**Centers for Medicare & Medicaid Services Response to Public Feedback Received for the Draft Medicare Transaction Facilitator Agreements**

The Centers for Medicare & Medicaid Services (CMS) released the draft Medicare Transaction Facilitator (MTF) agreements, both for dispensing entities and Primary Manufacturers, on December 17, 2024, for a 45-day feedback period that closed on January 31, 2025. In total, CMS received 14 timely public submissions from professional trade associations, pharmaceutical manufacturers, a health care company, and a vendor on the draft MTF agreements.

We note that some of the public feedback was outside the scope of the MTF agreements. Out-of-scope feedback is not addressed in this document. Feedback was considered out of scope if it did not pertain directly to the specific requirements and responsibilities regarding the use of the MTF system by Primary Manufacturers, dispensing entities, and the MTF contractors. However, much of the out-of-scope feedback raised issues that were addressed in CMS' responses to the summary of the timely public submissions CMS received on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027,which was released May 3, 2024, and was open for comment until July 2, 2024. CMS refers readers to the Medicare Drug Price Negotiation Program Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027, dated October 2, 2024, (hereinafter referred to as the "final guidance") for these responses, which address, among other things, policies concerning: 340B nonduplication; maximum fair price ("MFP") effectuation; policies for the return of unclaimed funds; prefunding payment accounts for the Medicare Drug Price Negotiation Program; Part D sponsors' and pharmacy benefit managers' reimbursement rates for selected drugs; mandatory participation in the MTF Data Module ("MTF DM"); and optional participation in the MTF Payment Module ("MTF PM"). A few of the out-of-scope feedback submissions raised issues that were addressed in CMS' responses to comments on our proposal to require Part D sponsors to include a provision in their network agreements with contracting pharmacies and dispensing entities that require such entities to be enrolled in the MTF DM, which was codified 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" that appeared in the April 15, 2025 Federal Register.

In finalizing the MTF agreements, CMS revised the structure of the agreements. Dispensing entities and Primary Manufacturers will only need to execute one agreement to use the MTF DM ("MTF Data Module User Agreement" or "MTF DM User Agreement"); this new approach reduces the number of agreements that each enrolling entity must sign from two (previously, "MTF Program Agreement" and "MTF DM Contractor Agreement") to one (now, "MTF Data Module User Agreement"). Primary Manufacturers that opt into the MTF PM will still be required to execute an additional agreement with the MTF contractor administering the MTF PM ("MTF PM User Agreement"). The updated MTF agreements structure streamlines the MTF DM onboarding process. In this document, all references to sections, paragraphs, and

subparagraphs correspond to the final version of the MTF agreements. As the structure and numbering have changed since the draft MTF agreements, references may not align with prior drafts. We encourage readers to review the final MTF agreements when locating specific clauses.

Summaries of the public feedback that are within the scope of the MTF agreements and responses to the public feedback are set forth in this document under the appropriate heading.

**Dispensing Entity Responsibilities**

**Comment**: A couple of commenters found the requirement on dispensing entities to keep records created in connection with the MTF and MFP refund payments for a period of ten (10) years overly burdensome and requested that this 10-year record retention timeframe be amended to three (3) years from the date of dispense of a selected drug. These commenters believe that the 3-year record retention period is appropriate and would be consistent with the record retention period required by Recovery Audit Contractors for Medicare and Medicaid.

**Response**: CMS thanks the commenters for their feedback and appreciates their suggestion. CMS considered the administrative burden on dispensing entities for maintaining records for ten (10) years after the date of dispense of a selected drug, including possible record storage and management costs. After consideration, CMS declines to adjust the record retention requirement to three (3) years. Our ten (10) year record retention policy is intended to align with potential discovery needs in False Claims Act litigation and parallels the record retention timeframe under Primary Manufacturers' MTF DM User Agreement. Therefore, CMS believes that this ten (10) year timeframe would best support compliance monitoring and audits with respect to MFP effectuation.

**Comment**: A couple of commenters opposed the requirement on dispensing entities to notify the agency of certain changes to Dispensing Entity MTF Enrollment Information, specifically concerning their financial information (for example, use of a third-party support entity, bankruptcy status, or banking information) and operational status (for example, change in ownership or updates on any new business opening and closures). One commenter questioned whether notices should be sent to the MTF DM Contractor or CMS.

**Response**: CMS thanks the commenters for their input. CMS clarifies that, during the enrollment process, dispensing entities will have the opportunity to authorize the MTF to leverage their information in the National Council for Prescription Drug Programs (NCPDP) database known as "dataQ." For dispensing entities that want the MTF to use the NCPDP dataQ, the MTF will collect dispensing entity data from the NCPDP dataQ during initial enrollment and automatically receive updates from the NCPDP dataQ over time. That means that dispensing entities who authorize the MTF to use the NCPDP dataQ need to ensure that all information maintained by them in the NCPDP dataQ is up-to-date, complete, and accurate (see section II(c) of the MTF DM User Agreement for dispensing entities). The MTF Data Module User Agreement does not establish specific timing or notice requirements on dispensing entities to make updates to the information within the NCPDP dataQ, but we encourage dispensing entities to regularly inspect their information in NCPDP dataQ to ensure the accuracy of the data that flows from NCPDP dataQ to the MTF DM. We note that, because banking information is not stored in NCPDP

dataQ, CMS must collect banking information and any changes to banking information (as well as certain financial information described in section II(b) of the MTF DM User Agreement) directly from dispensing entities and, as applicable, their third-party support entities. That means dispensing entities and their third-party support entities should update their banking information (as well as certain financial information described in section II(b) of the MTF DM User Agreement) in the MTF Data Module if their banking information changes (see section II(b) for the timespan in which such updates must be made). The effective date for when a new bank account can be used to receive MFP refund payments via the MTF Payment Module to the new account will be solely established by the MTF Contractors, which would include time for the MTF Contractors to prepare for operational impacts to the MFP refund payment process (that is, for example, the time it will take to confirm that a new bank account is valid and accessible). The effective date for the new bank account will be conveyed to the dispensing entity after the dispensing entity updates the MTF Data Module. This applies to third-party support entities as well. Finally, dispensing entities that do not authorize the MTF to leverage NCPDP dataQ must manually update all Dispensing Entity MTF Enrollment Information in the MTF Data Module, pursuant to section II(d) of the MTF DM User agreement, and timely send any special notifications for certain information under section II(d)(i) to MFPMedicareTransactionFacilitator@cms.hhs.gov.

**Comment**: One commenter requested clarification on how the federal Anti-Kickback Statute (AKS) is relevant to, or impacts, the MTF data and payment exchange process.

**Response**: CMS thanks the commenter for their question. The AKS prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients). The statute covers the payers of kickbacks—those who offer or pay remuneration—as well as the recipients of kickbacks—those who solicit or receive remuneration. Use of the MTF does not insulate manufacturers and dispensing entities from potential liability for violations of the AKS. CMS is including provisions in the MTF DM User Agreements specifying that Primary Manufacturers and dispensing entities are required to utilize the MTF in accordance with all applicable laws, regulations, and guidance, including, without limitation, the AKS, to ensure all parties have a common understanding of compliance expectations in the context of a new program.

**Comment:** One commenter asked CMS to include "when possible and applicable" where CMS requires dispensing entities to notify the agency about a change in Dispensing Entity MTF Enrollment Information.

**Response**: CMS thanks the commenter for their input. The timeframes set forth in the MTF DM User Agreement are necessary so that parties participating in the MTF have sufficient awareness of and time to account for changes to a dispensing entity's financial, ownership, or operational information. Thus, while CMS appreciates the commenter's suggestion, it declines to adopt the suggestion.

**Comment**: A couple of commenters asked that we revise dispensing entities' obligation to comply with the MTF Data Module Contractor's instructions, processes, and requirements to

"commercial" and "reasonable" instructions, processes, and requirements. These commenters were concerned that dispensing entities could be forced to comply with any activity requested by the MTF Data Module Contractor, including potentially illegal or counterproductive activities.

**Response**: CMS thanks the commenter for their feedback. CMS has included the term "reasonable" in the provision at section II(i) of the MTF DM User Agreement for dispensing entities, which now reads: "Dispensing Entity shall comply with reasonable instructions, processes, and requirements of the MTF Data Module Contractor that are associated with use and operations of the MTF DM."

**Manufacturer's Responsibilities**

**Comment:** One commenter stated that the draft MTF Program Agreement for Primary Manufacturers seeks to bind them to unknown future terms and obligations. Another commenter observed that CMS has the authority to modify the terms of the agreement for manufacturers through non-binding technical instructions and that this unilateral ability of CMS undermines the mutual understanding between the parties. Another commenter recommended that CMS list in an exhibit or schedule to the agreement providing for all the applicable guidance, regulations, or technical instructions that exist as of the date that manufacturers are required to sign the agreement pursuant to the Department of Health and Human Services Good Guidance Practices Rule.

**Response**: CMS appreciates the commenters' concerns. CMS has removed the reference to technical instructions from the MTF DM and PM User Agreements for Primary Manufacturers and declines to add an exhibit or schedule to each agreement. We note that we have not previously referenced technical instructions (or provided a similar exhibit or schedule) in the Medicare Drug Price Negotiation Program Agreement or the Coverage Gap Discount Program/Medicare Part D Manufacturer Discount Program Agreements, which only reference "applicable guidance and regulations."

**Comment**: A few commenters raised issues relating to "Secondary Manufacturers." One commenter observed that the draft MTF Program Agreement for Primary Manufacturers requires that Secondary Manufacturers comply with the terms of the agreement, even though Secondary Manufacturers are not parties to that agreement, and the Primary Manufacturer may have no contractual relationship with a Secondary Manufacturer. One commenter stated that only confidentiality and data use requirements of the agreement should apply to Secondary Manufacturers.

**Response**: CMS thanks the commenters for their input. As described in section 40.4.2.1 of final guidance, the Primary Manufacturer will be the sole manufacturer authorized to receive claim-level data directly from the MTF Data Module about its selected drug and will be responsible for receiving such data for all NDCs of the selected drug with an MFP in effect, including those marketed and sold by a Secondary Manufacturer. The Primary Manufacturer must ensure that any data sharing with and any activity by Secondary Manufacturer(s) or third-party vendor(s) contracted by the Primary Manufacturer comply with applicable privacy and security laws, regulations, and CMS requirements to protect the claim-level data elements received from the

MTF DM. The Primary Manufacturer also must ensure any activity by Secondary Manufacturer(s) complies with the requirements for the Primary Manufacturer to provide access to the MFP by ensuring an MFP refund reaches the dispensing entity when an MFP refund is appropriate, and the Primary Manufacturer must transmit reports with claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window. We have revised section II(e) of the MTF DM User Agreement for Primary Manufacturers to identify the specific terms of the agreement for which the Primary Manufacturer must ensure compliance of any Secondary Manufacturer; these include compliance with the record retention requirements in section II(f), "Audit Rights" (section VI), "Confidentiality Provisions" (section VII), and "Data Use Provisions" (section VIII; Exhibit A). For further discussion on our policies for identifying the Primary Manufacturer and Secondary Manufacturer and the requirements on Primary Manufacturers pertaining to Secondary Manufacturers, we refer readers to the final guidance.

**Comment**: One commenter requested that CMS clarify whether it is the manufacturer's responsibility to pay each claim that is processed through the MTF or whether a direct debit may be taken from the manufacturer's bank account.

**Response**: CMS thanks the commenter for their question. For Primary Manufacturers utilizing the MTF Payment Module, the MTF Payment Module Contractor will receive a payment file that contains the payment amount approved by the Primary Manufacturer on its submitted claim-level payment elements. The MTF Payment Module Contractor will then calculate a total payment amount, which accounts for any available credits with respect to that particular Primary Manufacturer and applicable dispensing entities, and withdraw that amount from the Primary Manufacturer's bank account on file with the MTF Data Module. Primary Manufacturers will be able to access a "receipt" that identifies the withdrawal amount and the associated paid claims.

**Comment:** One commenter noted that a Primary Manufacturer cannot ensure that electronic funds transfers or checks are issued in a timely, complete, and accurate manner because that facilitation process will be managed by the MTF Payment Module Contractor and not the manufacturer itself when the manufacturer elects to use the MTF Payment Module. This commenter felt that, at most, the Primary Manufacturer can ensure that it maintains sufficient funds in the bank account designated for MFP refunds that are authorized in the manufacturer's claim-level payment elements report.

**Response**: CMS appreciates the commenter's concern. Considering the MTF Payment Contractor's ministerial role, CMS accepted the commenter's recommendation to modify this particular requirement to align with the final guidance. As discussed in section 40.4.2.1 of the final guidance, CMS stated that when payment is passed through the MTF PM, the Primary Manufacturer will be considered to have transmitted payment within the 14-day window when the manufacturer sends the claim-level payment elements to the MTF DM on or before day 14. In section 40.4.3.1 of the final guidance, CMS also stated that, by transmitting the claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window, the Primary Manufacturer will authorize the electronic transfer of payment equal to the total refunds to be paid and the transmission of such MFP refund payments by the MTF PM to the dispensing entities identified in the claim-level payment elements (in the amounts directed by the claim-level payment elements).

**Comment:** One commenter noted a possible inconsistency between the final guidance and a provision in section II(i)(3) of the draft MTF Program Agreement for Primary Manufacturers about the triggering event for the 14-day prompt MFP payment window. This commenter observed that the draft agreement states in section II(i)(3): "… within the 14-day prompt MFP payment window that begins with the date of MTF DM transmission to the Manufacturer of the claim-level data"; whereas, the final guidance states that 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.

**Response:** CMS appreciates the commenter's observation. CMS has corrected the provision at issue by revising the language that now appears in section II(i)(7) of the MTF DM User Agreement for Primary Manufacturers to align with the policy in the final guidance.

**Comment**: One commenter pointed out that Primary Manufacturers will need additional information on how the Ledger System will work and the types of information that will be made available in order to agree to the requirement in the MTF Program Agreement that provided "Manufacturer shall review all credits and debits to confirm accuracy" for the Ledger System.

**Response:** CMS appreciates the commenter's input. CMS has revised the provision at issue, which now appears in section II(j)(5)(i) of the MTF DM User Agreement for Primary Manufacturers and states: "Manufacturer is responsible for reviewing credits and debits using data provided by the MTF DM to confirm accuracy." CMS acknowledges the commenter's need for additional information on the Ledger System and notes that further details about the Ledger System are forthcoming.

**Comment:** One commenter requested that, with respect to the responsibility to keep information current, the meaning of "Manufacturer MTF Enrollment Information" should be specified.

**Response**: CMS thanks the commenter for the comment. "Manufacturer MTF Enrollment Information" means the manufacturer's identifying and, if applicable, financial information as described in Section 1 of the Primary Manufacturer MFP Effectuation Plan, which was issued as part of the Medicare Transaction Facilitator Information Collection Request (CMS-10912, OMB 0938-NEW). Section 1 of the Primary Manufacturer MFP Effectuation Plan includes the Primary Manufacturer's responses to whether the Primary Manufacturer will use the MTF PM to provide retrospective reimbursements to dispensing entities (Q1); and, if applicable, details regarding the Primary Manufacturer's financial institution (Q2A), financial information (Q2B), and bank account information (Q2C).

**MTF Data Module Contractor's Responsibilities**

**Comment**: One commenter asked that CMS require the MTF Data Module Contractor to provide 24-hour, 7 days per week, 365 days per year customer support to MTF users. Another commenter requested that CMS hold the MTF Data Module Contractor responsible for disaster recovery and related policies, maintenance of backup systems, and notifications to MTF users not later than 24 hours after discovering any interruption to the system.

**Response**: CMS thanks the commenters for their input. The MTF Data Module Contractor will offer technical assistance and customer support to the MTF users. While the MTF Data Module Contractor does not offer 24/7 customer support, CMS and the MTF Data Module Contractor are committed to providing timely assistance. Inquiries can be sent at any time to an email inbox dedicated for the MTF (MFPMedicareTransactionFaciliator@cms.hhs.gov) and to the Help Desk (via the MTF Data Module user interface). We will diligently work to resolve inquiries as quickly and efficiently as possible.

**Comment**: One commenter requested that CMS add language in the agreement for dispensing entities that will obligate the MTF Data Module Contractor to limit the use and disclosure of data about dispensing entities, such as their identifying and financial information in Dispensing Entity MTF Enrollment Information, strictly to uses and disclosures necessary to facilitate payment to dispensing entities.

**Response**: CMS appreciates the commenter's request. CMS recognizes that the Dispensing Entity MTF Enrollment Information contains sensitive and confidential identifying and financial information. CMS agrees that the MTF Data Module Contractor must limit the use and disclosure of these data to such uses and disclosures necessary to facilitate manufacturer effectuation of MFPs of selected drugs and aid CMS in performance of its administrative duties and compliance monitoring related to the Negotiation Program pursuant to section 1196 of the Act. This requirement appears in section IV(t) of the MTF DM User Agreement for dispensing entities (and section IV(j) of the MTF DM User Agreement for Primary Manufacturers).

**Comment**: A couple of commenters were concerned that the MTF Data Module Contractor has the ability to include additional provisions, requirements, or terms on its own (without direction from CMS), and some other commenters were concerned about the amount of notice they would be provided in the event the contractor amended the agreement.

**Response**: CMS thanks the commenters for their comments and appreciates their concern. As a result of the restructuring of the draft agreements for manufacturers and dispensing entities, manufacturers and dispensing entities no longer will execute a contract with the MTF Data Module Contractor. As a result, the MTF Data Module Contractor no longer would have the ability to include additional provisions, requirements, or terms on its own. CMS retains the ability to amend the MTF DM User Agreements but, as feasible, will endeavor to provide manufacturers and dispensing entities, as applicable, with at least sixty (60) calendar days' notice of any amendments to the agreement.

**Penalty Provisions**

**Comment:** On the draft CMS MTF Program Agreement for dispensing entities (now the MTF DM User Agreement), one commenter asked that CMS remove the ability for CMS to temporarily or permanently suspend, modify, or condition a dispensing entity's or any third-party support entity's access to one or more features of the MTF Data Module for violations of the agreement or credible allegations of fraud or similar fault in connection with the MTF Data Module or MTF Payment Module (see section titled "Penalty Provisions"). This commenter

believes that this language would contradict the requirement for dispensing entities to be enrolled in the MTF Data Module that Part D plan sponsors are required to include in their contracts with dispensing entities.

**Response:** CMS thanks the commenter for their feedback. While Part D sponsors' agreements with contracting dispensing entities must require such entities to be enrolled in the MTF Data Module, CMS does not believe that equates to a guarantee of unrestricted use for a dispensing entity determined to have engaged in conduct that constitutes a breach of the terms of the agreement or where credible allegations of fraud or similar fault in connection with the MTF Data Module or MTF Payment Module exist. CMS reserves the right to take any of the actions specified in the agreement with respect to such dispensing entities to encourage compliance and proper use of the MTF Data Module.

**Audit Rights**

**Comment**: One commenter noted that for Primary Manufacturers there are certain parts of the draft MTF Program Agreement that are inconsistent; specifically, this commenter noted that the requirement to retain records under the section titled "Audit Rights" is for at least ten (10) years while the Data Use Provisions in Exhibit A allow manufacturers to retain certain data beyond the said timeframe and, in the event of terminating the agreement, require manufacturers to destroy certain data upon termination.

**Response**: CMS thanks the commenter for their comment. CMS revised the language in the Data Use Provisions in Exhibit A of the MTF DM User Agreement for manufacturers by removing "up to" in subparagraph (b)(2)(vi) and clarifying that the manufacturer agrees to destroy data as soon as the data is no longer needed after the 10-year retention period has passed. The Primary Manufacturer may retain the data beyond the 10-year timeframe if CMS Data are relevant to an unresolved audit, government investigation, or litigation, or if required by another applicable law.

**Comment**: One commenter felt CMS' authority to request any information from Primary Manufacturers "necessary to" monitor compliance is overly broad without specifying exactly what that information is.

**Response**: CMS thanks the commenter for their input. CMS has clarified that its right to request such information relates to its duties to monitor compliance with the Negotiation Program. Accordingly, in the MTF DM User Agreement for Primary Manufacturers under the section titled "Audit Rights" (i.e., section VI), CMS has revised paragraph (b) to state that "CMS reserves the right to request any additional information from the Manufacturer as is necessary to monitor compliance by the Manufacturer with the terms of the Negotiation Program Agreement(s)[.]"

**Comment**: A couple commenters objected to the frequency of audits and suggested that audits take place no more than once per year.

**Response**: CMS thanks the commenters for their comment. Limiting audits to once per year could impede program integrity and prevent timely identification of issues, particularly in response to any new information or emerging risks. CMS believes that the audit rights as

provided in the MTF agreements ensure that audits are available as a proactive tool to ensure compliance.

**Disclaimers**

**Comment**: Many commenters found the indemnification provisions in the disclaimers section of the draft agreements for Primary Manufacturers and dispensing entities overly broad. A few commenters requested that paragraphs (a) through (e) of the section titled "Disclaimers" of the draft MTF Program Agreement be removed in their entirety because the users of the MTF system have no control over the selection of the MTF contractors, their scope of work, and the establishment of the MTF systems. Regarding paragraph (a), a few commenters disagreed with language obligating MTF users to accept the MTF "as is" because MTF users do not have any visibility into the MTF end-to-end system requirements and are not part of the decision-making process in the design of the MTF. For paragraph (b), one commenter suggested that CMS revise language requiring MTF users to release CMS from all claims, demands, and damages arising out of or connected with the MTF because such language could be misconstrued to encumber the rights of stakeholders to bring legal claims relating to the Medicare Drug Price Negotiation Program against the agency. This commenter suggested that the agency state "directly stemming from the operation of the MTF" instead of "arising out of or connected with the MTF" as a solution. With respect to paragraph (c), a few commenters requested that this be stricken in its entirety because of their disagreement with the agency's decision to shift liability onto the users of the MTF. One commenter suggested that, if the agency does not strike paragraph (c), the agency should consider adding a "hold harmless" provision for MTF users that make good faith efforts to comply with MTF instructions and that act in reliance on the information made available to them via the MTF. Another commenter explained that, given the complexity of the MTF system and the compressed timelines for implementation, CMS and the MTF contractors may be at risk for defining technical and business requirements in a timely manner and MTF users must be held harmless. These commenters also requested that CMS strike the first sentence of paragraph (e), which provided that the agency would not be liable to MTF users for any indirect, special, incidental, or consequential damages under any circumstances and under any legal theory, including negligence.

**Response**: CMS thanks the commenters for their input. CMS believes that the "as is" clause in section X(a) of the MTF DM User Agreement for Primary Manufacturers and dispensing entities, respectively, is necessary to establish that the MTF system is being provided in its current state. With respect to section X(b), CMS accepts the commenter's suggestion to replace "arising out of or connected with the MTF" with "directly stemming from the operation of the MTF." As for paragraphs (c), (d), and (e) of the "Disclaimers" section in the draft MTF Program Agreement, CMS believes these are no longer necessary as they are duplicative of and subsumed by section X(a) and (b) in the MTF DM User Agreement. Accordingly, CMS did not finalize paragraphs (c), (d), and (e) from the draft MTF Program Agreement.

**Data Use Provisions**

**Comment**: A few commenters felt that the window for reporting occurrences where an MTF user "inadvertently receives any direct beneficiary identifiers or discovers any other Breach or

Incident involving CMS Data, loss of CMS Data or disclosure of CMS Data to any unauthorized persons" of one (1) hour within discovery is unusually short. A couple commenters requested CMS to clarify the need to report such occurrences to CMS in addition to the Office for Civil Rights (OCR) at the United States Department of Health and Human Services (HHS), per the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Breach Notification Rule, codified at 45 CFR §§164.400-414. One commenter suggested that if Breaches or Incidents involving the MTF system must be reported to CMS, CMS should adopt the 60-day reporting window under the HIPAA Breach Notification Rule. This commenter also stated that providing a reporting window of three (3) days within discovery would be an acceptable alternative as that timeframe is more common in industry.

**Response**: CMS thanks the commenters for their input. The Office of Budget and Management (OMB) Memorandum 17-12 (OMB-17-12), titled "Preparing for and Responding to a Breach of Personally Identifiable Information," provides guidance to CMS and other federal agencies on minimum requirements to develop and implement breach assessment and response plans. CMS, in accordance with OMB-17-12, reports certain breaches to the United States Computer Emergency Readiness Team within one hour of discovery. CMS is aligning with the one-hour reporting requirement with OMB 17-12. It is important for CMS to learn about incidents immediately to reduce the risk of harm to individuals that is created by a breach of sensitive data. Moreover, prompt reporting to CMS will guide its response activities, minimize harm to affected individuals and entities, and help contain the incident. We also note that this one-hour reporting requirement is a longstanding CMS policy and incorporated into the Manufacturer Discount Program Agreement (and previously the Medicare Coverage Gap Discount Program Agreement).

**Comment:** One commenter requested that subparagraph (b)(2)(vii)-(viii) in Exhibit A to the MTF DM User Agreement for Primary Manufacturers ("Data Use Provisions") be revised to mirror the data use provisions of the Coverage Gap Discount Program Agreement and the Manufacturer Discount Program Agreement, which provide that "the Manufacturer agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the CMS Data and to prevent unauthorized use [of] or access to it." This commenter stated that HIPAA regulations do not apply to manufacturers and questioned CMS' authority to impose HIPAA obligations on manufacturers under the Inflation Reduction Act (IRA).

**Response**: CMS thanks the commenter for their input. We acknowledge the commenter's position regarding the applicability of the HIPAA regulations to manufacturers. We have revised subparagraph (b)(2)(vii) in the Data Use Provisions of Exhibit A of the MTF DM User Agreement for Primary Manufacturers. This provision now provides in part: "The Manufacturer must implement appropriate administrative, technical, and physical safeguards that align with CMS' information security policies . . . to protect the confidentiality of CMS Data and to prevent unauthorized use or access to the CMS Data." We have also revised subparagraph (b)(2)(i) of the Data Use Provisions of Exhibit A of the MTF DM User Agreement for Primary Manufacturers, which now provides in part: "The Manufacturer agrees: (1) to ensure the integrity, security, and confidentiality of CMS Data by complying with the terms of this Agreement and applicable privacy and security laws[.]"

**Comment**: One commenter felt that the agreements for Primary Manufacturers lack protection around confidential and proprietary manufacturer information, risking unauthorized expansion of non-governmental agents' and designees' rights to access sensitive manufacturer information. This commenter asked CMS to prescribe terms and conditions that would allow manufacturers to (1) identify their own proprietary information in the MTF system and (2) challenge any potential release of such data prior to release. This commenter also asked for the agency to outline the firewall measures that will be undertaken to prevent any unauthorized use.

**Response**: CMS thanks the commenter for expressing their concerns. Protecting Primary Manufacturers' confidential and proprietary information in the MTF system is a top priority for CMS and the MTF Contractors. We have taken steps to safeguard such information and to prevent unauthorized access, use, or disclosure of such information. First, with respect to a manufacturer's MFP Effectuation Plan, through revisions in the 30-day version of the Medicare Transaction Facilitator Information Collection Request (CMS-10912, OMB 0938-NEW), CMS has indicated to manufacturers in that plan exactly which sections of the MFP Effectuation Plan will be viewable by only CMS or redacted for sharing with dispensing entities. We encourage Primary Manufacturers to pay close attention to the instructions in the MFP Effectuation Plan when describing any proprietary information. Second, the MTF system employs firewalls, encryption, identity proofing, and role-based access controls to ensure that only authorized CMS and MTF personnel can access Manufacturer MTF Enrollment Information, claim-level payment elements, and other sensitive information in the MTF Data Module. In accordance with federal requirements, including the Federal Information Security Modernization Act (FISMA) and Office of Budget and Management Memorandum 17-12 (OMB-17-12), titled "Preparing for and Responding to a Breach of Personally Identifiable Information," we have protocols in place to mitigate and respond to potential risks associated with data incidents (see, for example, "CMS Risk Management Framework (RMF), "CMS Acceptable Risk and Safeguards (ARS)", and information about the National Institute of Standards and Technology (NIST) and how NIST's policies and guidance relate to security and privacy at CMS).

**Comment**: One commenter noted that for Primary Manufacturers the draft MTF Program Agreement requires Primary Manufacturers to acknowledge potential penalties under section 1106(a) of the Social Security Act (the Act) and the Privacy Act, in addition to the penalties under the IRA.

**Response**: CMS thanks the commenter for their comment regarding the potential penalties in the Data Use Provisions. The agreement requires manufacturers to acknowledge these additional penalties to help ensure compliance with statutory requirements and to protect the integrity of the MTF system. These additional measures serve distinct purposes relating to the sensitive and confidential MTF data elements and supplement the penalties under section 1197 of the Act (see section 100, titled "Civil Monetary Penalties" in the final guidance).

**Comment**: One commenter observed that neither HIPAA nor Medicare Part D requires advance written prior approval for the handling of PII offshore. This commenter stated that Part D sponsors are required to comply with a specific attestation and that the MTF agreement should not be stricter than requirements on Part D sponsors.

**Response**: CMS thanks the commenter for their input regarding the proposed requirements for handling of MTF Data offshore. CMS understands the commenter's concerns about imposing standards on MTF users beyond existing CMS attestation requirements for Part D sponsors and has removed the requirement to seek advance written approval from CMS on offshore data handling requests.

**Comment:** One commenter asked why dispensing entities must agree to the Data Use Provisions when they are already bound by HIPAA and essentially accessing data in the MTF related to their own activities and claims. Another commenter stated that compliance with the HIPAA Privacy and Security Rules should be sufficient.

**Response**: CMS appreciates the commenter's perspective. CMS emphasizes the need for robust privacy and security protections and notes that the Data Use Provisions help ensure that CMS has control over sensitive data. For dispensing entities, CMS appreciates that certain aspects of the MTF Data Module will mainly consist of their own data and has revised the Data Use Provisions to caveat certain provisions to exclude data that originated from the dispensing entity.

**Termination**

**Comment:** Many commenters found CMS' unilateral authority for CMS to terminate the MTF Program Agreement and discontinue the MTF with 180 days' notice problematic. One commenter felt the possibility for such termination would make dispensing entities and manufacturers vulnerable and leave them with no recourse or ability to mitigate any operational interruptions. Some commenters asked that 180 days' notice be extended to 365 days' notice and to align the termination timeframe with the start of the Part D Plan Year in order to ensure that MTF users have sufficient time to adjust.

**Response**: CMS thanks the commenters for their input. CMS acknowledges the commenters' concerns. We note that 180 calendar days' is the minimum notice period we would provide. If CMS determines it will no longer provide the MTF as a service to manufacturers and dispensing entities, we intend to give more notice than the minimum of 180 calendar days, subject to any unforeseen circumstances.

**Comment:** One commenter suggested that, for the termination provisions in the draft agreement for dispensing entities, CMS replace "conduct that is inconsistent with the efficient and effective administration of the Medicare Drug Price Negotiation Program" with "as a result of a breach of [dispensing entity] obligations."

**Response:** CMS appreciates the commenter's input. CMS agrees that being specific about the conduct that constitutes a breach of contract is helpful for both parties. CMS has accepted the commenter's suggestion and incorporated it into the final agreement.

**Comment**: A couple of commenters requested that the effective date of termination by a dispensing entity be reduced from 180 calendar days to 90 calendar days following CMS' acknowledgment of receipt of a dispensing entity's notice of intent to terminate the agreement.

**Response**: CMS thanks the commenters for their feedback. We understand that a fixed 180-day termination timeframe may not provide the necessary flexibility in the event a dispensing entity chooses to terminate its agreement. Accordingly, CMS has revised the paragraph titled "Termination by the Dispensing Entity" under the section of the MTF DM User Agreement for dispensing entities titled "Effective Date, Term, Renewal, and Termination" (i.e., section IX) to state that the effective date of termination will be 90 calendar days after the date of CMS' receipt of the dispensing entity's notice of intent to terminate the agreement, unless CMS determines in its sole discretion that a later effective date is necessary to ensure continuity in the MTF operations for all participants. We anticipate reviewing each dispensing entity's notice of intent to terminate the agreement on a case-by-case basis, reserving discretion to set a later termination effective date when needed to ensure continuity in the MTF operations for all participants. We note that the requirements for proper notice are detailed in section IX(d)(2)(A) and (B) of the MTF DM User Agreement for dispensing entities. Specifically, the dispensing entity is required to specify the reason(s) for termination and provide an attestation that the dispensing entity (1) does not participate in any Part D sponsor network as of the date of its notice of intent to terminate the agreement; (2) agrees that it will re-enroll in the MTF DM if the dispensing entity contracts with a Part D sponsor to be a network pharmacy in the future by executing a new MTF DM User Agreement; and (3) agrees to provide all necessary information required for re-enrollment in the MTF DM at the time of re-enrollment.

**Certification**

**Comment**: A couple commenters requested that CMS add a "best knowledge" qualifier to the requirement for manufacturers to certify the completeness and accuracy of the MFP claim-level payment elements.

**Response**: CMS thanks the commenter for their suggestion. CMS has revised the attestation language in what is now section XII of the MTF DM User Agreement for Primary Manufacturers to provide that: "By signing this Agreement, the Manufacturer also attests that: 1. All information the Manufacturer provides to the MTF DM is and will be, to the best of the Manufacturer's knowledge, true, complete, and accurate and prepared in good faith after reasonable efforts." This attestation relates to "[a]ll information the Manufacturer provides to the MTF DM[,]" including claim-level payment elements. The language of the attestation is also consistent with the attestation language to which a manufacturer must agree when submitting claim-level payment elements as described in the Information Collection Request titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)" (CMS-10912, OMB 0938-NEW). CMS has determined to include the "best knowledge" qualifier but has supplemented the attestation to clarify that information provided to the MTF must be prepared in good faith and based on reasonable efforts to clarify CMS' expectation that manufacturers will take steps to verify the information submitted to the MTF DM. CMS believes this language establishes an appropriate standard for those submitting information to the MTF DM.

**Comment**: One commenter observed that dispensing entities are required to certify that the enrolling dispensing entity and any associated individuals and entities involved in the dispensing, billing, or administration of services to Medicare beneficiaries under the enrolling dispensing

entity are not currently on the CMS Preclusion List and HHS OIG List of Excluded Individuals/Entities (LEIE). This commenter stated that it was not clear why this requirement was in the draft agreement as it is addressed in the contracting pharmacy's network agreement with the Part D sponsor, who monitors and enforces this requirement. This commenter recommended that this provision be deleted from the final agreement.

**Response**: CMS thanks the commenter for their feedback. CMS believes that screening dispensing entities and individuals involved in the dispensing, billing, or administration of services to Medicare beneficiaries serves a beneficial program integrity safeguard.

**Comment**: One commenter requested that CMS replace "has obtained access in the MTF DM" to "will obtain access in the MTF DM" for the attestation by an individual stating that he or she has entered the MTF Data Module as an Authorized Signatory Official.

**Response**: CMS thanks the commenter for the feedback. To clarify, the MTF Agreements will be presented to the Authorized Signatory Official in the MTF Data Module user interface. Before reaching this stage, the Authorized Signatory Official will have already been invited to create an account within the MTF system, established their MTF username and password, logged into the MTF Data Module user interface, and verified their role-based access as an Authorized Signatory Official. Therefore, we declined to adopt the commenter's proposed edits.

**Miscellaneous**

**Comment**: Regarding the MTF Program Agreement for dispensing entities, one commenter requested that CMS replace the word "will" with "may" in the following recital: "WHEREAS, the Dispensing Entity is or *will* be a pharmacy for a Medicare Part D plan sponsor or otherwise anticipates it *will* dispense a selected drug to MFP-eligible individuals[.]" (Emphasis added.) This commenter was concerned that the word "will" means that CMS is mandating dispensing entities to dispense selected drugs.

**Response**: CMS appreciates the commenter's feedback. CMS disagrees with the commenter's reading of the recital at issue. CMS used "or" to convey that the dispensing entity entering into the agreement either is (or expects to become) a network pharmacy for a Part D plan *or* is not a network pharmacy for a Part D plan, but anticipates dispensing a selected drug. This recital does not impose any requirements on the dispensing entity related to the dispensing of selected drugs, but rather is intended to clarify the types of entities for which this agreement is intended.

**Comment**: A few commenters expressed concern about a provision allowing CMS to use information related to the agreements, including without limitation information about and generated by the MTF users, to promote compliance with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"); this provision would also allow CMS to disclose such information to law enforcement and regulatory authorities to promote compliance with law, regulations, and applicable guidance. One commenter stated that CMS cannot use manufacturers' proprietary information for any purpose other than negotiating the MFP and that such information is to be used "only by the Secretary (or GAO)".

**Response**: CMS appreciates the commenters' feedback. This provision, which now appears in section III(g) of the MTF DM User Agreement for manufacturers and section III(i) of the MTF DM User Agreement for dispensing entities, enables CMS to use information related to the MTF DM User Agreement or to disclose such information to other regulatory authorities, such as OIG or DOJ, when appropriate and in accordance with applicable law, and puts manufacturers and dispensing entities on notice of such uses and disclosures. CMS declines to remove this provision from the agreements, but has revised the provision to clarify that CMS will only use and disclose information subject to this provision "to the extent permitted by applicable law, including section 1193(c) of the Act."

**Comment**: One commenter observed that the confidentiality provision in section VI(a) of the draft MTF Program Agreement for Primary Manufacturers allows CMS and the MTF contractors to disclose MTF users' information "as necessary to carry out provisions of section 1196 of the Act or otherwise required by law." This commenter also observed that the HHS Office of Inspector General may also have access to MTF users' information in order to fulfill the Inspector General's responsibilities in accordance with applicable federal law. This commenter believes that because the OIG is part of HHS, the OIG would be limited from gaining access. According to this commenter, the IRA limits all of HHS from using information in ways that are beyond carrying out Part E of Title XI.

**Response**: CMS thanks the commenter for their feedback. CMS clarifies that this clause ensures that the confidentiality provision in section VII of the MTF DM User Agreement for manufacturers and section VII of the MTF DM User Agreement for dispensing entities is not interpreted in a way that would obstruct the statutory and regulatory oversight responsibilities of the HHS OIG. This language is consistent with federal oversight requirements and essential for transparency.

**Comment**: One commenter suggested that, with respect to the "Choice of Law and Forum" clause in the section titled "General Provisions" of the MTF Agreements, CMS explore mediation or arbitration for resolving certain issues, such as disputes over improper payments and cybersecurity incidents without requiring the parties to undertake full litigation.

**Response**: CMS thanks the commenter for their suggestion. CMS clarifies that this clause does not mandate that parties resort to litigation, as opposed to exploring mediation or arbitration and declines to make any revisions to the "Choice of Law and Forum" provision in the MTF DM User Agreement.

**Comment**: One commenter asked that CMS include language in the agreement for dispensing entities that will prohibit CMS from disclosing "information" to "commercial third parties, including plan sponsors, insurance companies, their associated third parties and/or firms" who might leverage such information for commercial purposes.

**Response**: CMS thanks the commenter for their feedback. Under the confidentiality provision of the MTF DM User Agreement for dispensing entities, CMS agrees to, among other things, hold the dispensing entity's MTF information in strict confidence and not to divulge that information to any third party unless such disclosure is required in the performance of the CMS' duties under

this Agreement or such disclosure is required by law. For example, this provision allows CMS to share certain Dispensing Entity MTF Enrollment Information with a Primary Manufacturer that has opted out of the MTF Payment Module, as stated in final guidance, or if CMS determines it should share enrollment status reports with Part D sponsors to assist Part D sponsors in monitoring their network pharmacies' compliance with the plan contractual requirement to be enrolled in the MTF DM, as described 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" that appeared in the April 15, 2025 Federal Register.