Medicare Transaction Facilitator: Manufacturer Frequently Asked Questions

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

This Frequently Asked Questions (FAQs) document contains information intended to support manufacturers[1] as they prepare to engage with the new Medicare Transaction Facilitator (MTF). To ensure the effectuation of the negotiated 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). For more information, please see the **MTF Fact Sheet**. Recent detailed guidance on 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 **Medicare Drug Price Negotiation Webpage**, please e-mail **MFPMedicareTransactionFacilitator@cms.hhs.gov** with your question and CMS will provide you with a response or point you to a relevant resource.

General Questions

Q1. What information is included in this FAQ, and what information will CMS provide in future technical instruction?

This FAQ addresses inquiries that CMS has received from Primary Manufacturers participating in the Medicare Drug Price Negotiation Program. In the future, CMS will provide further user and technical information on manufacturer-initiated claims reversals, the credit/debit ledger system, and other operational details, which will be available on the Medicare Drug Price Negotiation website. Additionally, CMS began engaging manufacturers regarding claims beta exchange testing in July 2025.

Manufacturer MTF DM Enrollment

Q2. Is there a limit on the number of individuals allowed to enroll per entity?

Manufacturers are allowed three Authorized Signatory Officials, three Access Managers, and 10 Staff End Users in the MTF.

Q3. Will authorized third-party vendors be allowed to have their own logins for the MTF DM?

Yes, manufacturers may invite third-party vendors to access the MTF DM on their behalf as a user aligned with the manufacturer's MTF account. Like all MTF users, each user invited from a third-party vendor will have their own logins.

Q4. If a bank letter or voided check is not available for upload to the MTF PM enrollment portal, may manufacturers instead upload a letter signed by their Treasurer confirming the bank account information?

Consistent with the Office of Management and Budget (OMB)-approved Information Collection Request (ICR), a manufacturer will need to submit either a voided check or a bank letter for use in account confirmation. CMS encourages manufacturers to plan ahead such that these confirmatory materials are available to complete enrollment by the applicable deadline.

Q5. How will data be shared between the MTF DM/MTF PM and manufacturers that opt out of the MTF PM?

While enrollment in the MTF PM is optional, manufacturers are required to enroll in the MTF DM.

[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.

The MTF DM will provide manufacturers with the information necessary to identify and provide any applicable MFP refund payments on claims for MFP-eligible individuals regardless of a manufacturer's election to use the MTF PM. Manufacturers are 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 the MFP available.

MTF Systems Testing

Q6. Can CMS provide additional clarity regarding MTF testing scheduling and milestones, the functionality that will be tested at these junctions, and system components manufacturers must have operational by these dates?

CMS initiated the system testing and integration process with manufacturers with selected drugs for Initial Price Applicability Year (IPAY) 2026 in July 2025. Note that system integration and testing for manufacturers with selected drugs for IPAY 2027 and beyond will take place in the months leading up to the MFP-effectuation start-date for those IPAYs.

MTF testing will take place in the MTF IMPL environment (a test version of the MTF which will function like the live system but contains no real data). This is a shared space and is used by multiple parties for testing purposes. As such, CMS plans to open this environment to manufacturers for discrete, time-bound, testing periods. MTF system testing and integration will proceed in a number of phases, beginning with system integration steps (e.g., establishing Amazon Web Services (AWS) Simple Storage Service (S3) system integration between the MTF and Primary Manufacturers) and basic system functionality testing (e.g., testing file download and upload capabilities), and progressing to include additional S3-to-S3 data exchange; Manufacturer Refund Notice (MRN) and Manufacturer Refund Advice (MRA) ingestion testing and processing; testing data exchange under various claims scenarios (e.g., file errors, adjustments, reversals), and ultimately end-to-end system testing.

Further, CMS will provide information for testing and integration with the MTF PM during this process to include, for example, exchanging relevant information (e.g., MTF PM address and ACH Company ID) to facilitate fund transfers, and pre-note testing to confirm banking connections. As each testing phase progresses, CMS will provide detailed instructions and requests for information necessary for the applicable manufacturers to participate.

Q7. Can manufacturers of drugs selected for IPAY 2027 conduct systems testing in advance, once the MTF platform is available?

Should CMS and a manufacturer successfully negotiate an MFP for the second cycle of negotiation beginning January 1, 2027, CMS expects to be in touch with individual manufacturers related to MFP effectuation in early-to-mid 2026. In the meantime, we encourage participation in the monthly manufacturer calls and review of posted materials.

Drug Data Processing System Claims Data

Q8. What claims data will the MTF DM transmit to manufacturers?

The claims-level data elements that the MTF DM will transmit to the manufacturers are based on data elements that the pharmacy transmits to Part D plan sponsors, who subsequently submit prescription drug event (PDE) data to the Drug Data Processing System (DDPS), a CMS system used to process all Medicare PDE records and related data. The data includes: date of service, service provider identifier (such as the national provider identifier (NPI) of the pharmacy), prescription/service reference number, prescriber identifier (NPI of the prescriber), fill number, product/service identifier (the national drug code (NDC) of the drug), quantity dispensed, days' supply, whether the claim was voluntarily reported as a 340B claim, and the plan contract number. Other data elements being transmitted to the manufacturer can be found in the **Medicare Drug Price Negotiation Program: Final Guidance for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027** that CMS published on October 4, 2024 (hereafter referred to as "2027 final guidance").

As discussed in section 40.4.2 of 2027 final guidance, the MTF DM will only facilitate the transfer of claims

data regarding the dispensing of a selected drug to an MFP-eligible individual. Further, manufacturers will only receive certain elements of this data; that is, even for this subset of claims, they will not receive the entirety of the information contained on each claim. You can see these elements in Table 2 (see page 202) of the 2027 final guidance. Manufacturers will not gain access to all Medicare Part D claims, all claims involving a drug selected for negotiation, or all claims a dispensing entity processes.

Q9. CMS guidance states that validations will be performed to ensure MFP eligibility of claims. Could CMS provide information on the validations that are performed?

As stated in section 40.4.2.1 of 2027 final guidance, "When a Part D plan sponsor receives a claim for a selected drug from a dispensing entity, the Part D plan sponsor verifies that the beneficiary listed on the claim paid by the Part D plan sponsor is enrolled in Medicare Part D and coverage is provided under Part D for the dispensed drug." Additionally, "CMS, using DDPS, also performs verification steps to validate that the individual was an eligible Part D enrollee at the time of the claim."

Q10. Will the MTF create visibility for rejected PDE claims, where rejected PDEs are PDEs that triggered DDPS edits? Which DDPS edits are related to the determination and verification of MFP eligibility? How will manufacturers have visibility into rejected PDE records that would trigger an 835 record with remittance advice remark code (RARC) N911?

As stated in section 40.4.2.1 of 2027 final guidance, "After CMS verifies MFP eligibility for the individual related to the claim, DDPS will transmit the PDE record for the Part D claim for the selected drug to the MTF DM," including DDPS edits. Therefore, the MTF will have visibility into whether the Part D claim has triggered any DDPS edits.

Additionally as stated in section 40.4.2 of the **Medicare Drug Price Negotiation Program: Draft Guidance for 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028** that CMS published on May 12, 2025 (hereafter referred to as "2028 draft guidance"), "CMS intends to maintain a list of DDPS edits that directly relate to the determination and verification of MFP eligibility for the purposes of the Negotiation Program, such as missing Service Provider Identifier or missing or invalid Date of Service." A preliminary list of edits can also be found in Appendix B of 2028 draft guidance. CMS intends to maintain this list of edits on the **Medicare Drug Price Negotiation Program website**. Further, "DDPS edits were identified as related to the determination and verification of MFP eligibility if they directly relate to the data elements listed in Table 2 in this draft guidance, impact the verification of an individual as MFP-eligible in accordance with section 1191(c)(2) of the Act, or identify duplicate PDE records."

The 2028 draft guidance continues to state that if the edits for a PDE record are not resolved within 90 calendar days following the receipt of rejected record status from CMS, "the MTF DM will notify the dispensing entity that no refund payment has been paid for the claim through a remittance." Part D plan sponsors have guidelines for resubmission of rejected PDE records that they follow.[2] Part D plan sponsors rarely fail to resolve rejected PDE records. Part D plan sponsor resubmission of PDE records will be processed through the MTF in an efficient manner to reduce time disruptions. Pharmacies may use the MTF Help Desk to file a complaint or dispute related to cash flow disruptions as a result of PDE records triggering DDPS edits. CMS reminds readers that 2028 draft guidance is draft policy at this time.

Q11. How are unique dispensing events identified? Is NDC used to identify uniqueness?

As discussed in section 40.4.2.1 of 2027 final guidance, "The combination of "Date of Service," "Service Provider Identifier Qualifier," "Service Provider Identifier," "Prescription/Service Reference Number," and "Fill Number" identify unique Part D claims." This methodology is based on how the DDPS processes adjustments and reversals for dispensing events. Therefore, any PDE records that the MTF DM receives with the same "Date of Service," "Service Provider Identifier Qualifier," "Service Provider Identifier,"

[2] Part D Reporting Requirements: **https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/part-d-reporting-requirements**

"Prescription/Service Reference Number," and "Fill Number" will be identified as corresponding to the same dispensing event. The product/service identifier, or the NDC, is not used to identify a unique dispensing event. Therefore, Part D plan sponsors can send an adjustment for a Part D claim to adjust the NDC, without needing to send a reversal to DDPS. If the MTF DM receives a PDE record that adjusts to a different NDC, then the MTF DM will assess whether the NDC is for the same selected drug or not. If the new NDC is for a different selected drug, then the MTF DM will send a reversal record in the MRN for the former claim (with the Internal Claim Number (ICN) of the previous claim in the "MTF XRef ICN" field) and send a new original record corresponding to the new PDE to the manufacturer of the selected drug. That new original record will not have the "MTF Xref ICN" field or fields about the previously paid MFP refund.

Q12. If the MTF provides invalid data (i.e., invalid NDC, invalid quantity, invalid 9-digit pharmacy NPI), how should Primary Manufacturers address this?

The MTF will validate the data, including through the plans and the DDPS system prior to the MTF receiving it. In Section 40.4.2.1 of 2027 final guidance, CMS stated that, "If a Primary Manufacturer believes that there is an error with the claim-level data received, it can submit a dispute by following the process outlined in section 90.2.2 of this final guidance".

National Council of Prescription Drug Programs Data

Q13. How will the National Council of Prescription Drug Programs (NCPDP) ID be referenced or used in relation to the credit/debit ledger system?

The credit/debit ledger maintained by the MTF will not include the NCPDP ID. The credit/debit ledger is meant to manage/reconcile claim adjustments and reversals as processed by the MTF DM and MTF PM.

Q14. Will CMS share dispensing entity information such as NPI, NCPDP ID, etc. with manufacturers?

As per 2027 final guidance section 40.4.2, CMS intends to share registered dispensing entity information with Primary Manufacturers to support payment to dispensing entities outside of the MTF. As stated in the **Final MTF DM User Agreement** between CMS and dispensing entities, CMS will, "… take reasonable precautions to protect… Confidential Information and… prevent unauthorized use or access to it; not… divulge Confidential Information or information derived therefrom to any third party unless such disclosure is required in the performance of the Receiving Party's duties under this Agreement, including but not limited to sharing with manufacturers identifying and financial data from the MTF DM as provided by the Dispensing Entity (i.e. Dispensing Entity MTF Enrollment Information)."

Manufacturer Refund Notice, Manufacturer Refund Advice, and Manufacturer Refund Report

Q15. What are the MRN, MRA, and Manufacturer Refund Report (MRR) files?

As discussed in section 40.4.2 of 2027 final guidance, Primary Manufacturers are required to participate in the MTF DM for purposes of data exchange to exchange key data files necessary for MFP effectuation. These key data files include, but are not limited to, the MRN, MRA, and MRR files. The layout of these files aligns with the claim-level data elements listed in Table 2 of 2027 final guidance (MRN) and the claim-level payment elements listed in Table 4, 5, and 6 of 2027 final guidance (MRA). The layout of each of these files will include all of the data elements, therefore, the MRN will include the claim-level payment elements that are normally present on the MRA but will either be blank or contain previously received data. For the MRA, manufacturers are expected to submit the corresponding claim-level data elements previously transmitted by the MTF DM. The MRR file will provide a notice to the Primary Manufacturer that acknowledges receipt and processing of MRA elements by the MTF DM.

For more information about the data elements, refer to section 40.4 of 2027 final guidance**.** CMS intends to share sample files for the MRA, MRN, and MRR during system integration and testing activities.

Q16. Where can I find the Interface Control Document (ICD) for the MRN and MRA?

The ICD defines the data elements used in MTF claims

and claim payments. It is available here: **Medicare Transaction Facilitator ICD**.

Q17. What will the notification process be for MRNs that are available?

The MTF DM will have a notification process that will indicate to manufacturers when files are available for transfer. The MTF DM intends to communicate to manufacturers when a file is not required for a specific day. However, CMS anticipates this to be a rare occurrence due to the likelihood of applicable claims each day.

14-Day Prompt MFP Payment Window

Q18. If the last day of the 14-day prompt MFP payment window falls on a weekend or holiday, is the due date modified? If so, how?

No, as stated in section 40.4.2.1 of 2027 final guidance, "The MTF DM's transmission of the claim-level data elements to the Primary Manufacturer starts the 14-day prompt MFP payment window, within which the Primary Manufacturer must transmit payment of an amount that provides access to the MFP when an MFP refund is appropriate and must transmit the claim-level payment elements… for each claim identified in the claim-level data elements that the MTF DM transmits to the Primary Manufacturer. The date of transmission of the claim-level data elements from the MTF DM to the Primary Manufacturer is considered day 0 of the 14-day prompt MFP payment window. If a retrospective refund is required to effectuate the MFP, the Primary Manufacturer must transmit payment no later than 11:59 PM PT on day 14. The Primary Manufacturer will be considered to have transmitted payment within the 14-day prompt MFP payment window if either (1) when payment is passed through the MTF PM, the Primary Manufacturer sends the claim-level payment elements to the MTF DM on or before day 14 authorizing payment to the dispensing entity or (2) when payment is made outside of the MTF PM, the Primary Manufacturer sends the claim-level payment elements to the MTF DM and sends the MFP refund amount to the dispensing entity on or before day 14."

Q19. Can manufacturers respond back to an MRN with MRA payment elements on any day of the calendar year, as the 14-day prompt MFP payment window is based on calendar days? Specifically, holidays, weekends, etc.?

The MTF will accept data submissions/transfers on any day, including weekends and holidays. As per 2027 final guidance section 40.4, "the Primary Manufacturer must transmit (as described in section 40.4.2.1 of this final guidance) an MFP refund amount within 14 days, as opposed to ensuring the dispensing entity has received the MFP reimbursement within 14 days, in order to comply with the 14-day prompt MFP payment window."

Q20. Can CMS clarify how CMS or the MTF will establish transmission timestamps for MRN data relative to the 14-day prompt MFP payment window, including the impact of portal outages on the transmission time?

The MTF DM will notify the manufacturer through a notification process that will indicate to manufacturers when files are available for transfer. Notification timing will also be the date-stamp against which CMS will assess compliance with the 14-day prompt MFP payment window. In 2027 final guidance, section 40.4.2.1, Table 2 includes the variable "Process Date." The field will contain the date stamp indicating when the 14-day prompt MFP payment window begins for the specific claim.

Claims Adjustments/Reversals

Q21. Can manufacturers initiate a reversal or adjustment to a claim via the MRA?

Yes, manufacturers can initiate a reversal or adjustment via the MRA. The manufacturer would initiate a reversal or adjustment by sending to the MTF DM a new MRA with the data elements from the previous MRN, a new final refund amount (e.g., a new final refund amount for a reversal would be zero dollars).

Q22. If the MTF initiates an adjustment, will the MTF only send an adjustment MRN claim line after the manufacturer responds to the original MRN claim?

Per the 2027 final guidance, "Transaction Code" will be populated by the MTF when sending claim-level data elements to Primary Manufacturers and by Primary Manufacturers when sending claim-level payment elements to the MTF. Additionally, in section 40.4.3.2,

"To address adjustments and reversals, whether these occur before the 14-day prompt MFP payment window has elapsed or after the Primary Manufacturer has transmitted MFP refund payment through the MTF PM or outside of the MTF PM through an alternative payment method, the MTF DM will transmit updated claim-level data elements to the Primary Manufacturer, including the "MTF XRef ICN" (see Table 2) of the original claim." Therefore, the MTF will send an adjustment MRN record after it receives the data that, "has been verified by the Part D plan sponsor and DDPS." Further detail on use of the Transaction Code field will be provided in future technical instructions.

Q23. What is the expected timeframe for the reconciliation or adjustment of claims submitted through the MTF DM?

As discussed in section 40.4.2.1 of 2027 final guidance, the MTF DM will provide Primary Manufacturers with data that has been verified by both the Part D plan sponsor and DDPS, resulting in dual verification of both an individual's eligibility for Part D and Part D coverage of the selected drug for each claim being transmitted. Currently, Part D plan sponsors have 30 days to submit complete PDE records to DDPS. CMS finalized in the **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** rule a change effective in contract year 2026 to shorten the current 30-day window for plans to submit initial PDE records to seven days for selected drugs to facilitate more timely payment of MFP refunds to dispensing entities. CMS intends that the MTF DM will transmit claim-level data elements to Primary Manufacturers on a near-daily basis, subject to regular system downtime. As discussed in CMS' response to comments submitted regarding MTF data facilitation included in 2027 final guidance (Page 48), the frequency of data transmission will operate based on the capabilities of DDPS, which will submit claims to the MTF DM daily Monday through Saturday.

As discussed in section 40.4 of 2027 final guidance, the Primary Manufacturers must transmit an MFP refund amount within 14 calendar days of when the MTF sends data that verify the selected drug was dispensed to an MFP-eligible individual to the Primary Manufacturers (referred to as the "14-day prompt MFP payment window"). The 14-day prompt MFP payment window is intended to align with the timing requirement in the longstanding prompt pay rules in Part D for plan sponsors.

While the 14-day prompt MFP payment window is intended to align with the timing requirements in the Part D prompt pay rules, dispensing entities should be aware that they may not receive payment from a Part D plan sponsor for the Part D claim on the same date that the Primary Manufacturers provides a retrospective MFP refund to the dispensing entity. Due to operational differences between the Part D program and the Negotiation Program, the respective prompt payment windows for a particular dispense may start on different dates for the Part D plan sponsor and the Primary Manufacturers.

File Questions

Q24. Will errors related to MRA file transmission include information, such as fields names or other contextual details, in order to help manufacturers understand what the errors are?

CMS anticipates that errors likely would occur due to improper formatting. The MRA only requires a small number of data points, as shown in the Draft MRN and MRA ICD (available here: **Medicare Transaction Facilitator ICD**). For example, if a field is blank and requires a value, the MTF DM would return an error. CMS will provide more details on the specific error codes in future technical instruction.

Q25. CMS' 2028 draft guidance states that the MFP per-unit price will be rounded to the sixth decimal place. What rounding precision should be used for other components of the MFP refund calculation, such as the Wholesale Acquisition Cost (WAC) per-unit price, dispensed units, or the Standard Default Refund Amount (SDRA)?

When converting from the package price to the per-unit price, CMS is using the level of precision "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," (section 40.4.1 of 2027 final guidance). CMS is using Medi-Span as the source of drug information and pricing data. For example, if the reported WAC Package Price for a given NDC is $46.90 and there are 30 units in

a package, then the stored WAC NDC Unit price is $1.56333. If a PDE has a dispensed quantity of 30, the total WAC price for that claim would be $1.56333 x 30.000 = $46.89990.

Additionally, when calculating SDRA, rounding will occur after WAC and MFP prices are multiplied by dispensed units. The MTF DM plans to store and transmit all available decimal places for WAC (5 decimal places in Medi-Span), MFP (6 decimal places in the MFP File), and quantity (3 decimal places in PDE). Once multiplied to calculate SDRA, the MTF DM will engage in standard rounding to two decimal places (round up to the next decimal if 5 or more, round down if less than 5).

To continue the example earlier, the SDRA calculation would be ($1.56333 - $0.985223) x 30.000 = $17.343210, which rounds to $17.34. On the MRN, it would report:

- WAC Per Unit on Date of Service of Part D Claim (WAC): 1.56333
- MFP Per Unit on Date of Service of Part D Claim (MFP): 0.985223
- Quantity Dispensed (Units): 30.000
- SDRA: 17.34

Q26. How many MRN files will manufacturers receive per day, and will they be separated by payer?

The MRN files will be generated at the Manufacturer/selected drug level. The manufacturer will receive one file per day, as often as daily.

Q27. Will S3 transmissions be available to manufacturers as a means of collecting MRN files?

Yes, S3 transmissions will be available for manufacturers to receive MRN files and transmit MRA files back to the MTF. CMS will work with manufacturers to set up the necessary S3 connections as an early step in the system integration and testing process. Manufacturers will also have access to system functionality to download MRNs, and upload MRAs, directly in the MTF DM user interface.

MTF PM Credit/Debit Ledger System

Q28. What is the Credit/Debit Ledger System?

CMS discusses the purpose and basic content of the credit/debit ledger system in 2027 final guidance section 40.4.3.2, which states that, “the MTF will maintain a credit/debit ledger system that tracks credits and debits related to MFP refunds at the dispensing entity NPI-level, for each selected drug, based on information reported by the Primary Manufacturer in the claim-level payment elements.” Additionally, as stated in Section I of the **Final MTF DM User Agreement** between CMS and manufacturers, a “Ledger System” means the system within the MTF PM, as described in applicable guidance and regulations, to track credits and debits for MFP refund payments for each of the selected drug(s) at the dispensing entity NPI-level.

This means that the credit/debit ledger system is able to track MFP refunds and to account for reversals, adjustments, and other claim revisions inevitable in a dynamic claims payment system.

Q29. What type of aggregation will the MTF PM perform on the credit/debit ledger system in the MTF PM for purposes of MTF PM payment facilitation?

According to section 40.4.3.2 of 2027 final guidance, the MTF PM will execute the credit/debit ledger system at the dispensing entity NPI-level, for each selected drug based on information reported by the Primary Manufacturers in the claim-level payment elements.

Q30. Will manufacturers need to authorize payments before claims, including reversals or credits, are applied to the financial ledger?

As per section 40.4.3.2 of 2027 final guidance, reversals will automatically update the credit balance in the credit/debit ledger system without any need for manufacturer action. Additionally, per section 40.4.3.2 of 2027 final guidance, the MTF credit/debit ledger will automatically apply credits to claims that the manufacturer has authorized to be paid in the MRA when applicable credits (e.g., credits aligned with the manufacturer-drug-NPI grouping) are available in the ledger system.

Additionally, as per section 40.4.3.2 of 2027 final guidance, the MTF PM will apply any available credits to refund payments. Specifically, "If the Primary Manufacturer has credits accrued with respect to a selected drug for the dispensing entity NPI for which it has provided MFP refund payment, the MTF PM will credit the Primary Manufacturer and the MTF PM will indicate to the MTF DM that, for impacted claims, an accrued credit was applied."

Q31. How will the MTF process MRAs and manage the ledger when receiving MRA authorizing payments for claims that have been reversed?

The credit/debit ledger system is meant to manage changes in MFP refund amounts due to claim adjustments and reversals and Primary Manufacturer requests.

As stated in section 40.4.3.2 of the 2027 final guidance, for MFP refund payments made through the MTF PM, the impact of the reversal depends on whether the MTF receives the reversal from DDPS before or after the Primary Manufacturer has transmitted the MFP refund, as defined in section 40.4.2.1. CMS stated, "For claims designated as full reversals from DDPS before the Primary Manufacturer has transmitted the MFP refund, the Primary Manufacturer will see the claim removed in its feed of claim-level data elements." Therefore, the MTF DM will forward the full reversal to the manufacturer in the claim-level data elements (MRN) and the manufacturer will no longer be expected to send claim-level payment elements (MRA) for the previous claim. Additionally, "For claims designated as a full reversal after the MFP refund has been transmitted, the MTF DM will instruct the MTF PM to issue a credit equal to the previously paid MFP refund payment. Primary Manufacturers will not need to submit claim-level payment elements back to the MTF DM for full reversals."

As stated in section 40.4.4.4 of 2027 final guidance, for MFP refund payments made outside of the MTF PM, "The MTF will not maintain a credit/debit ledger system to address claim reversals, adjustments, and other changes in status that occur after an MFP refund payment has been made outside of the MTF PM."

Further, "the MTF DM will send all Primary Manufacturers claim-level data elements for all reversals and adjustments received for claims previously sent to that Primary Manufacturer. For MFP refund payments made outside of the MTF PM, Primary Manufacturers must submit claim-level payment elements as described in section 40.4.4.1 for these claims to provide the MTF DM with information on any changes to previously paid MFP refund amounts for purposes of program monitoring and oversight."

Q32. How quickly will the MTF update the credit/debit ledger after receiving an adjustment or reversal from manufacturers via a revised MRA? How quickly will the MTF provide the manufacturer an MRR after receiving an MRA?

For instances where the manufacturer initiates a reversal or adjustment via the MRA, the manufacturer would indicate this via a code in the Transaction Code field that indicates this MRA is a manufacturer-initiated adjustment to a previous response. This scenario will be detailed in future technical instructions. The ledger will be maintained and updated in real time. MRRs will be made available after a payment is processed for a given claim, with timing depending on the circumstance for processing that claim.

Q33. Can manufacturers use Transaction Code 7 to selectively apply credits? If so, can CMS provide additional details on the process?

No. Transaction Code 7 should be used when the refund amount transmitted was adjusted by a credit amount on manufacturer-maintained credit/debit ledger (e.g., for MFP refund payments processed outside of the MTF PM). Manufacturers will not be able to direct the application of credits present in the MTF PM credit/debit ledger, as the system will automatically apply credits when available to a particular manufacturer-NPI-drug relationship.

Q34. Will the MTF DM collect data at the aggregate level, or will it maintain granular data (i.e. claim-level detail at the NPI/NDC-11) and then aggregate for the application of adjustments and offsets?

The MTF DM and PM will maintain claim-level data for calculation and tracking purposes. The MTF DM and PM will aggregate certain information for the application of credits, including by payee (NPI).

Q35. Does the "manufacturer-maintained credit/debit ledger" refer to a ledger operated by the manufacturer in conjunction with the MTF PM, or to a manufacturer issuing payment outside of the MTF PM?

This refers to a manufacturer issuing payment outside of the MTF PM.

Q36. Can CMS clarify the field from the Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form that relates to the MFP refund amount paid by manufacturers?

As shown in the **final MTF ICR**, CMS is planning to collect the, "Amount of Payment Transmitted as the MFP Refund." On page two of Appendix C of the final MTF ICR, CMS states, "In situations where MFP refund payments are facilitated by the MTF PM, if reflecting an adjusted refund amount, this field should reflect the intended total refund amount for the claim (e.g., previously paid refund was $100 and intended refund is $80, this field should contain $80). The MTF will calculate credits based on previously paid refunds and update the ledger or calculate the difference between the previously paid refund and the updated refund amount and request this difference from the Primary Manufacturer's bank." This field is the total refund amount authorized for the claim.

Q37. Can the NCPDP Relationship ID be used as a unique ledger identifier?

The credit/debit ledger maintained by the MTF will not include the NCPDP ID. The credit/debit ledger is meant to manage/reconcile refund payments accounting for claim adjustments and reversals. CMS intends to use the dispensing entity's NPI in the credit ledger system.

According to section 40.4.3.2 of 2027 final guidance, the MTF PM will execute the credit/debit ledger system, "at the dispensing entity NPI-level, for each selected drug, based on information reported by the Primary Manufacturer in the claim-level payment elements." While we are working to finalize specifics, we anticipate aggregation to be at the Drug+NPI-level.

MFP Refund Payment

Q38. Are funds pulled from a manufacturer bank account for the purposes of paying MFP refunds kept in a government-owned bank account or a bank account owned by the third-party vendor operating the MTF PM?

The funds pulled from a Primary Manufacturer's bank account are temporarily transferred to an account owned by the contractor operating the MTF PM. Funds are kept in this account only until the funds have been verified by the financial institution used by the MTF PM contractor and subsequently dispersed to the appropriate recipient account(s), or, in cases where a dispensing entity requests a paper check, until the check is cashed.

Remittance and Electronic Remittance Advice

Q39. Is CMS planning to publish guidance on its implementation of the 835 to assist manufacturers and other stakeholders in mapping remittance transactions in a consistent manner?

The Final MTF 835 Companion Guide, available **here**, clarifies and specifies the data content when exchanging transactions electronically with the MTF.

Q40. Is there an expectation that every record on an 835 electronic remittance advice (ERA) created by the MTF DM or by a manufacturer will contain the 307 claim adjustment reason code (CARC) and one RARC?

CARC and RARC codes will only be used when the payment amount for an MFP claim is not equal to the SDRA. CARC 307 will be used along with one RARC to further describe the adjustment made to the SDRA.

Q41. For an 835 ERA created by the MTF DM or by a manufacturer, will a RARC be applied if no CARC is present?

No, CMS does not expect to apply a RARC if no CARC is present.

Stakeholder Engagement

Manufacturer Meetings

Q42. How is CMS connecting with manufacturers?

CMS will continue to communicate with manufacturers through monthly systems calls and offers situational one-on-one engagement opportunities at key milestones in the MTF development process, including in testing (described above), as needed. It is our intention that these sessions will align with our iterative development process, ensuring that manufacturers receive technical and functional updates as they become available. For additional questions, please send inquiries to **MFPMedicareTransactionFacilitator@cms.hhs.gov**, and CMS will provide responses. CMS recognizes the importance of providing timely information to support manufacturers in developing their own systems and processes for participation in MTF DM and will continue to communicate updates accordingly.

Q43. Is CMS available to attend MTF enrollment webinars produced by external stakeholders for our members?

Yes, the CMS team is available to speak at external stakeholder events subject to scheduling availability. Please send a request to our inbox at **MFPMedicareTransactionFacilitator@cms.hhs.gov**.

Complaint & Dispute Resolution

Q44. Is there a timeframe within which a manufacturer must respond to or resolve pharmacy-submitted complaints, prior to their escalation to CMS?

Section 90.2.2 of the 2027 final guidance states that, "Complaints and disputes must be submitted to CMS no later than 120 calendar days from the date of the subject of the complaint or dispute." In order to submit a timely complaint, a pharmacy would expect to receive a Primary Manufacturer's response within that timeframe. Particular circumstances related to communications between the parties, including any received responses or failures to respond, would be evaluated by CMS on a case-by-case basis during the investigation process and considered if CMS were to determine that MFP had not been made available.

Q45. Can a designated third-party work to resolve complaints escalated to CMS on a manufacturer's behalf?

CMS has no objection to a Primary Manufacturer designating a third-party as the primary point of contact for complaint resolution. The delegation of authority should be clearly communicated to CMS in the Primary Manufacturer's MFP Effectuation Plan, and the Primary Manufacturer must be prepared to submit supporting documentation establishing the legal relationship between the Primary Manufacturer and the third-party upon CMS request.

Q46. How will manufacturers be notified if a pharmacy has initiated a complaint against them through the MTF, and what data will be captured as part of a dispute?

For the most up-to-date information on the complaints and disputes process, manufacturers should refer to section 90.2.2 of the 2027 final guidance. Manufacturers may additionally refer to the MTF ICR Complaints and Disputes Form included as part of the **Medicare Transaction Facilitator For 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request.** All documents can be accessed from the **Medicare Drug Price Negotiation Program website**. CMS also intends to provide additional technical instructions on the complaint and dispute process.