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Re: Notice of Information Collection Request "Medicare Transaction Facilitator for 2026 and2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)" [CMS–10912]

Dear Director Parham:

Thank you for the opportunity to comment on CMS' Information Comment Request CMS–10912, titled "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act" (ICR) and published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on April 1, 2025.[1]

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues, which includes more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. CVS Health offers Medicare Advantage Prescription Drug (MAPD) plans in forty-four states and D.C. and standalone prescription drug plans (PDPs) in all fifty states and D.C. Our healthcare model gives us an unparalleled insight into how healthcare systems may be better designed to eliminate barriers to care access and how implementation of innovative services may better serve individuals' personal health needs through being a trusted partner for every meaningful moment of health.

CVS Health appreciates CMS' support and on-going efforts to ensure the Medicare Transaction Facilitator (MTF) has access to the necessary details to support dispensing entity enrollment, manufacturer MFP effectuation plans, manufacturer payment elements, and the complaint and dispute process. These processes and corresponding

[1] See 90 Fed. Reg. at 14373 (April 1, 2025).

forms must be precise and comprehensive as they replace what dispensing entities would typically have access to through a real-time claim billing and response transactions with associated contract terms. Gaps in the MFP effectuation process managed by the MTF could overburden the complaint and dispute system and increase dispensing entity cash flow risks. Based on current interpretations of the content of these forms, the following subject areas are of greatest concern:

- Appendix A Dispensing Entity Enrollment Form: Lacks sufficient detail to identify the necessary contacts and the support the X12-835 electronic data interchange (EDI) process.
- Appendix B Manufacturer Effectuation Plan Form: Lacks sufficient detail to identify manufacturer and selected products associated to the effectuation plan and creates a significant gap in transparency for dispensing entities to identify the payment approach.
- Appendix C Manufacturer Payment Elements Form: Lacks sufficient detail and clarity to confirm compliance with 835 financial balancing.
- Appendix D Complaint and Dispute Form: Lacks sufficient detail to support an effective and efficient dispute process, and assurance of expected MFP refund payments to dispensing entities.

CVS Health has provided detailed comments and summary recommendations below, which we believe are critical in establishing a streamlined and efficient Medicare Transaction Facilitator (MTF) process necessary to effectuate access to the maximum fair price (MFP) to beneficiaries and dispensing entities as required under the Medicare Drug Negotiation Program.

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I. Appendix A: Dispensing Entity and Third-Party Support Entity Enrollment Form

CVS Health appreciates CMS' support and ongoing efforts to establish a streamlined MTF-DM enrollment process for dispensing entities. This is a critical component of the MFP refund process. CMS use of the NCPDP Data Q file will be a beneficial enhancement that will reduce potential errors with manual data entry, particularly for chain pharmacies. Transparency to data elements in the Data Q file that the MTF-DM will use is important, so that Chain Home Offices (CHO) can ensure their information is accurate and up to date with NCPDP.

CVS Health believes there are additional opportunities to streamline and enhance the enrollment process to ensure all downstream processes that leverage this information, including MFP 835 file creation and connectivity, work as expected.

I. General Instructions

CMS states[2] that, among other functionalities, using the MTF will allow dispensing entities to:

- Instruct the MTF-DM where MFP refund payments and remittance advice should be sent, including to a linked third-party support entity (TPSE), as applicable,
- Review manufacturer MFP Effectuation Plans, including plans for dispensing entities self-identifying with cash flow issues (expected this Fall)
- Review and sign MTF Agreements with CMS and their MTF contractors that will be responsible for operating the MTF

[2] See CMS webpage, Resources for Pharmacies and Dispensing Entities.

The updated Enrollment Form does not detail how some of these functionalities will be made available. For example, the Enrollment Form does not clarify where the dispensing entity should provide the information for where the 835-remittance advice should be sent, including IP addresses and other necessary technical details for these transactions. CVS Health is also concerned that dispensing entities will not have sufficient time to review the final dispensing entity agreement forms or have access to the necessary details in the Manufacturer Effectuation Plans, before initiating enrollment with the MTF-DM. If the dispensing entity is not aligned with the terms in the final agreement documents or is unable to confirm the manufacturer payment approach, what options will the dispensing entity have to address valid concerns identified with these documents after they have enrolled with the MTF-DM?

CVS Health appreciates CMS support for a parent organization with multiple dispensing entities using different bank accounts to be able to establish distinct CHO enrollment to align MFP payments with the appropriate bank account. This flexibility will allow reimbursement to be appropriately directed to the correct business entity within the larger organization. We also request CMS to clarify that multiple Reference Codes (aka: chain codes) assigned to pharmacies under a CHO of a parent organization can register with the same bank account within the MTF-DM. For example, CVS Retail pharmacies would be considered a CHO, but will have seven different Reference Codes within the NCPDP file, where all will be registered with the same bank account.

II. Dispensing Entity MTF DM User Roles

Section 1 requires the entity completing Part I to assign MTF-DM user roles for any individuals they wish to have user access to the MTF portal. However, the enrollment instructions do not explain how the initial user from the CHO is identified, contacted and then how to access the MTF-DM system to begin assigning the different user roles. CVS Health requests CMS add this level of detail to the enrollment form to reduce the number of different materials a CHO must reference.

CVS Health also requests that CMS outline any necessary steps a CHO should take in the event changes are made to the Authorized Official (AO) within the NCPDP pharmacy where this information has an impact to existing enrollment records within the MTF-DM that may be linked to a different AO.

CVS Health requests CMS outline the necessary steps for a CHO to change the Authorized Signatory within existing enrollment records, specifically when the original signatory is no longer with the company to be able to complete any user access authentication steps and submit a change in roles.

CVS Health requests CMS confirm that for a CHO, the MTF-DM will leverage the AO from the Chain level data set, and not from the pharmacy location level data set, to send the initial MTF-DM enrollment invitation to the CHO. This is critical for pharmacies where the AO contact information in the pharmacy location level data set points to a

general e-mail box. The AO contact information for individual who should receive the email invitation is only available within the Chain level data set.

III. Section 2: Dispensing Entity Identification Information

Certain data elements are required to be submitted or are pulled from the NCPDP Pharmacy File, including the mailing and business address. CVS Health requests CMS clarify where within the NCPDP Pharmacy file the Mailing and Business Addresses will be pulled and how this information will be used by the MTF-DM and manufacturers. CVS Health recommends the "Physical Address" data field from the NCPDP Pharmacy file be used to confirm the location of a pharmacy. However, for a CHO, this address should never be used for correspondence between the MTF-DM or the manufacturer and the pharmacy. Instead, we recommend the address within the Chain level file be used for any MTF-DM and manufacturer correspondence, as this represents the business address for the CHO.

CVS Health also requests that CMS clarify how the NCPDP Parent Organization ID will be used by the MTF-DM, MTF-PM, or the manufacturer. This is a NCPDP assigned ID, based on NCPDP data organization, and not a value entered by the CHO. CVS Health wants to ensure payments, remittance advices, or correspondences are directed to the applicable parent organization.

Question 3 in Section 2 allows the dispensing entity to indicate anticipated cash flow concerns with the MTF refund process. However, the instructions for Question 3 create some concerns with how and when any support to reduce the cash flow risks will be managed. First, the instructions suggest that only certain types of pharmacies are likely to have cash flow issues. We request that CMS make clear that all pharmacy types, including chain pharmacies, may experience cash flow issues. Alternatively, the limited examples should be removed.

Based on the information within the updated forms, it appears the dispensing entity enrollment form must be completed before the manufacturer can complete its effectuation plan as manufacturers need this information to complete the effectuation plan form that includes the manufacturer's approach to reduce the cash flow risk. However, dispensing entities need access to the manufacturer effectuation plan, specifically the payment approach, to determine their cash flow risk. The only solution to this issue would be to require manufacturers to provide their payment approach before July1, of each iPay year. Manufacturers should also be required to outline their plan to reduce cash flow risks for all pharmacies supporting a standardized process that can be audited, versus developing unique solutions for specific pharmacy NPIs.

While CMS guidance has set a time frame for Part D plans to submit MFP PDEs to CMS and requires the manufacturers to respond to the MFP refund requests within 14 days of receipt from the MTF-DM, there are other steps in the MFP refund process where the timing has not been defined. CVS Health requests CMS clarify the frequency of the data flows between DDPS and MTF-DM and MTF-DM to the manufacturers.

IV. Section 3: Dispensing Entity Financial Information

CVS Health is concerned that the Enrollment Form does not request sufficient detail to support the transmission of an electronic remittance advice (ERA) to the dispensing entity's designated location. The 835-remittance advice could be set up as either a push or pull transport mechanism; however, based on question 1A, it appears this will be a push mechanism. CVS Health prefers the push mechanism and requests CMS to require all manufacturers, not leveraging the MTF-DM, support the push connectivity approach as well.

CVS Health recommends additional data elements be included in the enrollment form to ensure the necessary information is captured to support the transfer of the ERA from the MTF-DM or manufacturer to the dispensing entity. CVS Health requests the MTF-DM, manufacturers or their contracted vendors supplying the 835 files, support the SFTP connectivity method. CVS Health also requests the MTF-DM share the MTF-DM key with dispensing entity within the applicable technical documents. This enables the dispensing entity to send a file to the MTF-DM when encryption may be necessary, including IPs the pharmacy may need to white-list and the MTF-DM technical contact. This also applies to any manufacturers not using the MTF-PM.

Payment reconciliation processes include validation that the expected payment and processes to manage liabilities when the payment received is lower (underpayment) or higher than (overpayment) the expected amount. MFP refund expected amount will be based on the payment approach the manufacturer identified within their effectuation plan (which dispensing entities must have access to). When the dispensing entity's reconciliation system identifies an overpayment, the dispensing entity needs a means to report the claim level detail and return the applicable amount to the manufacturer or MTF-PM. This process is not addressed within the any of the ICRs, that will result in administrative barriers as the MFP process is implemented January 2026. CVS Health requests CMS address this gap within detailed technical guidance and define the claim detail the dispensing entity would return to the MTF-DM through a secure file transfer process.

The MTF-DM and all manufacturers not using the MTF-PM should also coordinate certification testing with the dispensing entities prior to December 1, 2025, to ensure compliance with data security transport.

Recommended Additional Data Elements to be Added to Section 3 of the Enrollment Form:

1. DELIVERY METHODOLOGY (CHOOSE 1)

Method	Description	Yes/No
Dispensing Entity*	Dispensing entity pulls files from a folder location housed by MTF.	

Connecting to MTF	*** *Complete the MTF System access Section*	
MTF Connecting to Dispensing Entity*	File will be delivered to the dispensing entity's site. (MTF pushes to our server) *** *Dispensing entity to also complete External System Access Section and provide a public key for server authentication.*	
Bidirectional Connectivity	Dispensing entity to deliver files to the MTF site, and any files requested from MTF will be delivered by the MTF to the dispensing entity site. *** *Complete Both System access and External System Access Sections*	

*Dispensing entity may be the dispensing entity or their contracted vendor for 835 processing.

2. FILE LEVEL ENCRYPTION

Method	Description	Key
PGP	*If encryption is necessary, dispensing entity to include their encryption Key file.*	

3. **Dispensing Entity Connecting to MTF Connection Methodology Details**

Contact Information

Designate the contact for the confidential access credentials. It is the responsibility of the customer to notify the MTF if credentials need to change due to employee transitions**.**

Name	Email

Connection Methodology (choose 1)

Method	Description	Yes/No
FTPS	File transfer over SSL. TLS/SSL Explicit Encryption	
SFTP	File transfer over SSH. Requires SSH v2 protocol.	
Web Transfer	File transfer via web page upload/download. SSL Encrypted (https)	

Connecting IP Addresses

Provide all Dispensing Entity's IPs' that will be necessary for MTF to white-list (as necessary) for the dispensing entity to connect to the MTF.

IPs	IPs Range	Port

4. MTF Connecting to Dispensing Entity Connection Methodology Details

Contact Information

This can be a group distribution list email.

Name (1 – Business Contact, 2. IT Contact)	Email
1.	
2.	

Connection Methodology (choose 1)

Method	Description	Yes/No
FTPS	File transfer over SSL. TLS/SSL Explicit Encryption	
SFTP	File transfer over SSH. Requires SSH v2 protocol.	
AS2	File transfer over HTTPS	
HTTPS	Connecting to an OUTSIDE website for file transfers	

Connection Requirements for SFTP

Method	Details	Notes
Host Name (URL)		
Port Number		
User ID		
Authentication	Key	SSH public key to be provided by MTF-DM or manufacturer/vendor
Directory to upload files		

CVS Health recognizes that refund payments are the responsibility of the manufacture; however, we are concerned with the form language disclaiming any CMS responsibility to ensure that refund payments are made by manufacturers in compliance with the IRA. Dispensing entities are mandated to enroll in the MTF-DM through Part D plan sponsor network agreements, and to agree to terms that ultimately place all the risk on the dispensing entity in the event a manufacturer fails to pay the required refund. Since the IRA places the responsibility for making dispensing entities whole with respect to the MFP squarely on the manufacturers, and manufacturers generally do not contract with dispensing entities directly, we ask that CMS create an agreement between manufacturers and dispensing entities that states the manufacturer's responsibilities with respect to dispensing entities and that must be signed by both parties as part of the MTF-DM enrollment process. We also request that CMS address the steps it will take to ensure that manufacturers comply with their responsibilities to pay the refunds owed to dispensing entities in accordance with the IRA.

CVS Health requests CMS clarify what is expected for the Dispensing Entity NPI field for a CHO enrollment and distinct bank account. Specifically, will the CHO have to enter or upload all associated NPIs? Otherwise, this will create confusion as there may be multiple chain codes associated with a CHO, all using a single bank account. The Parent Organization ID within the NCPDP pharmacy file is not an option, as this ID may be the same across pharmacy business units with multiple, distinct bank accounts. CVS Health recommends this section of the form be revised to support multiple chain codes that may be associated with a single bank account.

V. Section 4: Dispensing Entity MFP Refund Payment Instructions for Primary Manufacturers Not Participating in the MTF Payment Module

CVS Health requests that the MTF-DM be required to notify the dispensing entity of any manufacturer not using the MTF-PM, identifying the manufacturer and their designated vendor that will receive the dispensing entity's banking information, where applicable. This notification should occur before the information is shared with the manufacturer, allowing the dispensing entity to approve the transfer at that point in time, versus a blanket approval at the time of the dispensing entity enrollment. This more precise notification process that must include the manufacturer and associated vendor contact information. This allows the dispensing entity to coordinate ERA certification and internal set-up processes to recognize a new payer. It also offers the dispensing entity the opportunity to coordinate necessary steps if there are concerns with the EFT/ERA capabilities of the manufacturer or their designated vendor.

F. Section 5: Dispensing Entity Contact Information

CVS Health requests Section 5 of the form include the specific subject areas and both business and technical contacts of the dispensing entity. This aligns with the comments in Section 3, requesting business and technical contacts for the management of the 835 remittance. We also recommend that the contact phone number information be optional and require an e-mail address. This will reduce lost phone calls if the contact does not have a direct phone number and can only be reached through an operator.

The following is a suggested format to collect the dispensing entity or their third-party support system's contact information for management of all MTF-DM processes.

Subject Area (Drop Down) **- Enrollment - Banking - 835 Transport - Disputes/Complaints**	**Contact Type** (Drop Down) **- Business - Technical, Maintenance**	**Contact Name** (Individual or Group Name)	**Contact E-Mail** (Required)	**Contact Phone** (Optional)
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

VI. CVS HEALTH RECOMMENDATION SUMMARY FOR APPENDIX A

- CMS should make the final Dispensing Entity Agreement Forms with CMS and the MTF-DM available before the start of the MTF-DM enrollment process. CMS should allow dispensing entities to enroll with the MTF-DM without having to agree to these agreement forms in the event the non-negotiable terms of the agreement forms create undue burden and risk for the dispensing entity. These considerations are necessary to not exacerbate the fragile cash flow situation for dispensing entities.
- CMS should clarify which specific data elements from the NCPDP Data Q file will be used by the MTF-DM to facilitate the manufacturer MFP refund and EFT/ERA processes. This is critical for chain pharmacies enrolled as a CHO to ensure the pharmacy physical address and chain code addresses are used appropriately. We recommend the pharmacy physical address only be used to for pharmacy location verification as needed and chain pharmacy business address be used for all MFP- related banking, remittance advice and correspondence. Clarification is also needed as to how the MTF-DM will leverage the NCPDP Parent Origination ID as the same ID may apply to different business units with distinct bank accounts.
- CMS should clarify that multiple Reference Codes (aka: chain codes) assigned to pharmacies under a CHO of a parent organization can register with the same bank account within the MTF-DM.
- CMS should revise Section 3, question 1C, to support entering multiple chain codes for a CHO, versus a single NPI.
- CMS should revise Section 3 to include the dispensing entity's technical details for the transfer of the 835 electronic remittance files as described in our detailed comments above. At a minimum, the MTF-DM, manufacturers, or their contracted vendors supplying the 835 files should be required to support the SFTP connectivity method.
- The MTF-DM should provide dispensing entities the MTF-DM key to allow the dispensing entity to send a file to the MTF-DM when encryption may be necessary.
- The MTF-DM and all manufacturers not using the MTF-PM should also coordinate certification testing with the dispensing entities prior to December 1, 2025, to ensure compliance with data security transport.
- CMS should replace the Cash Flow question within the enrollment form, with a requirement for all manufacturers to outline within their Effectuation Plan their process to mitigate unnecessary delays and expedite the MFP refund process as all pharmacies will experience significant cash flow risks.
- CMS should address the fact that dispensing entities currently bear all the risk and have little to no recourse in the event a manufacturer fails to timely pay the required refund to the dispensing entity in accordance with the IRA.
- The MTF-DM should be required to notify dispensing entities if a manufacturer is not using the MTF-PM, identifying the manufacturer and its designated vendor, and should allow the dispensing entity to determine whether its banking information should be shared with a particular manufacturer.

- Section 5 of the enrollment form should be revised to collect all applicable dispensing entity contact information for the MTF-DM or manufacturer when not using the MTF-PM to direct communications. Reciprocal MTF-DM or manufacturer contact information should also be provided in applicable technical guidance to support dispensing entity communication with the applicable contact.

II. Appendix B Manufacturer Effectuation Plan

CVS Health appreciates CMS's support and on-going efforts to ensure manufacturer MFP effectuation plans are precise and comprehensive with applicable details made available to dispensing entities to support electronic fund transfer and payment reconciliation processes.

The Manufacturer Effectuation Form is the primary document that replaces what is typically coordinated through proprietary detailed contract terms, therefore its content must be agreeable to all impacted parties and support resolutions to disputes. Of the four portions of this ICR, the Manufacturer Effectuation Form is the most concerning due to its current lack of detail made available to the dispensing entities.

CVS Health requests CMS consider the comments outlined below before finalizing the Manufacturer Effectuation Plan form as well as how the critical detail will be made available to dispensing entities through the MTF-DM system.

A. Overview

CVS Health recommends CMS add a new section to the MFP Effectuation Plan form that requires "MFP Selected Drug Manufacturer Information," allowing dispensing entities to locate the distinct effectuation plans for each manufacturer. The critical information needed includes:

- Primary Manufacturer Name
- Primary Manufacturer Payer ID (to be returned in REF01/REF02 of the 835)
- Selected Drug(s) Name subject to this effectuation plan
- MFP Effectuation Plan Effective Date
- NDC -11 IDs for all selected products associated to the primary manufacturer's labeler code and subject to this effectuation plan
- Secondary Manufacturer Name
- NDC -11 IDs for all selected products associated to the secondary manufacturer's labeler code and subject to this effectuation plan

CMS should enumerate and date the submitted effectuation plans to track modifications across distinct effectuation plans. CMS should also require that the Primary Manufacturer name submitted in the form coincides with the payer information returned in the MFP 835 remittance (Payer Identification Segment). The primary and secondary manufacturer information submitted in the form will allow dispensing entities to

associate an 835 record with an NDC from a secondary manufacturer and a payer name of the primary manufacturer to the primary payer name established in their payment reconciliation system.

If the manufacturer has multiple selected drugs, where the MFP effectuation plans differ across these selected drugs or same drug with different NDCs, CMS should require the manufacturer complete a formal distinct effectuation plan where the plans differ. Dispensing entities need to be able to clearly identify the MFP effectuation plan for each selected drug and the associated NDCs (11-digit). If the effectuation plan is being updated to include newly released NDCs for a selected drug, this should be an update to include the additional NDCs to an existing effectuation plan and align to the effective date of the NDC being added to the CMS MFP NDC list.

This form should also outline how enrolled dispensing entities will access the applicable details of the manufacturer effectuation plan within the MTF-DM system. It is our interpretation that the critical detail of the manufacturer's effectuation plan will be in Section 4, which will be redacted from view for MTF-DM enrolled pharmacies. Section 4, specifically Question 8, identifies the payment approach the manufacturer will apply to the claim data received from the MTF-DM. These payment approaches are basically the same as contract terms between the dispensing entity and the manufacturer. Dispensing entities must have access to the specific payment approach (e.g., 1. SDRA, 2. Pharmacy Actual Acquisition Cost - MFP, or 3. Proxy to WAC or pharmacy actual acquisition – MFP) no later than September before the effective date of the iPAY year to code this information within their payment reconciliation systems. The expected payment per the manufacturer effectuation is then compared to the payment amount returned in the 835-remittance file to identify under or over payments.

B. Section 1: Primary Manufacturer's Description of Participation in the MTF PM

Under the original Manufacturer Effectuation Plan form, Section 1 included Manufacturer contact information. These sections were removed in the updated form, creating another gap in transparency for the dispensing entities. This form should be updated to require the manufacturer contact information for the MTF-DM and the dispensing entities to correspond to the applicable manufacturer contact to research and resolve technical and payment questions and disputes. The contact information for manufacturers not using the MTF-PM is critical to the dispensing entities to be able to coordinate the necessary SFTP connections, 835 companion guides, etc. Manufacturer contact information should be similar to the details recommended for dispensing entity contacts, where contacts for each subject area should be provided. For example:

- Enrollment
- Banking
- 835 Transport
- MFP Effectuation Mgt; and
- Disputes/Complaints

CVS Health is concerned with the first question presented. It allows a manufacturer to use the MTF-PM and their proprietary systems to support the EFT/ERA process with dispensing entities. Dispensing entities cannot manage to a "payer" sending payments through multiple channels. This presents risks where the dispensing entity's banking information is being shared with manufacturers. As noted under Appendix A comments, a dispensing entity's banking information should only be shared with a manufacturer after the dispensing entity has been notified of the specific manufacturer needing this information and has approved the release of the banking information. Similar to how the manufacturer's banking information is being redacted from the Effectuation Plan form, the dispensing entity's banking information must also be redacted. If the manufacturer elects to use the MTF-PM, then all MFP payments should go through the MTF-PM.

CVS Health requests CMS clarify how the dispensing entity will identify the manufacturer banking information necessary to coordinate the EFT/ERA process if only manufacturers using the MTF-PM are required to provide their banking information and this information will be redacted within the MTF-DM system. CVS Health recommends that Question 2 be required to be completed by all manufacturers regardless of their answer to Question 1 regarding use of the MTF-PM. As outlined in our comments to Appendix A (Section 3), the MTF-DM must make the manufacturer banking information available to dispensing entities to support the EFT/ERA process. Dispensing entities need access to the banking information for all manufacturer's not using the MTF-PM to be able to establish the necessary accounts and remittance processing. Dispensing entities also need access to the banking information for all manufacturers, regardless of their use of the MTF-PM, for MFP refund liability management. Dispensing entities need to be able to provide a secure file of the impacted claims and deposit the applicable funds into the manufacturer's account if and when MFP refund overpayments are determined.

C. Section 2: Managing Relationships with Dispensing Entities

CVS Health recommends manufacturers have access to the dispensing entity enrollment information, specifically the recommended expanded Contacts, to know where to send their MFP correspondence.

As noted under the comments for Appendix A, the dispensing entity enrollment timeline, and the manufacturer deadline to submit their effectuation plan will create a barrier for the manufacturer to provide their Cash flow disruption plan by pharmacy NPI. All dispensing entities will incur major cash flow disruptions where this portion of the manufacturer effectuation plan should apply to all dispensing entities and not be NPI specific.

D. Section 3: Information Requested of Primary Manufacturers Declining Use of the MTF PM

As noted in the Overview and Section 1 comments, manufacturer utilization of the MTF-PM should be for all selected drugs associated to that manufacturer. A single EFT/ERA

process with the associated vendors should be at the manufacturer level and not at the selected product or NDC level. Dispensing entities need to establish the EFT/ERA connections and processes at the payer level and cannot be subject to unpredictable changes by the manufacturer at the selected product level. Allowing manufacturers to alter the EFT/ERA process at the selected product level will add to the already significant cash flow and administrative barriers the MFP refund process is placing on dispensing entities.

CVS Health requests CMS adjust the title of Section 3 as it is specific to manufacturers not using the MTF-PM. The questions apply to all manufacturers effectuation plans regardless of their use of the MTF-PM. We recommend the details in this question specific to manufacturers not using MTF-PM also reference Table 6 from the final guidance, as Table 6 is specific to the manufacturer response to the MTF-DM when not using the MTF-PM.

Questions 5a through 5k must be completed by all manufacturers and the information made available to dispensing entities regardless of whether the EFT/ERA process is managed by the MTF-PM or the manufacturer. These questions further describe the manufacturer's MFP effectuation process, not the EFT/ERA process. Appendix B as presented references the description of the manufacturer's effectuation plan in Section 4, however per Section 4, this will not be available to dispensing entities. Questions 5a – 5k should be added as distinct questions in Section 4 and required to be completed by all manufacturers regardless of their EFT/ERA approach. Lastly, Section 4 would need to be made available to dispensing entities. This gap must be addressed as soon as possible to ensure dispensing entities have access to all manufacturer MFP effectuation plans and be available as of July 1 of each subsequent iPAY year.

E. Section 4: MFP Effectuation

(Not accessible in MTF-DM, CMS Use Only)
As noted in Section 3 above, Questions 5a – 5k should be added as distinct questions to Section 4 and required to be completed by all manufacturers regardless of their EFT/ERA approach and be available to dispensing entities as of July 1st of each subsequent iPAY year.

These questions should be shared with the manufacturer during the price negotiation period to allow the manufacturer access to required details early in the process. This will enable the manufacturer responses to be made available to dispensing entities by July 1st prior to the effective iPay year.

As noted with all questions within Section 4, the manufacturer approach to determining 340B duplicates is also critical information for the dispensing entities. Without this information, the dispensing entities will not have the necessary references to determine when on what basis to submit a dispute. This is another situation that places the dispensing entity at financial risk.

CVS Health strongly recommends that CMS provides dispensing entities access to manufacturer responses to Question 8 as this defines the prospective or retrospective payment approach that will be used by the manufacturer. The MFP refund payment cost basis used by the manufacturer for retrospective MFP effectuation is most critical, as dispensing entities or their financial system vendor will need to document these terms to establish system rules for identifying under or overpayments. If dispensing entities do not have access to this detail, it will create bottlenecks in the dispute process or place the dispensing entity in financial jeopardy.

MFP Payment Approach Options per Section 4, Question 8:

1. The Primary Manufacturer primarily plans to use the Standard Default Refund Amount (SDRA) set forth in the final guidance to calculate and make the retrospective MFP refund payments to a dispensing entity.

2. The Primary Manufacturer generally plans to contact dispensing entities to obtain their actual acquisition cost to calculate the MFP refund.

3. The Primary Manufacturer generally plans to use a proxy for acquisition cost other than WAC to calculate and make the retrospective MFP refund payments to a dispensing entity.

4. The Primary Manufacturer does not intend to use one of the methods listed above as its primary approach and instead intends to use a variety of approaches (e.g., using the SDRA for some dispensing entities while using actual acquisition costs for others) to calculate MFP refunds

5. The Primary Manufacturer does not intend to use retrospective reimbursements to effectuate the MFP.

Manufacturers should not be able to select options #1 and #3 for the same effectuation plan, as the dispensing entities will not be able to determine whether the MFP refunds will be based on option #1 or option #3. While the manufacturer could select option # 1 with option #2 within the same effectuation plan, this would require documented coordination with the applicable dispensing entities. The same applies to manufacturers selecting option # 3 and option #2 for the same effectuation plan. If option #5 is selected, this should be the only option where the prospective purchase price that is no greater than MFP is available to all dispensing entities. If option #3 is selected, the effectuation plan must require the manufacturer to identify the proxy payment calculation (e.g., WAC-2%) under Question 9.

To ensure accurate information is submitted and can be used by the dispensing entities, the following minor modifications should be applied to items 1-5 under Question 8:

1, update the terminology to state “Primary Manufacturer will use the Standard Default Refund Amount (SDRA) set forth in the final guidance to calculate and make the retrospective MFP refund payments to a dispensing entity. Option #1 cannot be combined with option # 3 within the same effectuation plan.”

2, update the terminology to state “Primary Manufacturer will apply the pharmacy actual acquisition cost for claims where the manufacturer has documented coordination with the applicable dispensing entity.

3, update the terminology to state, “Primary Manufacturer will use a proxy for acquisition cost other than WAC to calculate and make the retrospective MFP refund payments to a dispensing entity. Option #3 cannot be combined with option #1 in the same effectuation plan. Manufacturer must complete Question #9 and identify the specific proxy payment calculation e.g., WAC - 2%.”

#4, remove this option, as the manufacturer must identify the specific payment approach options that will apply to the effectuation plan. The form should establish data entry rules that allows options 1 and 2, or 3 and 2 to be selected and not allow options 1 and 3 be selected for the effectuation plan.

#5, update the terminology to state “Primary Manufacturer supports availability of the MFP to dispensing entities using the prospective approach.

CVS Health also recommends that CMS re-evaluate the X12 CARC and RARC codes that have been created to align with the MFP refund payment options that could occur. Based on codes currently available, options #2 and #3 would be mapped to CARC code 307 and RARC code N909. Applying the same CARC/RARC codes to these distinctly different payment approaches creates a barrier for pharmacy remittance processing.

CVS Health requests CMS update CARC 307 to describe payment option #2 (pharmacy acquisition cost) and create a new CARC to align with option ##3 (proxy to WAC). Using distinct CARCs support the critical need for the associated adjustment (difference between SDRA and Option #2 or option#3) within the CAS Adjustment Amount field (e.g., CAS03, Loop 2110). This allows compliance to the 835 balancing requirements where [CLP03 - (sum of CAS Adjustment Amts) = CLP04] and the Charged Amount reported in CLP03 will always be SDRA.

CVS Health interprets Questions 11-15 as informational for potential changes to the manufacturer’s MFP effectuation plan, and therefore should not alter the payment approach that is currently in place as captured under Question 8. If this is the intent of these questions, and the change in the effectuation plan is initiated solely by the manufacturer versus an agreement between the manufacturer and the dispensing entity, manufacturers must be required to contact all impacted dispensing entities at least 90 days before the effective date of the updated effectuation plan. Dispensing entities need a 90-day period, at minimum, to coordinate technical and operational updates, establish applicable agreements with manufacturers, determine the impact to MFP refund tracking and dispute processes, and identify resource constraints. If the effectuation plan is being updated to include newly released NDCs for a selected drug, this should be an update to include the additional NDCs to an existing effectuation plan and align to the effective date of the NDC being added to the CMS MFP NDC list.

CVS Health requests CMS clarify the intent of Questions 11-15 to ensure the appropriate detail is captured in the form and made available to dispensing entities. For example, if these questions are to identify manufacturer effectuation plans where the

MTF-PM is not used, or the manufacturer has a proprietary agreement with a dispensing entity where this plan captured in Question 11-15 replaces the detail requested in Questions 8-10, the structure of the form needs to be updated to clearly reflect the details of the effectuation plan that is being submitted with the associated effective date as requested un as new Section 1.

F. Section 5: Primary Manufacturer Acknowledgements Regarding MFP Availability

Q21: CVS Health recommends CMS include a reference within the manufacturer acknowledgement statement that the manufacturer must provide the MFP refund response and associated payment to the dispensing entity no later than 14 days from the date the MTF-DM provided the claim data (Table 2) to the manufacturer.

Q23: CVS Health recommends this acknowledgment statement make reference to proposed changes to the manufacturer's MFP effectuation plan must be submitted to CMS and available to the dispensing entities at least 180 days before the anticipated effective date of the change.

CVS Health also requests CMS add another question to Section 5 Acknowledgment that confirms the manufacturer commitment of all outstanding MFP refunds in the event of manufacturer divestiture of MFP products or the sale, liquidation, or bankruptcy of the manufacturer

VII. CVS HEALTH RECOMMENDATION SUMMARY FOR APPENDIX B

- Require manufacturers to support either the MTF-PM EFT/ERA service or a non-MTF-PM EFT/ERA service per dispensing entity. Do not allow manufacturers to use both MTF-PM and a non-MTF-PM service for their selected drug(s) for the same dispensing entity unless agreed upon between the manufacturer and the dispensing entity.
- Create a new Section 1 that requires the manufacturer to provide the Primary Manufacturer Name, Primary Manufacturer Payer ID (835), Selected Drug(s), Effectuation Plan Effective Date, Secondary Manufacturer Name, NDC-11 IDs per Primary and Secondary Payer Name information for the distinct effectuation plan submitted and enumerated by CMS, allowing dispensing entities to identify these plans, establish the payer and the associated MFP refund payment approach within their payment reconciliation systems.
- Questions 6-15 of Section 4 must be made available to enrolled dispensing entities as this information is critical for dispensing entity payment reconciliation systems to establish the payer account and payment term details and support payment liability and general ledger processes. Dispensing entities cannot consume the EFT/ERA details with an expectation the content is accurate, as this would be considered negligent within an appropriate financial reconciliation process.

- Update the manufacturer payment options under Q8, using the recommended terminology, removing option #4 and limit the payment option combinations that can be checked for a single effectuation plan.
- Update CARC 307 and a new CARC to support the distinction of payment options 2 and 3 within the 835, where the difference between SDRA and the selected payment approach calculations is reported as an Adjustment Amount in CAS03, for financial balancing compliance.

III. Appendix C: Manufacturer Payment Element Form

CVS Health appreciates CMS' support and ongoing efforts to ensure the data elements shared between the MTF and the manufacturer are sufficient to facilitate the MFP refund process. This form should align MTF refund justification codes with the manufacturer effectuation plan payment approach terminology and support compliance to the X12 835 standard while minimizing the release of PHI and proprietary business terms. The Manufacturer Payment Element form should also be similar to an NCPDP claim response transaction, containing sufficient details to ensure the applicable response is linked to the record from the MTF-DM and can support 835 formats currently supported by pharmacy payment reconciliation systems. Based on the information available, there are gaps within the Manufacturer Payment Element form that, unless addressed, will create gaps in the transaction tracking and payment reconciliation process. CVS Health requests CMS consider the detailed comments outlined below before finalizing the Manufacturer Payment Element form.

A. Submission Method Additional Instructions

CVS Health requests CMS clarify which system will manage adjustments to claim level payment elements. The instructions referenced are interpreted to state that the manufacturer provides a specific "Amount of Payment Transmitted as the MFP Refund" within the payment element form for a specific Medicare claim reported by the MTF-DM; However, the MTF may adjust the payment amount for adjustment credit and debits. It is unclear if the manufacturer will manage payment adjustments based on historical tracking of the claim level data, or the MTF-DM will manage adjustments, credits and debits based on the payment elements returned by the manufacturer. If both the manufacturer and the MTF manage MFP payment adjustments, CMS technical guidance inclusive of 835 formatting and the Manufacturer Payment Element form need to be updated to address the following concerns:

- How will the dispensing entity know whether the claim level adjustment came from the manufacturer or the MTF and the reason for the adjustment?
- How does the dispensing entity identify which entity (manufacturer or MTF) to return payments to when the reconciliation process identifies an overpayment?
- How will potential duplicate adjustments (from both the manufacturer and MTF) be prevented?

- Will the MTF-DM and the manufacturers associate the MTF Internal Control Numbers (ICNs) from both the current adjusted refund record and the prior record to which the debit/credit applies to, within the 835-claim level detail?
- If the MTF can apply adjustments to the claim level payment determined by the manufacturer, how would this be supported for manufacturers not using the MTF for EFT/ERA processes?

Since a manufacturer may need to support the EFT/ERA process, all adjustments may need to be supported by the manufacturer. Clear technical guidance should be made available to the manufacturers to ensure standardization of the process. Technical guidance may need to include various use case examples where adjustments may occur e.g.,

- subsequent claim reversal,
- subsequent edit to claim where dispensed quantity is changed for same date of service,
- subsequent 340B discount identification,
- duplication of a PDE record due to PDE resubmission,
- changes in PDE reject management,
- changes to MFP NDC list/unit price,
- adjustments to WAC prices,
- changes to manufacturer MFP payment approach.

CMS Technical guidance as to how the MTF-DM and manufacturers will identify when an adjustment would apply is critical. This guidance should also identify the specific X12 CARC/RARC codes that would apply to an MTF-DM adjustment versus a manufacturer adjustment (payment element #6). New CARC may be necessary to clearly identify adjustments the MTF-DM made to the payment amount returned by the manufacturer. Detailed guidance inclusive of the mapped CARC/RARC codes is critical for dispensing entities to accurately reconcile the financials within their ledger. CMS technical guidance must also ensure all MFP refund 835s comply with financial field balancing.

Example Potential RARC Codes: (specific to a payment adjustment from the manufacturer)

- N419: Claim payment was the result of a payer's retroactive adjustment due to a retroactive rate change.
- N689: Alert: This reversal is due to a retroactive rate change.
- N692: Alert: This reversal is due to an incorrect rate on the initial adjudication.
- N693: Alert: This reversal is due to a cancellation of the claim by the provider.
- N694: Alert: This reversal is due to a resubmission/change to the claim by the provider.

CMS should also consider near term changes in the PDE and Table 2 data elements to support the availability of the Reconciliation ID (B98-34) field in NCPDP Telecommunication Standard vF6. The Reconciliation ID field will better support linking reversals to prior claims and identification of a subsequent claim for the same RX/Fill and date of service.

B. Additional Instructions Leading to Section 1

CVS Health requests CMS add two new data elements to Section 1 to support the creation of primary keys that will ensure the manufacturer payment element data is linked to the correct records within the MTF-DM Table 2 file, and to the CMS PDE record for the associated Medicare claim. This would align to how NCPDP claim request and responses are linked, repeating specific attributes in the response that were submitted in the request.

The Manufacturer Payment Element Form should include the following additional attributes from the corresponding claim record from Table 2:

- MTF Internal Control Number (ICN)
- Transaction Code
- Date of Service
- Medicare Part D Claim Authorization # (prior request to add this to Table 2)
    - Telecommunication vD.0 = NCPDP field 503-F3, vF6 = B98-34

As requested in prior correspondence with CMS, Table 2, the Manufacturer Payment Element Form and the 835 must include the Authorization number (NCPDP field 503-F3, B98-34) from the Medicare Part D claim response so that dispensing entities, the MTF-DM, and CMS can locate the specific Medicare transaction associated to the MFP refund record.

C. Payment Element 3: Method for Determining MFP Refund Amount

CVS Health requests CMS align the Method for Determining MFP Refund Justification Codes under Payment Element #3 and the code/value descriptions from Table 5 (CMS MFP Final Guidance) to the payment approaches in Section 4, question 8 of the Manufacturer Effectuation Plan form (Appendix B). The codes and values listed in these three tables all describe the basis of the MFP refund payment. However, the payment approaches within Appendix B are more distinct than the Justification codes from the Payment Element form and the code/values in Table 5. This will create a gap in the dispensing entity reconciliation process, as CARC 307 and RARC N909 do not make a distinction between pharmacy actual acquisition cost or a proxy to WAC.

Appendix B distinguishes non-SDRA based payments as #2 - pharmacy acquisition cost (based on documentation from pharmacy) and #3 - proxy to WAC as the basis from which the MFP price is deducted to determine the MFP refund amount. If Justification code #7 is intended to align with Payment Approach #3, this clarification should be made in both forms and technical guidance. If #7 is not associated with payment approach #3, then CMS should clarify the terms behind #7 and how the dispensing entity would know when this would apply.

CMS should also provide guidance as to what action the dispensing entity is able to take when Justification Codes 5 and 6 are returned and define the situations that would result in these responses. Would these be associated to a Table 2 file transmission error between MTF-DM and the manufacturer? If so, what is the resolution process, and should these value descriptions indicate a communication error occurred where the MTF-DM will resubmit the file for manufacturer processing?

Dispensing entities must have clear visibility to these payment justification codes and the manufacturer effectuation plan payment approaches (Section 4), where these values and description are aligned and clearly reflected in the 835 CARC/RARC codes. Terminology across these data elements need to be aligned to ensure standardization is use accuracy in payment reconciliation.

The following table associates the Effectuation Plan payment approaches with the Payment Element form Justification Codes, and the specific MFP related CARC and RARCs. Highlighted items represent payment situations where there may be misalignment or missing code values that require further technical guidance.

Effectuation Plan Payment Approach (Appendix B, Q8)	**Payment Element Form Method for Determining MFP Refund Justification Code**	**835 CARC/RARC**
1. SDRA	1. SDRA	N/A
2. Pharmacy Acquisition Cost	**TBD** (2, 7 or new distinct code as the same justification code should not apply to two different payment approaches)	307/N909 **Distinct CARC may be necessary so that the adjustment amount can be reported in CAS03 as the difference between SDRA and the pharmacy acquisition cost.**
3. Proxy for acquisition cost other than WAC	2. Amount other than SDRA	307/N909 **Distinct CARC may be necessary so that the adjustment amount can be reported in CAS03 as the difference**

		between SDRA and the proxy to WAC.
4. Manufacturer using a variety of approaches e.g.,1, 2 and 3. See comments to Appendix B	See comments to Appendix B	See comments to Appendix B
5. Prospective vs retrospective approach	3. No Refund Transmitted – Prospective MFP Access	307/N908
N/A	4. No Refund Transmitted – Section 1193(d)(1) Exception	307/N907
N/A	5. No Refund Transmitted – Payment Transmission Attempted but Unsuccessful	**TBD: N910?**
N/A	6. No Refund Transmitted – Other	**TBD: N911?**
TBD	7. Refund Transmitted Consistent with Alternative Reconciliation	**TBD**

C. Payment Element 6: MFP Refund Adjustment

As noted in the Additional Instructions comments, CMS technical guidance is needed to further define the MFP refund adjustment process, the use of specific Transaction Code values (Table 2), and the situations where the MTF-DM would apply an adjustment to the payment amount recorded by the manufacturer.

The use of the Yes/No Refund Adjustment Payment Element in this form is unclear. We are curious about a situation where a manufacturer would apply an adjustment, but that adjustment is not in reference to a previously paid refund? How would the MTF or the manufacturer use this Refund Adjustment Payment Element values of Yes/No to return the applicable CARC/RARC code within the 835?

All claim level adjustments adjustment should be reflected in the payment amount of the 835 (CLP04) and would be specific to when the Total Charged Amount (CLP03 - to which MFP 835 mapping guidance is necessary) minus any claim level adjustments in the CARC segment. No further credits/debits should apply to the payment amount reflected in CLP04.

The MFP Refund Adjustment field and defined values as presented in this form appear to be incomplete, where the specific adjustment reason as mapped to an 835 CARC/RARC should be selected, to allow the MTF or the manufacturer to provide a compliant 835 file.

D. CVS HEALTH RECOMMENDATION SUMMARY FOR APPENDIX C

- Include additional data elements to the Manufacturer Payment Element file to support transaction validation, ensure the manufacturer response aligns to the applicable MFP refund request record from the MTF-DM, and payment adjustments are applied to the appropriate transaction.
- Align the Manufacturer Payment Justification Codes and the manufacturer effectuation plan payment approaches (Section 4, Question 8), where these values and description are aligned and clearly reflected in the 835 CARC/RARC codes.
- Limit management of MFP refund payment adjustments to the manufacturer versus allowing both the manufacturer and the MTF to apply adjustments to the claim level refund payment.
- Replace Payment Element #6 with defined adjustment reasons that would apply to the MFP refund process and align these reasons to X12 835 CARC/RARC codes.

IV. Appendix D: Complaints and Dispute Form

CVS Health appreciates CMS' support and on-going efforts to establish a streamlined dispute process for dispensing entities. As the dispute process through the MTF-DM may be the only recourse the dispensing entity may have to address financial and technical barriers to the MFP refund process, the content and usability of the form will be critical. As noted in the following comments, there are additional opportunities to streamline and enhance the dispute and complaint process to ensure all downstream processes that leverage this information work as expected and proprietary data is not mis-used.

A. General Instructions

We understand the need to set some limits to better control access to the associated detail within the MTF-DM, manufacturer, and dispensing entity systems; however, 120 days could be insufficient depending on the event. For example, DDPS PDE rejects, alternate claim billing processes such as long-term care post consumption billing, or manufacturer timelines to identify 340B duplication that could not be resolved directly between the dispensing entity and the manufacturer. We therefore request CMS extend the120-day restriction from when the dispute can be filed from the date when the issue was identified by the dispensing entity to support a 365-day period as there are always delays across the impacted data transfer processes.

We are concerned with CMS' definition of a Dispute as limited to a challenge with a "technical" aspect of the MTF system or process. This suggests a system error and may create confusion as to whether a financial dispute regarding the amount reimbursed would be considered a dispute that warrants CMS review. CVS Health recommends the term "technical" be removed from the definition and the dispute categories under Section 2 be modified and expanded to include additional sub-categories.

Below are our recommendations for such definitions:

- Dispute: Identifiable challenge to the MTF system and process. A dispute will warrant CMS review and will be assessed based on available relevant information. The submitter will select the primary and secondary category that best describes the dispute. If the dispute does not fall under a pre-set sub-category, the submitter should select the applicable category and Other as the sub- category.

  Dispute Categories:

  1. Technical issue pertaining to MTF system functionality or processes
     - MTF-DM user access
     - MTF-DM secure file transfer process
     - MTF-DM and DDPS connectivity, downtime
     - MTF-DM user interface concerns
     - MTF-DM data integrity concerns
     - MTF-PM secure file transfer process
     - MTF-PM data integrity concerns
     - MTF-PM and banking institution connectivity, downtime
     - Delayed 835 remittance files
     - MTF-DM 835 file format, missing detail
     - Manufacturer 835 file format, missing detail
     - Other (includes text field for description)
  2. Technical issue with the underlying data processed through the MTF
     - Pharmacy enrollment – NCPDP Data Q conflicts
     - Missing PDE records
     - WAC, MFP, SDRA price discrepancy
     - Other (includes text field for description)
  3. 340B Duplication
     - RARC N907 discrepancy
     - Submission Clarification Code 20 discrepancy
     - Other (includes text field for description)
  4. MFP effectuation and dispensing entity's receipt of an MFP refund
     - MFP refund payment delay (greater than 14 days post MTF Process Date)
     - MFP refund payment discrepancy (e.g., RARC N909)
     - MFP refund payment missing (e.g., RARC N908, N910, N911)

- Other (includes text field for description)

- **Complaint:** 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. 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. Submitter to select the category that best describes the complaint. If the dispute does not fall under a pre-set category, the submitter should select Other and provide a detailed description.
    1. Beneficiary access to MFP selected drugs
    2. Dispensing entity access to MFP selected drug
    3. Dispensing entity cash flow risk
    4. Other (includes text field for description)

CVS Health asks that all reimbursement discrepancies meet the definition of a dispute so that CMS oversight can ensure a response is provided by the manufacturer. We also request that CMS define a non-appealable finding, explain what recourse the dispensing entity may have for disputes that are classified as such, and outline the criteria that would determine a non-appealable finding.

We request the MTF-DM provide the MTF-DM contact information by subject area in a location either in the web-portal that does not require user log-on, and/or within MTF-DM technical guidance.

CMS should communicate as soon as possible as to when the additional instructions will be available for the MTF-DM user interface URL, as dispensing entities may need to white-list this site within multiple internal systems/servers.

We request CMS clarify that the online form established for non-MTF users to submit a complaint contain only the same fields as the MTF-user form. We also request CMS outline how the dispensing entity will be alerted to a complaint and what if any resolutions have been applied by the MTF-DM, CMS, or the manufacturer when a submitter (e.g., beneficiary) submits a complaint that implicates a specific pharmacy.

B. Section 1: Identifying Information of the Submitter Question 1: Contact Information

CVS Health requests CMS consider supporting a mechanism within the Dispute portal that can link to the dispensing entity contact information provided under Section 5 of the Enrollment form, allowing the submitter to select the applicable contact and the detail to be auto populated in the dispute form. If the submitter of the dispute is not listed in the dispensing entity contact information of the enrollment form, the submitter can manually enter the requested detail.

C. Section 2: Description of Issue Question 2: Issue Category

As noted above, we recommend various categories and sub-categories under a DISPUTE or a COMPLAINT. This will streamline processing and resolution of the issue. If specific categories are not defined for a Dispute, resolution will be delayed, or not addressed at all, further impacting cash flow risks for dispensing entities.

Submitted disputes should not be rejected in the event the selected category is determined to be inaccurate by the MTF, CMS or the manufacturer. The MTF-DM system should be flexible to be able to determine the core issue and direct the details to the applicable entity to research, obtain additional detail, and resolve.

D. Section 2 Question 3: Selected Drug & Claim Information

Dispensing entities will not have visibility to many of the processes and details managed by the MTF-DM, as the data used by the MTF-DM does not come directly from the dispensing entity. The dispensing entity does not have an MFP refund claim request record to reference. This is why it is critical for the Part D plan to include the claim transaction authorization number on the PDE, where this is also included in Table 2 from the MTF-DM to the manufacturer and repeated in the MFP refund 835. This is the only way for the dispensing entity to identify the specific Medicare claim that may be in dispute.

CVS Health requests the drug name drop down selection under Q3B includes all marketed drug names inclusive of authorized generics to ensure al related disputes can be reported and directed to the applicable contacts to resolve.

CVS Health requests CMS clarify how and when the claim/transaction control numbers under items Q3F and Q3G will be used and where these values are obtained. Is Q3F Claim ID(s) or Transaction Control Number (TCN)(s) referring to the Medicare Part D transaction authorization number (which is available to the dispensing entity), since Q3G is referring to the MTF ICN from Table 2? If not the Medicare claim transaction control number, what transaction control number is it referring to? CVS Health also requests CMS consider Q3G as an optional data element for a dispute to be submitted, as the dispute may be related to a missing MFP refund payment therefore there is no related 835 detail to extract. In this situation, it would be too cumbersome for the dispensing entity to look up each Medicare claim in the MTF-DM to extract this ICN value. The MTF-DM system should be able to locate the related MFP transaction data based on the distinct key comprised of the pharmacy NPI, RX Number, Fill Number, claim Date of Service, NDC.

The selected drug and claim information questions in Section 2 suggest that multiple values can be added on a single entry. For example, the dispute is reporting multiple prescription numbers for multiple NDCs under the same selected drug and same pharmacy. We ask CMS to clarify within the form, whether the multiple values should be comma or semi-colon separated.

CVS Health requests the MTF-DM support an SFTP file transport process, where the dispensing entity can drop a file of the related transactions associated to the specific dispute. This file should contain at a minimum the following attributes:

- CHO Name
- Pharmacy NPI
- RX #
- Fill #
- Date of Service
- NDC
- Quantity Dispensed
- Medicare Part D Authorization ID (NCPDP vD.0 field 503-F3, or vF6 field B34-98)
- MTF Internal Claim Number(s) or Reference ID(s) on X12 835 - (This should be an optional data element as the dispute may be that the MFP refund payment is missing, therefore the MTF-ICN will not be available on the 835)

Additionally, the dispute process and system technology to support expedited dispute resolution needs to be flexible as stakeholders identify new use cases that need to be supported.

E. Section 2 Question 5: Supporting Documentation

CVS Health requests the form clearly indicate that Supporting Documentation is optional, where the answers to questions 3 and 4 may be sufficient for the dispute to be researched and resolved.

F. CVS HEALTH RECOMMENDATION SUMMARY FOR APPENDIX D

- Replace the 120-day restriction as to when the dispute can be filed from the date when the issue was identified by the dispensing entity, with at least a 365-day period.
- Provide the criteria that would determine a dispute to be non-appealable.
- Update the definition of a Dispute to remove the reference to “technical” and include clearer categories and sub-categories to streamline processing and resolution of the issue and mitigate further cash flow risks for dispensing entities.
- Include in the MTF-DM technical guidance, MTF-DM contact information by subject area such as User Access, IT Technical (e.g., SFTP connectivity), 835 Remittance format, Complaint/Dispute Status, etc.
- Require manufacturers not using the MTF-PM to include in their Effectuation plan, the manufacturer contact information by subject area such as IT Technical (e.g., SFTP connectivity), 835 Remittance format, etc.
- Require all manufacturers to include in their Effectuation plan, the manufacturer contact information to address Complaints/Disputes.

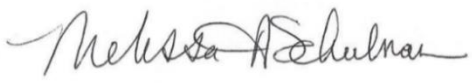
- Communicate as soon as possible the additional instructions including the URL to the MTF-DM user interface to allow dispensing entities to coordinate the IT technical details to support user access (e.g., white-listing).
- Confirm that the online Complaint form for non-MTF users does not contain any additional fields than what is in the MTF user form.
- Provide the process as to how the dispensing entity implicated in a submitter (e.g., beneficiary) complaint will be alerted to the complaint and what if any resolutions have applied by the MTF-DM, CMS, or the manufacturer.
- Under Section 1 of the form, support a mechanism within the Dispute portal that can link to the dispensing entity contact information from the Enrollment form to allow the submitter to auto populate it in the dispute form.
- Under Section 2 of the form, disputes should not be rejected or delayed in the event the dispute category the submitter selected is determined to be inaccurate. The MTF-DM system should be flexible to be able to determine the core issue and direct the details to the applicable entity to research and resolve.
- Under Section 2, include all marketed drug names inclusive of authorized generics to ensure al related disputes can be reported and directed to the applicable contacts to resolve.
- Under Section 2, clarify how and when the claim/transaction control numbers under items Q3F and Q3G will be used and where these values are obtained. CVS Health strongly recommends CMS include the Medicare claim authorization number returned on the Paid response, be required in the PDE, added to Table 2 MTF-DM to manufacturer data elements and required in the MFP-refund 835.
- Under Section 2, recommend the below data elements be reported by the dispensing entity when filing a dispute related to a Medicare MFP claim:
    - CHO Name
    - Pharmacy NPI
    - RX #
    - Fill #
    - Date of Service
    - NDC
    - Quantity Dispensed
    - Medicare Part D Authorization ID (NCPDP vD.0 field 503-F3, or vF6 field B34-98)
    - MTF Internal Claim Number(s) or Reference ID(s) on X12 835 - (This should be an optional data element as the dispute may be that the MFP refund payment is missing, therefore the MTF-ICN will not be available on the 835)
- Under Section 2, include the ability for the MTF-DM to support an SFTP file transport process, where the dispensing entity can drop a file of the related transactions associated to the specific dispute. This can be coordinated with bi-directional SFTP set-up within the 835 EDI enrollment process (Refer to comments to Appendix A).

- Under Section 2, the form should indicate the specific delimiter value that should be used in text fields where multiple entries can be reported (e.g., RX#, NDC, ICNs).
- Under Section2, the form should clearly indicate that Supporting Documentation is optional.

The dispute process and system technology should be flexible as stakeholders identify new use cases that need to be supported. Create a form that outlines the information CMS will return to the submitter of the dispute or complaint. The contents of this form should contain the submitter, date reviewed, reference to prior dispute/complaint records under the same issue or claim, projected timing of response, and the entity responsible for resolution.

Thank you for considering our comments and recommendations. CVS Health is committed to collaborating with CMS as it finalizes the applicable Medicare Transaction Facilitator agreements to facilitate the secure and accurate transmission of MTF data and payments to pharmacies. We support affordable, comprehensive care that provides beneficiaries with innovative coverage choices to meet their needs. We welcome any follow-up questions you may have and stand ready to support CMS as it works to refine the Program to ensure it achieves its intended goals as smoothly and efficiently as possible.

Sincerely,



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CVS Health