

Medicare Transaction Facilitator: Pharmacies and Other Dispensing Entities Frequently Asked Questions



This Frequently Asked Questions (FAQs) document contains information intended to support 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 negotiated maximum fair prices (MFPs) agreed upon by CMS and applicable Manufacturers¹ 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). For more information, please see the MTF Fact Sheet. Guidance and other important documents about the Negotiation Program can be found on the CMS website [here](#).

These FAQs will be updated periodically and are organized by topic area. If you do not see the answer to your question within this document, guidance, or additional resources available on the [Resources for Pharmacies and Dispensing Entities webpage](#), please email MFPMedicareTransactionFacilitator@cms.hhs.gov with your question and CMS will provide you with a response or point you to a relevant resource.

MTF Enrollment: Dispensing Entities

Q1. Why should I enroll in the MTF DM?

The Medicare Transaction Facilitator will be a critical tool for pharmacies as they continue, or begin, to dispense drugs with negotiated MFPs on or after January 1, 2026. When the negotiated MFPs are active (January 1, 2026), pharmacy reimbursement from Part D Plan Sponsors will be no more than those prices which may be less than the acquisition costs pharmacies will pay for the drugs. By enrolling in the MTF, pharmacies will gain access to the system necessary for them to receive refund payments from

these drugs’ manufacturers to accompany their reimbursement from Part D Plans as applicable. Enrolling in and using the MTF is free for pharmacies and does not place any requirement on pharmacies to dispense any drugs under the Medicare Part D program. Following enrollment, the MTF will be there if needed. That is, once the pharmacy has enrolled in the MTF, the MTF will be available to support effectuation of the MFPs as soon as that pharmacy dispenses any of the drugs with negotiated MFPs under the Part D program, as applicable, at any time. Following enrollment, the pharmacy will not need to take any further action for the MTF to support data and payment exchange, when necessary, outside of the pharmacy’s normal course of doing business (e.g., dispensing the selected drugs, submitting claims to the Part D Plan Sponsor). Pharmacies may be passive users of the MTF after enrollment, with the system supporting their business in the background, or they may actively engage with the systems’ features (e.g., reporting) to help monitor their processing claims and MFP refund payments. Enrolling in and using the MTF will provide critical benefits to the pharmacy community.

Q2. As a dispensing entity, do I have to enroll in the MTF DM?

Yes, if a dispensing entity intends to dispense Part D drugs that have an MFP taking effect in 2026 or future years, they need to enroll in the MTF DM. In the final rule titled, “[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](#)” published on April 15, 2025, CMS finalized the proposal that Part D sponsors’ network participation agreements with contracting

¹ For the purposes of this document, “Manufacturers” refers to pharmaceutical manufacturers that have been designated the manufacturers by CMS for drugs selected by CMS for the Medicare Drug Price Negotiation Program, as defined in applicable guidance or regulations adopted in accordance with section 1193 of the Act.

pharmacies, including any contracts with first tier, downstream, and related entities, must require such pharmacies to be enrolled in the Medicare Drug Price Negotiation Program's Medicare Transaction Facilitator Data Module ("MTF DM") and that such pharmacies certify the accuracy and completeness of their enrollment information in the MTF DM. CMS believes the inclusion of the requirement for Part D sponsors' network pharmacies to be enrolled in the MTF DM that will be added to Part D sponsors' network contracts with pharmacies will facilitate continued beneficiary access to selected drugs, promote access to negotiated MFPs under the Negotiation Program for both beneficiaries and dispensing entities, and help ensure accurate Part D claims information and payment. As described in Q1 above, CMS emphasizes that enrollment in the MTF will provide critical benefits dispensing entities, allowing them to receive MFP refunds if/when they dispense a negotiated drug for IPAY 2026 and into the future; however, enrollment in the MTF is not accompanied by any inherent obligation to dispense selected drugs with MFPs.

Q3. Does enrolling in the MTF constitute an agreement to contract terms with a Part D plan sponsor?

No, enrollment in the MTF does not impact your ability to opt in or out of a contract with a Part D plan sponsor or a Pharmacy Benefit Manager (PBM). The MTF is a tool to support receiving reimbursement from a Manufacturer if you choose to dispense Part D drugs that have an MFP taking effect in 2026 or future years.

Q4. When will the MTF be available to accept enrollments from dispensing entities?

The MTF will be available for enrollment beginning in June 2025.

Q5. How do I initiate the MTF enrollment process?

CMS will distribute invitations to enroll via email to a 'first user' for each pharmacy, drawing on data from the National Council on Prescription Drug Programs (NCPDP) database to identify and validate initial dispensing entity users. These email invitations will be sent by CMS over the course of several weeks beginning after the MTF Launch Event

on June 5, 2025. If you do not receive an immediate invitation by email, it is no cause for concern; CMS anticipates distributing all initial email invitations by the end of June 2025. You may send any enrollment related questions or concerns to the MTF help desk at MFPMedicareTransactionFacilitator@cms.hhs.gov. MTF enrollment will be open on a rolling basis, meaning you will be able to sign up at any time. However, we strongly encourage you to enroll beginning in June 2025 when you receive your invitation to enroll and no later than November 15th, 2025, to ensure a smooth transition and avoid potential delays when the first cycle of MFPs goes into effect in January 2026.

Q6. What are the steps of the MTF enrollment process? Enrolling in the MTF will be a straight-forward process using a web-based enrollment form. First, the enrollee will begin by creating an account with the CMS Identity Management system (CMS IDM), unless they already have a CMS IDM account from other CMS programs. This is an important step for the security of the MTF, enabling CMS to ensure that only verified and identified users are able to create accounts and access the MTF. During this process, the user will set a username and password connected to their verified CMS identity that will be used to access the MTF.

Next, each enrolling dispensing entity will review and sign the [MTF DM User Agreement](#), outlining the roles and responsibilities of all the parties involved in the MTF to facilitate successful and sustainable operations. The MTF DM User Agreement must be signed by an individual authorized to sign on behalf of the entity, if the 'first user' is not the correct individual, they can invite the correct individual to create their own MTF account in order to review and sign the User Agreement.

Then, the enrollee will access the MTF DM via an online web-based portal and complete a standardized enrollment form to provide the information the MTF needs to operate. This includes things like identifying MTF DM users for the pharmacy, providing entity demographics, third-party support entity (TPSE) (e.g., a PSAO) relationships, and preferences for how the entity will receive MFP refund payments. The standardized enrollment form ("Dispensing Entity Enrollment Questionnaire") from CMS' Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction

Act (IRA) Information Collection Request (MTF ICR) is approved and available for viewing on [OMB's website](#). Click "all" to see full details.

CMS plans to publish a User Guide in Summer 2025 with detailed instructions on what steps dispensing entities will need to take to enroll. To stay informed of upcoming events and opportunities to learn about the enrollment process, we encourage you to check the [Pharmacies and Dispensing Entities webpage](#) frequently for updates and to sign up to receive emails about the MTF by clicking [this link](#), entering your email address, and selecting "Medicare Transaction Facilitator" under the Center for Medicare.

Q7. OAs a dispensing entity, what information will I need to provide during enrollment?

The Dispensing Entity Enrollment Questionnaire (available for viewing on [OMB's website](#); click "all" to see full details) shows the information that the MTF DM will collect during enrollment. You can review this form in advance of enrolling to prepare the information you'll need. Here are some things to note about the information you can expect to provide:

Before gaining access to the MTF, users will be required to create an account with CMS IDM and complete a process called Remote Identity Proofing, which entails giving personal details to verify that the individual is who they say they are. This critical step helps ensure system security for all stakeholders.

Additionally, during the enrollment process, if you authorize the MTF DM to use and rely on your information as reported to NCPDP Pharmacy Database, you will need to provide several key pieces of information. This includes: 1) either your legal business name (exactly as it appears in that database), 2) doing business as (DBA) name, 3) NCPDP Relationship ID (for chains, when NCPDP relationship type = 01), or NCPDP Provider ID (for non-chains). This will enable the MTF DM to import your identifying information, such as name, addresses, NPI, and Tax Identification Number (TIN) for your verification.

You'll also need to provide the name of your TPSE (e.g., PSAO) if you indicate during enrollment that you are using a TPSE to process your MFP refund payments and/or receive remittance advice on your behalf. If you work with a TPSE, they will also get an email from CMS to enroll and set up an MTF account. Note that both

the pharmacy and the TPSE must also enroll in the MTF to support the linking the dispensing entity with the correct TPSE.

Additionally, if you choose to receive MFP refund payments via electronic transfer of funds, you'll need to provide your banking information and account type. Please note that if you are using a TPSE to process your MFP refund payments, their banking information will be used for payment facilitation, and your banking information will be stored in the MTF DM and used as needed in case of unforeseen circumstances that interrupt sending payment to your TPSE. If you choose to receive MFP refund payments via paper check, you will need to provide the addresses where you wish payment and remittance to be sent.

Lastly, you'll need to provide contact information for two points of contact within the dispensing entity who are knowledgeable about your responses to the [Dispensing Entity Enrollment Questionnaire](#) (including any data pre-populated from the NCPDP Pharmacy Database) and are able to respond to any inquiries from CMS if clarifications or additional information is needed. This is not a separate user role and could be an MTF user or an individual at the dispensing entity that is not an MTF user.

Q8. As a dispensing entity, once I have enrolled in the MTF DM, do I also need to enroll in the MTF Payment Module (MTF PM) in order to receive MFP refund payments?

No, dispensing entities do not have to enroll in the MTF PM. After enrolling in the MTF DM, the information you provide will be available to the MTF PM to facilitate the MFP refund payment process with no further action needed from the pharmacy.

Q9. Is CMS going to leverage data already provided to the National Council of Prescription Drug Programs (NCPDP) to facilitate dispensing entities in enrolling in the MTF?

Yes, CMS plans to utilize the National Council of Prescription Drug Programs (NCPDP) dataQ[®] Pharmacy Database ("NCPDP Pharmacy Database") to identify and validate initial dispensing entity users, or "first users," for access to the MTF DM. CMS will use the contact information stored in the Relationship Demographic (Relationship ID/Chain ID for chains)

or Provider Information (NCPDP ID for independent pharmacies) in the NCPDP Pharmacy Database to determine who these first users may be. These points of contact are also known as the “Authorized Official” in NCPDP’s Access Online system, or Chain Code Contact, if the user is a chain pharmacy and their chain code has a contact listed that is different from their Authorized Official. These users will be responsible for verifying their identity, creating an account, and attesting to their role in their organization for the MTF DM. In addition, the first user will be responsible for inviting downstream users from their organization to register for access.

When the first user enrolls in the MTF, they will be assigned privileges to be an Authorized Signatory Official or Access Manager for their organization, based on an attestation for their organization. If they are not the Authorized Signatory Official and are unable to enter into binding agreements on behalf of the enrolling dispensing entity, the initial user will be able to invite that user to join the MTF on behalf of their organization. Therefore, please ensure your NCPDP profiles and Points of Contact (for the chain relationship for chain pharmacies and at the provider level for non-chain pharmacies) are up to date and are accurate prior to the dispensing entity onboarding targeted for early June 2025.

Additionally, during the enrollment process, dispensing entities will be given the option to pre-populate certain identifying data on the enrollment form using self-reported dispensing entity and TPSE information including National Provider Identifies (NPI), address, state license number, federal tax identification number, and other data from the NCPDP Pharmacy Database if desired. For a full list of the information that can be populated from the NCPDP Pharmacy Database if desired, please see Section 2, Question 2, of the Dispensing Entity Enrollment Questionnaire.

If you work with a TPSE, they will also get an email from us about setting up an account, but you must also complete the MTF enrollment process and list your TPSE in that questionnaire to support the MTF linking your dispensing entity with your TPSE. For additional guidance on how TPSEs will enroll, please see the FAQs that follow within the “MTF Enrollment: Third-Party Support Entities” section.

Q10. How can a pharmacy update their NCPDP profile and points of contact? What should a pharmacy do if they have listed a resource email box and not an individual in the NCPDP database?

CMS will be using the information in dispensing entity NCPDP profiles to identify where to send MTF DM email invitations. It is critical that dispensing entities ensure your NCPDP profiles and Points of Contact (for the chain relationship for chain pharmacies and at the provider level for non-chain pharmacies) are up to date and are accurate prior to the dispensing entity onboarding targeted for early June 2025. To review your current profile information, and make updates if necessary, visit [NCPDP Online](#), login to your profile, and follow the steps to make any applicable updates. If you need help, please contact NCPDP at pharmacyhelp@ncdpd.org.

Q11. How will the MTF DM pharmacy enrollment process use the NCPDP relationship IDs for chains in the NCPDP Pharmacy Database? Will the pharmacy be able to access all the applicable pharmacy records for that chain?

The relationship ID variable is the key variable that the MTF uses to determine which entries are affiliated with a chain in enrollment. For a dispensing entity that is a chain, all of the pharmacies associated with that chain in the NCPDP Pharmacy Database, according to the relationship ID variable, will roll up and be imported into MTF DM enrollment interface. If a parent organization has multiple chains as defined by different relationship IDs in the NCPDP database, then each chain will have to enroll separately into the MTF and maintain that information in the MTF DM separately.

Q12. What are the various user role types in the MTF DM?

There are three distinct user roles in the MTF DM:

Authorized Signatory Official (ASO): An appointed individual of the dispensing entity with authority to legally bind that organization in agreements, represent the organization in an official capacity, and act on behalf of an organization. To be eligible,

the Authorized Signatory Official must meet one or more of the following criteria: (1) serve as the Chief Executive Officer (CEO), where the individual has been duly appointed by the organization's board or other governing body; (2) serve as the Chief Financial Officer (CFO), where the individual has been duly appointed by the organization's board or other governing body; (3) serve in a role other than as the CEO or CFO, where the individual has authority that is equivalent to a CEO or CFO; or (4) serve in a role, where the individual has been granted directly delegated authority to legally bind the organization on behalf of one of the individuals previously noted in (1)-(3). ASOs also have the ability to invite additional users to serve any available role in the MTF DM.

Access Manager (AM): An individual, of the dispensing entity authorized to act on behalf of the organization to view, modify, submit, and certify the completeness and accuracy of information in the MTF DM on behalf of the organization. AMs also have the ability to invite additional users to serve any available role in the MTF DM.

Staff End User: An individual, designated by the Access Manager or the Authorized Signatory Official of the dispensing entity authorized to view information in the MTF DM and submit complaints and disputes in the MTF DM on behalf of the organization.

Q13. Is there a limit on the number of individuals allowed to enroll per company?

Each MTF user will be allowed up to 3 Authorized Signatory Officials, up to 3 Access Managers, and up to 10 Staff End Users.

Q14. Could a chain pharmacy have 3 different signatories depending on its line of business (e.g., one for retail, one for mail order and one for specialty pharmacy)?

This depends upon how a pharmacy is set up in the NCPDP Pharmacy Database, as enrollment is at the chain code-level for chain pharmacies. If different lines of business are registered with NCPDP under different NCPDP IDs, then a pharmacy could have multiple distinct enrollments, with distinct users. However, the MTF DM user management structure will be designed to enable users to align with multiple organizations such that they may seamlessly access information for applicable enrollments while using the MTF.

Q15. Who will receive the email from CMS to enroll in the MTF when the MTF DM enrollment module is open?

Each "Authorized Official" in the NCPDP Pharmacy Database with a valid email address listed will receive an e-mail from CMS to enroll in the MTF DM. For instructions on how to update your organization's authorized official, please visit [NCPDP Online](#). If you need help, please contact NCPDP at pharmacyhelp@ncdp.org.

Q16. Once enrolled, how do I access and use the MTF DM?

Once enrolled, an individual user can use their CMS IDM login to access the MTF DM web-based platform. Once logged in, users can manage their accounts and access the various features that will be available within the MTF DM. 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.

For a user to keep their CMS IDM active, they must log in to the MTF DM every 60 days. Users will get email reminders to login from IDM.

Q17. What functionality will the MTF DM have for dispensing entities?

The MTF DM will serve as a single point of access to assist dispensing entities with receiving and reconciling MFP refund payments from Manufacturers who have opted to use the MTF PM to facilitate payment. Among other functionalities, using the MTF will allow dispensing entities to:

During Enrollment and Prior to January 2026

- Self-identify as anticipating material cash flow issues as defined in section 40.4.2.2 of final guidance as applicable;
- Access helpful information on using the MTF
- Invite users and assign system roles;
- Access a streamlined enrollment procedure leveraging pre-populated pharmacy information, if enrolling dispensing entity authorizes use of accurate and up-to-date NCPDP data;

- Instruct the MTF DM where MFP refund payments and remittance advice should be sent, including to a linked TPSE (e.g., PSAO) as applicable;
- Review MFP Effectuation Plans, including plans for dispensing entities self-identifying with cash flow issues (expected Fall, 2025);
- Review and sign MTF DM User Agreement.

During Implementation

- Receive MFP refund payments from Manufacturers who have opted to use the MTF PM;
- Receive remittance for payment made by paper check or Electronic Remittance Advice (ERA) that uses the X12 835 standard adopted under the Health Insurance Portability and Accountability Act (HIPAA) for electronic payments;
- Access technical instructions in the User Guide;
- Update enrollment information and manage users on an as-needed basis;
- Submit complaints or disputes;
- View reports on the status of Prescription Drug Event (PDE) data processing through the MTF DM to aid in financial planning.

The MTF DM will also serve as a central repository for 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 refund payments within the 14-day prompt MFP payment window; CMS will share such self-identifications 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 sharing MFP effectuation information about where pharmacies have indicated MFP refunds should be directed (e.g., banking information, preference for electronic payment or paper check) with manufacturers who have opted not to use the MTF PM. CMS intends for dispensing entities to view reports on the status of PDE data processing through the MTF. This ability to track the status of data processing through the MTF may help dispensing entities better manage their cash flow or aid their financial planning to meet other administrative burdens or operational costs.

Remittance advice will also be made available to dispensing entities within the MTF DM when they receive MFP refund payments for Manufacturers that use the MTF PM. This helps dispensing entities know the final disposition of MFP refund claims.

Q18. Will non-dispensing entities (like pharmacy trade associations) have access to the MTF DM?

CMS does not anticipate trade associations or other entities not directly involved in the process of dispensing and/or reimbursing dispenses of drugs under the Medicare program will have access to the MTF DM.

Q19. What should I do if I never received an email invitation to the MTF DM, or if I lost my email invitation?

If you believe you should have received an email from CMS to enroll in the MTF but have not received one by the end of June 2025, or you have lost your original invitation, please contact the MTF Helpdesk at MFPMedicareTransactionFacilitator@cms.hhs.gov.

Q20. Do MTF DM email invitations expire?

Yes, MTF DM email invitations expire 72 hours after being sent. If your invitation has expired, please contact the MTF Helpdesk at MFPMedicareTransactionFacilitator@cms.hhs.gov to request a new invitation.

Q21. What happens if a pharmacy opts to pre-populate its data in the MTF DM from the NCPDP Pharmacy Database, but the data populated is incorrect?

CMS encourages all dispensing entities, especially those who intend to use the NCPDP database to pre-populate information during the enrollment process, to update their information as soon as possible and at least two weeks before beginning the enrollment process. To avoid inconsistencies in these data across sources, all updates to NCPDP data must be made directly in the NCPDP Pharmacy Database; these updates cannot be made in the MTF enrollment interface. There will be approximately a two-week lag between updating NCPDP and having those updates populate in the MTF DM. If you notice any information that is outdated or incorrect during the MTF enrollment process, please return to your

NCPDP profile to update your information and then resume your MTF enrollment at a later date once that information has been updated.

To review your current profile information, and make updates if necessary, visit: [NCPDP Online](#), log in to your profile, and follow the steps to make any applicable updates. If you need help, please contact NCPDP at pharmacyhelp@ncdpd.org.

MTF Enrollment: Third-Party Support Entities (TPSEs)

Q22. I use a Pharmacy Services Administrative Organization (PSAO) to assist with processing payments to my pharmacy. Will they be able to access and enroll in the MTF DM?

Yes, a TPSE such as a PSAO may enroll in the MTF DM. The TPSE must be listed in the NCPDP Pharmacy Database with a Payment Center ID or Primary Remit/Recon ID in order to establish an account with the MTF DM. TPSEs must also complete the Third-Party Support Entity Enrollment Questionnaire (Part 2 of the Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Form) in the MTF DM. Dispensing entities must enter the TPSE they work with as part of filling out the Dispensing Entity Enrollment Questionnaire and the information they enter must exactly match what the TPSE provides the MTF DM in their Third-Party Support Entity Enrollment Questionnaire in order for the dispensing entity and TPSE to be linked in the MTF DM; CMS encourages TPSEs to provide information to their associated pharmacies to facilitate consistent data entry and successful matching in the system. Additionally, dispensing entities can direct their remittance information or payment to TPSEs if they provide that information when they fill out their Dispensing Entity Questionnaire.

TPSEs can expect to support dispensing entities in much the same manner they do today. The MTF DM was designed to align with industry standards for central payment and claims reconciliation to ensure a familiar process for TPSEs and dispensing entities.

Q23. As a PSAO that only collects remittances (835s) but not payments, do I need to enroll in the MTF?

Yes, you will need to enroll in the MTF to facilitate remittance-only functionality. The MTF distinguishes between third-party roles for collecting payments and collecting remittances, or collecting remittances only. These are the only two functions for TPSEs within the MTF DM.

Q24. How will TPSEs know which of their member pharmacies have enrolled in the MTF?

CMS anticipates that the MTF DM will provide reporting functionalities to help TPSEs track enrollment of their member pharmacies. CMS will also monitor which pharmacies have and have not enrolled, especially when linking TPSEs and pharmacies.

Q25. Can a TPSE complete the Dispensing Entity Enrollment Questionnaire for independent pharmacy clients?

Each dispensing entity must enroll in the MTF DM independently. And, each TPSE must enroll in the MTF DM as well. The independent pharmacy should fill out the Dispensing Entity Enrollment Questionnaire and identify any appropriate third-party support entities in that questionnaire. In the Enrollment Questionnaire, TPSEs can enter a profile in the MTF DM to be matched to a pharmacy enrollment request to link to a TPSE. For more information on TPSE MTF DM enrollment, please see the final MTF ICR [available here](#).

Q26. Can the pharmacy designate a TPSE to receive 835 or remittance on their behalf while still receiving MFP refund payments directly via electronic funds transfer (EFT)?

Yes, dispensing entities will be able to designate a location where they wish to receive the remittance or 835. This can include third parties as identified by the dispensing entity.

MTF DM User Agreements

Q27. As a dispensing entity, what do I need to know about the MTF DM User Agreement?

The MTF will house and process sensitive information. As such, the **MTF DM User Agreements** (both for dispensing entities and drug manufacturers) are in place to outline the general roles and responsibilities for operating and using the system. For dispensing entities, the **final MTF DM User Agreement** outlines roles and responsibilities of CMS, CMS' MTF DM Contractor, and the Dispensing Entity users; establishes CMS' audit rights and penalties for violations of the agreement (e.g., using the MTF for nefarious actions); describes confidentiality and data use policies surrounding information submitted and exchanged through the MTF DM; and includes disclaimers and general contract provisions governing termination rights and other legal terms applicable to CMS and the Dispensing Entity. The final MTF DM User Agreement is a result of targeted revisions after CMS' careful consideration of interested parties' feedback on the draft MTF agreements (formerly "MTF Program Agreement" and "MTF Data Module Contractor Agreement") during the public feedback period (December 17, 2024, through January 31, 2025). The MTF DM User Agreement reflects the policies established in section 40.4.2.2 in the **final guidance** published on October 2, 2024 ("Dispensing Entity Enrollment in the MTF DM") and applies to any pharmacy or dispensing entity that is or will be a member of a Medicare Part D sponsor's network and dispenses drugs with a negotiated MFP to MFP-eligible individuals.

An authorized individual from each enrolling dispensing entity is required to execute the MTF Data Module User Agreement and can execute the agreement by e-signature in the MTF DM during the entity's onboarding process.

Q28. How will CMS ensure confidentiality of dispensing entities' enrollment information and protection from disclosure of proprietary information? What is CMS' procedure for any disclosure or data breach that may occur related to the MTF DM?

CMS recognizes the nature of sensitive information stored in the MTF DM and will handle all enrollment

data in compliance with federal privacy and security standards, such as the Federal Information Security Modernization Act (FISMA), a framework of guidelines and security standards to protect government information and operations. The MTF DM will implement safeguards, including access controls and regular monitoring, to protect against unauthorized access or disclosure. In the event of a breach, CMS will follow the steps prescribed by federal policies and guidelines to assess the risk, conduct a breach analysis, and mitigate any resulting harm. Such applicable privacy laws, regulations and policies are outlined in confidentiality and data use provisions in the MTF Data Module User Agreement.

Maximum Fair Price (MFP) Refund

Q29. How will dispensing entities know which Manufacturers will use the MTF PM to pass through MFP refund payments?

During their enrollment and onboarding, and as a component of the MFP Effectuation Plan, drug manufacturers will indicate whether they are opting to use the MTF PM to pass through MFP refund payments. CMS intends to make this information available to dispensing entities within the MTF DM user interface. In the event a Manufacturer chooses to forgo use of the MTF PM, they will be required to provide details of their approach to effectuating the MFP in the MFP Effectuation Plan, due to CMS no later than September 1, 2025. They must follow the requirements for effectuating MFP outlined in section 90.2.1 of the 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 and their third-party support entities through the MTF DM. Interested dispensing entities can find the "MTF DM Manufacturer MFP Effectuation Plan Form" available [here](#) in the final ICR.

Q30. When will dispensing entities be able to view the redacted MFP Effectuation Plans?

Redacted MFP Effectuation Plans will be available for review by dispensing entities via the MTF DM in Fall of 2025.

Q31. Will manufacturers submit one MFP Effectuation Plan to the MTF DM or will there be a specific plan for each pharmacy?

A: Each Manufacturer will submit one MFP Effectuation Plan that applies generally to their approach for effectuating the MFP. The MFP Effectuation Plan may include information on how different categories of dispensing entities will be treated. If a particular dispensing entity and a particular Manufacturer reach a separate agreement on effectuating the MFP, that agreement would be between the dispensing entity and Manufacturer and would be considered proprietary and would not be stored or made available in the MTF. The MFP Effectuation Plan form in the **final MTF ICR** has been updated to clearly show which sections of the form are pharmacy-facing and those likely to contain proprietary manufacturer operational information.

Q32. How much should a dispensing entity expect to receive for each MFP refund payment?

As discussed in Section 90.2.1 of the final guidance, the Manufacturer is responsible for making the MFP available to dispensing entities and may do so in a variety of ways, including prospectively selling the selected drug to the dispensing entity at MFP or via a retrospective MFP refund payment. Given that the statutory obligation to effectuate the MFP rests with the Manufacturers, the Manufacturers are responsible for calculating the correct MFP refund payment 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 (WAC) and MFP. The SDRA will be based on the WAC as published in pharmaceutical pricing database compendia on the date of service of the Part D claim. Alternatively,

Manufacturers may provide refunds at an alternative amount if they maintain supporting documentation demonstrating why MFP refund payments were provided at an amount other than the SDRA. CMS will be monitoring any payments not using the SDRA to assess the extent to which the MFP is being made available.

In the MFP effectuation process, Part D Plan sponsors will provide an estimated MFP refund amount based on the SDRA 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 Part D sponsor may not reflect the final amount that Manufacturers provide to make MFP available.

Q33. Will the Standard Default Refund Amount be calculated based on the WAC on the date of service of the Part D claim?

Yes. In CMS' **final guidance** section 40.4.1, CMS clarified that the MTF will use Wholesale Acquisition Costs (WAC), as published in pharmaceutical pricing database compendia on the date of service of the Part D claim, as the standardized pricing metric to calculate the SDRA that will be included with the claim-level data elements provided by the MTF DM to Primary Manufacturers.

Q34. What do I do if I disagree with the amount of an MFP refund payment that I received from the Manufacturer?

If you disagree with the refund amount received from the Manufacturer, as a first action, CMS encourages Manufacturers and dispensing entities to work together to mitigate the issue. To facilitate this coordination, CMS requires that Manufacturers provide a plan or procedures for communicating with dispensing entities 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. 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 "Drug Price Negotiation Program Complaint

and Dispute Intake Form” available in the final MTF ICR package available on [OMB’s website](#) (click “all” to see full details). The complaints and disputes process is described in section 90.2.2 of [final guidance](#).

Q35. CMS’ final guidance notes an opportunity for dispensing entities to raise concerns about cashflow during MFP effectuation. What action should a dispensing entity take if they anticipate material cashflow concerns consistent with those described in the final guidance?

CMS understands the importance of the opportunity for pharmacies to self-identify as having anticipating material cashflow concerns. The final ICR MTF DM Dispensing Entity Questionnaire 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 sponsor to a combination of Part D sponsor payment plus potentially lagged MFP refund payments from the Manufacturer. CMS will provide these self-identifications to each Manufacturer for consideration via the MTF DM user interface 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.

Q36. What is the plan to address complaints or concerns raised by dispensing entities regarding a Manufacturer’s 340B and MFP reconciliation process?

The complaint and dispute process is outlined in section 90.2.2 of the final guidance. CMS has encouraged Manufacturers and dispensing entities to work collaboratively to resolve complaints; however, CMS will not become involved in disagreements between two private parties unless it is brought to CMS through the outlined complaint process and is within scope of the Medicare Drug Price Negotiation

Program. For example, CMS will accept complaints raising concerns that MFP was not appropriately made available based on inaccurate 340B nonduplication, and the Complaint and Dispute Intake Form provides a field for the submitter to identify their submission as related to this area.

If a dispensing entity submits a complaint raising a concern that the MFP was not appropriately made available based on inaccurate 340B nonduplication, CMS will investigate to assess whether the Manufacturer’s Report was accurate and whether an MFP refund payment was owed. As part of that investigation, CMS will review the extent to which the Manufacturer reasonably believed the reported claim-level payment elements were correct and whether the Manufacturer has timely complied with its statutory obligation to offer the lesser of the MFP or the 340B ceiling price, including assessing the role that any operational barriers played in the Manufacturer taking timely actions related to the claim. If CMS determines that the MFP should have been made available for the claim, CMS will give the Manufacturer the opportunity to take corrective action to make the MFP available before pursuing enforcement action.

If a claim is determined to be 340B-eligible and the 340B price is lower, and the Manufacturer has paid an MFP reimbursement, then the Manufacturer should request credit be applied via the claim-level payment elements with the MTF DM. CMS encourages Manufacturers and dispensing entities to work collaboratively to resolve disputes.

Remittance and Electronic Remittance Advice (ERA)

Q37. In cases when the Manufacturer does not use the MTF PM, who is responsible for creating the remittance or ERA?

As outlined in section 40.4.4.1 of CMS’ final guidance, the Manufacturer is responsible for making remittance (for payments issued via paper check) or an ERA (for payments issued via electronic funds transfer) available to dispensing entities when the Manufacturer opts-out of the MTF PM. CMS also noted in its final guidance that it is the responsibility of the Manufacturer to ensure that the ERA created and transmitted to the dispensing entity uses the X12

835 standard adopted under the Health Insurance Portability and Accountability Act as applicable. For funds issued via paper check, it is the responsibility of the Manufacturer to ensure that the remittance is created and made available to the dispensing entity.

Q38. Will CMS publish the specifications for CMS' implementation of the 835, including the claim adjustment reason code (CARC) and the five remittance advice remark codes (RARC) codes and their meanings?

CMS' specifications for the 835 will be detailed and released in future technical instructions ahead of the January 1, 2026, implementation date. Additionally, CMS released a draft "MTF 835 Companion Guide" for preliminary review, [available here](#).

CMS anticipates posting a Final MTF 835 Companion Guide in Summer 2025.

CMS has worked with X12 and the CMS RARC Committee to create a CARC and five RARCs to describe adjustments made to the SDRA on ERAs or remittance made available to dispensing entities. The following CARC and RARCs are effective as of on March 1, 2025, and can be viewed at:

<https://x12.org/codes/claim-adjustment-reason-codes> and <https://x12.org/codes/remittance-advice-remark-codes>.

MTF 835 CARCs and RARCs

Claim Adjustment Reason Code	307	Medicare Maximum Fair Price Standard Default Refund Amount Adjustment. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT). Usage: To be used only for the Medicare Drug Price Negotiation Program.
Remittance Advice Remark Codes	N907	No refund because this claim has been identified as 340B-eligible with a ceiling price lower than the maximum fair price.
	N908	No refund because this drug has been prospectively purchased at the maximum fair price.
	N909	Refund amount has been calculated using a methodology that differs from the Standard Default Refund Amount calculation ((Wholesale Acquisition Cost minus Maximum Fair Price times Quantity)
	N910	A refund cannot be provided for this claim at this time. Contact the Manufacturer directly regarding your eligibility.
	N911	This claim cannot be reimbursed by the Manufacturer until the Part D plan submit a corrected prescription drug event data to CMS for maximum fair price validation.