Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program (the Negotiation Program), codified in sections 1191 through 1198 of the Social Security Act (the Act). The Act establishes the Negotiation Program to negotiate a maximum fair price (MFP), defined at section 1191(c)(3) of the Act, for certain high expenditure, single source drugs covered under Medicare Part B and Part D (selected drugs). In accordance with section 1193(a) of the Act, any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must provide access to the MFP to MFP-eligible individuals, defined in section 1191(c)(2)(A) of the Act, and to pharmacies, mail order services, other dispensing entities, providers and suppliers with respect to such MFP-eligible individuals who are dispensed that selected drug during a price applicability period.

To facilitate the effectuation of the MFP, CMS will engage a Medicare Transaction Facilitator (MTF). The MTF system will be comprised of two modules: the MTF Data Module (MTF DM), and the MTF Payment Module (MTF PM). Primary Manufacturers participating in the Negotiation Program are required to participate in the MTF DM. Further, CMS has proposed in rulemaking to require Part D plan sponsors to include in their network pharmacy agreements provisions requiring dispensing entities to be enrolled in the MTF DM for purposes of data exchange. As discussed in section 40.4 of 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 (final guidance), CMS will engage the MTF DM to facilitate the exchange of certain claim-level data elements and payment elements for selected drugs. The data exchange component of the MTF will involve both the transmission of certain claim-level data elements to the Primary Manufacturer and receipt of claim-level payment elements from the Primary Manufacturer.

The Primary Manufacturer Payment Elements ICR form will support CMS' oversight and administration of the Medicare Drug Price Negotiation Program and allow CMS to collect payment-related data elements via the MTF DM for each claim for a selected drug from Primary Manufacturers indicating whether a refund was paid, and the amount of the refund paid to make the MFP available, as applicable.

General Instructions

<u>Overview</u>

The Primary Manufacturer, inclusive of any of the Primary Manufacturer's contracted parties, will be required to transmit specified claim-level payment elements back to the MTF DM for every set of claim-level data elements transmitted to the Primary Manufacturer by the MTF DM. The payment elements must be transmitted back to the MTF DM within 14 calendar days of receipt of claim-level data elements from the MTF DM and be accompanied by the corresponding information from the MTF claim-level data elements outlined in section 40.4.1 of the final guidance.

<u>Submission Method</u>

- The MTF DM will transmit an electronic file to Primary Manufacturers including claim-level data elements and payment elements fields to be completed by the Primary Manufacturer. A Primary Manufacturer, or its contracted parties, will populate the payment element fields within the electronic file and transmit it back to CMS via Secure File Transfer Protocol.
- Primary Manufacturer payment elements must be transmitted to the MTF DM on a frequency determined by the Primary Manufacturer that is in compliance with the requirement to transmit the payment elements within 14 calendar days of receipt of claim-level data elements from the MTF DM. *See* section 40.4.2.1 of the final guidance (explaining the circumstances in which the Primary Manufacturer will be considered to have transmitted payment within the 14-day prompt MFP payment window).
- CMS will provide Primary Manufacturers with additional technical instructions for gaining access to the MTF DM, obtaining technical assistance, and transmitting payment elements to the MTF DM before January 1, 2026 for initial price applicability year 2026, and before January 1, 2027 for initial price applicability year 2027.

<u>Additional Instructions</u>

- The instructions in this section apply to all payment elements required to be submitted by Primary Manufacturers of selected drugs. For purposes of this information collection request, all defined terms referenced in this ICR have their meaning set forth in the final guidance.

- Questions about the final guidance should be sent to IRARebateandNegotiation@cms.hhs.gov. Additional information regarding the Medicare Drug Price Negotiation Program can be found on CMS' website here.

- Each set of payment elements are in response to a specific set of data elements that are derived from a drug claim. A Primary Manufacturer may batch multiple sets of payment elements, including for different selected drugs if a Primary Manufacturer has more than one selected drug, into a single file of payment elements to submit to the MTF DM.

- Response formats are indicated within each payment element description in this ICR.

- In situations where MFP refund payments are facilitated by the MTF PM, by transmitting the claim-level payment elements to the MTF DM, the Primary Manufacturer authorizes the electronic funds transfer of the MFP refund payments included in the payment elements file. Upon receipt of the payment elements, the MTF PM will initiate the process to transmit MFP refund payments to the dispensing entities identified in the claim-level payment elements, in an amount not to exceed the MFP refund amount directed by the claim-level payment elements for all applicable claims. MFP refund amounts transmitted to dispensing entities may differ from the amount directed by the claim-level payment elements in situations such as adjustment by the application of credits.

- The MTF PM's transfer of the Primary Manufacturer's authorized MFP refund payment to the dispensing entity shall not in any way indicate or imply that CMS or its MTF Contractors have evaluated or determined that the amount paid by the Primary Manufacturer is

sufficient to make the MFP available to the dispensing entity or has otherwise evaluated or determined whether the transaction is consistent with applicable law.

- To transmit the payment elements to the MTF, the Primary Manufacturer must attest, to the best of its knowledge, that the information being sent through the payment elements is complete and accurate, and the payment elements were prepared in good faith and after reasonable efforts. This attestation will be included in the workflow for transmission of the payment elements within the MTF DM.

- The information contained in the payment elements is being provided in connection with the Primary Manufacturer's responsibility to ensure MFP is made accessible on MFP-eligible claims of selected drugs of the Primary Manufacturer in accordance with section 1193(a)(3) of the Social Security Act and will be relied upon by the MTF in transmitting MFP refund payments to dispensing entities.

Section 1: Manufacturer Claim-Level Payment Elements

Payment Element 1: MTF PM Facilitation Indicator

- The Primary Manufacturer will use this payment element to indicate, for each MFP refund payment, whether transmission of the MFP refund to the dispensing entity should be facilitated through the MTF PM.
- Primary Manufacturers who elected to participate in the MTF PM can choose to have their MFP refunds facilitated through the MTF PM (by selecting "Y") or not (by selecting "N") with each refund payment.
- Primary Manufacturers who have not elected to participate in the MTF PM cannot have their MFP refunds facilitated through the MTF PM and must select "N" for this field.
- In situations where the MFP was accessed via prospective sale, this payment element will contain "N".

Field	Response Format
MTF PM Indicator	Y/N

Payment Element 2: MFP Refund Transmission Date and Time

- The Primary Manufacturer will use this payment element to indicate when the MFP refund was transmitted.
- This payment element is only required from Primary Manufacturers when the MFP refund payment to a dispensing entity is made outside of the MTF PM.
- For MFP refunds paid via electronic payment, this payment element contains the date and time when electronic payment was transmitted to the dispensing entity. For MFP refunds paid via paper check, this payment element contains the date on which the paper check was mailed to the dispensing entity.
- The payment element should be omitted if the claim was prospectively purchased or a refund was not sent.

Field	Response Format
MFP Refund Transmission Date and Time	MM/DD/YYYY; hh:mm:ss

Payment Element 3: Method for Determining MFP Refund Amount

- The Primary Manufacturer will include a mandatory payment element, "Method for Determining MFP Refund Amount," to be populated with one of several pre-identified justification codes from Table 1 to indicate whether the MFP refund payment was at the Standard Default Refund Amount, a different amount, or the reason an MFP refund payment was not provided.
- The Primary Manufacturer must report the code that most accurately describes the method for determining the MFP Refund Amount consistent with applicable regulations, guidance, and technical instructions.
- Codes should be based on the final disposition of a refund.
- Primary Manufacturers should use Code 2 for refunds calculated using a methodology different than the Standard Default Refund Amount. Code 7 should be used when the refund amount transmitted was adjusted by a credit amount on manufacturer-maintained credit ledger.
- Codes and values presented in Table 1 below are preliminary and may be updated by CMS over time in technical instructions.

Field	Response Format
Method for Determining MFP Refund Amount	Numeric

Table 1

Code	Value
1	Standard Default Refund Amount Transmitted
2	Amount Other than Standard Default Refund Amount Transmitted
3	No Refund Transmitted – Prospective MFP Access
4	No Refund Transmitted – Section 1193(d)(1) Exception
5	No Refund Transmitted – Payment Transmission Attempted but Unsuccessful
6	No Refund Transmitted – Other
7	Refund Transmitted Consistent with Alternative Reconciliation

Payment Element 4: Quantity of Selected Drug

- The Primary Manufacturer will use this payment element to indicate the number of units of the selected drug included in the MFP refund paid. This data element should be completed even if the MFP refund amount is a zero-dollar amount.
- In cases where the payment elements represent a claim that was adjusted or reversed, the Primary Manufacturer will indicate the new number of units of the selected drug included in the adjusted MFP refund paid or reversed as a positive value.

- ~~Quantity should be reported in the same unit of measure used in the claim-level data elements received from the MTF.~~

~~Field~~	~~Response Format~~
~~Quantity of Selected Drug~~	~~Numeric~~

Payment Element ~~5~~4: Amount of Payment Transmitted as the MFP Refund

- The Primary Manufacturer will use this payment element to provide the amount of payment transmitted as the MFP refund. Monetary amounts must be reported in United States dollars (USD) and include two decimal places (i.e., dollars and cents).
- This payment element should be omitted (i.e., left blank) if the claim was prospectively purchased or a refund was not transmitted.
- In situations where MFP refund payments are facilitated by the MTF PM, this payment element will contain the amount to be transmitted as the MFP refund by the MTF PM, before the application of any applicable credits. This amount may be an initial MFP refund payment amount, or an adjusted amount if the claim is being re-processed following a previous submission.
- In situations where MFP refund payments are facilitated by the MTF PM, if reflecting an adjusted refund amount, this field should reflect the intended total refund amount for the claim (e.g., previously paid refund was $100 and intended refund is $80, this field should contain $80). The MTF will calculate credits based on previously paid refunds and update the ledger or calculate the difference between the previously paid refund and the updated refund amount and request this difference from the Primary Manufacturer's bank.
- In situations where MFP refund payments are not facilitated by the MTF PM, this payment element will contain the amount of MFP refund transmitted, before the application of any applicable credits.

> **Commented [JS2]:** Added expectation of situations where the MTF PM did NOT facilitate the payment.

Field	Response Format
Amount of Payment Transmitted as the MFP Refund	$

Payment Element ~~6~~5: ~~MFP Refund Adjustment~~Transaction Code

- The Primary Manufacturer will use this ~~payment~~claim-level data element, received from the MTF DM, to indicate whether the claim-level payment elements are sent in response to a set of claim-level data elements sent by the MTF DM, or are sent independent of claim-level data elements received from the MTF DM to adjust claim-level payment elements previously sent by the Primary Manufacturer.
- ~~if the refund payment adjusts a previously paid refund (i.e., the claim was included in a previous submission of payment elements and is being included again due to the manufacturer's determination that an adjustment to the previous MFP refund amount is needed). For this payment element, the Primary Manufacturer will provide one of the codes provided in Table 2.~~
- This ~~payment~~data element will utilize the Transaction Code field sent by the MTF DM. The Primary Manufacturer will replace the Transaction Code value sent by the MTF DM with a

Transaction Code that indicates the intent of the claim-level payment elements.be used to understand whether to match the refund payment to a previously paid refund payment and calculate a credit or debit.

- Codes and values will be defined by CMS in technical instructions.

Field	Response Format
MFP Refund AdjustmentTransaction Code	NumericY/N

Table 2

Code	Value
Yes	Indicates the MFP refund payment adjusts a previously paid refund to a new payment amount
No	Indicates the MFP refund payment is not adjusting a previously paid refund

Attestation Statement

The information included in the payment elements transmitted in this submission is, to the best of this Primary Manufacturer's knowledge, complete and accurate, and was prepared in good faith and after reasonable efforts. I understand the information contained in this submission is being provided to and will be relied upon by CMS for administering the Negotiation Program, including to support effectuation of the MFP, in accordance with sections 1193(a) and 1196(b) of the Social Security Act. The Primary Manufacturer agrees to transmit corrected payment elements should any error be identified within the submission. I also understand that any misrepresentations may give rise to liability, including under the False Claims Act, and may result in other enforcement action such as serving as the basis for civil monetary penalties and assessments.

[ ] Acknowledge and Agree