Supporting Statement – Part A

Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) (CMS-10849, OMB 0938-1452)

This information collection request (ICR) was formerly titled "Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)" and has been changed to "Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) (CMS-10849)." This title change reflects the merger of the information collection request for the "Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10847, OMB 0938-1449)" into the information collection request for the "Drug Price Negotiation Process (CMS-10849, OMB 0938-1452)." CMS-10847, OMB 0938-1449 has expired and will not be reinstated. For clarity, the currently approved information collection pertaining to the Drug Price Negotiation Process (CMS-10849, OMB 0938-1452) will continue with revisions reflected in this 30-day notice and incorporate the information previously collected under expired CMS-10847, OMB 0938-1449. CMS requests the renewal of one Office of Management and Budget (OMB) currently approved Medicare ICR Form: Counteroffer Form (CMS-10849, OMB 0938-1452[1]) (hereinafter, the "Statutory Written Counteroffer Form"), with revisions.

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"), 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").[2] For initial price applicability year 2027, CMS will select for negotiation up to 15 high expenditure, single source drugs covered under Part D. Any MFPs that are negotiated for these drugs will apply beginning in initial price applicability year 2027. The negotiation period for initial price applicability year 2027 begins February 28, 2025, or when the manufacturer of a selected drug enters into a Medicare Drug Price Negotiation Program Agreement (an "Agreement") with CMS, whichever is sooner.

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[1] Available for viewing at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-009.

[2] For the purposes of this ICR, qualifying single source drug has the same definition as it is given in section 30.1 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 (referenced hereinafter as "final guidance").

For the purposes of this ICR, a selected drug for initial price applicability year 2027 is defined as a drug included on the selected drug list published by CMS not later than February 1, 2025. In section 1191(c)(1) of the Act, the statute adopts the definition of manufacturer established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. In accordance with section 40 of the final guidance, 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 2027, CMS will 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 the "Primary Manufacturer"). Likewise, in accordance with section 40 of the final guidance, for initial price applicability year 2027, CMS will refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either: (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer as a "Secondary Manufacturer."

This ICR addresses two components of the Negotiation Program. First, section 1194(e) of the Act requires CMS to consider two sets of factors as the basis for determining offer(s) and counteroffer(s) throughout the negotiation process: (1) certain data that must be submitted by the manufacturer of each drug selected for negotiation in section 1194(e)(1); and (2) evidence about alternative treatments, as available, with respect to each selected drug and therapeutic alternative(s) for each selected drug in section 1194(e)(2) collectively, (the "Negotiation Data Elements" (NDE)). Second, in accordance with section 1194(b)(2)(C) of the Act, a manufacturer may submit an optional written counteroffer (the "Counteroffer"), including an Addendum populated with the counteroffer proposal for the MFP as described in section 60.4.2 of the final guidance, if CMS' written initial offer is not accepted by the Primary Manufacturer (the "Drug Price Negotiation Process").

For purposes of recognition, for initial price applicability year 2027, CMS is requesting that the information collection request for the Negotiation Data Elements be incorporated into this revised information collection package for CMS-10849, OMB 0938-1452, which was previously limited in scope to the information collection for the negotiation process counteroffer. Adding the information collection for the Negotiation Data Elements to the existing ICR package for the Drug Price Negotiation Process will streamline the review process for the pharmaceutical industry and other interested parties when reviewing Paperwork Reduction Act (PRA) renewals for this notice. For background, CMS issued the information collection requests for the Counteroffer Form and the Negotiation Data Elements separately for initial price applicability year 2026 to provide flexibility and separate time for review as it was the first year of the Negotiation Program. Because some manufacturers and other interested parties are now familiar with these processes, CMS is consolidating them under one PRA package for ease of review and renewal. Interested parties other than Primary Manufacturers of selected drugs for initial price applicability year 2027 may refer to Section I of the Negotiation Data Elements Form.

Both of these ICR forms pertain to the negotiation process of selected drugs for initial price applicability year 2027 and therefore are being advanced through the same PRA review process.

If information within a section of this Supporting Statement applies to only either the Negotiation Data Elements or the Counteroffer, a subtitle heading corresponding to the name of the applicable collection form will be listed before the applicable information.

CMS solicited public comments on the policies and defined terms related to this ICR through a 60-day comment period on the draft guidance. CMS has incorporated revisions to the final guidance that are applicable to this ICR via this 30-day public notice of this ICR.

A. Background

Negotiation Data Elements ICR Form

In accordance with section 1193(a)(4) and section 1194(b)(2)(A) of the Act, the manufacturer must submit, in a form and manner specified by CMS, information on the non-Federal average manufacturer price ("non-FAMP") for the selected drug as defined in 38 U.S.C. § 8126(h)(5) for the selected drug and information that CMS requires to carry out the negotiation process, including the factors outlined in section 1194(e)(1) of the Act, which, in conjunction with the available evidence on the factors outlined in section 1194(e)(2), will serve as the basis for determining the initial offer, any offer(s) associated with negotiation meeting(s), and the final offer, if applicable. In addition, manufacturers and the public may submit information on the factors outlined in section 1194(e)(2) of the Act, which describes evidence about the selected drug and its therapeutic alternative(s).

In accordance with section 50 of the final guidance, CMS will collect certain data from the Primary Manufacturer, including information on non-FAMP and the data identified in section 1194(e)(1) of the Act, and will collect information on evidence about a selected drug and its therapeutic alternatives per section 1194(e)(2) of the Act from any interested party. This ICR Form serves as one of multiple ways that CMS will collect data per section 1194(e)(2) of the Act.

Statutory Written Counteroffer ICR Form

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 2027 no later than June 1, 2025. In accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer will respond to CMS' written initial offer no later than 30 days after the date of receipt of the written initial offer from CMS. If the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer will submit a written counteroffer (referred to herein as the "statutory written counteroffer"), including an Addendum populated with the proposal for the MFP. In accordance with section 1194(b)(2)(D) of the Act, CMS will provide a written response to the statutory written counteroffer. CMS will provide this response within 30 days of receipt or within 60 days

of sharing the written initial offer, whichever is later. Section 60.4 of the final guidance describes the remainder of the negotiation process in detail.

Every written offer and counteroffer will include an Addendum populated with the proposal for the MFP. If an agreement on the MFP is reached at any point during the negotiation process as described in section 60.4 of the final guidance, the Addendum to the Agreement, as described in section 40.3 of the final guidance, will be executed by both parties and will constitute agreement on the MFP. The MFP included in the executed Addendum will apply for the selected drug for initial price applicability year 2027 and will be updated according to section 1195(b)(1)(A) of the Act for subsequent years in the price applicability period, as applicable. Refer to section 60.6 of the final guidance for information on how the MFP will be updated for subsequent years in the price applicability period.

As described in final guidance, CMS considered changes to the negotiation process and solicited comments in the draft guidance from interested parties on the most efficient and effective approach to facilitating negotiation within the statutory deadlines, including whether it would be preferable to contemplate an additional written offer to be made in lieu of one or more negotiation meetings. In section 60.4.5, CMS stated that CMS and Primary Manufacturers will have additional opportunities to exchange written offers and counteroffers for the MFP within the CMS HPMS during the negotiation process. CMS is not revising the Statutory Written Counteroffer Form or the associated burden estimate for the 30-day comment period to account for these changes in the negotiations process as the Statutory Written Counteroffer Form will be used exclusively for the statutory written counteroffer described in section 1194(b)(2)(C) of the Act. Revisions to the negotiation process in the final guidance do not affect this form.

B. Justification

1. Need and Legal Basis

Negotiation Data Elements ICR Form

Manufacturer-Specific Data

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining its offers, as described in section 60 of the final guidance. As described in section 50.1 of the final guidance, these factors include data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. Submission of these data by the Primary Manufacturer is required if an Agreement is signed.

These data include the following and are required to be reported by the Primary Manufacturer to CMS by March 1, 2025:

1. Research and development (R&D) costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;

2. Current unit costs of production and distribution of the selected drug, averaged across the Primary Manufacturer and any Secondary Manufacturer(s);
3. Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;
4. Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the selected drug; and
5. Market data and revenue and sales volume data for the selected drug in the United States for the Primary Manufacturer and any Secondary Manufacturer(s).

As specified in section 50.1 of the final guidance, the Primary Manufacturer should submit information in the CMS HPMS for the NDC-11s of the selected drug, inclusive of any NDC-11s that the Primary Manufacturer submits for the list of NDC-11s pursuant to section 40.2 of the final guidance. As noted above, CMS requires the Primary Manufacturer to aggregate data from both the Primary Manufacturer and any Secondary Manufacturer(s) for the following: non-FAMP, current unit costs of production and distribution, and certain data pertaining to market data and revenue and sales volume data for the selected drug.

Additionally, as specified in section 50.1 of the final guidance, the Primary Manufacturer has an ongoing obligation to timely report certain updates to data submissions required of Primary Manufacturers under sections 1193(a)(4)(A) and 1194(e)(1) of the Act and previously submitted to CMS through the initial response to the Negotiation Data Elements ICR Form.

Evidence About Alternative Treatments

Section 1194(e)(2) of the Act requires CMS to consider certain data on selected drugs and their alternative treatments. Because the statute does not specify where these data come from, as described in section 50.2 of the final guidance, CMS will allow for optional submissions from Primary Manufacturers and the public, including Secondary Manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, patients or patient organizations, and other interested parties. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in section 1194(e)(2) to ensure consideration of such factors. Primary Manufacturers may submit this information as part of their Negotiation Data Elements ICR Form. The public may optionally submit evidence about selected drugs and their alternative treatments.

Section 1194(e)(2) lists additional factors that CMS will consider, as available:

- The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
- Prescribing information in the FDA-approved labeling for the selected drug and for its therapeutic alternatives, as available;
- Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill,

children, and other patient populations); and
- The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

The Negotiation Data Elements ICR Form for manufacturer-submitted data elements and public submissions about evidence about alternative treatments must be submitted to CMS not later than March 1, 2025, for initial price applicability year 2027.

Statutory Written Counteroffer ICR Form

Section 1194(b)(2)(C) of the Act provides that if the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer may submit an optional statutory written counteroffer no later than 30 days after the date of receipt of CMS' written initial offer. If the Primary Manufacturer chooses to develop and submit such statutory written counteroffer to CMS' written initial offer during the drug price negotiation process for initial price applicability year 2027, the Primary Manufacturer must submit the Statutory Written Counteroffer Form.

2. Information Users

Under the authority of sections 1193 and 1194 of the Act, CMS is authorized to collect data and information required for negotiation. CMS will use the submitted information to negotiate and seek to reach agreement on an MFP for the selected drug with the Primary Manufacturer.

3. Use of Information Technology

Negotiation Data Elements ICR Form

Manufacturer-Specific Data

CMS has developed an automated tool within an existing information technology system used by manufacturers of drugs covered under Medicare Part D, the CMS Health Plan Management System (CMS HPMS), for Primary Manufacturers to provide the Negotiation Data Elements using the ICR form. Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)" PDF. [3] Instructions for gaining signatory access to the CMS HPMS are also included in this PDF. Technical assistance will also be made available.

The individuals who certify the Primary Manufacturer's data elements submission in the CMS HPMS must be: (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, who has authority equivalent to a CEO or a CFO of the Primary Manufacturer, or (4) an

[3] https://www.cms.gov/about-cms/information-systems/hpms/user-id-process.

individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Evidence About Alternative Treatments

As specified in section 50.2 of the final guidance, the Primary Manufacturer of a selected drug may optionally submit any evidence about their selected drugs and their alternative treatments as part of their larger data submission in the CMS HPMS.

As specified in section 50.2 of the final guidance, members of the public may optionally submit evidence about alternative treatments via a publicly available web link that will be posted on CMS.gov and the CMS HPMS landing page (https://hpms.cms.gov). In order to access the questions in Sections I and J through the web link, the respondent must provide an email address. A confirmation email message from CMS will be sent to the respondent-provided email address and the respondent must follow the steps contained in the email message to obtain access to the questions in Sections I and J. Additional instructions to access this public web application will be forthcoming from CMS and made available on CMS.gov.

Statutory Written Counteroffer ICR Form

CMS has developed an automated tool within the CMS for Primary Manufacturers to submit the statutory written counteroffer using the Statutory Written Counteroffer Form. Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)" PDF. [4] Instructions for gaining signatory access to the CMS HPMS are also included in this PDF. Technical assistance will also be made available.

The individuals who certify the Primary Manufacturer's counteroffer submission in the CMS HPMS must be: (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, who has authority equivalent to a CEO or a CFO of the Primary Manufacturer, 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

Negotiation Data Elements ICR Form

Manufacturer-Specific Data

Some manufacturer-specific data described in sections 1193(a)(4) and 1194(e)(1) of the Act and section 50.1 of the final guidance may already be collected from manufacturers by CMS or other federal agencies. For example, drug manufacturers currently submit data related to manufacturer financials, such as total net revenue (e.g., 10-K filings with the Securities and Exchange

[4] https://www.cms.gov/about-cms/information-systems/hpms/user-id-process.

Commission). Additionally, in accordance with the terms of the National Drug Rebate Agreement and section 1927(b)(3)(A) of the Act, drug manufacturers participating in the Medicaid Drug Rebate Program (MDRP) are required to report Average Manufacturer Price (AMP) to CMS each quarter for their covered outpatient drugs. For purposes of calculating the federal ceiling price, drug manufacturers also report the quarterly and annual non-FAMP on an annual basis to the Department of Veterans Affairs (VA). The Federal Supply Schedule[5] and the Big Four[6] are prices negotiated by the VA and available publicly. In addition, some of the requested data may be publicly available, although CMS may not be able to ensure that such data are complete or up-to-date. Data that is publicly available may not match the ICR specifications, including time periods required for the Negotiation Program. CMS believes that the Primary Manufacturer is best positioned to provide the requested data and the statute and the final guidance provide that manufacturers participating in the Negotiation Program will submit the requested data.

Evidence About Alternative Treatments

The information collection of evidence about selected drugs and their alternative treatments required by section 1194(e)(2) of the Act and section 50.2 of the final guidance may be obtained through multiple sources, such as academic studies and papers, extant systematic reviews of evidence, government and other reports, and clinical guidelines, and is optional for the Primary Manufacturer and public to submit. CMS intends to consider clinical evidence available through academic studies and papers, extant systematic reviews of evidence, government and other reports, subject matter experts, clinical experts (e.g., Medicare beneficiaries, academic experts, clinicians, caregivers, patients or patient organizations, and other interested parties), and data analyses.

Statutory Written Counteroffer ICR Form

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 toward minimizing the reporting burden for Primary Manufacturers, which are the only entities required to submit manufacturer-specific data and evidence about selected drugs and their alternative treatments. Only drugs with the highest total expenditures under Medicare Part D will be selected for negotiation for initial

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[5] The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government. See: https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule/about-gsaschedule#:~:text=The%20GSA%20Schedule%2C%20also%20known,reasonable%20prices%20to%20the%20government .

[6] The Big Four price is the maximum price a drug manufacturer is allowed to charge the "Big Four" federal agencies, which are the VA, Department of Defense (DoD), the Public Health Service, and the Coast Guard. See generally 38 U.S.C. § 8126; https://www.cbo.gov/publication/57007.

price applicability year 2027. Because of this basis for selection, Primary Manufacturers with selected drugs to which this ICR applies are manufacturers of drugs with high expenditures, reducing the likelihood that the information collection imposes a burden on small businesses. Moreover, the Statutory Written Counteroffer Form component of this ICR is required only 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, and Primary Manufacturers are the only entities authorized by statute to submit this information. 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) (the Small Biotech Exception, OMB 0938-1443), that excludes from selection certain qualifying covered Part D drugs based on Part D total expenditures from selection in initial price applicability year 2027.[7] This exception further reduces the potential that the information collection would impose any reporting burden on small businesses. Where a manufacturer is subject to the information collection, 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

Negotiation Data Elements ICR Form

Manufacturer-Specific Data

Forgoing collection of this information, or collecting the information less frequently are not options because Primary Manufacturers are required to submit non-FAMP data and information required to carry out negotiation per section 1193(a)(4) of the Act. Without these data, CMS would not be able to conduct drug price negotiations as directed by the IRA.

Evidence About Alternative Treatments

Submission of information about selected drugs and their alternative treatments (as outlined in section 1194(e)(2) of the Act) will be voluntary for both manufacturers and the public. Should CMS forgo this information request, manufacturers and the public would not be able to provide input on negotiation factors that the agency is required to consider when developing and negotiating the MFP. CMS believes that additional information from patients and consumers, Part D plan sponsors and Medicare Advantage organizations, Primary and Secondary Manufacturers of selected drugs, manufacturers of therapeutic alternatives for a selected drug, hospitals and health care providers, wholesalers, pharmacies, researchers, and other members of the public may provide additional insight into selected drugs and their alternative treatments. By

[7] The Small Biotech Exception and Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027" was published for a 30-day public comment period on October 2, 2024 and the comment period closed on November 1, 2024. The final package approved by the Office of Management and Budget is available at: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10844.

making this portion of the information request voluntary, CMS seeks to alleviate unnecessary burden while still providing interested parties with the opportunity to comment.

Statutory Written Counteroffer ICR Form

Less frequent collection would not be an option because the statute contemplates a Primary Manufacturer would submit the information only once, if applicable, in response to the initial offer from CMS for each selected drug for which the Primary Manufacturer chooses to engage in negotiation with CMS for initial price applicability year 2027.

7. Special Circumstances

Negotiation Data Elements ICR Form

Non-FAMP data are proprietary, as are certain other data required under section 1193(c)(1) of the Act. In accordance with section 1193(c) of the Act, information submitted that is proprietary information, as determined by the Secretary, shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out Part E of Title XI of the Act (i.e., 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 Freedom of Information Act ((FOIA) (5 U.S.C. § 552(b)(3), (4)).[8] While CMS neither requests nor requires protected health information (PHI) or personally identifiable information (PII) in this information request, interested parties may potentially submit information considered by CMS to be PHI or PII.

Statutory Written Counteroffer ICR Form

Information collected through the Statutory Written 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 Freedom of Information Act ((FOIA) (5 U.S.C. § 552(b)(3), (4)).[9]

There are no special circumstances that would require information collection for the Negotiation Data Elements ICR Form or the Statutory Written Counteroffer ICR Form to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;

[8] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.
[9] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

- 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;
- 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 54824) on July 2, 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 (89 FR 92940) on November 25, 2024 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 Negotiation Data Elements, CMS sought input from other federal agencies. CMS consulted with the VA regarding the Federal Supply Schedule and the Big Four pharmaceutical drug prices and the FDA regarding pharmaceutical drug identifying information, such as National Drug Codes (NDCs).

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents for participation.

The information submitted on the Statutory Written Counteroffer Form 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 CMS may issue a revised offer for the MFP based on the Primary Manufacturer's counteroffer submission.

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 Exemption 3 and/or Exemption 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).[10]

As discussed in final guidance, CMS is implementing a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information including Exemption 3 and/or Exemption 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. Thus, for initial price applicability year 2027, CMS will treat information on non-FAMP (as defined in 38 U.S.C. § 8126(h)(5)) as proprietary.

For initial price applicability year 2027, CMS will also treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) and section 1194(e)(2) of the Act as proprietary if the information constitutes commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer that cannot be found publicly. Specifically, CMS will treat R&D costs and recoupment, unit costs of production and distribution, pending patent applications, market data, and revenue and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat the data on prior Federal financial support and approved patent applications, exclusivities, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS believes these data are publicly available.

Pursuant to section 1195(a)(2) of the Act, CMS is required to publish the explanation of the MFP by March 1, 2026, for initial price applicability year 2027 (described in final guidance). Alongside this narrative explanation, CMS will release redacted information regarding the section 1194(e)(1) and section 1194(e)(2) data submitted by the Primary Manufacturer and the public, the exchange of offers and counteroffers, and the negotiation meetings, if applicable. CMS will also make high-level comments about the section 1194(e)(1) and section 1194(e)(2) data submitted to CMS that are determined to be proprietary, without sharing any proprietary information reported to CMS under section 1193(a)(4) for purposes of the negotiation.

CMS requests that respondents submitting information for this ICR identify if there is information submitted in response to questions pertaining to section 1194(e)(1) and section 1194(e)(2) data that the respondent believes qualifies for Exemption 3 and/or Exemption 4 of FOIA, if CMS has not already identified such information as proprietary and/or confidential as discussed in section 40.2.1 of the final guidance.

[10] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimates (Hours & Wages)

Negotiation Data Elements ICR Form

A Primary Manufacturer must complete and submit the information requested on the Negotiation Data Elements ICR Form for the purpose of negotiation for a selected drug. The data required from the Primary Manufacturer are outlined in sections 1193(a)(4) and 1194(e)(1) of the Act and final guidance. The Primary Manufacturer must submit information in the CMS HPMS for the NDC-11s of the selected drug, inclusive of any NDC-11s that the Primary Manufacturer submits for the list of NDC-11s pursuant to final guidance. Information submission for factors outlined in section 1194(e)(2) of the Act are voluntary and open to all interested parties. By soliciting input from the public on factors outlined in section 1194(e)(2) of the Act, the intent of this information request is to obtain data from any interested party, including patients and consumers, Part D plan sponsors and Medicare Advantage organizations, Primary and Secondary Manufacturers, manufacturers of therapeutic alternatives for a selected drug, hospitals and health care providers, wholesalers, pharmacies, and researchers.

To derive wage estimates, CMS used data from the Bureau of Labor Statistics' May 2023 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 Negotiation Data Elements ICR Form.[11] When industry-specific wage estimates were not available, the Bureau of Labor Statistics' May 2023 Occupational Employment and Wage Statistics data was used. Tables 1-6 below present the estimated median hourly wage, the cost of fringe benefits and overhead, total burden hours, and total cost to submit this form.

Manufacturer-Specific Data

The Primary Manufacturer is best positioned to provide the requested data and the statute provides that manufacturers participating in the Negotiation Program will submit the requested data.

Thus, Primary Manufacturers that have agreed to participate in the Negotiation Program are required to report the information provided for in sections 1193(a)(4) and 1194(e) of the Act. Table 1 presents the estimated median hourly wage, the adjusted hourly wage (inclusive of fringe benefits and overhead), total burden, and total cost to submit the data outlined in the justification section of this supporting statement and the information collection. Although CMS expects Primary Manufacturers to have some of the data readily available for submission, there is some

[11] 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).

uncertainty to the estimate in Table 1 as some of the data required may not be readily available and may take time to compile, such as R&D costs that manufacturers have recouped, as required under section 1194(e)(1) of the Act. Given this uncertainty, the burden estimate is provided along with a high estimate and low estimate in Table 2. For initial price applicability year 2027, CMS will provide manufacturers with a new file import option for certain data-intensive questions in Sections A, B, D, F, and G to reduce Primary Manufacturer burden. Upon import, HPMS will populate the data entry form fields, after which manufacturers will use the existing save/complete functionality to save and validate the imported data. CMS expects that these changes would reduce manufacturer burden compared to initial price applicability year 2026. Direct data entry will also remain available for these questions if preferred.

Evidence About Alternative Treatments

As previously noted, information on selected drugs and their alternative treatments required by section 1194(e)(2) of the Act may be gathered from several sources and submission of such information is voluntary and open to the Primary Manufacturer of a selected drug as well as the public. Where possible, data are used to inform this burden estimate. However, there is considerable uncertainty as interested parties will differ in time spent gathering and submitting data, resources available to each party to submit such data, and other considerations that could impact the burden estimate.

CMS estimates the burden associated with data collection in two separate estimates below, one estimate for the Primary Manufacturer which includes the mandatory data collection under sections 1193(a)(4) and 1194(e)(1) of the Act as well as the optional submission of data for 1194(e)(2) of the Act; the second estimate is for interested parties submitting data for factors under 1194(e)(2) of the Act. CMS seeks comment on these estimates and assumptions. While data under section 1194(e)(2) of the Act is optional for the Primary Manufacturer, CMS expects the Primary Manufacturer will participate in this submission.

A. Estimated Burden for Primary Manufacturers

CMS anticipates collecting data from a Primary Manufacturer in response to Sections A through J of this ICR for up to 15 selected drugs for initial price applicability year 2027, which will be collected in 2025. For purposes of this information collection, CMS assumes there will be up to 15 Primary Manufacturers, one for each selected drug, and up to 15 drugs selected for negotiation, which represents the statutory maximum. The collection of these data will be a one-time cost for each selected drug and CMS assumes each Primary Manufacturer will spend, on average, the same amount of time to collect, aggregate, analyze, and report the data for a selected drug. While a Primary Manufacturer may have multiple selected drugs, CMS assumes that a Primary Manufacturer would require the same time and effort to submit data for each selected

drug. The Primary Manufacturer must also gather and submit the data required under the Act on behalf of the Secondary Manufacturer[12] of a selected drug, if applicable.

CMS estimates it will take a business operations specialist or team of business operations specialists, on average, 200 hours, at a cost of $89.88 per hour, to gather cost data and compile required information, as specified in the data elements instructions, such as data on prior Federal financial support, pending and approved patent applications, exclusivities recognized by the FDA and applications and approvals, and market data, and revenue and sales volume data. After the relevant data have been gathered and compiled, it is estimated that it will take an economist or team of economists, on average, 600 hours, at a cost of $111.28 per hour, to perform necessary economic analyses, including the R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs, the selected drug's cost of production and distribution, and other data elements specified in the data element instructions. The estimated hourly burden per Primary Manufacturer for initial price applicability year 2027 was increased following public feedback received during the 60-day comment period; however, CMS notes that a new file import option for certain data-intensive questions in Sections A, B, D, F, and G will also reduce Primary Manufacturer burden for data entry. Although submitting evidence about therapeutic alternatives is optional, this burden estimate assumes that all Primary Manufacturers will choose to perform analyses related to therapeutic advances conferred by the selected drug, the costs of existing alternatives, unmet medical need, and comparative effectiveness.

Once these analyses are performed, CMS estimates that it will take a financial manager, on average, 50 hours, at a cost of $173.08 per hour, to review the results of all the analyses and cost estimates prior to submission to CMS. CMS estimates it will take a lawyer 4 hours, on average, at $230.00 per hour, to review the compiled data submission.

CMS estimates that it will take a cost estimator, on average, 142 hours, at a cost of $71.88 per hour, to compile and report the required data to CMS, per the data element form instructions.

Finally, CMS estimates that it will take a chief executive officer (CEO), on average, 4 hours, at $230.00 per hour, to review the data submission and log in to the CMS HPMS to certify the submission. Certification must be done by (1) the CEO, (2) the chief financial officer (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 one-time costs are presented in Table 1. The estimate yields a total burden of 15,000 hours (1,000 hrs. per Primary Manufacturer per selected drug * 15 selected drugs) and total cost of $1,581,674.40 for all 15 selected drugs ($105,444.96 per respondent per selected drug * 15 selected drugs).

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[12] The burden estimate assumes some coordination between the Primary Manufacturer and the Secondary Manufacturer, as necessary, to collect and submit the data.

TABLE 1: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR 15 SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2027

Occupation Title	Median Hourly Wage	Cost per hour*	# Hours	# Respondents	Total Burden Hours	Total Cost
Financial Manager (11-3031)	$86.54	$173.08	50	15	750	$129,810.00
Cost Estimator (13-1051)[13]	$35.94	$71.88	142	15	2130	$153,104.40
Business Operations Specialists (13-1000)	$44.94	$89.88	200	15	3000	$269,640.00
Economist (19-3011)[14]	$55.64	$111.28	600	15	9000	$1,001,520.00
Lawyer (23-1011)	$115.00	$230.00	4	15	60	$13,800.00
Chief Executive (11-1011)	$115.00	$230.00	4	15	60	$13,800.00
Total (15 Manufacturers)	-	-	15,000	15	15,000	$1,581,674.40
Total per Manufacturer	-	-	1,000	1	1,000	$105,444.96

** As previously noted, this estimate assumes 100 percent increase to account for fringe benefits and overhead. This adjustment is a broad approximation as fringe benefits and overhead costs vary significantly across employers and methods of estimating these costs vary widely across studies.*

An additional low estimate and high estimate is provided in Table 2 below to illustrate the possible variability for this burden estimate. To calculate the low estimate, the base estimate (Table 1 Total) has been reduced by half for each labor category. For the high estimate, the

[13] Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2023 Occupational Employment and Wage Statistics data used. Available here: https://www.bls.gov/oes/current/oes_nat.htm#00-0000.
[14] Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2023 Occupational Employment and Wage Statistics data used. Available here: https://www.bls.gov/oes/current/oes_nat.htm#00-0000.

required time and cost associated with each labor category from the base estimate has been doubled.

TABLE 2: COST RANGE ESTIMATES FOR PRIMARY MANUFACTURER

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	500	$52,722.48	$790,837.20
Base Estimate (from Table 1)	1000	$105,444.96	$1,581,674.40
High Estimate	2,000	$210,889.92	$3,163,348.80

B. Estimated Burden for General Public

To generate burden estimates for initial price applicability year 2027, CMS reviewed the public feedback that was received for the initial price applicability year 2026 negotiation period. CMS received 106 submissions from individuals and organizations for the section 1194(e)(2) data collection. Approximately 55% of these submissions were from organizations. Due to the increased number of drugs possibly selected for negotiation and greater awareness around the public input process for the Drug Price Negotiation Program, CMS assumes it will receive approximately three times as many public submissions for initial price applicability year 2027 compared to initial price applicability year 2026. This results in approximately 325 total submissions, with 150 individual respondents and 175 organizations.

This estimate assumes as many as 150 individual respondents may spend, on average, 3 hours to review literature and submit information to CMS for a selected drug. Additionally, CMS assumes that there will be other organizations that develop responses that will take additional resources. CMS estimates that as many as 175 organizations may take, on average, 30 hours to review literature and submit information to CMS. For initial price applicability year 2027, new question prompts are included in Section I (increasing from five total questions for initial price applicability year 2026 to 34 total questions for initial price applicability year 2027) and CMS has increased the burden estimate to reflect that, while not all respondents may respond to all questions, some respondents may respond to all questions and respondents may review and consider potential responses to all questions. CMS also increased the burden estimate for individuals and organizations following feedback from interested parties on the amount of time it took to complete the section 1194(e)(2) data submission for initial price applicability year 2026. The U.S. Bureau of Labor Statistics' labor category of "all occupations" was used for this estimate given individual and organizational labor estimates will vary; the estimate includes overhead and fringe benefits at 100 percent of the hourly wage. This estimate yields a total burden of 5,700 hours (17.54 hrs. * 325 respondents) and total cost of $263,454.00 dollars (5,700 hrs. * $46.22), as displayed in Table 3.

TABLE 3: SUMMARY OF INFORMATION COLLECTION REQUEST FOR PUBLIC FEEDBACK FOR 15 SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2027

Type of Respondent	Occupation Title	Median Hourly Wage*	# Respondents	Hours per response	Total hours	Total Cost
Individual	All Occupations 00-0000	$46.22	150	3	450	$20,799.00
Organization	All Occupations 00-0000	$46.22	175	30	5,250	$242,655.00
Total	**-**	**-**	**325**	**17.54**	**5,700**	**$263,454.00**

**Includes fringe benefits and overhead of 100 percent of median hourly wage.*

An additional low estimate and high estimate is provided in Table 4 and Table 5 below to illustrate possible variability for this burden estimate. To calculate the low estimate, the base estimate (Table 3 Total) has been reduced by half for the "individual" and "organization" categories. For the high estimate, the required time and cost associated with individuals and organizations has been doubled.

TABLE 4: COST RANGE ESTIMATES FOR AN INDIVIDUAL FOR PUBLIC FEEDBACK FOR INITIAL PRICE APPLICABILITY YEAR 2027

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	**1.5**	**$69.33**	**$10,399.50**
Base Estimate (from Table 3)	**3**	**$138.66**	**$20,799.00**
High Estimate	**6**	**$277.32**	**$41,598.00**

TABLE 5: COST RANGE ESTIMATES FOR AN ORGANIZATION FOR PUBLIC FEEDBACK FOR INITIAL PRICE APPLICABILITY YEAR 2027

	Hours per Respondent	**Cost per Respondent**	**Total Cost**
Low Estimate	**15**	**$693.30**	**$121,327.50**
Base Estimate (from Table 3)	**30**	**$1,386.60**	**$242,655.00**
High Estimate	**60**	**$2,773.20**	**$485,310.00**

Total burden estimates are displayed in Table 6.

TABLE 6: SUMMARY OF BURDEN FOR INITIAL PRICE APPLICABILITY YEAR 2027

Occupation Title	**Total Burden Hours**	**Total Cost**
Primary Manufacturers (n=15)	15,000	$1,581,674.40
Individuals (n=150)	450	$20,799.00
Organizations (n=175)	5,250	$242,655.00
Total	**20,700**	**$1,054,291.20**

Statutory Written Counteroffer ICR Form

A Primary Manufacturer must complete and submit the information requested on the Statutory Written Counteroffer Form if it both chooses not to accept CMS' initial offer and chooses to submit a statutory written 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 2023 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 Statutory Written Counteroffer Form.[15] When industry-specific wage estimates were not available, the Bureau of Labor Statistics' May 2023 Occupational Employment and Wage Statistics data was used. Table 7 below presents the estimated median hourly wage, the cost of fringe benefits and overhead, total burden hours, and total cost to submit this form.

CMS will select up to 15 high expenditure, single source drugs covered by Medicare Part D for negotiation for initial price applicability year 2027. Statutory written counteroffers will be submitted by Primary Manufacturers for up to 15 selected drugs, and completing the Statutory Written Counteroffer Form will be a one-time cost for each selected drug for which a Primary Manufacturer submits a statutory written counteroffer. The statute envisions that statutory written counteroffer submissions for initial price applicability year 2027 will occur in 2025, 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 June 1, 2025, and if the Primary Manufacturer chooses to submit a statutory 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 statutory written 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 statutory written counteroffer information for each selected drug.

CMS estimates up to 15 total respondents for initial price applicability year 2027. CMS chose this number because by statute only up to 15 drugs covered by Medicare Part D can be selected for negotiation for 2027, 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 fifteen respondents for initial price applicability year 2027. 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 Statutory Written 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 Statutory Written Counteroffer Form.

- CMS estimates it will take a business operation specialist, or a team of business operations specialists, 27 hours, on average, at $89.88 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

[15] 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).

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 $126.98 per hour) for pharmacists, 5 hours (on average, at $104.76 per hour) for nurses, and 5 hours (on average, at $214.72 per hour) for doctors.
- CMS estimates it will take an economist, or team of economists, 64 hours, on average, at $111.28 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 $167.78 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 $230.00 per hour, to review counteroffer options and draft a justification for the selected counteroffer proposal for the MFP.
- 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 Statutory Written Counteroffer Form, and submit the Statutory Written Counteroffer Form to CMS.
- CMS estimates that it will take a Chief Executive, on average, 10 hours, at $230.00 per hour, to review the counteroffer proposal, make a decision on the counteroffer proposal for the MFP, review the counteroffer information prior to submission, and log in to the CMS HPMS to certify the submission. Certification must be done by (1) the CEO, (2) the 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 7 below. CMS estimates a total burden of 3063.75 hours (204.25 hrs.* 15 respondents) and total cost of $486,924.68 ($32,461.65 per respondent * 15 respondents).

TABLE 7: SUMMARY OF INFORMATION COLLECTION FOR DEVELOPING A STATUTORY WRITTEN COUNTEROFFER SUBMISSION PER SELECTED DRUG, FOR THE ONE-TIME COST OVER THE ONE-YEAR PERIOD

Occupation Title	Median Hourly Wage	Cost per hour⁂	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
Business Operations Specialists (13-1199)	$44.94	$89.88	27.00	15	405.00	$36,401.40
Pharmacists (29-1051)	$63.49	$126.98	15.00	15	225.00	$28,570.50
Registered Nurses (29-1141)	$52.38	$104.76	5.00	15	75.00	$7,857.00
General Internal Medicine Physicians (291216)[16]	$107.36	$214.72	5.00	15	75.00	$16,104.00
Economist (193011)[17]	$55.64	$111.28	64.00	15	960.00	$106,828.80
General and Operations Managers (111021)	$83.89	$167.78	14.25	15	213.75	$35,862.98
Lawyer (231011)	$115.00	$230.00	64.00	15	960.00	$220,800.00
Chief Executive (11-1011)	$115.00	$230.00	10.00	15	150.00	$34,500.00
Total	-	-	204.25	15	3063.75	$486,924.68

[16] Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2023 Occupational Employment and Wage Statistics data used.
[17] Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2023 Occupational Employment and Wage Statistics data used.

Occupation Title	Median Hourly Wage	Cost per hour⁂	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
Cost per Respondent	-	-	-	-	-	$32,461.65

⁂*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

Negotiation Data Elements ICR Form

The federal government cost is based on the efforts expended by CMS staff with the following assumptions to receive, review, and process data from drug manufacturers and the public for the negotiation processes.

To generate salary estimates reflected in Table 8 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.[18] In this regard, Table 8 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 as follows:

- CMS will review and analyze information submitted by Primary Manufacturers and the public in the Negotiation Data Elements Form to inform initial offers; and
- CMS will provide technical direction to a contractor to modify the Drug Price Negotiation module in the CMS HPMS for Primary Manufacturers and the public to submit the Negotiation Data Elements Form.

In addition, CMS staff and one contractor will complete work in the CMS HPMS to accommodate this ICR.

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

TABLE 8. BURDEN ESTIMATE COST FOR CMS STAFF FOR INITIAL PRICE APPLICABILITY YEAR 2027

Staff	FTE Equivalent	Hourly Wage	Total Burden Hours	Total Cost
Section 1194(e) Review				
GS-13, step 1	7	113.04	691	$546,932.74
GS-14, step 1	3	133.58	691	$276,991.49
GS-15, step 1	2	157.12	173	$54,300.67
Modification of the Existing CMS HPMS				
GS-13, step 1	2	113.04	80	$18,086.40
Contractor	4.5	246.97	200	$222,273.00
Total Cost to Government Over One Year				**$1,118,584.30**

Statutory Written Counteroffer ICR Form

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

To generate salary estimates for the table below, CMS used the 2024 General Schedule (GS) Locality Pay Tables[19] published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region. In this regard, Table 9 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. The estimates below account for reviewing statutory written 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 Statutory Written Counteroffer Form to inform negotiations; and
- CMS will provide technical direction to a contractor to modify the Drug Price Negotiation module in the CMS HPMS for Primary Manufacturers to submit the Statutory Written Counteroffer Form.

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

TABLE 9. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT THE STATUTORY WRITTEN COUNTEROFFER PROCESS FOR SELECTED DRUGS

Staff	FTE Equivalent	Hourly Wage	Total Burden Hours	Total Cost
Counteroffer Review				
GS-13, step 1	5	113.04	288	$162,777.60
GS-14, step 1	5	133.58	288	$192,355.20
GS-15, step 1	2	157.12	72	$22,625.28
Senior Executive Service	1	188.54	36	$6,787.58
Modification of the Existing CMS HPMS				
GS-13, step 1	1	113.04	40	$4,521.60
Contractor	2	246.97	80	$39,515.20
Total Cost to Government Over One Year				**$428,582.46**

15. Changes to Burden

This is a revision of a currently approved ICR.

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

To the Negotiation Data Elements ICR form, based on public feedback on the 60-day notice, CMS revised the burden estimates upwards to an estimated middle average of 1,000 hours for manufacturers to complete of the form for initial price applicability year 2027. CMS retained an estimated range of hours for completion. Of note, CMS expects that a new file import option for certain data-intensive questions in Sections A, B, D, F, and G will also reduce Primary Manufacturer burden for data entry.

CMS revised the title of the “Counteroffer ICR Form” to “Statutory Written Counteroffer ICR Form” to align with revisions to the final guidance.

The 60-day proposed revisions for initial price applicability year 2027 included:

To the Negotiation Data Elements ICR form, CMS added and revised certain defined terms consistent with the draft guidance. Additionally, CMS revised the instructions to change word counts to character counts, include information regarding a Primary Manufacturer's obligation to provide updated data from its original submission to Sections A through G to CMS consistent with the draft guidance and to add instructions regarding the optional identification of information submitted by any respondent that may be exempt from disclosure under FOIA. CMS also included the following revisions within specific sections:

- Section A:
    - Added the following columns: Sample package, inner package, outer package, private label, National Council for Prescription Drug Programs (NCPDP) unit, total NCPDP units per package, AMP unit, total AMP units per package.
    - Removed the following columns: Dosage form, strength, unit.
- Section B:
    - Split calendar quarter and year columns to allow for non-FAMP of calendar year 2021 or the first calendar year post entry to be reported.
    - Revised column heading from "total package unit volume" to "total NDC-11 package volume" to clarify CMS is asking for package volume (e.g., total number of bottles) instead of unit volume (e.g., total number of tablets across bottles).
    - Removed dosage form unit column.
    - Added a new table with similar column headings to collect non-FAMP for calendar year 2024 per statute for IPAY 2027.
- Section C:
    - Separated instructions and questions for each R&D category such that the numerical response is a distinct question from the free response.
    - Added a new question asking manufacturers to indicate whether the selected drug was assigned to an FDA expedited program.
- Section D:
    - Revised column heading of "indicate unit used" to "NCPDP unit."
    - Added "costs are not available" and "explanation of why costs are not available" columns to allow manufacturers to explain why costs are not available for prepopulated rows.
- Section E:
    - Added instructions for reporting in-kind contributions and Cooperative Research and Development Agreements (CRADAs).
    - Added categories to Federal financial support to include CRADAs, in-kind contributions, and support for failed or abandoned indications for the selected drug.
- Section G:
    - Revised period of data collection across all section G questions from most recent five years to three years ending December 31, 2024.
    - Revised column heading of "unit type (each, ML, GM)" to "NCPDP Unit (EA, ML, GM)" in questions 16, 20, 22, and 24.

    - Revised column heading of "unit type" to "AMP Unit (injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie)" in question 18.
    - Added a column to questions 16, 18, 20, 22, and 24 to allow the manufacturer to tell us why a particular price wasn't reported (e.g., explanation of why WAC was not reported (if applicable)).
    - Added a new price to be reported in questions 25 and 26, "Manufacturer net Medicare Part D price."
- Section I:
    - Added an optional request for demographic information for respondents that self-identify as a patient.
    - Revised Section I questions to capture indication-specific information related to the selected drug and that selected drug's therapeutic alternatives.
    - Ordered questions by potential respondent group types, but all questions may be answered by any respondent.
    - Added list of FDA-approved indications for the selected drug for respondent reference.
    - Added a request for a list of possible therapeutic alternative(s) for the selected drug's clinical outcomes measures.
    - Added request for: evidence on clinical comparative effectiveness, prevalence of identified indications among the Medicare population, estimate of Medicare utilization of the selected drug for each indication, and estimates of health care resource utilization for the population using the selected drug and its therapeutic alternative(s).
    - Added additional questions and revised previous questions on patient experience.
    - Revised the question on unmet medical need.

For initial price applicability year 2027, CMS edited the Statutory Written Counteroffer ICR Form to not require Primary Manufacturers to type in the name of the selected drug. This is to reflect updates to the CMS HPMS, where the selected drug is picked from a dropdown menu earlier in the module.

CMS adjusted the burden estimates to manufacturers, the public, and the federal government to account for the selected drug list growing from 10 drugs in initial price applicability year 2026 to up to 15 selected drugs in initial price applicability year 2027. CMS also adjusted the burden estimate on the information collection request for public feedback to reflect experience with submissions in initial price applicability year 2026. Furthermore, CMS adjusted the burden estimate to modify the existing CMS HPMS system downwards as negotiation-specific modules were built for the first year of negotiations and will only need to be updated with data specific to initial price applicability year 2027 in the next year.

The burden in Tables 1-7 for the submission of information for the up to 15 selected drugs from Primary Manufacturers and the public has been revised to reflect May 2023 wages in the pharmaceutical and medicine manufacturing industry (NAIC 325400) to the extent that the job occupation code exists in the U.S. Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) for a specified job code (i.e., financial manager and business

operations specialist). The burden estimate in Tables 8-9 for the cost to the federal government were updated to reflect 2024 wages.

CMS will provide manufacturers with a new file import option for certain data-intensive questions in Sections A, B, D, F, and G to reduce Primary Manufacturer burden. Direct data entry will remain available for these questions. Upon import, HPMS will populate the data entry form fields, after which manufacturers will use the existing save/complete functionality to save and validate the imported data. CMS expects that these changes will reduce manufacturer burden.

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 negotiation factors in section 1194(e) of the Act, therefore summarized or redacted information may be shared with the public. In this public explanation and any other public documents discussing the MFP, CMS will make public the section 1194(e)(1) and section 1194(e)(2) data submitted by the Primary Manufacturer and the public that are determined to be non-proprietary, but will not include any PHI or PII (see section 40.2.1 of the final guidance).

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.