Supporting Statement – Part A

Information Collection Request (ICR) for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10849, OMB 0938-NEW)

A. Background

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 will select up to 10 high expenditure, single source drugs covered by Medicare Part D for negotiation. The list of selected drugs will be published no later than September 1, 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 intends to designate 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 with the goal of negotiating to achieve agreement on "the lowest [MFP] for each selected drug" consistent with 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.

[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 September 1, 2023.

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, 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. CMS is requesting OMB approval for this New Collection that focuses on information required for the submission of counteroffers during the drug price negotiation process for initial price applicability year 2026. The Counteroffer Form will collect the name of the drug, the Primary Manufacturer's counteroffer for the MFP, the justification for the counteroffer, attestations on the use of cost-effectiveness measures in data submitted, and certification by authorized representatives of the Primary Manufacturer.

B. Justification

1. Need and Legal Basis

The statute provides that, after receiving CMS' written initial offer for a selected drug, the Primary Manufacturer may, in accordance with section 1194(b)(2)(C) of the Act, submit an

optional written counteroffer (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. 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 Primary Manufacturer must submit the Counteroffer Form.

2. Information Users

Section 1194 of the Act authorizes CMS to engage in negotiation with manufacturers, including by collecting information related to the Primary Manufacturer's written counteroffer, if applicable. CMS will use the submitted information to negotiate and seek to reach agreement on an MFP, as defined in section 1191(c)(3) of the Act, for the selected drug with the Primary Manufacturer.

3. Use of Information Technology

Primary Manufacturers should complete the Counteroffer Form, if applicable, which CMS intends to make available in the Drug Price Negotiation module within an existing information technology system, the CMS Health Plan Management System (CMS HPMS). Manufacturers of drugs covered under Part D currently use this system for other program needs. This ICR form will be available and must be submitted in the CMS HPMS. The counteroffer component of this module is scheduled to be available no later than February 1, 2024. Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in HPMS" PDF. In the event that completion of the Drug Price Negotiation module in the CMS HPMS is delayed, CMS will accept completed Counteroffer Forms via Box and will provide further instructions on submission.

The individuals who certify the Primary Manufacturer's counteroffer submission in the CMS HPMS must be 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).

4. Duplication of Efforts

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

5. Small Businesses

This collection of information has been designed with a view towards minimizing the reporting burden for Primary Manufacturers, which are the only entities authorized by statute to submit this information. Only drugs with the highest total expenditures under Medicare Part D will be selected for negotiation for initial price applicability year 2026. During the negotiation process,

this collection of information is relevant if Primary Manufacturers of selected drugs choose to make a counteroffer submission to the agency's proposed MFP for the selected drug in the written initial offer. Because this information collection is only relevant to Primary Manufacturers of a selected drug, it is highly unlikely this information collection would apply to any manufacturer that is a small business. The potential that a small business could be a Primary Manufacturer to which this information collection is relevant is further reduced by the exception for small biotech drugs, in accordance with section 1192(d)(2), that excludes qualifying drugs covered under Part D from being eligible for negotiation and thus selection in initial price applicability year 2026.[3] This exception will minimize the reporting burden for small businesses. The impact of this collection on a Primary Manufacturer is estimated to be the same regardless of the size of the Primary Manufacturer.

6. Less Frequent Collection

Less frequent collection would not be an option because a Primary Manufacturer is expected to submit the information only once, if applicable, for each selected drug for which the Primary Manufacturer engages in negotiation with CMS for initial price applicability year 2026. The negotiation process, including the Primary Manufacturer's submission of this information, is specified in the statute.

7. Special Circumstances

Information collected through the Counteroffer Form may contain proprietary, trade secret, or other confidential information. In accordance with Section 1193(c) of the Act, information submitted to CMS by a manufacturer of a selected drug that is determined by CMS to be proprietary information of that manufacturer shall be used only 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 secret and confidential commercial or financial information, would also be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).[4]

There are no special circumstances that would require this information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

[3] Following a 60-day and 30-day comment period, the Small Biotech Exception Information Collection Request (ICR) was approved on May 26, 2023 (OMB Control Number: 0938-1443).
[4] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

- 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 on April 18, 2023 (88 FR 23680). CMS received 16 comments from 15 entities in response to the 60-day notice. Of the 16 comments, 13 were relevant to this ICR, 2 were general comments that were not relevant to the ICR, and 1 was a duplicate. The comments identified issues/themes/concerns including but not limited to: burden estimates, the counteroffer justification and restrictions on the submission, methodology for calculating the price per 30-day equivalent supply, the form certification, and form edits. Attached as a supplemental document in this ICR is a summary of comments and our responses.

A 30-day notice is scheduled to publish to the Federal Register on July 25, 2023 (88 FR 47880) for the public to submit written comment on the information collection requirements. The Draft Federal Register Notice has been attached to the submission as a supplemental document.

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents for completing the information collection. The information submitted may be used to reach an agreement on the MFP for the selected drug of the Primary Manufacturer. For example, CMS may accept the Primary Manufacturer's counteroffer or adjust its final offer for the MFP based on the Primary Manufacturer's counteroffer submission.

If a Primary Manufacturer accepts the written initial offer for the selected drug in accordance with Section 1194(b)(2)(C) of the Act, then a counteroffer submission is not relevant. If a Primary Manufacturer does not accept CMS' written initial offer, then a written counteroffer and justification must be submitted in accordance with Section 1194(b)(2)(C) of the Act if the manufacturer wishes to participate in the Negotiation Program.

10. Confidentiality

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 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(3), (4)).[5]

As discussed in section 40.2.1 of the revised guidance, CMS will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information including Exemptions 3 and/or 4 of FOIA, and that strikes an appropriate balance between (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating information that does not qualify for such protection as proprietary.

Pursuant to section 1195(a)(2) of the Act, CMS is required to publish the explanation of the MFP by March 1, 2025, for initial price applicability year 2026 (described in section 60.6.1 of the revised guidance). In this public explanation and any other public documents discussing the MFP, CMS will release redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable.

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimates (Hours & Wages)

A Primary Manufacturer must complete and submit the information requested on the Counteroffer Form if it both chooses not to accept CMS' initial offer and chooses to submit a counteroffer for a selected drug. The burden estimate for this information collection is detailed in this section.

To derive wage estimates, CMS used data from the Bureau of Labor Statistics' May 2022 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry, when available, to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the Counteroffer Form.[6] When industry-specific wage estimates were not available, the Bureau of Labor Statistics' May 2022 Occupational Employment and Wage Statistics data was used. Table 1 below presents the estimated mean hourly wage, the cost of fringe benefits and overhead, total burden hours, and total cost to submit this form.

CMS will select up to 10 high expenditure, single source drugs covered by Medicare Part D for negotiation for initial price applicability year 2026. Counteroffers will be submitted by Primary

[5] See: https://www.justice.gov/media/1144226/dl?inline and https://www.justice.gov/media/1181316/dl?inline.

[6] See May 2022 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#29-0000.

Manufacturers for up to 10 selected drugs, and completing the Counteroffer Form will be a one-time cost for each selected drug for which a Primary Manufacturer submits a counteroffer. The statute envisions that counteroffer submissions for initial price applicability year 2026 will occur in 2024, as the statute instructs CMS to make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug no later than February 1, 2024, and if the Primary Manufacturer chooses to submit a written counteroffer, the statute provides that it must do so no later than 30 days after the date of receipt of the written initial offer. CMS assumes each Primary Manufacturer will spend, on average, the same amount of time to develop and submit counteroffer information for each selected drug. While a Primary Manufacturer may have multiple selected drugs, CMS assumes that the Primary Manufacturer would require the same time and effort to submit counteroffer information for each selected drug.

CMS estimates up to 10 total respondents for initial price applicability year 2026. CMS chose this number because by statute only up to 10 drugs covered by Medicare Part D can be selected for negotiation for 2026, and for each selected drug CMS will undergo negotiation with only one Primary Manufacturer, so it is not possible that there would be more than ten respondents for initial price applicability year 2026. CMS believes that collection of these data will be a one-time cost for each Primary Manufacturer.

CMS expects the Primary Manufacturer will have a team preparing the Counteroffer Form. CMS expects this team to consist of chief executives, lawyers, health care professionals, economists, general and operations managers, and business operation specialists. The estimate below accounts for the burden of preparing and submitting the Counteroffer Form.

- CMS estimates it will take a business operation specialist, or a team of business operations specialists, 27 hours, on average, at $91.10 per hour, to review CMS' initial offer and justification and compare it to current prices, revenue, and other market and clinical data for the selected drug. CMS also expects this business operation specialist, or team, to compare CMS' justification with the data the Primary Manufacturer submitted as part of the section 1194(e)(1) and (2) factors and the section 1194(e)(2) data from other interested parties shared by CMS with the Primary Manufacturer, if feasible, and put together recommendations on how the initial offer compares to what was submitted and develop counteroffer options and justifications.
- CMS also estimates it will take a team of healthcare professionals, such as doctors, advanced practice nurses/nurses, and/or pharmacists, 25 hours, on average, to compare CMS' initial offer and justification to the section 1194(e)(2) factors around the selected drug and therapeutic alternatives and develop counteroffer options and justifications. CMS estimates these 25 hours will be divided into 15 hours (on average, at $119.00 per hour) for pharmacists, 5 hours (on average, at $106.04 per hour) for nurses, and 5 hours (on average, at $216.60 per hour) for doctors.
- CMS estimates it will take an economist, or team of economists, 64 hours, on average, at $123.26 per hour, to consider team recommendations of the business operations specialist(s) and healthcare professionals, model counteroffer options, and recommend counteroffer options.

- CMS estimates it will take a general or operations manager, or a team of general or operations managers, 14 hours, on average, at $178.42 per hour, to review counteroffer options and justifications and develop a counteroffer proposal.
- CMS estimates it will take a lawyer, or team of lawyers, 64 hours, on average, at $204.74 per hour, to review counteroffer options and draft a justification for the selected counteroffer price.
- CMS estimates that it will take a general or operations manager, on average, 15 minutes, or 0.25 hours, to examine the gathered information, populate the Counteroffer Form, and submit the Counteroffer Form to CMS.
- CMS estimates that it will take a Chief Executive, on average, 10 hours, at $333.90 per hour, to review the counteroffer proposal, make a decision on the counteroffer price, review the counteroffer information prior to submission, and log in to the CMS HPMS to certify the submission. Certification must be done by the (1) CEO, (2) 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).

The cost estimates for this subsection are in Table 1 below. CMS estimates a total burden of 2042.5 hours (204.25 hrs.* 10 respondents) and total cost of $327,313.85 ($32,731.39 per respondent * 10 respondents).

TABLE 1: SUMMARY OF INFORMATION COLLECTION FOR DEVELOPING A COUNTEROFFER SUBMISSION PER SELECTED DRUG, FOR THE ONE-TIME COST OVER THE ONE-YEAR PERIOD

Occupation Title	Mean Hourly Wage	Cost per hour⁂	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
Business Operations Specialists (13-1199)	$45.55	$91.10	27	10	270	$24,597.00
Pharmacists (29-1051)	$59.50	$119.00	15	10	150	$17,850.00
Registered Nurses (29-1141)	$53.02	$106.04	5	10	50	$5,302.00
General Internal Medicine Physicians (291216)[7]	$108.30	$216.60	5	10	50	$10,830.00
Economist	$61.63	$123.26	64	10	640	$78,886.40

(193011)[8]						
General and Operations Managers (111021)	$89.21	$178.42	14	10	142.5	$25,424.85
Lawyer (231011)	$102.37	$204.74	64	10	640	$131,033.60
Chief Executive (11-1011)	$166.95	$333.90	10	10	100	$33,390.00
Total		-	204.25	10	2042.5	$327,313.85
Cost per Respondent						$32,731.39

⁂*As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies.*

13. Capital Costs

There are no anticipated capital costs associated with this information collection.

14. Cost to Federal Government

The federal government cost estimate is based on the efforts expended by CMS staff with the following assumptions to receive and review counteroffer submissions from Primary Manufacturers.

To generate salary estimates for the table below, CMS used the 2023 General Schedule (GS) Locality Pay Tables[9] published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region. In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. The estimates below account for reviewing counteroffer submissions and technical operations and IT builds. Staffing estimates are based on CMS duties as follows:

- CMS will review and analyze information submitted by Primary Manufacturers in the Counteroffer Form to inform negotiations; and

[7] Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2022 Occupational Employment and Wage Statistics data used

[8] Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2022 Occupational Employment and Wage Statistics data used

[9] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB_h.pdf.

- CMS will provide technical direction to a contractor to develop the Drug Price Negotiation module in the CMS HPMS for Primary Manufacturers to submit the Counteroffer Form.

TABLE 2. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT THE COUNTEROFFER PROCESS FOR SELECTED DRUGS

Task	**Estimated Cost**
Counteroffer Review	
GS-13 (step 1): (5 FTEs x $107.34 x 192 hours)	$103,046.40
GS-14 (step 1): (5 FTEs x $126.86 x 192 hours)	$121,785.60
GS-15 (step 1): (2 FTEs x $149.20 x 48 hours)	$14,323.20
Senior Executive Service: ($179.04 x 24 hours)	$4,296.96
Modification of the Existing CMS HPMS	
GS-13 (step 1): (1 FTE x $107.34 x 33 hours) Contractor: (1 x $245.54 x 200 hours)	$52,650.22
Total Cost to Government Over One Year	$296,102.38

15. Changes to Burden

This a new information collection request. The burden has been revised to use the Bureau of Labor Statistics' (BLS) May 2022 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry for selected occupations, when available. When industry-specific wage estimates were not available, the Bureau of Labor Statistics' May 2022 Occupational Employment and Wage Statistics data was used. Industry-specific estimates were used, when available, to provide a more accurate estimate of burden. As most wage estimates for the industry were higher than the broader BLS estimates for the same roles, this resulted in an increase to the burden cost. The burden hours were also increased in response to comments that CMS had initially underestimated the burden to prepare the counteroffer and due to policy updates in the revised guidance that CMS will aim to share section 1194(e)(2) data submitted by other interested parties with the Primary Manufacturer of a selected drug when feasible. Non-burden-related changes incorporated in the 30-day public notice are included in the 60- to 30-Day Drug Price Negotiation Process Cross Walk.

16. Publication/Tabulation Dates

As required by section 1195(a)(2) of the Act, CMS will publish an explanation for the MFP with respect to the factors in section 1194(e) of the Act. The Primary Manufacturer may request that certain details contained in the counteroffer submission be included in the public explanation for the agreed-upon MFP for the selected drug. A summary of the information considered in the negotiation process, including the counteroffer submission, may be shared with the public; however, proprietary information, personal health information, and personally identifiable information in the counteroffer submission will not be shared by CMS.

17. Expiration Date

The expiration date and OMB control number will be displayed within the data collection information technology system.

18. Certification Statement

There are no exceptions to the certification statement.