Information Collection Request (ICR) Form for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

(CMS-10849, OMB 0938-NEW)

Introduction

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") with manufacturers, defined at section 1191(c)(3) of the Act, for certain high expenditure, single source drugs[1] covered under Medicare Part B and Part D ("selected drugs").[2] For the first year of the Negotiation Program, CMS selected 10 high expenditure, single source drugs covered by Medicare Part D for negotiation. The list of selected drugs was published on August 29, 2023. The MFPs that are negotiated for these drugs will apply beginning in initial price applicability year 2026. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of manufacturer established in section 1847A(c)(6)(A) of the Act. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS designated the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the selected drug to be "the manufacturer" of the selected drug (hereinafter "Primary Manufacturer").

In accordance with section 1191(b)(4) of the Act, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement (herein referred to as an "Agreement"), or, for initial price applicability year 2026, October 1, 2023. CMS intends to implement the offer and counteroffer process consistent with the statutory goal of negotiating to achieve agreement on "the lowest [MFP] for each selected drug," established in section 1194(b)(1) of the Act. In accordance with sections 1191(d)(5)(B) and 1194(b)(2)(B) of the Act, CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug for initial price applicability year 2026 no later than February 1, 2024.

After the written initial offer from CMS is sent to the Primary Manufacturer, the negotiation process may include the following steps, depending on when and whether agreement on the MFP is reached and an offer is accepted:

(1) in accordance with section 1194(b)(2)(C) of the Act, an optional written counteroffer, including an Addendum populated with the counteroffer MFP as described in section 60.4.2 of Medicare Drug Price Negotiation Program: Revised Memorandum,

1 Hereinafter, "drug" includes drugs and biologics pursuant to the definition of a "qualifying single source drug" at section 1192(e)(1) of the Act.

2 For the purposes of this Information Collection Request (ICR), a selected drug for initial price applicability year 2026 is defined as a drug included on the selected drug list published by CMS on August 29, 2023.

Implementation of Sections 1191—1198 of the Social Security Act for Initial Price Applicability Year 2026 (the "revised guidance"), from the Primary Manufacturer (if CMS' written initial offer is not accepted by the Primary Manufacturer) that must be submitted no later than 30 days after the date of receipt of the written initial offer from CMS;

(2) in accordance with section 1194(b)(2)(D) of the Act, a written response from CMS to the optional written manufacturer counteroffer, which CMS will provide within 30 days after receipt of the counteroffer;

(3) if the Primary Manufacturer's written counteroffer is not accepted by CMS, up to three possible in-person, virtual, or hybrid negotiation meetings between the Primary Manufacturer and CMS; and

(4) a final written offer, including an Addendum containing the final offer MFP as described in section 60.4.4 of the revised guidance, made by CMS to the Primary Manufacturer, if no agreement is reached before the end of the negotiation meetings.

Every offer and counteroffer will include an Addendum populated with the offered/counteroffered MFP. If an agreement is reached at any point during the negotiation process by the Primary Manufacturer accepting CMS' written initial offer or final offer (as described in section 60.4.4 of the revised guidance), CMS accepting the Primary Manufacturer's counteroffer, or an agreement being reached in association with the negotiation meetings, the Addendum to the Agreement, as described in section 40.3 of the revised guidance, will be executed by both parties and will constitute agreement on the MFP. Section 60.4.4 of the revised guidance describes how and when the Addendum will be created and signed. The MFP included in the executed Addendum will apply for the selected drug for initial price applicability year 2026 and will be updated according to section 1195(b)(1)(A) of the Act for subsequent years in the price applicability period, as applicable.

This document describes the information collection that may occur during the negotiation process if the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS' written initial offer during the drug price negotiation process for initial price applicability year 2026.

The estimated burden of the information collection for a written counteroffer submission from a Primary Manufacturer of a selected drug and review of the written counteroffer submission by CMS staff is provided in the accompanying Supporting Statement. More information on the negotiation process can be found in the revised guidance.

Note: This ICR focuses on information required for the submission of counteroffers during the drug price negotiation process for initial price applicability year 2026.

Instructions for Completing the Counteroffer Form

A Primary Manufacturer that seeks to submit a counteroffer for its selected drug must complete and submit the information requested in the Counteroffer Form in the CMS Health Plan Management System (CMS HPMS) in order for CMS to consider the Primary Manufacturer's counteroffer.

To complete the Counteroffer Form, the Primary Manufacturer must provide the following:

- The name of the selected drug as it is named in CMS' initial offer for which the Primary Manufacturer is submitting a counteroffer;
- The Primary Manufacturer's written counteroffer for the price per 30-day equivalent supply of the selected drug (as described in section 60.1 of the revised guidance);
- Subject to the 2,500-word limit, a justification of the counteroffer based on the factors in section 1194(e) of the Act. The Primary Manufacturer's counteroffer justification should focus on the elements described in section 1194(e) of the Act and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer under section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternatives as described in section 1194(e)(2) of the Act, does not support the written initial offer made by CMS and better supports the Primary Manufacturer's counteroffer. These section 1194(e) data may be information already submitted to CMS by the Primary Manufacturer or other interested parties, information submitted as part of the counteroffer, or information that is otherwise available and considered by CMS. A Primary Manufacturer may also include in its counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) to support the counteroffer and additional information it deems relevant, such as a request to include certain information from the counteroffer justification in CMS' public explanation of the MFP, and;
- A certification, including an attestation on the use of cost-effectiveness measures, by the (1) the chief executive officer (CEO), (2) the chief financial offer (CFO), (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Additional instructions for submitting the Counteroffer Form are as follows:

- If the Primary Manufacturer chooses to submit the Counteroffer Form, this form must be completed and submitted within the CMS HPMS within 30 days of receiving the written initial offer from CMS.
- Question 2 asks the Primary Manufacturer to input its counteroffer price for a 30-day equivalent supply of the selected drug. CMS will interpret this price as a single price per 30-day equivalent supply (rather than per unit – such as tablet, capsule, injection - or per volume or weight metric), and weighted across dosage forms and strengths, if applicable. The Primary Manufacturer may reference information provided by CMS during the negotiation process regarding the application of a single MFP across dosage forms and strengths of the selected drug to understand how the 30-day equivalent supply counteroffer price will convert into prices for each dosage form and strength of the selected drug.
- The Primary Manufacturer should answer Question 3 in narrative (text) form. Responses will be limited to the 2,500-word limit, 10 visual representations of data, and a maximum of 50 citations.

- Submissions may include, but are not limited to, published or unpublished material such as peer-reviewed articles, whitepapers, case studies, and government reports. CMS reserves the right to review submitted materials for relevance and in accordance with the standards outlined in section 50.2 of the revised guidance.
- The Primary Manufacturer should provide citations to published material rather than copies of articles. The Primary Manufacturer is responsible for ensuring that its submission complies with applicable law, including, but not limited to, copyright law. If data are unpublished, clearly indicate this in the citation. For unpublished data without a citation, the Primary Manufacturer should summarize key findings as appropriate and upload any relevant visual representations as additional materials as described below.
- The Primary Manufacturer should provide citations in the National Library of Medicine (NLM) style format appropriate for the source of information (e.g., a journal article). Information on how to format citations is available for free through the NLM at: https://www.ncbi.nlm.nih.gov/books/NBK7256/
- When information in Question 3 is supported by a citation, the Primary Manufacturer should label the end of the sentence in the free text response with a number (e.g., [1], [2]) that corresponds to the number assigned to the provided citations.

- In addition to the counteroffer justification, the Primary Manufacturer may upload up to 10 charts, tables, or graphs as part of the ICR to support the justification. Data that are not in a visual form, such as a table or chart consisting only of text, will not be considered by CMS. PDF files will be accepted within specified file size limits for visual representations. The free text response should include clear numbers/references to the charts, tables, or graphs submitted. When information in Question 3 is supported by a chart, table, or graph, the Primary Manufacturer should label the end of the sentence in the free text response with a letter (e.g., [A], [B]) that corresponds to the letter assigned to the provided document.
- CMS will review submitted charts, tables, and graphs that use cost-effectiveness measures to determine if the data are relevant to the selected drug and/or its therapeutic alternative(s) and to ensure any cost-effectiveness measure used does not value extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Respondents must indicate via the checkboxes in the form if their submission includes any cost-effectiveness measures. Cost-effectiveness measures include but are not limited to Quality-Adjusted Life Years (QALYs), Equal Value of Life-Years Gained (evLYG), Equal Value Life-Year (evLY), Health Years in Total (HYT), and Generalized Risk-Adjusted Cost-Effectiveness (GRACE).
- If a Primary Manufacturer is the holder of the NDA(s)/BLA(s) for multiple selected drugs for an initial price applicability year, a separate form must be submitted for each selected drug for which the Primary Manufacturer chooses to submit a counteroffer.

Appendix. Counteroffer Form

Centers for Medicare & Medicaid Services

Counteroffer 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, codified in sections 1191 through 1198 of the Social Security Act (the Act), for initial price applicability year 2026. In accordance with section 1194(b)(2)(B) of the Act, CMS has provided the Primary Manufacturer of the selected drug named below with a written initial offer that contains CMS' proposal for the selected drug's maximum fair price (MFP), as defined in section 1191(c)(3), and a concise justification based on the factors described in section 1194(e). Submission of this form indicates that the Primary Manufacturer has not accepted CMS' written initial offer and is submitting a written counteroffer in accordance with section 1194(b)(2)(C).

In order for CMS to consider the Primary Manufacturer's counteroffer, this form must be certified by (1) the chief executive officer (CEO) of the Primary Manufacturer, (2) the chief financial officer (CFO) of the Primary Manufacturer, (3) an individual other than a CEO or CFO of the Primary Manufacturer, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Question 1: Please list the name of the selected drug for which the Primary Manufacturer is submitting a counteroffer.

Name of Selected Drug

Question 2: Please provide the Primary Manufacturer's counteroffer price for the selected drug in the table below. CMS will interpret this price as a single price per 30-day equivalent supply (rather than per unit – such as tablet, capsule, injection - or per volume or weight metric), and weighted across dosage forms and strengths, if applicable. The Primary Manufacturer may use information previously shared by CMS on the application of a single MFP across dosage forms and strengths of the selected drug to understand how this counteroffer price will apply to the dosage forms and strengths as identified on the list of National Drug Codes (NDCs) of the selected drug maintained by CMS.

Counteroffer price per 30-day equivalent supply of [selected drug name]
$

Question 3: Please provide a justification of the counteroffer price based on the factors in section 1194(e) of the Act. This counteroffer justification should also respond to the justification provided in CMS' written initial offer and provide the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the factors in section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternatives as described in

section 1194(e)(2) of the Act, does not support the written initial offer made by CMS and better supports the Primary Manufacturer's counteroffer.

FIELD	**RESPONSE FORMAT**
Counteroffer Justification	*Text* (2,500-word limit)
Additional Materials to Support the Justification	*Text* (Up to 50 citations) [file upload] (Up to 10 tables/charts/graphs)

Does the evidence submitted include a cost-effectiveness measure:
[ ] Yes
[ ] No
[ ] Don't know

If yes to the question above, please select the applicable statement.
[ ] The evidence submitted includes QALYs or cost-effectiveness measures that treat extending the life an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

[ ] The evidence submitted includes cost-effectiveness measures that DO NOT treat extending the life an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

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 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 is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including determination of a MFP, as defined in section 1191(c)(3) of the Act. I understand further that the proposed price submitted in this Counteroffer Form, if accepted by CMS, is intended to be the MFP as defined in section 1191(c)(3) of the Act for the selected drug for purposes of section 1193(a)(1) of the Act. I certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I also understand that any misrepresentations may give rise to liability, including under the False Claims Act.

Yes [] No []

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-NEW (Expires XX/XX/XXXX)**. This is a required information collection to retain or obtain a benefit. Specifically, a Primary Manufacturer must submit the Drug Price Negotiation Information Collection Request- Counteroffer Form in order to submit a counteroffer for a selected drug. The time required to complete this information collection is estimated to average 204 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.