

Supporting Statement – Part A

Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) **(CMS-10912, OMB 0938-NEW)**

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.

The purpose of this information collection request (ICR) is for CMS to collect information from manufacturers of drugs covered under Part D selected for negotiation under the Inflation Reduction Act for the initial price applicability years 2026 and 2027 and the dispensing entities that dispense the selected drugs to MFP-eligible individuals. To facilitate the effectuation of the MFP, CMS will engage a Medicare Transaction Facilitator (MTF). The MTF system will be composed 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 pharmacy agreements provisions requiring dispensing entities to be enrolled in the MTF DM for purposes of data exchange.¹ As such, for the purposes of this ICR, CMS assumes full participation in the MTF DM by affected Primary Manufacturers and dispensing entities. Meanwhile, participation in the MTF PM, for use in passing through payment from the Primary Manufacturer to dispensing entities, will be optional for Primary Manufacturers; as a result, dispensing entities may receive fund transfers from the MTF PM, or via an alternative process established by a Primary Manufacturer. 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”),² CMS will engage the MTF DM to facilitate the exchange of certain claim-level data elements and payment

¹ <https://www.federalregister.gov/documents/2024/12/10/2024-27939/medicare-and-medicaid-programs-contractyear-2026-policy-and-technical-changes-to-the-medicare>

² <https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-andmanufacturer-effectuation-mfp-2026-2027.pdf>

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. Both Primary Manufacturers and dispensing entities will need to provide certain information at the onset of their enrollment in the MTF DM system to facilitate effectuation of the MFP via refunds from Primary Manufacturers. Dispensing entities, through their enrollment in the MTF DM, will also receive access to view the status of MFP refund payments where the Primary Manufacturer chooses to pass payment through the MTF PM, and to access the complaint and dispute system.

This ICR includes the following forms:

- Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form (Appendix A)
- Drug Price Negotiation Program MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form (Appendix B)
- Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form (Appendix C)
- Drug Price Negotiation Program Complaint and Dispute Intake Form (Appendix D)

To fulfill the statutory requirements for information collection and program burden, CMS is requesting OMB approval for this new collection that focuses on information that Primary Manufacturers and dispensing entities must submit to CMS to enroll in the MTF DM, for Primary Manufacturers to participate in the voluntary MTF PM, and for both MTF and non-MTF users to submit complaints and disputes.

All defined terms referenced in this collection have their meaning set forth in the final guidance.

Background

Section 1193(a) of the Act requires that the Primary Manufacturer provide access to the MFP for the selected drug to pharmacies, mail order services, and other dispensing entities with respect to MFP-eligible individuals who are dispensed such drugs. As described in section 40.4 of the final guidance, the Primary Manufacturer may make the MFP available by: (1) using retrospective reimbursement to issue refunds to dispensing entities as required to ensure the MFP is made available to dispensing entities; (2) providing access to the MFP through prospective sale of selected drugs at prices no greater than the MFP; or (3) using some combination of these two approaches. CMS will engage the MTF to facilitate the exchange of certain claim-level data elements and payment elements for selected drugs to support effectuation of the MFP.

The MTF will consist of two key functionalities: 1) the MTF DM and 2) the MTF PM. Participation in the MTF PM is voluntary for Primary Manufacturers and no information will be collected by the MTF PM; the MTF PM is structured exclusively as a pass through mechanism to assist affected parties in the transfer of Primary Manufacturer funds.³ In accordance with

³ The MTF DM will share information with the MTF PM for the purposes of facilitating MFP refund payments from Primary Manufacturers participating in the MTF PM to dispensing entities.

sections 1193(a)(5) and 1196 of the Act, for the purposes of administering and monitoring compliance with the Negotiation Program, Primary Manufacturer participation in the MTF DM is mandatory. Because the Primary Manufacturer's participation in the MTF DM is mandatory and Primary Manufacturers with an active Medicare Drug Price Negotiation Program Agreement ("Agreement") are already engaged in the Negotiation Program, CMS will leverage existing information to establish Primary Manufacturer access to the MTF DM platform. The MTF DM will establish accounts for each Primary Manufacturer that is participating in the Negotiation Program and will provide information to each participating Primary Manufacturer to facilitate access to the MTF DM platform.

As described in section 40.4.2 of final guidance, the MTF DM is intended to accomplish the following tasks in the administration of the Negotiation Program: (1) to support verification that the selected drug was dispensed to an MFP-eligible individual and to furnish the Primary Manufacturer with certain claim-level data elements confirming that a selected drug was dispensed to an MFP-eligible individual and identifying which dispensing entity dispensed the selected drug to the MFP-eligible individual, (2) to initiate the 14-day prompt MFP payment window for transmitting the MFP refund for each claim for a selected drug, where applicable, (3) to collect claim-level payment elements for each claim for a selected drug from Primary Manufacturers indicating whether a refund is being paid and the amount of the refund being paid to make the MFP available, and (4) make available an Electronic Remittance Advice that uses the X12 835 standard adopted under HIPAA (ERA) for electronic payments or remittance for payment made by paper check to dispensing entities for payments the Primary Manufacturer passes through the MTF PM. The MTF DM will also include a centralized intake system for receiving complaints and disputes from Primary Manufacturers and dispensing entities, as well as a portal for non-MTF users. As described in section 40.4.3 of final guidance, Primary Manufacturer participation in the MTF PM is voluntary. The purpose of the MTF PM is to facilitate connecting the Primary Manufacturer to the dispensing entity by passing through payment of an MFP retrospective refund on MFP-eligible claims of selected drugs from the Primary Manufacturer to the dispensing entity in accordance with section 1193(a)(3) of the Act.

Consistent with section 40.4.2.2 of the final guidance, 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. CMS has proposed that, under such a requirement, dispensing entities would be required to be enrolled with the MTF DM. During enrollment, dispensing entities must furnish information necessary for the completion of an ERA for electronic transfer of funds or remittance for paper checks, as well as other information required by CMS to conduct administration and oversight of the Negotiation Program; the complete set of enrollment data elements are included in the Form in Appendix A.

As described in more detail in section 90.2.1 of final guidance, CMS requires that a Primary Manufacturer submit its plan for making the MFP available, including its process for nonduplication of 340B eligible claims (pursuant to section 1193(d) of the Act and section 40.4.5 of the final guidance) for the selected drug, in writing to CMS at least four months before the start of the first initial price applicability year for the selected drug. This requirement is in

accordance with sections 1196(a)(3)(A) and 1196(b) of the Act, which require in part that the Secretary establish procedures to carry out the Negotiation Program with respect to MFP-eligible individuals and monitor compliance with the terms of the Agreement. Similarly, as described in section 90.2.2 of final guidance, CMS will establish a centralized intake system as part of the MTF DM for receiving complaints and disputes from Primary Manufacturers, dispensing entities, and other interested parties related to access to the MFP with respect to MFP-eligible individuals and the pharmacies, mail order services, and other dispensing entities that provide selected drugs to MFP-eligible individuals.

The following sections of the final guidance provide detailed information and background on the data being collected in each form:

- Section 40.4.1: Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount
- Section 40.4.2: Medicare Transaction Facilitator Data Facilitation
- Section 40.4.3: MTF Payment Facilitation
- Section 40.4.4: MFP Refund Payments When Primary Manufacturer Makes Payment Outside of the MTF PM
- Section 40.4.5: Nonduplication with 340B Ceiling Price
- Section 90.2.1: Manufacturer Plans for Effectuating MFP
- Section 90.2.2: Negotiation Program Complaints and Disputes

Under section 90.2.1 of the final guidance, a Primary Manufacturer must retain for at least 10 years from the date of sale, any records relating to sales of the selected drug to wholesalers and entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensing entities. CMS may request such records in the course of investigating MFP availability or during routine program monitoring and oversight on a case-by-case basis. The record retention requirements for Primary Manufacturers include, but are not limited to, the examples in “Table 5: Examples of Justification Codes and Values for the ‘Method for Determining MFP Refund Amount’ Claim-Level Payment Element for Primary Manufacturers” in section 40.4.3.1 of the final guidance. Under section 90.2.2, in connection with complaints and disputes, the disputing party must submit supporting documentation as a part of their submission.

A. Justification

1. Need and Legal Basis

In accordance with sections 1193(a)(5) and 1196 of the Act, for the purposes of administering and monitoring compliance with the Negotiation Program, Primary Manufacturer participation in the MTF DM is mandatory. Mandatory participation for Primary Manufacturers in the MTF DM is necessary to administer the Negotiation Program and promote compliance consistent with the Primary Manufacturer’s responsibility in accordance with section 1193(a) of the Act to provide access to the MFP for the selected drug to the dispensing entity. In accordance with sections 1196(a)(3)(A) and 1196(b) of the Act, which require in part that the Secretary establish procedures to carry out the Negotiation Program with respect to MFP-eligible individuals and

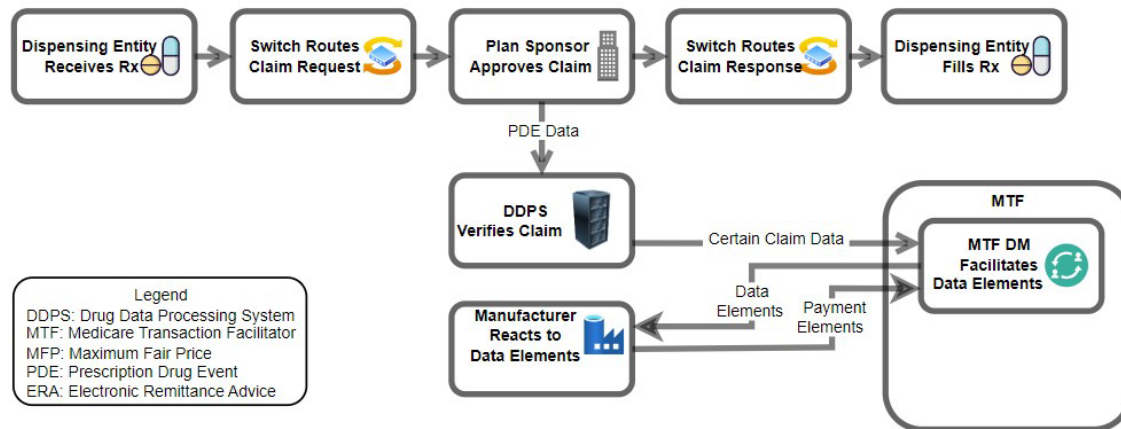
monitor compliance with the terms of the Agreement, CMS is establishing the MTF DM as a centralized system for exchanging claim-level data elements related to access to the MFP with respect to MFP-eligible individuals and the pharmacies, mail order services, and other dispensing entities that provide selected drugs to MFP-eligible individuals. Further, the MTF DM will collect and maintain each Primary Manufacturers' MFP Effectuation Plan as required by section 90.2.1 of the final guidance and consistent with the Primary Manufacturer's responsibility in accordance with section 1193(a) of the Act to provide access to the MFP for the selected drug to the dispensing entity. The MFP Effectuation Plans will be an important component of CMS' administration of the Negotiation Program and enhance the ability for the agency to conduct robust monitoring and oversight of MFP availability.

Consistent with section 40.4.2.2 of the final guidance, 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 40.4.2.2 of the final guidance, dispensing entity enrollment in the MTF DM is needed for necessary operations related to administration of the Negotiation Program and the Part D program, including creating and making available ERAs or remittances, maintaining access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are covered Part D drugs, and ensuring accurate Part D claims information and payment. The MTF will provide dispensing entities with the ERA or remittance necessary to reconcile MFP refund payments when a Primary Manufacturer utilizes the MTF PM. These files are required to close out any accounts receivable for each claim for which a Primary Manufacturer owes an MFP refund. Dispensing entity enrollment in the MTF DM is also important to CMS fulfilling its obligation to provide program administration and oversight. CMS intends for dispensing entities to have access to real-time information about the status of the MFP refunds they are owed and to allow access to the Negotiation Program's complaint and dispute intake system to report any issues accessing the MFP.

2. Information Users

Under the authority of sections 1193 and 1196 of the Act, CMS is authorized to collect data and information required for negotiation, as well as any information necessary for administration and oversight of the program. The information collected by CMS will be used to operate the MTF which is a key facet in administering the Negotiation Program and facilitating MFP effectuation; the MTF will also play a key role in CMS' oversight efforts as a central repository for monitoring access to the MFP and processing complaints and disputes. The MTF is a new IT platform that will enable the transmission of certain claims data and payment data, between the MTF DM, MTF PM, Primary Manufacturers, and dispensing entities to facilitate MFP effectuation for Medicare beneficiaries via dispensing entities.

Figure 1. Data Flow Functionality of the MTF DM



Key elements of information and supporting documentation needed for CMS to facilitate and monitor effectuation of the MFP are held by Primary Manufacturers and dispensing entities and are not available to CMS. Primary Manufacturers and dispensing entities must submit information and supporting documentation (as described in Appendix A, B, C, and D as applicable) to enroll in the MTF DM and to ensure the MFP is made available. Figure 1 above illustrates the flow of information in the MTF DM process.

3. Use of Information Technology

Each applicable Primary Manufacturer and dispensing entity will engage in information submission via the MTF DM user interface. Dispensing entities will use the MTF DM to submit and maintain their enrollment-related information, and to submit complaints and disputes as needed. The Primary Manufacturers will use the MTF DM to maintain their user information, their MFP Effectuation Plan, their payment elements data, and to submit complaints and disputes as needed. A separate landing page will be available for interested parties who are not MTF DM users but have an interest in the program (e.g., Medicare beneficiaries, caretakers, manufacturers without a selected drug, beneficiary groups, disease groups and other professional or trade associations) to submit complaints associated with MFP availability. There is not currently a system in place to collect such data required to administer the Negotiation Program. Information will be collected through the MTF DM, which is a novel platform built for the sole purpose of administering the Negotiation Program and effectuating MFP.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source.

5. Small Businesses

Small businesses that participate in the MTF are subject to the same requirements as other businesses. The requirements do not impose any greater burden on small businesses than on large businesses.

6. Less Frequent Collection

The frequency of collection varies across each form attached to this ICR. Most of the information collection will occur on a one-time basis, with the possibility of periodic updates to capture updates and information changes (e.g., changes to contact information, banking information). Dispensing entity enrollment information, as well as the Manufacturer MFP Effectuation Plan will be collected one time, with the potential for periodic updates. Primary Manufacturer payment elements require recurring collection and are due within 14 days of a Primary Manufacturer receiving claim-level data elements from the MTF DM to ensure dispensing entities are reimbursed in a timely manner. Less frequent reporting of this data is not feasible in the course of administering and providing oversight of the Negotiation Program as these claim-level data elements are a key component to facilitating timely reimbursements to dispensing entities. Both those with access to the MTF DM and those who do not use the MTF DM will have access to submit complaints and disputes on an ongoing basis, with collection occurring as needed from the interested parties. In developing this approach to information collection, CMS worked to minimize the required frequency for all data submission. Less frequent collection of data reported in the forms listed would impede CMS' ability to effectively administer the Negotiation Program and facilitate timely MFP effectuation.

7. Special Circumstances

For the *Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form* (Appendix C), payment elements are transmitted more often than quarterly. As outlined in section 40.4.2 of the final guidance, these payment elements will be due to CMS on a rolling basis, with a deadline of 14-days following the Primary Manufacturers' receipt of claim-level data elements from the MTF DM. Based on the flow and volume of data that will be provided to Primary Manufacturers, CMS anticipates Primary Manufacturers may receive data as frequently as daily, establishing a daily deadline for claim-level payment elements, lagged by 14-days for each batch of data transmitted to the Primary Manufacturer. As long as the 14-day deadline is met, Primary Manufacturers may establish a preferred reporting cadence, including consolidating reporting in batches such that daily submissions are not required. Given the volume of data in these claim-level payment elements, CMS anticipates Primary Manufacturers will automate their reporting to the extent possible and may engage third-party vendors to support timely and complete reporting. Primary Manufacturers may express their preferred reporting approach to CMS in their *Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form* (Appendix B). Regular and recurring submission of the information in the *Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form* (Appendix C) is necessary because Primary Manufacturer payment elements collection will 1) be used to authorize timely processing of MFP refunds in the MTF PM (for those Primary Manufacturers that choose to pass payment through the MTF PM) on a recurring basis, and 2) support CMS' oversight and administration of the Negotiation Program regardless of whether the Primary Manufacturer chooses to pass MFP refunds through the MTF PM. The MTF DM will provide CMS with claim-level payment elements for a selected drug from Primary Manufacturers, indicating whether a refund was paid, the amount of the refund paid to make the MFP available, and the timeliness of the refund payment for payments processed both using the MTF PM and any payments processed via a Primary Manufacturer's alternative payment approach.

Primary Manufacturers will be required to retain certain records other than health, medical, government contract, grant-in-aid, or tax records for more than three years. As outlined in section 90.2.1 of the final guidance, a Primary Manufacturer must retain for at least 10 years from the date of sale, any records relating to sales of the selected drug to wholesalers and entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensing entities. This information will be provided to CMS upon request, as needed during the course of CMS' monitoring and oversight efforts. CMS provides a list of examples of the types of documentation that Primary Manufacturers may retain to meet this requirement in Table 5 of the final guidance.

Other than the exceptions for Appendix C, noted above, there are no special circumstances that will require information collection for MTF ICR Forms to be conducted in a manner that requires respondents to:

- Submit more than an original and two copies of any document;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

A 60-day notice was published in the Federal Register (89 FR 85538) on October 28, 2024, for the public to submit written comment on the information collection requirements. CMS made appropriate revisions based on its consideration of timely submissions of public comments to the 60-day notice package as well as further consideration of the issues. This 30-day notice is being published in the Federal Register on April 1, 2025, for the public to submit written comment on the information collection requirements. CMS will make appropriate revisions based on its consideration of timely submissions of public comments to the 30-day notice package.

Outside Consultation

In the development of the information collection request for the MTF forms, CMS sought input from trade associations representing manufacturers, various types of pharmacies (e.g. chains, independent community pharmacies), and other entities in the pharmaceutical marketplace (e.g. Pharmaceutical Benefit Managers, Pharmacy Services Administrative Organizations, reconciliation vendors), as well as data vendors, all with expertise in the pharmaceutical supply chain and prescription drug payment claim system flows.

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents for completing the information collection. The information submitted as part of this ICR will be used to ensure the MFP is made available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities that dispense the selected drug to MFP-eligible individuals.

10. Confidentiality

The MTF will collect and store banking information and federal tax identification numbers (Employer Identification Number or Social Security Number). Confidentiality will be maintained to the extent provided by the law and stated in the Final Guidance in Section 40.2.1. Information that is deemed proprietary shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. Proprietary information, including trade secrets and confidential commercial or financial information, will also be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or Exemption 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).⁴

11. Sensitive Questions

This information collection does not contain sensitive questions.

12. Burden Estimates (Hours & Wages)

CMS used data from the Bureau of Labor Statistics' (BLS) May 2023 National Industry Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with Primary Manufacturers completing each ICR Form for the MTF, form submission, and recordkeeping.⁵ Tables 1-24 present the median hourly wage, the cost of fringe benefits and overhead, the adjusted hourly wage, along with total burden and total cost for each form. Where industry-specific data was not available, CMS used BLS Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates.⁶

The burden estimates associated with the information collected in the following forms and record retention requirements are discussed below:

- Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form (Appendix A)

⁴ See: <https://www.justice.gov/oip/doj-guide-freedom-information-act-0>.

⁵ See May 2023 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 - Pharmaceutical and Medicine Manufacturing. Available at [https://www.bls.gov/oes/current/naics4_325400.htm#\(5\)](https://www.bls.gov/oes/current/naics4_325400.htm#(5)).

⁶ See May 2023 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at: https://www.bls.gov/oes/current/oes_nat.htm#13-0000

- Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form (Appendix B)
- Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form (Appendix C)
- Drug Price Negotiation Program MTF DM MTF and non-MTF User Complaint and Dispute Intake Form (Appendix D)

A. Estimated Burden for Dispensing Entity to Complete Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form (Appendix A)

The *Drug Price Negotiation Program Dispensing Entity and Third-Party Entity Enrollment Form* (Appendix A) collects data related to dispensing entity and third-party support contact and banking information that CMS expects such entities would have readily available for submission. Based on 2023 Prescription Drug Event data,⁷ CMS expects approximately up to 95,000 pharmacies, including both chain and non-chain pharmacies may enroll in the MTF DM; this assumption represents CMS' maximum expectation for participation. CMS believes collection of these data will be a one-time cost for each submitting dispensing entity enrolling in the MTF and that a significant majority of pharmacies will enroll in or before 2026. Since most pharmacies would be enrolled prior to January 1, 2026, and remain enrolled over time, the burden estimates and tables below reflect the year 2026 and not both 2026 and 2027. CMS expects any updates to this information would be negligible and require minimal time to update.

The burden estimates to complete this form are subdivided into chain pharmacies, non-chain pharmacies, and third-party support entities (TPSE).

CMS expect chain pharmacies to enroll individual stores through a central office. There are an estimated 760 chain pharmacies representing approximately 39,000 stores. In the burden estimate, CMS uses 760 chain pharmacy respondents. The remaining estimated 56,000 non-chain pharmacies will individually enroll in the MTF DM. CMS also anticipates approximately 100 TPSEs will enroll in the MTF DM to support their clients' receipt of MFP refunds and remittances as is standard practice in the industry today. These TPSEs encompass organizations that provide administrative support or billing services to pharmacies, including managing prescription drug billing, receiving remittances, and matching claims with payments. These entities may need access to the MTF to provide these services to enrolled dispensing entities. These organizations include, for example, Pharmacy Services Administrative Organizations (PSAOs), reconciliation vendors, switches, Pharmacy Management Systems (PMSs), and wholesalers, and are considered Business Associates under HIPAA regulations.

CMS expects a TPSE to enroll in the MTF to support payment to their pharmacy clients. Clients of such entities would also be required to enroll in the MTF DM and would indicate their relationship to the entity in order to support payment.

⁷ <https://resdac.org/cms-data/files/pde>

For a non-chain pharmacy enrolling in the MTF DM, CMS expects a team including a Financial Manager, Business Operations Specialist, Pharmacist, and Lawyer, to spend approximately two hours each collecting and submitting enrollment information. As specified below in Table 1, each respondent would spend 8 hours for a total cost of \$1,065.48 responding, and the total annual burden hours across 56,000 respondents would be approximately 448,000 hours, with a total cost of \$59,666,880.00.

TABLE 1: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A NON-CHAIN PHARMACY COMPLETING THE ONE-TIME DISPENSING ENTITY ENROLLMENT FORM 2026

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response per Occupation	Cost per Occupation per Response
Financial Manager (11-3031)	\$86.54	\$173.08	2	\$346.16
Business Operations Specialists (13-1199)	\$44.94	\$89.88	2	\$179.76
Pharmacist	\$64.81	\$129.62	2	\$259.24
Lawyer (23-1011)	\$70.08	\$140.16	2	\$280.32
Total			8	\$1,065.48

TABLE 2: SUMMARY OF TOTAL ANNUAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL NON-CHAIN PHARMACIES COMPLETING THE ONE-TIME DISPENSING ENTITY ENROLLMENT FORM 2026

Respondents	Time per Response	Total Annual Burden (Hours)	Total Annual Cost
56,000	8	448,000	\$59,666,880.00

For a chain pharmacy home office enrolling its individual retail pharmacy stores in the MTF DM, CMS expects a team including a Financial Manager, Business Operations Specialist, Pharmacist, and Lawyer, to spend approximately four hours each collecting and submitting enrollment information. As specified below in Table 3, each respondent would spend 16 hours for a total cost of \$2,130.96 responding, and the total annual burden hours across all 760 respondents representing 39,000 pharmacies would be approximately 12,160 hours, with a total cost of \$1,619,529.60.

TABLE 3: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A CHAIN PHARMACY COMPLETING THE ONE-TIME DISPENSING ENTITY ENROLLMENT FORM 2026

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response	Cost per Occupation per Response
Financial Manager (11-3031)	\$86.54	\$173.08	4	\$692.32
Business Operations Specialists (13-1199)	\$44.94	\$89.88	4	\$359.52
Pharmacist	\$64.81	\$129.62	4	\$518.48
Lawyer (23-1011)	\$70.08	\$140.16	4	\$560.64
Total			16	\$2,130.96

TABLE 4: SUMMARY OF TOTAL ANNUAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL CHAIN PHARMACIES COMPLETING THE ONE-TIME DISPENSING ENTITY ENROLLMENT FORM 2026

Respondents	Time per Response (hours)	Total Annual Burden (Hours)	Total Annual Cost
760*	16	12,160	\$1,619,529.60

For a TPSE enrolling its individual retail pharmacy stores in the MTF DM, CMS expects a team including a Financial Manager, Business Operations Specialist, Pharmacist, and Lawyer, to spend approximately one hour each collecting and submitting enrollment information. As specified below in Table 5, each respondent would spend four hours for a total cost of \$532.74 responding, and the total annual burden hours across 100 respondents would be approximately 400 hours, with a total cost of \$53,274.00.

TABLE 5: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A THIRD-PARTY SUPPORT ENTITY COMPLETING THE ONE-TIME DISPENSING ENTITY ENROLLMENT 2026

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response	Cost per Occupation per Response
Financial Manager (11-3031)	\$86.54	\$173.08	1	\$173.08
Business Operations Specialists (13-1199)	\$44.94	\$89.88	1	\$89.88
Pharmacist	\$64.81	\$129.62	1	\$129.62
Lawyer (23-1011)	\$70.08	\$140.16	1	\$140.16

Total			4	\$532.74
--------------	--	--	----------	-----------------

TABLE 6: SUMMARY OF TOTAL ANNUAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL THIRD-PARTY SUPPORT ENTITIES COMPLETING THE ONE-TIME DISPENSING ENTITY ENROLLMENT FORM 2026

Respondents	Time per Response (hours)	Total Annual Burden (Hours)	Total Annual Cost
100	4	400	\$53,274.00

B. Estimated Burden for Primary Manufacturer to Complete Drug Price Negotiation Program MTF DM MFP Effectuation Form

For purposes of estimating burden, CMS assumes maximum participation for 2026 and 2027. For 2026, CMS expects a total of 10 respondents consisting of the 10 Primary Manufacturers with selected drugs, with up to an additional 15 Primary Manufacturers for 2027. Of note, some manufacturers in IPAY 2027 have multiple drugs, and some are the same Primary Manufacturers as in IPAY 2026, and therefore the Primary Manufacturers who will submit in IPAY 2027 are not all new to the MTF DM. However, CMS is estimating response burden based on the number of selected drugs and the nature of the information collection requirements rather than the number of unique Primary Manufacturers. Collection of these data will be a one-time cost for each submitting Primary Manufacturer for each selected drug enrolling in the MTF. CMS expects any updates to this information would be negligible and require minimal time to update.

The *Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form* (Appendix B) collects data related to how a Primary Manufacturer intends to effectuate MFP within the MTF DM, including financial and banking information. CMS expects Primary Manufacturers would have some of this data readily available for submission; however, some information would take more time to gather and develop. CMS also anticipates some Primary Manufacturers will need to develop novel internal processes to establish their approach to MFP effectuation and engage with the MTF system.

For a Primary Manufacturer, CMS expects a team, including a Financial Manager, Business Operations Specialist, Lawyer, Chief Executive, and Compliance Officer to prepare information, complete, and submit its Primary Manufacturer MTF DM MFP Effectuation plan. As specified below in Table 7, a Financial Manager would spend 24 hours on the plan, a Business Operations Specialist, Lawyer, and Compliance Officer 48 hours each, and a Chief Executive 12 hours for an annual burden of 180 hours and total cost of \$25,760.64 per respondent. The estimated total annual burden hours for 10 Primary Manufacturers to complete this submission is 1800 hours for a total annual cost of \$257,606.40 in 2026.

TABLE 7: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A PRIMARY MANUFACTURER COMPLETING THE ONE-TIME PRIMARY MANUFACTURER MFP EFFECTUATION PLAN FORM 2026

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response	Cost per Occupation per Response
Financial Manager (11-3031)	\$86.54	\$173.08	24	\$4,153.92
Business Operations Specialists (13-1199)	\$44.94	\$89.88	48	\$4,314.24
Lawyer (23-1011)	\$115.00	\$230.00	48	\$11,040.00
Chief Executive (11-1011)	\$115.00	\$230.00	12	\$2,760.00
Compliance Officer (13-1041)	\$36.38	\$72.76	48	\$3,492.48
Total			180	\$25,760.64

TABLE 8: SUMMARY OF TOTAL ANNUAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL PRIMARY MANUFACTURERS COMPLETING THE ONE-TIME PRIMARY MANUFACTURER MFP EFFECTUATION PLAN FORM 2026

Respondents	Time per Response (hours)	Total Annual Burden (Hours)	Total Annual Cost
10	180	1,800	\$257,606.40

As noted above, for purposes of the burden estimate, CMS assumes an additional maximum of 15 Primary Manufacturers to submit an MTF DM Primary Manufacturer MFP Effectuation Plan. As previously mentioned, CMS is estimating response burden based on the number of selected drugs and the nature of information submitted versus the number of unique Primary Manufacturers. For IPAY 2027, there are nine Primary Manufacturers with a total of 15 selected drugs. The annual total burden hours per respondent would remain 180 hours at a total cost of \$25,760.64 per respondent. The estimated total annual burden hours for 15 Primary Manufacturers to complete this submission is 2700 hours for a total annual cost of \$386,409.60 in 2027.

TABLE 9: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A MANUFACTURER COMPLETING THE ONE-TIME PRIMARY MANUFACTURER MFP EFFECTUATION PLAN FORM 2027

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response	Cost per Occupation per Response
Financial Manager (11-3031)	\$86.54	\$173.08	24	\$4,153.92
Business Operations Specialists (13-1199)	\$44.94	\$89.88	48	\$4,314.24
Lawyer (23-1011)	\$115.00	\$230.00	48	\$11,040.00
Chief Executive (11-1011)	\$115.00	\$230.00	12	\$2,760.00
Compliance Officer (13-1041)	\$36.38	\$72.76	48	\$3,492.48
Total			180	\$25,760.64

TABLE 10: SUMMARY OF TOTAL ANNUAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL PRIMARY MANUFACTURERS COMPLETING THE ONE-TIME PRIMARY MANUFACTURER MFP EFFECTUATION PLAN FORM 2027

Respondents	Time per Response (hours)	Total Annual Burden (Hours)	Total Annual Cost
15	180	2,700	\$386,409.60

C. Estimated Burden for Primary Manufacturer to Complete Drug Price Negotiation Program MTF DM Payment Elements Form

The *Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form* (Appendix C) will support CMS' oversight and administration of the Negotiation Program and allow CMS to collect payment elements via the MTF DM for a selected drug from Primary Manufacturers. These payment elements will include: when a refund was paid (if a refund was paid outside the MTF PM and the selected drug was not prospectively purchased), the method for determining the refund amount, the National Provider Identifier (NPI) of the entity receiving the refund, the number of units of the selected drug included in the refund paid, the amount of the refund paid to make the MFP available, and whether the refund payment adjusts a previously paid refund; or, if the Primary Manufacturer chooses to pass payment through the MTF PM, these elements will be used to make payments. Primary Manufacturers, inclusive of any of the Primary Manufacturer's contracted parties, will be required to transmit the *Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form* with claim-level payment elements for all claims transmitted by the MTF DM to the Primary Manufacturer.

Claim-level payment elements must be transmitted 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 40.4.2 of the final guidance. As such, data will be collected as much as daily and on an ongoing basis. For purposes of this burden estimate, CMS assumes Primary Manufacturers will have a dedicated Quality Assurance Analyst or team of analysts reviewing sample claim-level payment elements, and that a General Manager would review such analysis on a daily basis.

As discussed in previous sections, for purposes of the burden estimates, CMS assumes a maximum of 10 Primary Manufacturers for 2026 and an additional maximum of 15 Primary Manufacturers in 2027. However, since data will be collected as much as daily and on an ongoing basis, CMS assumes a total 25 selected drugs in 2027.

CMS assumes a dedicated Quality Assurance Analyst would spend eight hours a day, five days a week for 52 weeks sampling and analyzing data in the payment reports for a total of 2,080 hours. A General and Operations Manager would spend three hours a day reviewing such analysis five days a week for 52 weeks for a total of 780 hours. Therefore, the total annual burden hours for each respondent is 2,860 hours, with a total annual cost per respondent of \$228,649.20. For 2026, the total annual burden hours for 10 respondents is 23,400 hours, with a total annual cost of \$2,286,492.00.

TABLE 11: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A PRIMARY MANUFACTURER COMPLETING PRIMARY MANUFACTURER PAYMENT ELEMENTS 2026

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response per Occupation	Cost per Occupation per Response
Quality Assurance Analyst (15-1253)	\$48.94	\$97.88	2,080	\$203,590.40
General and Operations Manager (11-1021)	\$48.69	\$97.38	780	\$75,956.40
Total			2,860	\$279,546.80

TABLE 12: SUMMARY OF TOTAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL PRIMARY MANUFACTURERS TO COMPLETE MANUFACTURER PAYMENT ELEMENTS 2026

Respondents	Time per Response	Total Annual Burden (Hours)	Total Annual Cost
10	2,860	28,600	\$2,795,468.00

As noted above, CMS assumes a maximum of 25 Primary Manufacturers will sample, analyze and review data collected in 2027. The total annual burden hours and cost per respondent remains the same for 2027. The total annual burden hours for 25 Primary Manufacturers is 71,500 hours, with a total annual burden cost of \$6,988,670.00 for 2027.

TABLE 13: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR PRIMARY MANUFACTURER COMPLETING PRIMARY MANUFACTURER PAYMENT ELEMENTS FORM 2027

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response per Occupation	Cost per Occupation per Response
Quality Assurance Analyst (15-1253)	\$48.94	\$97.88	2,080	\$152,692.80
General and Operations Manager (11-1021)	\$48.69	\$97.38	780	\$75,956.40
Total			2,860	\$279,546.80

TABLE 14: SUMMARY OF TOTAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL PRIMARY MANUFACTURERS COMPLETING PRIMARY MANUFACTURER PAYMENT ELEMENTS FORM 2027

Respondents	Time per Response	Total Annual Burden (Hours)	Total Annual Cost
25	2,860	71,500	\$6,988,670.00

D. Estimated Burden for a Primary Manufacturer and/or Dispensing Entity to Complete Drug Price Negotiation Program Complaint and Dispute Intake Form

CMS expects to receive a range inquires through the MTF DM from Primary Manufacturers and dispensing entities, including complaints and disputes collected via the *Drug Price Negotiation Program Complaint and Dispute Intake Form* (Appendix D) on an ongoing basis in 2026 and 2027.

For dispensing entities, CMS assumes 1% of 95,000 pharmacies of all types (both chain and nonchain pharmacies) will file a complaint or dispute per month for both 2026 and 2027, for a total of 11,400 respondents each year. CMS estimates each complaint or dispute would take a pharmacist and a business operations specialist approximately one hour each, for a total of 24 burden hours per year per respondent. For 2026 and 2027, CMS estimates a total burden for all 11,400 respondents of 273,600 hours at a cost of \$30,027,600.00 each year.

TABLE 15: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A DISPENSING ENTITY SUBMISSION OF A COMPLAINT OR DISPUTE 2026 and 2027

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response per Occupation	Cost per Occupation per Response
Business Operations Specialists (13-1199)	\$44.94	\$89.88	12	\$1,078.56
Pharmacist	\$64.81	\$129.62	12	\$1,555.44
Total			24	\$2,634.00

TABLE 16: SUMMARY OF TOTAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL DISPENSING ENTITIES COMPLETING A COMPLAINT OR DISPUTE INTAKE FORM 2026 AND 2027

Respondents	Time per Response	Total Annual Burden (Hours)	Total Annual Cost
11,400	24	273,600	\$30,027,600.00

For Primary Manufacturers, CMS estimates 15 hours/week on complaints and/or disputes that CMS expects would likely be batched versus on a claim-level with some level of automation. CMS does not anticipate this number will fluctuate extensively for dispensing entities or Primary Manufacturers for 2027. For purposes of the burden estimate, CMS assumes maximum 10 selected drugs in 2026 and an additional 15 selected drugs for a total of 25 selected drugs in 2027. Burden for complaints and disputes is estimated on a per drug basis rather than per unique Primary Manufacturer.

For a Primary Manufacturer in 2026, CMS estimates a business operations specialist would spend 15 hours a week on preparing and submitting complaints and/or disputes, for a total of 520 annual burden hours at a total cost of \$46,737.60 per year per respondent. CMS estimates the total burden for all 10 Primary Manufacturers to be 5,200 hours at a cost of \$467,376.00 for 2026.

TABLE 17: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A PRIMARY MANUFACTURER SUBMISSION OF A COMPLAINT OR DISPUTE 2026

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response per Occupation	Cost per Occupation per Response
Business Operations Specialists (13-1199)	\$44.94	\$89.88	780	\$70,106.40
Total			780	\$70,106.40

TABLE 18: SUMMARY OF TOTAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL PRIMARY MANUFACTURERS COMPLETING A COMPLAINT AND DISPUTE INTAKE FORM 2026

Respondents	Time per Response	Total Annual Burden (Hours)	Total Annual Cost
10	780	7,800	\$701,064.00

For 2027, CMS assumes a maximum of 25 selected drugs. As such, CMS estimates the total burden for an individual respondent will not change; however, the total annual burden across all 25 respondents will be 13,000 at a total cost of \$1,168,440.00 for 2027.

TABLE 19: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR MANUFACTURER TO COMPLETE A COMPLAINT OR DISPUTE INTAKE FORM 2027

Occupation Title	Median Hourly Wage	Cost per hour	# Of Hours per Response per Occupation	Cost per Occupation per Response
Business Operations Specialists (13-1199)	\$44.94	\$89.88	780	\$70,106.40
Total			780	\$70,106.40

TABLE 20: SUMMARY OF TOTAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL PRIMARY MANUFACTURERS TO COMPLETE A COMPLAINT OR DISPUTE INTAKE FOR 2027

Respondents	Time per Response	Total Annual Burden (Hours)	Total Annual Cost
25	780	19,500	\$1,752,660.00

E. Burden Estimate for a Non-MTF User to Complete Drug Price Negotiation Program MTF DM Complaint Intake Form

Lastly, CMS expects individuals or organizations (non-MTF DM users) may also make complaints through the MTF DM via a public facing unique landing page for other interested parties that do not use the MTF DM. This could be a range of individuals (e.g., Medicare beneficiaries or their caregivers) and/or organizations (e.g., trade associations, disease and patient groups, Secondary Manufacturers).

For 2026, CMS estimates 10,000 individuals and 50 organizations may make complaints through the MTF DM Complaints and Disputes Intake Form.

For purposes of the burden estimates, CMS assumes approximately 10,000 individuals may submit a complaint in 2026 based on 1-800-MEDICARE incoming call data. The call center received 3,800 calls on the IRA over a 6-month period – therefore, CMS estimates 8,000 or so for a 12-month period, and CMS expects it is reasonable for the first years of the program to receive a significant number of complaints. For this burden estimate, CMS assumes 50 organizations may submit a complaint based on the 50 organizations that provided comments on the final guidance. CMS expects organizations will be submitting complaints based on batches of issues that come up within the various populations the organizations represent versus individual complaints.

CMS estimates each submission would take both individuals and organizations one hour each to complete for a total of two burden hours. The total burden for 2026 is estimated to be 20,100 hours at a cost of \$926,711.00 for all 10,050 respondents.

TABLE 21: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN TO COMPLETE FOR A NON-MTF USER COMPLAINT AND DISPUTE INTAKE FORM 2026

Type of Respondent	Median Hourly Wage	# Of Hours per Response	Cost per Occupation per Response
Individual (All Occupations 00-0000)	\$46.22	1	\$46.22
Organization (All Occupations 00-0000)	\$46.22	1	\$46.22
Total		2	\$92.44

TABLE 22: SUMMARY OF TOTAL BURDEN OF INFORMATION COLLECTION REQUEST TO FOR ALL NON-MTF USERS TO COMPLETE A COMPLAINT AND DISPUTE INTAKE FORM 2026

Respondents - Individual and Organization	Time per Response (hours)	Total Annual Burden (Hours)	Total Annual Cost
10,050	2	20,100	\$929,022.00

For 2027, CMS expects the total burden hours per respondent to remain the same, however, assumes with the additional 15 selected drugs, it is reasonable to assume there will be a higher volume of complaints. CMS estimates approximately 25,000 individual complaints and 50 organization complaints for 2027. Therefore, CMS estimates a total annual burden of 50,100 hours at a total cost of \$2,315,622.00 in 2027.

TABLE 23: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A NON-MTF USER TO COMPLETE A COMPLAINT AND DISPUTE INTAKE FORM 2027

Type of Respondent	Median Hourly Wage	# Of Hours per Response	Cost per Occupation per Response
Individual (All Occupations 00-0000)	\$46.22	1	\$46.22
Organization (All Occupations 00-0000)	\$46.22	1	\$46.22
Total		2	\$92.44

TABLE 24: SUMMARY OF TOTAL BURDEN OF INFORMATION COLLECTION REQUEST BURDEN FOR ALL NON-MTF USERS TO COMPLETE A COMPLAINT AND DISPUTE INTAKE FORM 2027

Respondents - Individual and Organization	Time per Response (hours)	Total Annual Burden (Hours)	Total Annual Cost
25,050	2	50,100	\$2,315,622.00

13. Capital Costs

The capital cost of the MTF was considered in building the cost to respondents estimate. The MTF has multiple functions, with data collection functionality being foundational to the overall build for the MTF. Therefore, respondents will have no additional capital expenditure for the data collection activity. Cost to the government is calculated using the labor hours estimated to process and analyze the data.

14. Cost to Federal Government

The federal government cost is based on the efforts expended by CMS staff with the following assumptions to receive, review, and process data from Primary Manufacturers, dispensing entities, and the public for the MTF processes.

To generate salary estimates reflected in Table 14 below, CMS used the 2024 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region.⁸ In this regard, Table 14 presents the FTE equivalent of staff required for the task, the median hourly wage (adjusted for the cost of fringe benefits, calculated at 100 percent of salary), total burden hours, and the total cost of the information collection. Staffing estimates are based on CMS duties, including:

- CMS will develop policies and procedures for how data collected is used to implement the Negotiation Program, conduct oversight and monitoring, support beneficiary access to MFP and dispensing entity reimbursement; and

⁸ See: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/pdf/DCB_h.pdf

- CMS will review and analyze the information submitted by Primary Manufacturers in the payment elements, complaints/disputes, and the MFP effectuation plan forms; the information submitted by dispensing entities in the enrollment and complaints/disputes forms; and complaints submitted by non-MTF users.

CMS expects this work will require five GS-13, one GS-14, one GS-15 and one SES staff to develop policies and procedures related to the MTF DM. One additional GS-13 and a contractor will be required to process and analyze data submitted to CMS in Appendix A-D. The total cost to the federal government over a two-year period is estimated at \$562,943.84

TABLE 25: TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT THE MTF 2026 and 2027

	FTE	Hourly Wage	Total Burden Hours	Total Cost
Developing Policies and Procedures				
GS-13 (step 1)	5	\$113.04	288	\$162,777.60
GS-14 (step 1)	1	\$133.58	288	\$38,471.04
GS-15 (step 1)	1	\$157.12	72	\$11,312.64
Senior Executive Service	1	\$188.54	36	\$6,787.44

	FTE	Hourly Wage	Total Burden Hours	Total Cost
Processing and Analyzing Data in Forms				
GS-13 (step 1)	5	\$113.04	40	\$22,608.00
Contractor	2	\$246.97	80	\$39,515.20
Total Cost to Government Over One Year				\$281,472.92
Total Cost to Government Over Two Years				\$562,943.84

15. Changes to Burden

This a new information collection request, therefore there are no changes to burden compared to any previous collection.

A crosswalk describing the 30-day proposed revisions to the ICR package compared to the 60day proposed revisions to the ICR package is attached.

Based on public feedback on the 60-day notice, CMS revised the burden hours in the burden estimates. The burden hours for a Primary Manufacturer to complete Appendix C (the MFP Effectuation Plan Form) was increased by 25 percent from six hours to eight hours per day for

sampling and quality assurance activities. This increased the total annual burden hours from 23,400 hours to 28,600 hours in 2026 and from 58,500 hours to 71,500 hours for all Primary Manufacturers. Additionally, CMS increased the estimated burden hours for a Primary Manufacturer to complete Appendix D (the Complaint and Dispute Intake Form) from 10 hours per week to 15 hours per week. This increased the total annual burden hours from 5,200 hours to 7,800 in 2026 and from 13,000 hours to 19,500 in 2027 for all Primary Manufacturers.

CMS received a range of comments across all the forms from questions regarding definitions to clarification on instructions to form content to policy questions. Based on public comment, CMS revised the forms to clarify instructions and revised and streamlined various questions across the forms. CMS included the following revisions within each appendix:

Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form (Appendix A)

- CMS revised the form to pre-populate enrollment information from the National Council for Prescription Drug Programs (NCPDP) dataQ Pharmacy Database if authorization is given by the dispensing entity and the TPSE.
- CMS provided additional information and description of user roles and user management, resulting in minor, non-substantive revisions to the form.
- CMS eliminated the Pharmacy Demographic and Identifying Information section of the form (previously Section 2) as a component of leveraging the NCPDP data.
- CMS provided additional instruction related to the financial information section of the form to clarify submission requirements, including the addition of a field related to dispensing entity nonprofit status as necessary for tax purposes. CMS also streamlined the data elements being collected in this section.

Drug Price Negotiation Program MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form (Appendix B)

- CMS added content to the form reinforcing that proprietary information in the form will be redacted prior to sharing submitted information with other parties. Further, CMS reorganized the form and identified sections that it anticipates sharing with dispensing entities in their entirety to provide information critical to dispensing entity operations.
- CMS clarified instructions to note how engaging the MTF PM affects whether certain questions are required.
- CMS clarified the functionality of the ledger system as described in the final MFP Effectuation Plan's requirement for the Primary Manufacturer to provide a mechanism for contact between manufacturers and dispensing entities.

Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form (Appendix C)

- CMS removed the data element: "National Provider Identifier (NPI) of the Entity Receiving the MFP Refund or Prospective Sale" as this information will be available in the claim-level data elements that CMS provides to the manufacturers.

- CMS made minor clarifications to formatting and remaining questions, and provided additional instructions for clarity where applicable..

Drug Price Negotiation Program Complaint and Dispute Intake Form (Appendix D)

- In response to comments about question formatting, CMS made revisions, including adding options to several picklists, adding contextual fields related to the X12 835 ERA, rephrasing some questions for clarity, and re-ordering several sections in the form to improve flow and user experience.
- Based on public comment, CMS increased the number of supporting documents permitted for upload from 5 documents to 10 documents.

16. Publication/Tabulation Dates

The information collected via this ICR is for program operations, administration, and oversight uses by CMS and CMS' contractors only.

Primary Manufacturer plans to effectuate MFP, with proprietary information redacted, will be made available to dispensing entities via the MTF DM by January 1, 2026. In addition, CMS may release these redacted plans to other applicable stakeholders (e.g., supply chain entities) upon request.

17. Expiration Date

The expiration date and OMB control number will be displayed within the MTF Data Module information technology system on the log-in page.

18. Certification Statement

There are no exceptions to the certification statements.