

Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

Style Definition: Unresolved Mention

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 for the selected drug 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 ~~will propose~~ has proposed in ~~future~~ 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.

This form is designed to collect the necessary information from Primary Manufacturers related to the MFP Effectuation Plan. The following questions collect information applicable to any mechanism a Primary Manufacturer chooses to effectuate the MFP. CMS understands that some information provided by a Primary Manufacturer may be proprietary. CMS reiterates that the MFP Effectuation Plans will not be shared publicly by the agency and a limited subset of the information will be provided to MTF DM participants, and possibly interested stakeholders via request, in the form of a redacted MFP Effectuation Plan. Specifically, CMS plans to make Section 1, Question 1; Section 2, in its entirety; and Section 3, in its entirety, available within the MTF DM, while Section 1, Question 2; and Sections 4 – 6, in their entirety, will be redacted and collected solely for CMS’ use to ensure effectuation of the MFP. CMS notes that Primary Manufacturers will respond to Section 1 in the MTF DM user interface during their enrollment process; thus, the response to Question 1 will be attached to sections 2 and 3 and made available to dispensing entities within the MTF DM when they enroll in the system.

General information about CMS’ work related to the IRA is available at <https://www.cms.gov/inflation-reduction-act-and-medicare>.

The relevant statute pertaining to this information collection request (ICR) can be found at this link:
<https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf>

The relevant guidance pertaining to this ICR can be found at this link:
<https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>

General Instructions

Overview

For each of its selected drug(s), the Primary Manufacturer must complete Sections 1 through 6, which are specifically:-

- 1)- Primary Manufacturer MFP Effectuation Additional Points of Contact Information
- 2)- Information Requested from All Primary Manufacturers

Each Primary Manufacturer must complete Sections 1 through 6 of this form (listed below) detailing its plan for effectuating the MFP for the Primary Manufacturer's selected drug(s). In the event a Primary Manufacturer holds more than one selected drug with agreed upon MFPs, this plan should cover all such selected drugs. If the Primary Manufacturer has an effectuation approach that is differentiated across selected drugs, the Primary Manufacturer should indicate such within the details of its Plan, noting which approach is attached to which drug where applicable.

- 1) Primary Manufacturer's Description of Participation in the MTF PM
- 2) Managing Relationships with Dispensing Entities
- 3) Information Requested of Primary Manufacturers Declining Use of the MTF PM
- 4) ~~Assisting Dispensing Entities with Material Cashflow Concerns~~ Primary Manufacturer's Process for Effectuating the MFP
- 5) Primary Manufacturer Acknowledgements Regarding MFP Availability
- 6) Certification

Technical assistance for Primary Manufacturers will be made available. For technical assistance related to the submission of information in the MTF DM, questions should be sent to XXX@xxx.xxx.

Questions about MTF DM user access should be sent to XXX@xxx.xxx.

Submission Method

Primary Manufacturers will submit the information for Sections 1 through 6 via the MTF DM, which can be accessed here: [SYSTEM URL]. Instructions for Primary Manufacturers to gain access to the MTF DM to submit data related to Sections 1 through 6 will be available prior to the deadline for submitting the MFP Effectuation Plan (i.e., September 1, 2025 for IPAY 2026, and September 1, 2026 for IPAY 2027). Primary Manufacturers will complete Section 1 electronically in the MTF DM interface and Sections 2 through 6 via a downloadable PDF document on which the Primary

Manufacturer can input their responses to relevant questions and upload into the MTF system upon completion.

Explanation

- For purposes of this ICR, all defined terms referenced in this ICR have their meaning set forth in the final guidance.
- Response formats are indicated within each element description in this ICR.

Section 1: MFP Effectuation Additional Points of Contact Information

If the **Primary Manufacturer** would like to name representatives in addition to those established during MTF-DM account creation, then it may provide additional contact information below. For example, these individuals may play a specific role in operationalizing the manufacturer's MFP Effectuation Plan but were not included previously as Negotiation or MTF Points of Contact, or MTF-DM system users during account creation. Using the format provided in Section 1-Q2, the manufacturer may add multiple additional points of contact. **Manufacturer's Description of Participation in the MTF PM**

Formatted: Font: Bold

Formatted: Centered

Formatted: Font: Bold

Responses to Question 1 of this section will be made available to dispensing entities and, possibly, other interested stakeholders with no redactions. Any responses to Question 2, or its subparts, will be redacted in their entirety.

Q1. Respond to the following regarding the use of the MTF PM.

Field	Response Format
The Primary Manufacturer will use the MTF PM to provide retrospective reimbursements to dispensing entities.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Selecting 'Yes' indicates that the Primary Manufacturer intends to use the MTF PM to pass through MFP refunds as part of its approach to MFP access for any of its MFP-eligible claims; selecting 'Yes' does not preclude the Primary Manufacturer from also engaging in alternative arrangements to process MFP refunds without the MTF PM as described in Q11 – Q15 of this Form.	If the response is "Yes", then the Primary Manufacturer will move to Question 2 and provide their financial information. If the response is "No", then the Primary Manufacturer will be reminded to describe their reimbursement mechanism in Section 3 of the downloadable PDF and is not required to provide any financial information. The manufacturer will proceed directly to Section 2.

Formatted Table

[Remainder of this page is intentionally blank.]

Q2. If the Primary Manufacturer responds “Yes” to Q1, provide the following financial information and account details to facilitate payment and applicable remittance advice consistent with the instructions set forth. Financial information and account details must be provided to facilitate payment. This information may also be necessary for making available an Electronic Remittance Advice (ERA) or remittance. This question will be for internal CMS use only and will not be made public.

Instructions

- Fill out the tables with the contact information for the financial institution that holds the funds that will be transmitted to dispensing entities in order to make the MFP available.
- The name entered for the financial institution must be the financial institution's legal business name.
- When providing the financial institution's address, do not include P.O. Boxes.
- Account number should include applicable leading zeros.

Q1. Election to Provide Additional Points of Contact

Field	Response Format
Q1- Manufacturer does not wish to establish any additional Points of Contact:	Check box. If “checked, then none of the fields below are available:

Q2- Enter Additional MFP Effectuation Point of Contact, if Applicable:

Ability to make multiple entries will be available in the submission form using the below format:

Q2A. Financial Institution Contact Information.

Field	Response Format
Name	Text
Title	Text
Financial Institution's Name	Text
Financial Institution Contact Person's Name	Text
Address	Text
Email Address	Text
Phone Number	Text
Point of Contact Role Description	Text

Formatted Table

Formatted: Font: Not Bold

Formatted Table

Formatted: Font: Bold

Section 2: Q2B. Bank Account and Federal Tax Identification Number Information.

Formatted: Ligatures: Standard + Contextual

Field	Response Format
Routing Number	Text
Bank Account Number	Text

Confirm Bank Account Number	<u>Text</u>
Registered Financial Account Type (Checking or Savings)	<u>Text</u>
Federal Tax Identification Number (TIN) (e.g., Employer Identification Number) (EIN)	<u>Text</u>

Q2C. Confirmation of Bank Account Information. To verify the banking information provided, please upload one of the following documents to your submission: either (1) a voided check for the account listed, which shows the account holder's name, bank account number, and routing number—ensure that the check is clearly marked as "VOID" across the front; or, (2) a letter from the bank, printed on official bank letterhead, that confirms the account holder's name, account number, and routing number—the letter must be signed by a representative of the bank and include their contact information for verification purposes.

**[DOCUMENT UPLOAD] Requested
from All**

Section 2: Managing Relationships with Dispensing Entities

Beginning in Section 2, these questions will be included in a downloadable, fillable PDF that is accessible on the CMS website during the enrollment process for Primary Manufacturers in the MTF DM. Primary Manufacturers must complete Sections 2 to 6 of their MFP Effectuation Plan by entering the required information in the fillable PDF and uploading the completed PDF to the MTF user interface as a means for submission.

Formatted: Left

Formatted: Font: Not Bold

Formatted: Font: Not Bold

Responses to questions in this section will be made available to dispensing entities and, possibly, other interested stakeholders with no redactions.

Q3. Respond to the following question related to establishing communications with dispensing entities.

Field	Response Format
<u>Describe the Primary Manufacturer's process for contacting, receiving, and responding to communications from dispensing entities regarding MFP effectuation. The response should describe any proactive outreach to dispensing entities related to the Primary Manufacturer's MFP Effectuation Plan and its related policies and procedures, plans for disseminating or publishing key information, and the approach the Primary Manufacturer intends to establish for intaking and responding to communications initiated by dispensing entities as the program continues.</u>	<u>Text field (10,000-character limit)</u>

The Primary Manufacturer will be provided a list of dispensing entities that have self-identified as having material cashflow concerns at the start of a price applicability period with respect to a selected drug as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window.

Q4. Respond to the following question regarding interaction with dispensing entities that have indicated they have material cashflow concerns.

Field	Response Format
<u>Q4A. Describe the Primary Manufacturer's process for mitigating material cashflow concerns for dispensing entities.</u>	<u>Text field (15,000-character limit)</u>
<u>Q4B. Describe any qualifying criteria for dispensing entities to participate in the Primary Manufacturer's process to assist dispensing entities with material cashflow concerns, including but not limited to the dispensing entities that have self-identified as having such concerns.</u>	<u>Text field (15,000-character limit)</u>

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

This section is to be completed *only* for selected drugs for which the Primary Manufacturer has fully declined use of the MTF PM. If the Primary Manufacturer has elected to use the MTF PM for the selected drug(s) for which this form is being completed, or is using the MTF PM to pass through payments related to this selected drug(s) to some dispensing entities while using alternative arrangements that do not rely on the MTF PM to pay others, the Primary Manufacturer may proceed to Section 4 without completing this section. Primary Manufacturers are encouraged to be as specific as possible when describing their MFP Effectuation Plans, with policies and procedures to address the needs of a diverse range of dispensing entities and dispensing entity types.

Responses contained in this section will be made available to dispensing entities and, possibly, other interested stakeholders with no redactions.

Q5. Describe the Primary Manufacturer's processes for effectuating MFP with both an electronic and paper check method without using the MTF PM to pass through any MFP refunds. As discussed in section 90.2.1 of the final guidance, if a Primary Manufacturer declines to use the MTF PM, then it is required to provide, at a minimum, a functionally equivalent electronic reimbursement mechanism to that offered by the MTF PM and will be responsible for ensuring that paper checks are provided as a reimbursement mechanism for dispensing entities that do not wish to be reimbursed electronically. Further, the Primary Manufacturer will maintain responsibility for transmitting claims-level payment elements to CMS for payments processed outside the MTF DM (please reference Table 3 and Table 5 in sections 40.4.3.1, and 40.4.4.2 of the final guidance, describing required payment elements). Address each of the following questions to describe the Primary Manufacturer's process for contacting, reimbursing, and responding to dispensing entities to effectuate the MFP.

<u>Field</u>	<u>Response Format</u>
<u>Q5A. To the extent that any specific approaches are not included in the Primary Manufacturer's response to Q3, provide additional details describing the Primary Manufacturer's process for contacting and working with dispensing entities to integrate and assist them in receiving MFP refunds through the manufacturer's identified methods.</u>	<u>Text field (15,000-character limit)</u>
<u>Q5B. Describe the Primary Manufacturer's process for effectuating MFP electronically to each applicable dispensing entity within the 14-day prompt MFP payment window.</u>	<u>Text field (15,000-character limit)</u>
<u>Q5C. Describe the Primary Manufacturer's process for effectuating MFP via paper check to each applicable dispensing entity within the 14-day prompt MFP payment window.</u>	<u>Text field (15,000-character limit)</u>
<u>Q5D. Describe any additional mechanisms the Primary Manufacturer intends to implement to effectuate the MFP to each dispensing entity within the 14-day prompt MFP payment window, if applicable.</u>	<u>Text field (15,000-character limit)</u>
<u>Q5E. Describe the Primary Manufacturer's process for responding to dispensing entities if they express concern that MFP has not been made available to them.</u>	<u>Text field (15,000-character limit)</u>

<u>Q5F. Describe the Primary Manufacturer's process for ensuring the 14-day prompt payment window is met for both its electronic and paper options.</u>	<u>Text field (15,000-character limit)</u>
<u>Q5G. Describe the Primary Manufacturer's process for generating and timely sending a remittance either electronically or by paper using a comprehensive, GAAP-compliant system.</u>	<u>Text field (15,000-character limit)</u>
<u>Q5H. Describe the Primary Manufacturer's approach for completing internal auditing to ensure all transactions effectuate MFP.</u>	<u>Text field (15,000-character limit)</u>
<u>Q5I. Describe the Primary Manufacturer's method of reconciling over- or under-payments arising from situations such as adjusted or updated claim information (e.g., 340B, reversals, revisions, etc.) using a comprehensive, GAAP-compliant system.</u>	<u>Text field (15,000-character limit)</u>
<u>Q5J. The Primary Manufacturer confirms that its mechanism for MFP reimbursement will use a GAAP-compliant system that can be audited.</u>	<input type="checkbox"/> <u>Acknowledge</u>
<u>Q5K. The Primary Manufacturer confirms that it will submit claim-level payment elements to the MTF DM in accordance with the final guidance, including the specific payment elements discussed in sections 40.4.3 and 40.4.4, as required for purposes of administering the Negotiation Program consistent with section 1193(a)(5) of the Act</u>	<input type="checkbox"/> <u>Acknowledge</u>

Section 4: MFP Effectuation

The following questions collect information that is applicable to any mechanism a Primary Manufacturer chooses to use to effectuate MFP. These questions relate to the Primary Manufacturer's responsibilities set forth in ~~sections~~section 40.4 (and its associated subsections) and section 90.2.1 of CMS' final guidance.

Any responses to the questions in this section will be for CMS use only and will not be made public.

~~Q6Q3. Respond to the following question related to establishing communications with dispensing entities.~~

Field	Response Format
Describe the Primary Manufacturer's process for contacting, receiving, and responding to communications from dispensing entities regarding MFP effectuation. The response should indicate the extent to which the Primary Manufacturer's approach includes any proactive outreach to dispensing entities related to the Primary Manufacturer's MFP Effectuation Plan and its related policies and procedures, plans for disseminating or publishing key information, and the approach the Primary Manufacturer intends to establish for intaking and responding to communications initiated by dispensing entities.	Text field (10,000-character limit)

~~Q4.~~ CMS requires Primary Manufacturers to provide details on their ~~process~~processes for assessing the claims received ~~by the Primary Manufacturer~~ from the MTF DM for eligibility for the exception in section 1193(d)(1) of the Act, as described in section 40.4.5 of the final guidance.

Field	Response Format
Describe the Primary Manufacturer's process for <u>effectuating</u> nonduplication of claims that are 340B eligible and not subject to MFP availability. The response should include, at a minimum, descriptions of the following: <ul style="list-style-type: none">Manufacturer's valid and reliable process for identifying <u>claims that are 340B eligible</u> claims <u>and the 340B ceiling is lower than the MFP.</u>Process for effectuating the MFP for claims the Primary Manufacturer has not <u>definitively</u> <u>reasonably</u> determined to be 340B eligible.Approach to collection, review, and storage of documentation to support 340B nonduplication.Approach to monitoring the Primary Manufacturer's 340B nonduplication process over time to support reconciling <u>any duplicated discounts</u> as new data becomes available.Approach to using the MTF credit/debit ledger system for reconciliation of any 340B duplicate discounts (note: applicable only for claims for which MFP refund is made using the MTF PM).Approach for reconciling any 340B duplicate discounts for claims that were not processed through the MTF PM (if applicable).	Text field (15,000-character limit)

Q5Q7. As described in the final guidance, Primary Manufacturers are required to transmit their claim-level payment elements within 14 days of receiving claim-level data elements from the MTF DM. Describe the Primary Manufacturer's planned frequency of submission of the report of payment-related data below.

Field	Response Format
Describe the frequency that the Primary Manufacturer plans to transmit claim-level payment elements to the MTF DM (e.g., daily, weekly, etc.), why the Primary Manufacturer intends to adopt that frequency, and, if applicable, how any batched or consolidated reporting from the Primary Manufacturer will accomplish the data transmission to the MTF DM within each claim's 14-day prompt MFP payment window.	Text field (10,000-character limit)

Q6Q8. As described in the final guidance, the Primary Manufacturer is expected to include in its MFP Effectuation Plan ~~for making the MFP available~~ whether it will use the dispensing entity's actual acquisition cost or a reasonable proxy for such a cost, such as the Standard Default Refund Amount (SDRA) using wholesale acquisition cost (WAC)-, when providing retrospective reimbursements. Describe the Primary Manufacturer's general plan for calculating the MFP refund amount: if using a retrospective reimbursement model. If the Primary Manufacturer does not intend to use retrospective reimbursements, then it should select option 5 and provide its detailed MFP Effectuation Plan in response to Question 5

Field	Response Format
<p><u>1.</u> The Primary Manufacturer generally<u>primarily</u> 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.</p> <p>OR</p> <p><u>2.</u> The Primary Manufacturer generally plans to use<u>contact dispensing entities to obtain their</u> actual acquisition cost to calculate the MFP refund.</p> <p>OR</p> <p><u>3.</u> 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.</p> <p>OR</p> <p><u>4.</u> 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.</p>	<p>Check box. Select the option that reflects the Primary Manufacturer's plan.</p>

Formatted: List Paragraph, Numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.25"

Formatted: List Paragraph, Numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.25"

Formatted: List Paragraph, Numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.25"

OR

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

Formatted: List Paragraph, Numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0" + Indent at: 0.25"

Q7Q9. Respond to the following question to provide additional details on the response to Question 8.

Field	Response Format
Describe the Primary Manufacturer's methodology for determining the amounts it will reimburse dispensing entities when the Primary Manufacturer is not calculating an MFP refund using the Standard Default Refund Amount:SDRA . Include a description of the documentation the manufacturer intends to retain to support any MFP refund calculations that do not use the Standard Default Refund Amount:SDRA .	Text field (15,000-character limit)

Q8

Q10. Describe the Primary Manufacturer's procedures for collecting and maintaining documentation related to all aspects of MFP effectuation.

Field	Response Format
Describe your policies and procedures for collecting, maintaining, and producing documentation related to MFP effectuation that may be required during the course of CMS' monitoring and oversight activities: <u>as described in final guidance</u> . The response should include, at a minimum, descriptions of the types of supporting documentation the Primary Manufacturer anticipates maintaining to support use of the justification codes provided in Table 5 of the final guidance or in any subsequent technical instruction provided from CMS, procedures for maintaining documentation in an organized manner such that documents can be produced and shared with CMS upon request, and the process the Primary Manufacturer will use to respond to CMS document requests and provide the requested documents in a timely manner.	Text field (15,000-character limit)

Q9–Q13Q11 – Q15 The questions below collect necessary information to document alternative purchasing or reimbursement arrangements, such as prospective purchasing, that a Primary Manufacturer and dispensing entity may have entered into outside of the MTF PM. Even if the Primary Manufacturer has opted to use the MTF PM to facilitate making MFP refunds to dispensing entities, Primary Manufacturers and dispensing entities may enter into alternative arrangements to effectuate the MFP. This information is necessary to provide oversight and monitoring of alternative arrangements and to avoid duplicate reimbursement claims in the MTF PM. CMS recognizes the responses captured in this section are subject to change over time. In accordance with the requirements outlined in section 90.2.1 of the final guidance, Primary Manufacturers must timely

update their MFP Effectuation Plan should there be any changes in their alternative arrangements for MFP effectuation.

Field	Response Format
Q9 Q11. Does the Primary Manufacturer have in place, or expect with a high degree of likelihood that it will establish, alternative arrangements for providing access to the MFP outside of the MTF PM? If no, skip to Q13.	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>Q10Q12. If the Primary Manufacturer answered 'Yes' to Question 911, describe the nature of these alternative arrangements, including any planned arrangements that may not already be established. Include information such as who the arrangements are, or are planned to be, with (i.e., NPIs of applicable dispensers), when the arrangements take effect, and the duration of the arrangements. If the Primary Manufacturer has multiple such arrangements planned or in place, detail each arrangement separately, <u>including indicating the dispensing entities engaged in each arrangement.</u></p> <p>If the Primary Manufacturer enters<u>has entered</u> into, or expects with a high degree of likelihood that it will enter into, any arrangements with one or more third-party contractors to make MFP refund payments, please provide information regarding such arrangement(s), including whether the Primary Manufacturer has contracts in place for such arrangement(s), a description of the services performed under such arrangement(s), the contractor name(s), the term of the arrangement (s), and how the arrangement (s) with the contractor (s) would meet the requirements of the final guidance.</p> <p>If the Primary Manufacture has, or plans to have, alternative arrangements with a large number of dispensing entities, the manufacturer may upload a list of applicable NPIs to facilitate easier information submission. If multiple arrangements are in place, the uploaded file must clearly delineate which NPIs align to which arrangement.</p>	<p>Text field [No character limit]</p> <p>AND</p> <p>File Upload for Applicable NPI List, if needed.</p>
<p>Q11Q13. If the Primary Manufacturer answered 'Yes' to question 911, does the Primary Manufacturer have contracts for these arrangements in place?</p> <p>NOTE: CMS may request copies of these contracts, including, without limitation, in response to complaints from dispensers regarding lack of MFP availability, <u>or as part of routine audits,</u> or investigations related to MFP availability. <u>In addition, if the NPIs of affected dispensing entities are not contained within the contracts, then CMS may request documentation to support any instances of a Primary Manufacturer declining to pay a claim for a specific NPI based upon an alternative arrangement.</u></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Formatted Table

Q12Q14. If the Primary Manufacturer answered ‘ <u>Yes</u> ’ to <u>question 11</u> but ‘No’ to Question 11 <u>13</u> , please explain whether contracts will be put in place and indicate whether they will be in place prior to the start of the applicable initial price applicability year (i.e., Jan. 1, 2026 or Jan. 1, 2027).	Text field
Q13Q15. Please note the Primary Manufacturer must provide notice of any update to its alternative arrangements <u>(including if the Primary Manufacturer has selected “No” to Question 11 in this submission)</u> to CMS within 90 days of the arrangement. Such notice must include any updates to the NPI(s) of the dispensing entity(ies) affected by the change and the effective date(s) of the update. As it pertains to new arrangements, such notice must include the details collected in Q10 -Q12 – <u>Q14</u> for the new arrangement. Primary Manufacturer must check [Acknowledged] to advance to next question.	Checkbox for “Acknowledged” to advance to next question.

~~Q14~~ – ~~Q18~~

Q16 – Q20 The questions below collect information regarding MFP effectuation for a selected drug with Secondary Manufacturers. This information is necessary to provide oversight and monitoring to ensure access to the MFP is provided consistent with requirements of section 1193 of the Act. Describe policies and procedures for interacting with Secondary Manufacturers below. CMS reiterates that CMS will not enroll Secondary Manufacturers into the MTF DM. However, in their use of the MTF DM, a Primary Manufacturer may assign a user role to a representative from a Secondary Manufacture to establish access to the MTF DM for Secondary Manufacturers should the Primary Manufacturer deem such access necessary. In these cases, a Secondary Manufacturer can act as an authorized user to participate in the Primary Manufacturer’s MTF DM account.

Field	Response Format
Q14Q16. There are no Secondary Manufacturers with respect to the selected drug covered by this MFP Effectuation Plan.	Checkbox. If selected, Questions 15 – 18 <u>17 – 20</u> do not need to be addressed.
Q15Q17. Describe the Primary Manufacturer’s approach to engaging with any Secondary Manufacturers in connection with the Primary Manufacturer’s obligation to effectuate the MFP. The response should include, at a minimum, a description of the operational needs and processes established or expected to be established for complete and timely MFP effectuation, and a description of how the Primary Manufacturer will monitor the activities of the Secondary Manufacturer and ensure the Secondary Manufacturer’s activities in coordination with the Primary Manufacturer are sufficient to satisfy the requirement to provide access to the MFP.	Text field (15,000-character limit)

Q16Q18. Describe how secure data transmission will occur between the Primary Manufacturer and Secondary Manufacturers, including descriptions of the Primary Manufacturer's policies and procedures for complete and timely data transmissions, the types of data included in such transmissions, and policies related to ensuring data integrity and security during such transmissions.	Text field (15,000-character limit)
Q17Q19. Describe how the Secondary Manufacturer(s) will be incorporated into the Primary Manufacturer's review of incoming claims-level data elements, including the timeframe for contacting the Secondary Manufacturer after receiving claims data (if necessary for <u>the</u> MFP to be made available).	Text field (15,000-character limit)
Q18Q20. Describe any document retention requirements the Primary Manufacturer is placing on any Secondary Manufacturers to support MFP effectuation. Describe the Primary Manufacturer's approach to retention of any documentation maintained by the Secondary Manufacturer regarding MFP effectuation.	Text field (15,000-character limit)

~~Q19. Respond to the following regarding the use of the MTF PM.~~

Field	Response Format
<p>The Primary Manufacturer will use the MTF PM to provide retrospective reimbursements to dispensing entities.</p> <p>Selecting 'Yes' indicates that the Primary Manufacturer intends to use the MTF PM to pass through MFP refunds as part of its approach to MFP access for any of its MFP-eligible claims; selecting 'Yes' does not preclude the Primary Manufacturer from also engaging in alternative arrangements to process MFP refunds without the MTF PM as described in Q9—Q13 of this Form.</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>If the response is "Yes", then the Primary Manufacturer will skip Section 3 and proceed to Section 4.</p>

Formatted Table

~~Q20. If the Primary Manufacturer responds "Yes" to Q19, provide the following financial information and account details to facilitate payment and applicable remittance advice consistent with the instructions set forth. Financial information and account details must be provided to facilitate payment. This information may also be necessary for making available an Electronic Remittance Advice (ERA) or remittance:~~

Instructions

- ~~Fill out the tables with the contact information for the financial institution that holds the funds that will be transmitted in order to make the MFP available to dispensing entities.~~
- ~~The name entered for the financial institution must be the financial institution's legal business name.~~
- ~~When providing the financial institution's address, do not include P.O. boxes.~~
- ~~The account must bear the legal business name of the financial institution.~~
- ~~Account number should include applicable leading zeros.~~

Q20A. Financial Institution Contact Information:

Field	Response Format
Financial Institution's Name	Text
Contact Person's Name	Text
Address	Text
Email Address	Text
Phone Number	Text

Q20B. Bank Account Information:

Field	Response Format
Routing Number	Text
Depositor Account Number	Text
Registered Financial Account Type	Text

Q20C. Confirmation of Bank Account Information. To verify the banking information provided, please upload one of the following documents to your submission: either (1) a voided check for the account listed, which shows the account holder's name, bank account number, and routing number—ensure that the check is clearly marked as “VOID” across the front; or, (2) a letter from the bank, printed on official bank letterhead, that confirms the account holder's name, account number, and routing number—the letter must be signed by a representative of the bank and include their contact information for verification purposes.

[DOCUMENT UPLOAD]

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

Q21. Describe the Primary Manufacturer's processes for effectuating MFP with both an electronic and paper check method without using the MTF PM to pass through any MFP refunds. As discussed in section 90.2.1 of the final guidance, if a Primary Manufacturer declines to use the MTF PM, then it is required to provide, at a minimum, a functionally equivalent electronic reimbursement mechanism to that offered by the MTF PM and will be responsible for ensuring that paper checks are provided as a reimbursement mechanism for dispensing entities that do not wish to be reimbursed electronically. Please reference Table 3 and Table 5 in sections 40.4.3.1, and 40.4.4.2 of the final guidance, describing required payment elements which will be used for monitoring and oversight of refunds and reimbursements. Address each of the following questions to describe the Primary Manufacturer's process for contacting, reimbursing, and responding to dispensing entities to effectuate the MFP.

Field	Response Format
Q21A. To the extent that any specific approaches are not included in the Primary Manufacturer's response to Q3, provide additional details describing the Primary Manufacturer's process for contacting and working with dispensing entities to integrate and assist them in receiving MFP refunds through the manufacturer's identified methods:	Text field (15,000-character limit)

Q21B. Describe the Primary Manufacturer's process for effectuating MFP electronically to each applicable dispensing entity within the 14-day prompt MFP payment window.	Text field (15,000-character limit)
Q21C. Describe the Primary Manufacturer's process for effectuating MFP via paper check to each applicable dispensing entity within the 14-day prompt MFP payment window.	Text field (15,000-character limit)
Q21D. Describe any additional mechanisms the Primary Manufacturer intends to implement to effectuate the MFP to each dispensing entity within the 14-day prompt MFP payment window, if applicable.	Text field (15,000-character limit)
Q21E. Describe the Primary Manufacturer's process for responding if dispensing entities express concern that MFP has not been made available to them.	Text field (15,000-character limit)
Q21F. Describe the Primary Manufacturer's process for ensuring the 14-day prompt payment window is met for both its electronic and paper options.	Text field (15,000-character limit)
Q21G. Describe the Primary Manufacturer's process for generating and timely sending a remittance either electronically or by paper using a comprehensive, GAAP-compliant system.	Text field (15,000-character limit)
Q21H. Describe the Primary Manufacturer's approach for completing internal auditing to ensure all transactions effectuate MFP in compliance with the final guidance and Negotiation Program requirements.	Text field (15,000-character limit)
Q21I. Describe the Primary Manufacturer's method of reconciling over- or under-payments arising from situations such as adjusted or updated claim information (e.g., 340B, reversals, revisions, etc.) using a comprehensive, GAAP-compliant system.	Text field (15,000-character limit)
Q21J. The Primary Manufacturer confirms that its mechanism for MFP reimbursement will use a CAAP-compliant system that can be audited.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Q21K. The Primary Manufacturer confirms that it will submit verification of reimbursement to the MTF via the report of claim-level payment elements discussed in sections 40.4.3 and 40.4.4 of the final guidance, as required for purposes of administering and monitoring compliance with the Negotiation Program consistent with section 1193(a)(5) of the Act	<input type="checkbox"/> Yes <input type="checkbox"/> No

Section 4: Assisting Dispensing Entities with Material Cashflow Concerns

Q22. Respond to the following question regarding interaction with dispensing entities that have indicated they have material cashflow concerns:

Field	Response Format
Q22A. The Primary Manufacturer acknowledges that it has, or will be provided, a list of dispensing entities that have self-identified as having material cashflow concerns at the start of a price applicability period with respect to a selected drug as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window.	Checkbox for "Acknowledged" to advance to B & C.
Q22B. Describe the Primary Manufacturer's process for mitigating such material cashflow concerns for dispensing entities.	Text field (15,000-character limit)
Q22C. Describe the qualifying criteria for dispensing entities to participate in the Primary Manufacturer's process to assist dispensing entities with	Text field (15,000-character limit)

such material cashflow concerns, including but not limited to the
dispensing entities that have self-identified.

Formatted: Font: Not Bold

Section 5: Primary Manufacturer Acknowledgements Regarding MFP Availability

This Section collects necessary information related to the Primary Manufacturer's responsibility to ensure MFP availability as well as to obtain official acknowledgment of key requirements of the statute governing the program.

Responses in this section will be for CMS use only and will not be made public.

Field	Response Format
Q23Q21. The Primary Manufacturer understands that it must comply with all applicable requirements for the Negotiation Program set forth in statute and in all applicable guidance and regulations. Those requirements include but are not limited to, providing access to the MFP to dispensing entities, receiving claim-level data directly from the MTF DM for all NDCs of the selected drug, and abiding by all relevant privacy laws, regulations, and agreements when handling both the claim-level data and dispensing entities bank account information.	Checkbox for "Acknowledged" to advance to next question.
Q24-Q22. The Primary Manufacturer understands that it is solely responsible for making MFP available under section 1193(a)(3). The Primary Manufacturer is not absolved of this obligation due to any actions or omissions by a Secondary Manufacturer that result in the failure to effectuate the MFP; the Primary Manufacturer is responsible for ensuring any Secondary Manufacturer complies with any applicable requirements set forth between the parties relating to MFP effectuation.	Checkbox for "Acknowledged" to advance to next question.
Q25Q23. Per section 90.2.1 of the final guidance, the Primary Manufacturer acknowledges that any future changes to this MFP Effectuation Plan must be submitted to CMS via an updated MFP Effectuation Plan <u>as soon as practicable</u> , signed by the Authorized Signatory, with a summary of changes listed as an attachment to its previous <u>newly-submitted</u> MFP Effectuation Plan. Additionally, upon request, the Primary Manufacturer must submit copies of any new agreements that memorialize any substantive changes to alternative arrangements with dispensing entities within 90 days of the change.	Checkbox for "Acknowledged" to advance to next question.
Q26Q24. If <u>the</u> Primary Manufacturer is submitting an updated MFP Effectuation Plan consistent with Question 25 <u>23</u> , then upload the summary of changes and, upon request, new copies of agreements here.	Provide ability to upload documents.

Formatted: Font: Not Bold

Formatted: Font: 11 pt

Section 6: Certification

This Section collects necessary information to confirm the accuracy and completeness of the Primary Manufacturer's submission. ~~This information is necessary to execute a legally binding submission.~~

~~Q27~~ Responses in this section will not be made public.

Q25. Signature of ~~GEO/Authorized~~ Representative Legally Authorized to Bind the Primary Manufacturer

Field	Response Format
I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission will be used by CMS for administering the Negotiation Program, including to support MFP effectuation through the MTF-DM and MTF-PM, and to inform CMS' monitoring and oversight efforts as described in section 90.2.1 of the final guidance. , in accordance with sections 1193(a) and 1196(b) of the Social Security Act.	E-signature capability with system time stamp to record date.