Appendix D. Drug Price Negotiation Program Complaint and Dispute Intake Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program ("the Negotiation Program"), codified in sections 1191 through 1198 of the Social Security Act ("the Act"). The Act establishes the Negotiation Program to negotiate a maximum fair price ("MFP"), defined at section 1191(c)(3) of the Act, for certain high expenditure, single source drugs covered under Medicare Part B and Part D ("selected drugs"). In accordance with section 1193(a) of the Act, any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP 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 has proposed in the Contract Year 2026 Medicare Advantage (MA) and Part D Proposed Rule 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. 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 for Primary Manufacturers, dispensing entities, beneficiaries and other interested parties to submit a complaint or dispute related to effectuating the MFP. Completing this form either within the MTF DM module's user interface, or via the public-facing version (for non-MTF users) initiates the complaint and dispute process. This form will need to be completed whenever an interested party needs to file a new complaint or dispute.

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 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

CMS will establish a centralized intake system to receive complaints and disputes regarding MFP effectuation. Complaints and disputes will be collected both through the MTF DM (for MTF users), and via a publicly accessible web-based platform (for non-MTF users).

Complaints and disputes must be submitted to CMS no later than 120 calendar days from the date of the subject of the complaint or dispute. Upon timely receipt of a reported issue, an initial triage will be conducted to route the concern to the appropriate track.

The complaint and dispute process will be set up with two "tracks" within one overall system. The first track is a dispute functionality within the MTF for qualifying disputes (see below description) from Primary Manufacturers or dispensing entities regarding a technical aspect of the MTF process. The second track is a complaint process that will intake complaints and will be available via a public portal to reach a broader audience, as well as in the MTF DM's user interface for Primary Manufacturers and dispensing entities, regardless of their degree of participation in any aspect of the MTF and will encompass any issues that do not qualify as disputes under the definition set forth below.

- **Dispute:** Identifiable challenge to a technical aspect of the MTF system and process (e.g., identification of duplicate claims processed through the MTF system, misapplication of credits). A dispute will warrant CMS review and issuance of a non-appealable finding and will be assessed based on available relevant factual information.
- **Complaint:** Any issue brought forward by an individual or entity that does not fall under the above definition of dispute; this covers a wide range of concerns from a broad range of interested parties. Complaints related to a lack of MFP availability may not always require a specific resolution but will be reviewed by CMS and may trigger an investigation under CMS' obligation to administer the Negotiation Program and to provide monitoring and oversight of MFP availability.

Questions about CMS MTF Portal user access should be sent to XXX@xxx.xxx. For technical assistance related to the submission of information in the MTF Portal, questions should be sent to XXX@xxx.xxx.

Submission Method

MTF DM users will submit complaints and disputes via the MTF DM user interface. Instructions for MTF users to gain access to the MTF DM will be available at [SYSTEM URL]. Non-MTF users, including beneficiaries and other interested parties, will submit complaints via an online form established by a CMS contractor and available broadly to the public. Parties will have the ability to upload supporting documents using the online form.

Additional Information

- Users of the complaint and dispute submission process within the platform will have the ability to upload supporting documentation, which may expedite a resolution to the complaint and dispute process. See Question 5 for examples of supporting documentation.
- For purposes of this information collection request, all defined terms referenced in this ICR have their meaning set forth in the final guidance.

Section 1: Identifying Information of the Submitter

Question 1: Contact Information

Please provide the following contact information. You may be contacted if additional information is needed as CMS reviews your submission.

Field	Response
Q1A. Submitter Type I am a:	Required – Select the option that best describes the submitter. a. Primary Manufacturer b. Secondary Manufacturer c. Dispensing Entity chain home office (CHO), (i.e., an entity such as a chain pharmacy, mass merchant, or supermarket that provides centralized management and administrative services from corporate headquarters to pharmacies or dispensing entities under common ownership) d. Non-Chain Dispensing Entity (e.g., LTC, VA, Independent) e. Third-party vendor acting on behalf of a Primary Manufacturer f. Third-party vendor acting on behalf of a dispensing entity g. Part D Plan Sponsor h. Patient/Beneficiary i. Caregiver j. Healthcare Provider k. Member of the General Public l. Trade or Advocacy Association, or other Interested Organization m. Other
If Other for Q1A	Text field
Q1B. (If "c," "d," or "f" selected in Q1A). Select the operating structure that best characterizes your dispensing entity.	☐ Chain Pharmacy ☐ Franchise Pharmacy ☐ Independent Pharmacy ☐ Specialty Pharmacy ☐ Mail Order Pharmacy ☐ Electronic or Online Pharmacy ☐ Long-term Care Pharmacy ☐ Indian/Tribal/Urban Indian (I/T/U) Pharmacy ☐ Veterans Affairs Pharmacy ☐ Other Governmental Pharmacy ☐ Other
If other for Q1B	Text Field
Q1C. Contact Name	Text field
Q1D. Company Name (if applicable)	Text field
Q1E. Contact Phone Number	Text field
Q1F. Contact Email	Text field

Section 2: Description of Issue

Question 2: Issue Category

Please select one of the following categories that best describes your submission:

- ☐ This submission is reporting a technical issue pertaining to MTF system functionality or processes, or a technical issue with the underlying data processed through the MTF. For example, these issues may include concerns with MTF data calculations, contents of data files transmitted by the MTF DM, application of MFP refund credits, or other technical concerns directly related to the functions of the MTF system.
- ☐ This submission is reporting an issue related to nonduplication of the MFP and the 340B ceiling price.
- ☐ This submission is reporting an issue related to MFP effectuation; for example, a Primary Manufacturer making the MFP available, and/or a dispensing entity's receipt of an MFP refund.
- ☐ This submission is about something else. If selected, please provide a brief description:

Text (100-character limit)

Question 3: Selected Drug & Claim Information

Please provide the following information about the selected drug(s) related to your submission, if known. This information provides useful context to support the potential investigation and resolution of your submission. While you may not have information for all items in this section, please provide as much information as possible.

Field	Response
Q3A. Selected Drug Name(s) related to this submission.	Required – Check box list, with the ability to select more than one. ☐ Eliquis (apixaban) ☐ Enbrel (etanercept) ☐ Entresto (valsartan / sacubitrilat) ☐ Farxiga (dapagliflozin) ☐ Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill (insulin aspart, human) ☐ Imbruvica (ibrutinib) ☐ Januvia (sitagliptin) ☐ Jardiance (empagliflozin) ☐ Stelara (ustekinumab) ☐ Xarelto (rivaroxaban) ☐ Non-drug specific technical issue *[Selected drug list to be updated annually to reflect current selected drugs]*
Q3B. Applicable National Drug Code(s) (NDCs) (if known); NDC-9s or NDC-11s accepted.	Text field (*optional)*
Q3C. Prescription Number(s)	Text field *(optional)*

Q3D. Pharmacy/Dispensing Entity Name	Text field *(optional)*
Q3E. Pharmacy/Dispensing Entity National Provider Identifier (NPI), if applicable.	Text Field (*optional)*
Q3E. Pharmacy/Dispensing Entity Full Address (list website address if mail order)	Text field *(optional)*
Q3F. Claim ID(s) or Transaction Control Number (TCN)(s)	Text field *(optional)*
Q3G. MTF Internal Claim Number(s) or Reference ID(s) on X12 835	Text field *(optional)*
Q3H. Relevant Dates (including date of service, date of claim, and/or date of prescription fill)	Date field *(optional)*
Q3I. Please indicate the context for the relevant dates provided by noting, for example, whether this date is the date of service, the date of the claim, the date of the prescription fill, etc.	Text field *(optional)*

Question 4: Detailed Description of Issue

Please provide a detailed description of your complaint or dispute. Be as specific as possible, including the full names and addresses of people and businesses involved. Include all relevant dollar amounts, interactions, timeframes, and other pertinent details to aid in the potential investigation and resolution of your submission.

Text (10,000-character limit)

Question 5: Supporting Documentation

Question 5A: Please upload any supporting documentation that is relevant to this submission to aid in the potential investigation and resolution of your submission. Examples of possible supporting documentation may include but are not limited to: Receipts, Explanation of Benefits statements (EOB), plan formulary and coverage documents, electronic remittance advice or other remittance, wholesale acquisition cost (WAC) published in the pricing compendia at date of dispensing, documentation of good faith attempts to make payment, bank statements, proof of 340B status, acquisition cost documentation, agreements signed between the dispensing entity and the Primary Manufacturer, proof of timely payment, documentation explaining why a retrospective refund was not paid, invoices from the dispensing entity, invoices for prospectively purchased units of the selected drug, and financial data.

Materials must be submitted in English; any documents not originally in English must be accompanied by an English translation with an attestation that the translation is complete and accurate, as well as the

name~~, address, and a brief statement of the qualifications~~ and contact information of the person making the translation.

Document Upload
Allowed extensions: .csv, .doc, .docx, .jpg, .jpeg, .pdf, .png, .tif, .tiff, .txt, .xls, .xlsx. Maximum size: 50MB per file. File limit: 10

Question 5B. Explanation of Submitted Documentation
Please provide a brief explanation of the supporting documentation uploaded with your submission.

Text (2,000-character limit)

Section 3: Privacy Statement

You Must Read and Agree to the Security & Privacy Agreement:

Privacy Notice and Terms of Use By using this Drug Price Negotiation Program Complaint and Dispute Form (the Form), you agree to the collection and use of information in accordance with this Privacy Notice and Terms of Use, which includes a Privacy Act Statement required under the Privacy Act of 1974.

You must read and agree to the Privacy Notice and Terms of Use below The Centers for Medicare & Medicaid Services (CMS) ("us", "we", or "our") operates the complaints and disputes process and help desk, including providing an avenue for a complaints form available online or by phone. Users will submit the Form electronically to CMS, or may contact CMS by phone for assistance filing a complaint. The information on this page tells you about our policies regarding the collection, use and disclosure of the Personal Information we receive from users of this form. It also includes specifics about Personal Information and other information that may be collected about you when you use the Form. Note that the information transmitted in this form will be stored in a secure environment and only accessible by authorized users. This Privacy Notice and Terms of Use cover activities as a part of the complaints and disputes process. If you have any questions or concerns regarding your privacy related to this submission, please contact IRARebateandNegotiation@cms.hhs.gov.

Permission for information submitted By submitting the Form, you represent that you have permission from all of the people whose information is on the form if you are submitting their information to CMS on their behalf, and to receive any communications about their complaint or dispute, statuses, and decisions from CMS and entities operating on its behalf or other federal and state agencies who may be required to assist in researching and resolving your complaint or dispute.

CMS/HHS Vulnerability Disclosure Policy CMS is committed to ensuring the security of the American public by protecting their information from unwarranted disclosure, available at: https://www.cms.gov/vulnerability-disclosure-policy

CMS.gov Privacy Policy Protecting your privacy is very important to us. This privacy policy describes what information we collect, why we collect it, and what we do with it, available at https://www.cms.gov/privacy

Medicare Drug Price Negotiation Program Privacy Act Statement – effective January 1, 2026

CMS is collecting this information as authorized by sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), in the course of the agency's obligation to collect information necessary to administer and monitor the Medicare Drug Price Negotiation Program. This law directs CMS to establish a process to monitor compliance regarding the implementation of the Negotiation Program. We need the information provided about you and the other individuals or entities you identify to process your complaint or dispute and, when applicable, to otherwise support resolution of your complaint or dispute in the course of our oversight and enforcement of Medicare Drug Price Negotiation Program's requirements. The information will be used to determine the validity of your complaint or dispute, inform CMS' investigation and resolution of the complaint or dispute, and to conduct ongoing monitoring and oversight of the Negotiation Program. The contact information you provided will be used to contact you if we need more information or documentation about your complaint or dispute, and to notify you of the resolution, if appropriate. We will also use the information you provide as necessary to enable us to fulfill a requirement of a Federal statute or regulation. Providing the requested information is voluntary. In order to process your complaint or dispute, we may need to share with persons or entities outside of CMS, selected information you provide, including to CMS contractors engaged to perform a function related to, or in support of, complaints and disputes in the Medicare Drug Price Negotiation, and/or to parties relevant to your complaint or dispute and their authorized representatives, including dispensing entities and manufacturers you identify as relevant to your complaint or dispute.

Changes to this Privacy Notice and Terms of Use

This Privacy Notice and Terms of Use is effective as of January 1, 2026 and will remain in effect except with respect to any changes in its provisions in the future, which will be effective immediately upon posting on this page.

We reserve the right to update or change this Privacy Notice at any time, and you should check this page periodically for updates. Your continued use of the Form after we post any modifications to the Privacy Notice on this page will constitute your acknowledgment of the modifications and your consent to abide and be bound by the modified Privacy Notice.

If we make any material changes to this Privacy Notice, we will notify you either through the email address you have provided us, or by placing a prominent notice on our website.

[ ] Acknowledge and Agree

Section 4: Certification

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and that 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.

[ ] Acknowledge and Agree