign agreements with CMS and the MTF DM Contractor?

The MTF will be a system that houses sensitive information, such as certain elements of individual information, as well as dispenser and manufacturer financial information. The MTF user agreements are designed to outline the specific responsibilities of all involved parties and establish requirements for safeguarding information and interacting with the system. These agreements will establish responsibilities for all parties involved, including CMS, CMS' contractor(s), and system users, to support successful and consistent implementation of the MTF system aligned with all applicable laws, regulations, and Federal guidance. Each dispensing entity will need to enter into these agreements before accessing the full functionality of the MTF system. In the case of chain pharmacies, the agreements will be executed by the Chain Home Office for all aligned locations; that is, each location will not execute its own agreements. For independent and other pharmacies not aligned with a centralized Chain Home Office, each entity will review and execute the agreements independently during enrollment.

#### **Maximum Fair Price Refund**

## How will dispensing entities know which manufacturers will use the MTF PM to process MFP refunds versus their own processes for reimbursing dispensing entities?

Manufacturers will indicate in their MFP Effectuation Plan whether they will use the MTF PM versus their own processes for reimbursing dispensing entities. In the event a manufacturer chooses to use its own approach, they will be required to provide details of such an approach in the MFP Effectuation Plan to CMS. They must follow the requirements for effectuating MFP outlined in CMS' 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 ("final guidance").

Manufacturers must have contact information available for dispensing entities in their MFP Effectuation Plan should a dispensing entity have any questions. Ultimately, it is the sole responsibility of each manufacturer to ensure the MFP is made available to dispensing entities. CMS will make each manufacturer's MFP Effectuation Plan (redacted to protect any proprietary information) available to dispensing entities through the MTF DM. Interested dispensing entities can find a draft of the MFP Effectuation Plan form available in the ICR package published for the 60-day public comment period, here: MTF DM Primary Manufacturer MFP Effectuation Plan Form.

#### How much should a dispensing entity expect to receive for each MFP refund?

The manufacturer is responsible for making the MFP available to dispensing entities and may do so in a variety of ways, including selling the selected drug to the dispensing entity at MFP or via a retrospective MFP refund. Given that the obligation to effectuate the MFP rests with the manufacturers, the manufacturers are responsible for calculating the correct MFP refund amount for each applicable claim to make MFP available. CMS' final guidance noted that manufacturers may provide refunds at the Standard Default Refund Amount (SDRA), which is the difference between Wholesale Acquisition Cost and MFP. Alternatively, manufacturers may provide refunds at an alternative amount if they maintain supporting documentation demonstrating why MFP refunds were provided at an amount other than the SDRA. In the MFP effectuation process, Part D plan sponsors will identify an estimated MFP refund at SDRA based on recent instructions from the National Council for Prescription Drug Programs (NCPDP) and will provide this estimate to dispensing entities for each Part D claim for a selected drug to assist the dispensing entity in tracking the amount of outstanding refunds owed. The SDRA estimate provided by the plan sponsor may not reflect the final amount that manufacturers provide to make MFP available.

## What do I do if I disagree with the amount of an MFP refund that I received from the manufacturer?

If you disagree with the refund amount received from the manufacturer, CMS encourages manufacturers and dispensing entities to work together to mitigate the issue. To facilitate this coordination, CMS requires that manufacturers provide an avenue for dispensing entities to contact them regarding such concerns as a component of their MFP Effectuation Plan.

These concerns may also be submitted to CMS via the complaints and disputes portal in the MTF DM for review. In these submissions, CMS requests a detailed description of the issue, supporting documentation (if applicable), and contextual information to aid our review process. For more details on the information CMS intends to collect for a complaint and dispute submission, please see the draft of the MTF Complaint and Dispute Intake Form available in the ICR package published for the 60-day public comment period here: MTF ICR Complaints and Disputes Intake Form.

CMS' final guidance notes an opportunity for dispensing entities to raise concerns about cash flow during MFP effectuation. What action should a dispensing entity take if they anticipate material cashflow concerns consistent with those described in the final guidance?

The MTF DM Dispensing Entity Enrollment Form 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 from the manufacturer. CMS will provide these self-identifications to each manufacturer for consideration when implementing their planned approach to mitigate such concerns as required by the MFP Effectuation Plans. CMS will consider the information a manufacturer provides in its mitigation process when conducting a risk assessment of the manufacturer's MFP effectuation plan. Manufacturers with plans that CMS identifies

as having a greater risk of failing to make the MFP consistently available will be subject to increased scrutiny through CMS' monitoring and oversight activities.

#### **Other Questions**

## What resources and documents are currently available for future MTF users to learn more?

Please see the links below for information that future dispensing entity MTF users may find useful.

- Medicare Transaction Facilitator: Fact Sheet for Pharmacies and Other Dispensing Entities
- 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
- Information Collection Request: Medicare
  Transaction Facilitator for 2026 and 2027
  under Sections 11001 and 11002 of the
  Inflation Reduction Act
- 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
- Draft MTF Agreements

#### Where should I send my questions, input, and feedback on the MTF?

CMS welcomes questions, input, and feedback related to the MTF and will continue to maintain transparency as there is information to share. Please direct those inquiries to MFPMedicareTransactionFacilitator@cms.hhs.gov. Please use keywords in the subject line to help CMS sort and direct the email to the correct team.

