

Drug Price Negotiation Program Complaint Information Collection Request (ICR) Form for Non-MTF Users

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

To facilitate the effectuation of the MFP, CMS will engage a Medicare Transaction Facilitator (“MTF”). The MTF system will be comprised of two modules: the MTF Data Module (MTF DM), and the MTF Payment Module (MTF PM). Primary Manufacturers participating in the Negotiation Program are required to participate in the MTF DM. Further, CMS will propose in future rulemaking to require Part D plan sponsors to include in their pharmacy agreements provisions requiring dispensing entities to participate 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 non-MTF interested parties (e.g. Medicare beneficiaries and other organizations) to submit complaints related to the Drug Price Negotiation Program. Completing this form on the compliance contractor’s website will allow any interested party to initiate a complaint about MFP effectuation.

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

General Instructions

Overview

CMS will establish an intake system to receive complaints and disputes regarding MFP effectuation. Complaints and disputes will be collected through a CMS compliance contractor’s publicly accessible platform.

A CMS compliance contractor will support the successful administration of the Negotiation Program by collecting and investigating (as needed) complaints and disputes from dispensers, pharmacies, mail order services, manufacturers and other interested parties. The complaints and disputes are expected to include, among other topics, complaints related to lack of access to the maximum fair price, or lack of access to accurate cost-sharing. Non-MTF users will submit complaints via an intake process developed and maintained by the compliance contractor. The Contractor's intake system shall include the capacity to receive complaints directly in a manner that is user-friendly, readily available, and accessible to key interested parties (e.g. Medicare beneficiaries), through a web form.

Submission Method

Non-MTF users will submit complaints and disputes via an online form established by a CMS contractor. The form will have the ability to upload supporting documents.

Additional Information

The compliance contractor website has yet to be established. The intake process will have the ability to upload supporting documentation.

Section 1: Identifying information of the complainant

Question 1: Please provide the following contact information. You may be contacted if additional information is needed:

Field	Response
Complainant Type I am:	Required Multiple Choice (Patient/Beneficiary, Caregiver, Member of the General Public, Part D Sponsor, Other)
If Other	Text field
Contact Name	Text field
Company Name	Text field
Contact Phone Number	Text field
Contact Email	Text field

Question 2: Please provide the following drug information, if known:

Field	Response
Drug Name	Required – Check box list with the ability to select more than one. <input type="checkbox"/> Eliquis; <input type="checkbox"/> Enbrel; <input type="checkbox"/> Entresto; <input type="checkbox"/> Farxiga;

	<input type="checkbox"/> Fiasp; <input type="checkbox"/> Fiasp FlexTouch. Fiasp PenFill. NovoLog. NovoLog FlexPen. NovoLog PenFill; <input type="checkbox"/> Imbruvica; <input type="checkbox"/> Januvia; <input type="checkbox"/> Jardiance; <input type="checkbox"/> Stelara; <input type="checkbox"/> Xarelto (Updated selected drug list uploaded annually)
Prescription Number (found on prescription label or ask at pharmacy)	Text field
Pharmacy/Dispensing Entity Name	Text field
Pharmacy/Dispensing Entity Full Address (list website address if mail order)	Text field
Claim ID or TCN	Text field
Date(s) of Paid	Text field

Question 3: Please identify the following complaint category:

Field	Response
Issue category	Required - Check boxes with the option to pick more than one: Drug access issue, Formulary change, Cost sharing, Payment issue, Other

Section 2: Description of Issue

Question 4: Please provide a description of your complaint. 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 investigation and resolution:

Text (10,000-character limit)

Question 5: Please provide any supporting documentation in PDF format:

Examples of possible supporting documentation: Receipt, Evidence of Beneficiary statement (EOB), plan formulary and coverage documents.

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 of the person making the translation.