NCPA Member Summary: CMS' Final Part 2 Guidance on the Medicare Drug Price Negotiation Program

On Oct. 2, 2024, the Centers for Medicare and Medicaid Services (CMS) released its final guidance on part 2 of the Medicare Drug Price Negotiation Program of the Inflation Reduction Act. NCPA provided comments to the proposed guidance in July 2024. The negotiated prices of the first ten drugs in the program are set to go into effect in 2026, and details of the specific drugs and their maximum fair prices (MFPs) can be found here. CMS will announce the selection of up to 15 additional drugs covered by Part D for the second cycle of negotiations by February 1, 2025. This second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.

NCPA's analysis of 5,200 community pharmacies to determine the effect of this program on community pharmacies found that the average pharmacy will have to float over $27,000 every month waiting to be made whole for the MFP refunds from manufacturers. The impact on the cash flow on the roughly 20,000 independent pharmacies in the country will be a collective half a billion dollars every month. NCPA continues to be vocal about our concerns, and has published a survey on the impact of this program on our members.

Key highlights of the part 2 final guidance are below.

The Good, The Bad, and the Ugly

The Good

- Neither plans, PBMs, manufacturers, wholesalers, CMS nor any other entity will assess any fee on pharmacies to effectuate the Medicare Transaction Facilitator (MTF) or any aspect of the Medicare Drug Price Negotiation Program.
- CMS does not require pharmacies to identify 340B claims.
- The MTF must generate an Electronic Remittance Advice (ERA), or 835, to the pharmacy for purposes of reconciling manufacturer retrospective Maximum Fair Price (MFP) refunds.
- CMS intends to propose in future rulemaking to shorten the current 30-day window for plans to submit PDE records to seven days for selected drugs to facilitate more timely payment of MFP refunds to dispensing entities.
- There is a process for dispensing entities to self-identify as dispensing entities that anticipate "material cashflow challenges" because of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window, and describes a requirement for Primary Manufacturers to include their process for mitigating cashflow concerns in their MFP effectuation plans. However, there are no details on how this would work practically.
- CMS contractors engaged for the purpose of implementing the MTF system will maintain a helpdesk to address any operational issues.
- CMS will establish a centralized intake system for receiving reports related to access to the MFP with respect to MFP-eligible individuals and the pharmacies and other dispensing entities that provide selected drugs to MFP-eligible individuals.

The Bad

- CMS did not regulate PBM payment to pharmacies for MFP drugs – neither fair reimbursement nor dispensing fees.
- CMS notes that it is clarifying from the draft guidance that the Primary Manufacturer must **transmit** an MFP refund amount within 14 days of the MTF transmitting to the Primary Manufacturer data elements confirming an individual is eligible for the MFP, as opposed to ensuring the dispensing entity has **received** the MFP reimbursement within 14 days from dispensing, in order to comply with the 14-day prompt MFP payment window.
- Drug company utilization of the MTF for pharmacy payment facilitation is voluntary for purposes of effectuating the MFP.
- While NCPA has advocated for WAC – MFP as the manufacturer refund amount to pharmacies, CMS states in the final guidance that this standard default refund may not be universally appropriate or sufficient to effectuate the MFP, and manufacturers can use another metric such as pharmacy acquisition cost.

The Ugly

- Pharmacies will be getting paid low reimbursement by PBMs, and slow by manufacturers (likely 30 days or more for refund payments) while having to pay wholesalers on average two times per month. PBMs can still pay pharmacies below MFP and can still assess DIR fees.
- The program will be uglier for LTC pharmacies whose Medicare Part D revenue may approach 80%, while independent pharmacies have on average 35 percent of their total prescriptions in Medicare Part D.
- CMS intends to propose in future rulemaking a requirement that Part D plan sponsors include in their pharmacy agreements provisions requiring dispensing entities to enroll in the MTF Data Module (MTF DM), essentially forcing pharmacies to participate in the Medicare Drug Price Negotiation program.
- Manufacturers do not have to use the MTF Payment Module (MTF PM), so each manufacturer could stand up their own pharmacy refund payment platform, causing administrative and operational nightmares for pharmacies. The deadline for participating Primary Manufacturers to submit MFP effectuation plans is Sept. 1, 2025, therefore pharmacies will not know how manufacturers will provide their refunds until four months before the program starts on Jan. 1, 2026.

CMS does not require fair reimbursement, dispensing fees to pharmacy. CMS is not establishing requirements for dispensing fees for selected drugs but will monitor complaints and audits related to this issue. CMS encourages plan sponsors to work with pharmacies to ensure adequate and fair compensation for dispensing selected drugs.

- **CMS did not grant NCPA's ask.** While recognizing NCPA's ask that PBMs and plans should not be able to impose any pharmacy price concessions that would ultimately reduce patient access to MFP drugs, CMS merely stated that it will work to ensure plans and PBMs engage in sustainable and fair reimbursement practices with all pharmacies to ensure access to selected drugs, consistent with their statutory obligations, for individuals with Part D, and that CMS will closely monitor for whether further programmatic adjustments are needed to address any contrary practices that emerge.
- **CMS did not grant NCPA's ask.** NCPA had asked that pharmacy reimbursement will incorporate a negotiated price that is no lower than the maximum fair price and; 2) cover acquisition cost plus commensurate professional dispensing fee in line with Medicaid fee-for-service and should be paid within Medicare prompt pay requirements. CMS stated that dispensing entities will be reimbursed at or below the MFP plus dispensing fee. So PBMs can reimburse pharmacies less than MFP for selected drugs and are not obligated to pay any dispensing fees.

Payment within 14 days. CMS requires Primary Manufacturers to transmit payment of an amount that provides access to the MFP within 14 days of the MTF transmitting to the Primary Manufacturer data elements confirming an individual is eligible for the MFP. CMS notes that it is clarifying from the draft guidance that the Primary Manufacturer must **transmit** an MFP refund amount within 14 days, as opposed to ensuring the dispensing entity has **received** the MFP reimbursement within 14 days, to comply with the 14-day prompt MFP payment window.

- **CMS did not grant NCPA ask**. NCPA asked that CMS require that pharmacies be paid timely within Medicare prompt pay requirements, within 14 days of adjudicating the claim. CMS noted that while the 14-day prompt MFP payment window aligns with the timing requirements for Part D plan sponsors in prompt pay rules in Part D, 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 Manufacturer provides a retrospective MFP refund to the dispensing entity. CMS stated that 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 Manufacturer.
- **Pharmacies with "material cashflow challenges."** The final guidance describes a process for dispensing entities to self-identify as dispensing entities that anticipate material cashflow challenges because of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window, and describes a requirement for Primary Manufacturers to include their process for mitigating cashflow concerns in their MFP effectuation plans.
- **Frequency of payments.** CMS stated that it intends that the MTF Payment Module (MTF PM) will have the ability to receive payments from participating Primary Manufacturers and to distribute these payments to dispensing entities on a near-daily basis, subject to regular system downtime. However, it is important to note that manufacturers are NOT required to utilize the MTF PM.
- **Outline of MFP Refund Payment Timing Requirements:** CMS added a new table titled "Table 3: Primary Manufacturer Payment Approaches to MFP Effectuation" describing the timing and required action of Primary Manufacturers to meet the 14-day prompt MFP payment window based on the Primary Manufacturer's elected MFP effectuation method. That table is provided here:

Table 3: Primary Manufacturer Payment Approaches to MFP Effectuation

	Payment Passed Through MTF Payment Module (PM)	Payment Made Outside the MTF Payment Module (PM)	
Pathway Description	Passing MFP refund payments through the MTF PM	Typically passing MFP refund payments through the MTF PM, but has a mutually agreed upon separate payment arrangement with a dispensing entity	Not passing MFP refund payments through the MTF PM
Action to meet the 14-day prompt MFP payment requirement	Transmit claim-level payment elements to the MTF DM authorizing electronic fund transfer to and transmission of MFP refund payment by the MTF PM	Transmit the MFP refund payment to the dispensing entity, and transmit payment elements to the MTF DM once payment has been transmitted	
Deadline For Action	No later than 11:59 pm PT on Day 14 after the MTF DM transmits the claim-level data elements to the Primary Manufacturer, with the clock beginning (Day 0) on the day the MTF DM transmits the claims-level data to the Primary Manufacturer.		
Payment Transmission Date Recorded as:	The system-generated date and time the payment elements sent by the Primary Manufacturer are received by the MTF DM, authorizing electronic funds transfer to and transmission of MFP refund payment by the MTF PM	The date and time the MFP refund payment is transmitted from the Primary Manufacturer to the dispensing entity, as reported by the Primary Manufacturer in the claim-level payment elements*	
Result Following Action	MTF PM transmits MFP refund payment to the dispensing entity (electronically or via paper check)	MFP refund payment is required to be transmitted by the Primary Manufacturer prior to submission of claim-level payment elements. No required action by the MTF.	

* For MFP refunds via paper check, the payment transmission date should be recorded as the date on which the paper check was mailed.

CMS won't prefund MFP refund payments. CMS stated that the IRA did not include an appropriation to "prefund" MFP refund payments. CMS stated that is the sole responsibility of the Primary Manufacturer to provide dispensing entities access to the MFP for selected drugs.

- **CMS did not grant NCPA ask.** NCPA asked that CMS prefund the Medicare Transaction Facilitator (MTF) to expedite payment to pharmacies.

Future rulemaking to shorten time Part D plan sponsors submit PDE records. CMS intends to propose in future rulemaking to shorten the current 30-day window for plans to submit PDE records to seven days for selected drugs to facilitate more timely payment of MFP refunds to dispensing entities.

- **CMS hopefully will grant NCPA ask.** NCPA asked CMS that in the final guidance, it will shorten the current 30-day window of the time that Part D plan sponsors have to submit complete Part D Prescription Drug Event (PDE) records to CMS' Drug Data Processing System (DDPS), to 7 days. This would mean that the very best-case scenario for manufacturer refund payments to pharmacies would occur in 21 days. However, there is no guarantee that manufacturers would not take longer to refund pharmacies.

MTF DM Required to Produce Electronic Remittance Advice. CMS confirms that, if the Primary Manufacturer chooses to pass payment through the MTF PM, the MTF Data Module (MTF DM) will make available an Electronic Remittance Advice (ERA) that uses the X12 835 standard adopted under the Health Insurance Portability and Accountability Act (HIPAA) for electronic payments and a remittance for payment made via paper check. If the Primary Manufacturer

provides the MFP refund via electronic payment outside of the MTF PM, the Primary Manufacturer is required to make available an ERA that uses the X12 835 standard adopted under HIPAA. If the Primary Manufacturer provides the MFP refund via paper check outside of the MTF PM, the Primary Manufacturer is required to make available a remittance to the dispensing entity.

- **CMS granted NCPA's ask.** NCPA asked that the MTF generate an Electronic Remittance Advice (ERA), or 835, to the pharmacy for purposes of reconciling manufacturer retrospective MFP refunds.
- CMS will provide more detail on user functionality within the MTF DM in forthcoming technical instructions.
- **Collection of banking information.** In the MTF DM enrollment process, the MTF DM will collect banking information from dispensing entities. There is no standardized banking form for the primary manufacturers to give the dispensing entities. If a Primary Manufacturer chooses to pass payment through the MTF PM, the MTF PM will provide an avenue to make payment available to all dispensing entities enrolled in the MTF DM.
    - **Electronic transfer.** Should the dispensing entity indicate its preference to receive payment through electronic transfer of funds, the MTF PM will pass through such payment from the participating Primary Manufacturer via an electronic fund transfer, and the MTF DM will create and make available to the dispensing entity an ERA.
    - **Paper checks.** Should the dispensing entity indicate its preference to receive payment in the form of paper checks and the Primary Manufacturer elects to pass its payment through the MTF PM, the MTF PM will process such payment by issuing a paper check to the dispensing entity from the funds the Primary Manufacturer provided to the MTF PM, and the MTF DM will create and make available to the dispensing entity the remittance.

Pharmacies not assessed additional fees. CMS maintained that dispensing entities will not have to pay any fees to enroll in the MTF Data Module (MTF DM) or the MTF Payment Module (MTF PM), including but not limited to user fees or transaction fees, as CMS will bear the cost of operationalizing both. In addition, and regardless of whether the MFP refund is passed through the MTF PM or made outside of the MTF PM, neither primary manufacturers nor their third-party vendors shall charge dispensing entities any transaction or other fees for the pass through of the MFP refund to the dispensing entity.

- **CMS granted NCPA's ask.** NCPA asked CMS that neither plans, PBMs, manufacturers, wholesalers, CMS nor any other entity assess any fee on pharmacies to effectuate the MTF or any aspect of the Medicare Drug Price Negotiation Program whatsoever.

Pharmacies not required to add 340B claims indicators. CMS is not mandating that dispensing entities add a 340B claim indicator to claims at this time. CMS acknowledges feedback from commenters that requiring such a modifier has the potential to pose operational challenges, increase administrative burden, and may not be accurate in many circumstances. CMS is not pursuing a policy at this time to require the use of such a modifier and reiterates that use of the 340B submission clarification code is optional for dispensing entities based on current NCPDP standards.

- **CMS granted NCPA's ask.** NCPA supports CMS not requiring pharmacies to identify 340B claims, and re-emphasized the infeasibility of pharmacies identifying those claims either proactively or retroactively. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems.

WAC as standardized metric. 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 standard default refund amount (SDRA) that will be included with the claim-level data elements provided by the MTF DM to Primary Manufacturers. CMS clarified that the SDRA is WAC – MFP multiplied by the quantity dispensed.

- **CMS granted NCPA ask.** NCPA strongly urged CMS to require the use of WAC as the standardized metric and that any difference between WAC and MFP is the SDRA Amount.
- However, CMS acknowledged that the SDRA may not be universally appropriate or sufficient to effectuate the MFP. Under the statute, the obligation to calculate and pay an MFP refund amount that ensures the dispensing entity has access to the MFP rests with the Primary Manufacturer. A Primary Manufacturer can choose to refund an amount different than the SDRA if the Primary Manufacturer determines and can document some other amount is appropriate to make the MFP available (e.g., the dispensing entity purchased the selected drug at a cost above WAC). CMS encouraged Primary Manufacturers and dispensing entities to work together to establish an MFP refund amount using the SDRA or the dispensing entity's actual acquisition cost or an adjusted standardized pricing metric that ensures the MFP has been made available prior to the issuance of MFP refund payments between the interested parties. CMS recommends Primary Manufacturers and dispensing entities remediate MFP refund payment issues with each other directly. If remediation between the parties cannot be reached, Primary Manufacturers and dispensing entities may utilize the complaints process within the complaint and dispute system provided in the guidance to report that the MFP was not made available.

Helpdesk required. CMS requires that all contractors engaged for the purpose of implementing the MTF system maintain a helpdesk to address any operational issues relating to use of the MTF system. The MTF helpdesk will be accessible to quickly provide answers to Primary Manufacturers and dispensing entities regarding daily operations of the MTF. CMS did not stipulate that contractors outside of the MTF system would be required to maintain a helpdesk.

- **CMS granted NCPA's ask.** NCPA asked CMS to make this helpdesk required and not suggested.
- **Technical calls for pharmacies.** Additionally, starting in October 2024, CMS will host monthly technical calls for pharmacies that complement the existing monthly technical calls for Part D plans and drug companies.

Manufacturer participation in MTF PM is optional. CMS will engage with a Medicare Transaction Facilitator (MTF) that will serve as the infrastructure in the exchange of data and the optional facilitation of payments to ensure that eligible individuals with Medicare and the pharmacies that serve them have access to the maximum fair prices. Drug company utilization of the MTF for payment facilitation is voluntary.

- **CMS did not grant NCPA ask.** NCPA expressed concern that CMS has chosen to allow manufacturers to voluntarily effectuate the MFP via the MTF.

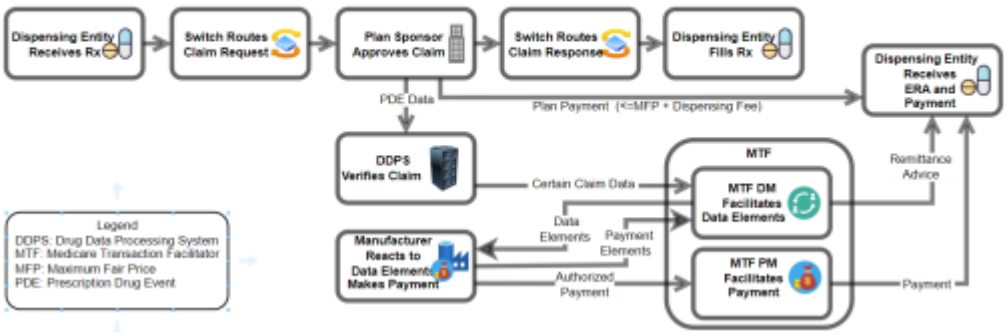
Manufacturer makes MFP available, but not required to sell drug. Access to the maximum fair price (MFP) with respect to a selected drug shall be provided by the Primary Manufacturer to MFP-eligible individuals at the pharmacy at the point of sale. Although the Primary Manufacturer is obligated to provide access to the MFP for all dosage forms, strengths, and package sizes of the selected drug that are dispensed to MFP-eligible individuals, the Primary Manufacturer is not obligated to make any sales of the selected drug.

Manufacturer can give MFP prospectively or retroactively. CMS reiterated that a Primary Manufacturer may provide access to the MFP prospectively or retrospectively. CMS maintains that a Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. Recognizing that there may be advantages and disadvantages to both approaches, CMS encourages Primary Manufacturers and dispensing entities to work together to reach agreements as to whether the dispensing entity will access the MFP prospectively or retrospectively for a given MFP-eligible claim.

Penalties for non-compliant manufacturers. If CMS determines through audits, investigations, or complaints from dispensing entities or other market participants, that the Primary Manufacturer has not consistently fulfilled its obligation to make the MFP available by transmitting payment of an amount that provides access to the MFP within the 14-day prompt MFP payment window (unless the dispensing entity's acquisition cost for the selected drug is equal to or less than the MFP), CMS will notify the Primary Manufacturer of its noncompliance and encourage the Primary Manufacturer to adopt process changes to address MFP refund payment discrepancies as soon as possible. Failure to make MFP available promptly may result in CMS imposing the appropriate civil monetary penalties as set forth in the revised guidance for initial price applicability year 2026 or this final guidance, as applicable.

MTF DM and MTF PM. In 2026 and 2027, CMS will engage an MTF Contractor for the MTF DM to facilitate the exchange of data between Primary Manufacturers and dispensing entities to support the verification that the selected drug was dispensed to an MFP-eligible individual. CMS will also engage an MTF Contractor for the MTF PM to provide optional facilitation of retrospective MFP refund payment from participating Primary Manufacturers to dispensing entities to help effectuate access to the MFP. MTF PM will pass through retrospective payment from participating Primary Manufacturers to dispensing entities to help effectuate access to the MFP, unless the Primary Manufacturer and dispensing entity establish a mutually agreed-upon method for effectuating the MFP outside of the MTF PM. CMS anticipates activities with respect to the MTF throughout late 2024 and 2025 that will include developing, building, testing, data collection and security, and onboarding of manufacturers and dispensing entities. CMS intends to publish the MTF for a 60-day public comment period in Fall 2024. CMS provided a diagram of MTF payment flow for primary manufacturers that participate in the MTF PM in Figure 3, replicated below:

Figure 3: Diagram of MTF Payment Flow for Primary Manufacturers that Participate in the MTF PM



Future pharmacy/MTF DM contracts. CMS intends to propose in future rulemaking a requirement that Part D plan sponsors include in their pharmacy agreements provisions requiring dispensing entities to enroll in the MTF DM. CMS states that dispensing entity enrollment in the MTF DM is needed for necessary operations related to administration of the Negotiation Program and the Part D program, including creating and making available remittances or ERAs, maintaining access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are covered Part D drugs, and ensuring accurate Part D claims information and payment. The MTF DM will provide dispensing entities with remittances or ERAs to reconcile MFP refund payments when a Primary Manufacturer chooses to pass payment through the MTF PM.

For payments made outside of the MTF PM, CMS also plans to provide Primary Manufacturers with access to view information through the MTF portal, such as a dispensing entity's banking information, in order to support the Primary Manufacturer in making available to the dispensing entity an ERA or remittance, as applicable. Interested parties

strongly requested that electronic MFP refunds be accompanied by an ERA or remittance. The ERA or remittance connects claims payment determination and amount with how the payment was made, including the electronic funds transfer information, if applicable. Dispensing entities need an ERA or remittance to close out open accounts receivable for each claim for which a Primary Manufacturer owes an MFP refund.

Credit/debit ledger system

Inside the MTF PM. For Primary Manufacturers that pass payments through the MTF PM, regardless of whether MFP refund payment is issued to dispensing entities electronically or through paper check, 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. CMS has received many requests to provide clarification on how MFP refunds will be reconciled when MFP refund payment occurs for a claim that is subsequently reversed or adjusted. To address changes in MFP refund payments due to claim reversals, adjustments, or determinations that a claim is not MFP-eligible after issuance of an MFP refund payment, 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, for each Primary Manufacturer that participates in the MTF PM and where payment is facilitated through the MTF PM. The credit/debit ledger system will accommodate a variety of revisions to incoming PDE information, including reversals or adjustments originating from updated PDE information received from DDPS. The Primary Manufacturer is responsible for reviewing all such credit amounts to confirm their accuracy.

For payments made outside the MTF PM. CMS has received many requests to provide clarification on how MFP refunds will be reconciled when payment outside of the MTF PM occurs for a claim that is subsequently reversed or adjusted. 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. Primary Manufacturers may establish different methods for handling changes in payment amounts for payments made outside of the MTF PM, so long as such methods are consistent with the Primary Manufacturer's statutory obligation to make MFP available and adhere to GAAP standards and procedures. Accounting for claims reversals and adjustments must be detailed in a manufacturer's MFP effectuation plan, and the Primary Manufacturer has an obligation to make these processes transparent to dispensing entities engaged with the Primary Manufacturer's approach.

Centralized Intake System for Complaints and Disputes Related to MFP Availability and MTF Functionality

CMS will establish a centralized intake system for receiving reports related to access to the MFP with respect to MFP-eligible individuals and the pharmacies and other dispensing entities that provide selected drugs to MFP-eligible individuals. This system is intended to address complaints and disputes related to MFP availability and MTF functionality and is not intended to receive general comments or feedback related to the implementation of the Negotiation Program as a whole. This intake system will include an avenue to report difficulty using, or errors related to, MTF data and/or payment system functionality. This complaints process will be available to parties notwithstanding their degree of participation in any aspect of the MTF. Primary Manufacturers and dispensing entities will be able to access the complaint and dispute process directly from the MTF DM user interface. Those outside the MTF will be able to access the complaints process via a publicly accessible portal. During registration, Primary Manufacturers will be required to furnish information necessary for the MTF DM to complete remittances and ERAs for refunds paid through the MTF PM by the Primary Manufacturer, including but not limited to bank account information if participating in the MTF PM, and to furnish information necessary for the MTF DM to support resolution of complaints and disputes, including circumstances where the Primary Manufacturer chooses not to pass payment through the MTF PM. CMS declined to extend the complaint and dispute process to cover PDE that are not received by the MTF DM system.

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. Upon timely receipt of a reported issue, an initial triage will be conducted to route the concern.

Disputes. Under the Negotiation Program, CMS considers a dispute to be a specific, identifiable challenge to a technical aspect of the MTF system and process (e.g., claims included as potentially requiring an MFP refund). A dispute will warrant CMS review and issuance of a non-appealable finding and will be assessed based on available relevant factual information. The disputing party will need to submit evidence supporting its position when making the report. To resolve disputes, CMS will consider information from the party submitting the dispute as well as any other relevant or underlying information and issue a finding resolving the dispute (either favorably or unfavorably) based upon the facts and data present for the particular situation.

Complaints. CMS will also collect complaints. Under the Negotiation Program, CMS considers a complaint as any issue brought forward by an individual or entity that does not fall under the above definition of dispute; this covers a wide range of concerns from a broad range of interested parties. Below, CMS has provided two examples of types of complaints; however, CMS understands that the types of complaints likely to be received would not be limited to the examples below.

One type of complaint may include operational issues with the MTF system originating from MTF system users participating in the MTF DM or the MTF PM. For this type of complaint, CMS will provide (through a CMS contractor(s)) help desk support to resolve these types of issues promptly to ensure that the system operates smoothly. The MTF helpdesk will be accessible to quickly provide answers to Primary Manufacturers and dispensing entities regarding daily operations of the MTF.

A second type of complaint may include reports that MFP was not made available, including instances where a dispensing entity expresses concern that they have not received a timely retrospective refund payment that effectuates the MFP or that the Primary Manufacturer did not transmit payment within the 14-day prompt-payment window. This type of complaint should include supporting documentation, such as an open accounts receivable demonstrating that the Primary Manufacturer did not provide access to a price for the selected drug that is equal to or less than the MFP. Dispensing entities may also use the complaint process if they have a concern regarding the credit/debit ledger system (see above) established in the final guidance. Before submitting a complaint to CMS, CMS encourages dispensing entities and Primary Manufacturers to work together in good faith to resolve any issues regarding MFP availability. Contact information for dispensing entities and/or Primary Manufacturers will be made available to facilitate these efforts. Proof of any efforts to resolve the issue should be submitted once the complaint is filed. All complaints submitted will receive a response from CMS explaining the next steps that CMS may take.

Complaints related to a lack of MFP availability may not always require a specific resolution but will be reviewed by CMS and may trigger an investigation under CMS' obligation to administer the Negotiation Program and to provide monitoring and oversight of MFP availability. Investigations may lead to enforcement action, as applicable, or audits.

Potential audits of manufacturers in the future. CMS intends to develop a robust monitoring and oversight program. CMS anticipates this will include targeted, issue-specific audits based on observations during program monitoring, and/or complaints received by CMS, as well as more generalized audits of manufacturer compliance with the program's requirements. CMS may issue more specific information about the frequency and volume of anticipated audits as program implementation continues. CMS also intends to monitor trends in complaints and disputes submitted by dispensing entities and other interested parties to track key topics and issues during program implementation; information identified through these monitoring efforts may guide priorities for audits and investigations.