

Supporting Statement – Part A

Drug Price Negotiation for Initial Price Applicability Year 2028 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 “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) (CMS-10849, OMB 0938-1452)” and has been changed to “Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) (CMS-10849, OMB 0938-1452).”

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”).¹ For initial price applicability year 2028, CMS will select for negotiation up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D. Any MFPs that are negotiated for these drugs will apply beginning in initial price applicability year 2028. The negotiation period for initial price applicability year 2028 begins February 28, 2026, or when the manufacturer of a selected drug enters into a Medicare Drug Price Negotiation Program Agreement (an “Agreement”) with CMS, whichever is sooner. For initial price applicability year 2028, CMS will also renegotiate MFPs for drugs selected for renegotiation (if any), in accordance with section 1194(f)(4) of the Act. For renegotiated drugs, Primary Manufacturers are obligated to make the renegotiated MFP available when the drug is dispensed, furnished, or administered to MFP-eligible individuals on or after January 1, 2028.

For the purposes of this ICR, a selected drug for initial price applicability year 2028 is defined as a drug included on the selected drug list published by CMS not later than February 1, 2026. CMS will also publish the selected drugs selected for renegotiation for initial price applicability year 2028 following the same timeframe as the newly selected drugs. A Primary Manufacturer that has an Agreement in effect, as discussed in section 40 of the final guidance, will be required to adhere to the process and deadlines described in the final guidance, including section 130. In section 1191(c)(1) of the Act, the statute adopts the definition of a manufacturer established in

¹ 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 2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027, and 2028 (referenced hereinafter as “final guidance”).

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 2028, 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 2028, 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, CMS considers two sets of factors as the basis for determining offer(s) and counteroffer(s) throughout the negotiation and renegotiation process in accordance with sections 1194(e) and 1194(f)(4)(B) of the Act and sections 60 and 130.4 of the final guidance: (1) certain data that must be submitted by the manufacturer of each drug selected as described in section 1194(e)(1); and (2) evidence, as available, with respect to each selected drug and therapeutic alternative(s) for each selected drug as described 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 (referred to herein as the “statutory written counteroffer”), including an Addendum populated with the counteroffer proposal for the MFP as described in section 60.4.3 of the final guidance, if CMS’ written initial offer is not accepted by the Primary Manufacturer. In accordance with section 1194(f)(4)(B) of the Act and to conform to the procedures, structure, and timing of the negotiation process as described in section 130.4.3 of the final guidance, a manufacturer may submit an optional written counteroffer (referred to herein as the “renegotiation written counteroffer”) if CMS’ written initial offer is not accepted by the Primary Manufacturer during the renegotiation process.²

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 separately through a 45-day comment period on a draft version of the final guidance. CMS incorporated revisions included with the final guidance that are also applicable to this ICR via the 30-day public notice of this ICR.

² The statutory written counteroffer and renegotiation written counteroffer are hereinafter collectively referred to as the “Counteroffer.”

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”) 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 1194(f)(4)(B) of the Act and section 130.3 of the final guidance, CMS will apply a similar approach regarding data collection once a drug is selected for renegotiation of the MFP, if any drugs are selected for renegotiation.

In accordance with sections 50 and 130.3.2 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 described in section 1194(e)(2) of the Act.

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 1194(b)(2)(B) and 1194(f)(4)(B) of the Act and sections 60.4.2 and 130.4.3 of the final guidance, CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug or the proposal of a renegotiated MFP for a selected drug for initial price applicability year 2028 no later than June 1, 2026. In accordance with sections 1194(b)(2)(C) and 1194(f)(4)(B) of the Act and sections 60.4.2 and 130.4.3 of the final guidance, 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 the Statutory Written Counteroffer ICR Form or the Renegotiation Written Counteroffer ICR Form, as applicable, including an Addendum populated with the proposal for the MFP.³ In accordance with sections 1194(b)(2)(D) and 1194(f)(4)(B) of the Act and sections 60.4.2 and 130.4.3 of the final guidance, CMS will provide a written response to the statutory

³ The Statutory Written Counteroffer ICR Form and the Renegotiation Written Counteroffer ICR Form are collectively referred to as the “Counteroffer ICR Form.”

written counteroffer and the renegotiation written counteroffer, respectively. CMS will provide this response within 30 days of receipt or within 60 days of sharing the written initial offer, whichever is later. If CMS rejects the Primary Manufacturer's Counteroffer, CMS and Primary Manufacturers can choose to initiate additional, written offers and counteroffers via the additional price exchange module in the CMS HPMS. Sections 60.4 and 130.4 of the final guidance describe the remainder of the negotiation and renegotiation processes in greater detail, respectively.

Every written offer and counteroffer, including a 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 or renegotiation process pursuant to sections 60.4 and 130.4 of the final guidance, respectively, 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.⁴ The MFP included in the executed Addendum will apply for the selected drug for initial price applicability year 2028 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.

CMS is requesting approval of revisions to this ICR package based on lessons learned from implementation of the Negotiation Program for initial price applicability year 2027 to improve clarity of instructions to ensure high quality and consistent data across submissions and to improve CMS' ability to conduct compliance reviews of such submissions. Additionally, CMS incorporates policy revisions, as applicable, to reflect parallel changes made to the final guidance. CMS believes that the changes will contribute to a more efficient preparation process for respondents in preparing to answer the Drug Price Negotiation ICR.

B. Justification

1. Need and Legal Basis

Negotiation Data Elements ICR Form

Manufacturer-Specific Data

In accordance with sections 1194(e) and 1194(f)(4)(B) of the Act and sections 60 and 130 of the final guidance, CMS will consider certain factors, as applicable to the selected drug, as the basis for determining its offers. As described in sections 50.1 and 130.3.2 of the final guidance, these factors include data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. A Primary Manufacturer that has an Agreement in effect, as discussed in section 40 of the final guidance, will be required to adhere to the process and deadlines for negotiation and

⁴ To the extent applicable, any references in this draft guidance to the "MFP" includes a renegotiated MFP.

renegotiation, including related to data submission, described in the final guidance, including sections 50 and 130.

These data include the following and are required to be reported by the Primary Manufacturer to CMS by March 1, 2026:

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 U.S. Food and Drug Administration (FDA), and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or section 351(a) of the Public Health Service Act (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).

Pursuant to sections 50.1 and 130.3.2 of the final guidance, the Primary Manufacturer should submit information in the CMS Health Plan Management System (the “CMS HPMS”) for each 11-digit National Drug Code (NDC-11) 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

In accordance with sections 1194(e)(2) and 1194(f)(4)(B) of the Act and sections 60 and 103.4 of the final guidance, CMS will consider certain data on selected drugs and their alternative treatments. Because the statute does not specify where these data come from, as described in sections 50.2 and 130.3.2 of the final guidance, CMS will allow for optional submissions once a drug is selected for negotiation or renegotiation 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;
- 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, 2026, for initial price applicability year 2028.

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 negotiation process for initial price applicability year 2028, the Primary Manufacturer must submit the Statutory Written Counteroffer ICR Form.

Section 1194(f)(4)(B) of the Act provides that CMS shall, to the extent practicable, establish a renegotiation process that is consistent with the methodology and process established for negotiation under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act. Consistent with the negotiation process described in section 60.4 of final guidance, if the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer may submit an optional renegotiation written counteroffer no later than 30 days after the date of receipt of CMS' written initial offer in accordance with section 130.4.3 of the final guidance. If the Primary Manufacturer chooses to develop and submit such renegotiation written counteroffer to CMS' written initial offer during the renegotiation process for initial price applicability year 2028, the Primary Manufacturer must submit the Renegotiation Written Counteroffer ICR 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 and renegotiation. CMS will use the submitted information to negotiate or renegotiate, as applicable, and seek to reach agreement on an MFP, as applicable, 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 HPMS, for Primary Manufacturers to provide the Negotiation Data Elements using the ICR form. Manufacturers of drugs payable under Medicare Part B currently use the CMS HPMS for the Medicare Prescription Drug Inflation Rebate Program.⁵ Instructions for manufacturers to gain access to the CMS HPMS can be found in the “Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (CMS HPMS) for the Medicare Drug Price Negotiation Program” PDF. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.⁶

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 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

Pursuant to sections 50.2 and 130.3.2 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.

In accordance with sections 50.2 and 130.3.2 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>). A registered email address is no longer required to access the landing page for Sections I and J for

⁵ For more information, refer to the “Action Needed: Medicare Prescription Drug Inflation Rebate Program Onboarding” memo, available at <https://www.cms.gov/files/document/medicare-prescription-drug-inflation-rebate-program-onboarding-memo.pdf>.

⁶ <https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf>.

initial price applicability year in this 30-day version, as was required in past versions of this ICR. Additional instructions to access this public web application will be forthcoming from CMS and made available on CMS.gov.

Counteroffer ICR Form

CMS has developed an automated tool within the CMS HPMS for Primary Manufacturers to submit the Counteroffer using the Statutory Written Counteroffer ICR Form or the Renegotiation Written Counteroffer ICR Form, as applicable. Instructions for manufacturers to gain access to the CMS HPMS can be found in the “Instructions for Requesting Drug Manufacturer Access in the CMS HPMS for the Medicare Drug Price Negotiation Program” PDF.⁷ Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

The individuals who certify the Primary Manufacturer’s Counteroffer submission in the CMS HPMS must be: (1) the CEO of the Primary Manufacturer, (2) the 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 sections 50.1 and 130 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 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 Schedule⁸ and the

⁷ <https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf>.

⁸ 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.>

Big Four.⁹ are prices negotiated by the VA and are 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

In accordance with sections 1194(e)(2) and 1194(f)(4)(B) of the Act and sections 60 and 103.4 of the final guidance, CMS will consider certain data on selected drugs and their alternative treatments. Pursuant to sections 50.2 and 130.3.2 of the final guidance, this information 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.

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. Only drugs with the highest total expenditures payable under Medicare Part B and/or covered under Medicare Part D will be selected for negotiation for initial price applicability year 2028. Drugs selected for renegotiation, if any, were initially selected for negotiation because they were drugs with the highest expenditures covered under Medicare Part D. 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 Counteroffer ICR Form 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

⁹ 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>.

which this information collection is relevant is further reduced by the exception for small biotech drugs, in accordance with section 1192(d)(2) of the Act that excludes from selection certain qualifying drugs payable under Part B and/or covered under Part D based on Part B or Part D total expenditures from selection in initial price applicability year 2028. 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 and renegotiation per sections 1193(a)(4) and 1194(f)(4)(B) of the Act. Without these data, CMS would not be able to conduct negotiations and renegotiations as directed by the IRA.

Evidence About Alternative Treatments

Submission of information about selected drugs and their alternative treatments 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 carrying out negotiation and renegotiation. 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 making this portion of the information request voluntary, CMS seeks to alleviate unnecessary burden while still providing interested parties with the opportunity to comment. CMS has continued to consider design alternatives for Section I with each annual cycle to both simplify the steps for respondents to access the submission webpage and options for submission of responses to the form that reduce respondent burden. CMS also requested comment on the process to access the form and in alternative formats for submitting question responses in lieu of a question-by-question submission method in the 60-day package. As discussed in the Response to Public Comments Received document that accompanies this Supporting Statement – Part A, CMS received some public comments regarding the submission process for Section I. CMS removed the requirement to register an email address to access the Section I questions in this 30-day version.

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 2028. In accordance with section 1194(f)(4)(B) of the Act and section 130.4.3 of the final guidance, the same considerations apply for renegotiation.

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))).¹⁰ 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.

Counteroffer ICR Form

Information collected through the Statutory Written Counteroffer ICR Form and the Renegotiation Written Counteroffer ICR 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)).¹¹

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

- Report information to the agency more often than quarterly;

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

¹¹ 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

CMS published a 60-day notice on 6/30/2025 within the Federal Register (90 FR 27869) for the public to submit written comments on the information collection requirements. A crosswalk document describing the proposed changes from the 60-day version of this ICR to the proposed 30-day version is also attached. CMS may make appropriate revisions based on its consideration of timely submissions of public comments to the 30-day notice package as well as further consideration of the issues. If additional revisions are included, CMS will provide this final version for Office of Management and Budget approval.

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 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 ICR Form and the Renegotiation Written Counteroffer ICR 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)).¹²

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 the 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 2028, CMS will treat information on non-FAMP (as defined in 38 U.S.C. § 8126(h)(5)) as proprietary.

For initial price applicability year 2028, 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 confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer. 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 prior Federal financial support, approved patent applications, exclusivities, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that are publicly available as non-proprietary.

Within a Primary Manufacturer's response to a particular data element required in the Drug Price Negotiation ICR, the response may include information that is non-proprietary because it is publicly available or otherwise does not represent trade secrets and confidential commercial or financial information, such as the introductory language within an explanation field of a data element. Additionally, if a Primary Manufacturer provides a Common Technical File or Drug Master File, that is what is commonly titled "a drug dossier," within the manufacturer's submission of data submitted to CMS in accordance with section 1194(e)(2) of the Act, CMS will treat the submission of a drug dossier as proprietary because CMS understands that this type of document is typically not publicly available. In the Primary Manufacturer's submission of information in response to the Drug Price Negotiation ICR, the Primary Manufacturer may identify for CMS which information the Primary Manufacturer believes should be withheld from disclosure by CMS consistent with existing federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, and that are not included in this section as proprietary by CMS.

Pursuant to sections 1195(a)(2) and 1194(f)(4)(B) of the Act and as discussed in sections 60.6.1 and 130.4.5 of the final guidance, CMS is required to publish the explanation of the MFP by March 1, 2027, for initial price applicability year 2028. In this public explanation and any other

¹² See: <https://www.justice.gov/oip/doj-guide-freedom-information-act-0>.

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, the exchange of offers and counteroffers, and the negotiation meetings, if applicable, without sharing any PHI / PII, proprietary information, or other information protected by federal law reported to CMS. CMS may 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 PHI / PII or any proprietary information reported to CMS.

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 the FOIA, if CMS has not already identified such information as proprietary and/or confidential.

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 or renegotiation, as applicable, 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 sections 50 and 130.3 of the 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 2024 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.¹³ When industry-specific wage estimates were not available, the Bureau of Labor Statistics' May 2024 Occupational Employment and Wage Statistics data was used. Tables 1-8 below present the estimated median

¹³ See May 2024 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 - Pharmaceutical and Medicine Manufacturing. Available at <https://data.bls.gov/oes/#/industry/325400>.

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)(1) of the Act and described in sections 50.1 of the final guidance. Pursuant to section 1194(f)(4)(B) of the Act and section 130.3.2 of the final guidance, Primary Manufacturers are required to submit new information on section 1194(e)(1) data elements and data on NDC-11s of the selected drug that may be payable under Part B (if any) but are not covered under Part D, which are necessary to carry out renegotiation. 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 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. With respect to data collection for renegotiation, CMS expects Primary Manufacturers to have some of the data readily available for submission, particularly because the data is responsive to similar questions and reporting metrics used for collection of data required to be submitted in the course of negotiating the MFP and the Primary Manufacturer will be familiar with the process of compiling, calculating, and submitting this data to CMS; however, there is some uncertainty to the estimate in Table 3 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 incurred since the periods reflected in their prior submissions 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 4. CMS does not intend for the Primary Manufacturer to provide information in response to this ICR Form that the Primary Manufacturer provided in its original full submission of section 1194(e)(1) data to CMS for the negotiation period in which the selected drug's MFP was negotiated.

Evidence About Alternative Treatments

As previously noted, information on selected drugs and their alternative treatments as specified 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. Revisions included in the 60-day ICR package include revisions to

streamline the collection of visual information and citations for evidence submitted with Section I. Because the same overall volume of these types of information may be submitted compared to the currently approved ICR Form, CMS has not adjusted the burden to account for these revisions. CMS removed the requirement to register an email address to access the Section I questions; however, this step does change the burden to respond to Section I.

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 in accordance with sections 1193(a)(4), 1194(e)(1), and 1194(f)(4)(B) of the Act and sections 50.1 and 130.3.2 of the final guidance, as well as the optional submission of data for factors outlined at 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 is soliciting comments 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 choose to participate in this submission.

A. Estimated Burden for Primary Manufacturers

Selected Drugs for Negotiation: 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 2028 for negotiation, which will be collected in 2026. 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 any Secondary Manufacturer(s)¹⁴ 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 \$93.10 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 \$111.00 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. Although submitting evidence about therapeutic alternatives is optional, this burden estimate assumes that

¹⁴ The burden estimate assumes some coordination between the Primary Manufacturer and the Secondary Manufacturer, as necessary, to collect and submit the data.

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 \$172.66 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 \$66.42 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 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 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 \$1,576,869.60 for all 15 selected drugs (\$105,124.64 per respondent per selected drug * 15 selected drugs).

**TABLE 1: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR 15
SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2028**

Occupation Title	Median Hourly Wage	Cost per hour*	# Hours	# Respondents	Total Burden Hours	Total Cost
Financial Manager (11-3031)	\$86.33	\$172.66	50	15	750	\$129,495.00
Cost Estimator (13-1051)	\$33.21	\$66.42	142	15	2130	\$141,474.60
Business Operations Specialists (13-1000)	\$46.55	\$93.10	200	15	3000	\$279,300.00
Economist (19-3011) ¹⁵	\$55.50	\$111.00	600	15	9000	\$999,000.00
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	\$1,576,869.60
Total per Manufacturer	-	-	1,000	1	1,000	\$105,124.64

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

¹⁵ Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2024 Occupational Employment and Wage Statistics data used. Available here: <https://data.bls.gov/oes/#/industry/000000>.

TABLE 2: COST RANGE ESTIMATES FOR PRIMARY MANUFACTURER

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	500	\$52,562.32	\$788,434.80
Base Estimate (from Table 1)	1000	\$105,124.64	\$1,576,869.60
High Estimate	2,000	\$210,249.28	\$3,153,739.20

Selected Drugs for Renegotiation: CMS anticipates collecting a subset of the data in response to Sections A through J of this ICR from a Primary Manufacturer for a maximum of 25 selected drugs for initial price applicability year 2028 for renegotiation, which will be collected in 2026. For drugs without a change in monopoly status, CMS does not expect that it would be likely that renegotiation would result in a significant change to the agreed-upon MFP for drugs selected for initial price applicability years 2026 and 2027, except in unanticipated or unusual circumstances. As such, CMS anticipates that fewer than 25 drugs will be selected for renegotiation, but CMS cannot provide definitive assumptions about how many drugs may be selected for renegotiation. 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 any Secondary Manufacturer(s).¹⁶ of a selected drug, if applicable.

CMS assumes a lower burden for data submissions for drugs selected for renegotiation relative to the original submission of data for negotiation because Primary Manufacturers will need to report only new data for a short period of time in response to this ICR. For example, the Primary Manufacturer will only need to complete Section B for drugs payable under Part B, if applicable, and the Primary Manufacturer will only need to provide new data in Sections C, E and F for a limited time period, if applicable. All Primary Manufacturers of drugs selected for renegotiation will need to provide data in response to Section G, but for a shorter period of time compared to the original submission. CMS estimates it will take a business operations specialist or team of business operations specialists, on average, 150 hours, at a cost of \$93.10 per hour, to gather cost data and compile required information, as specified in the data elements instructions, such as new data on prior Federal financial support, pending and approved patent applications, exclusivities recognized by the FDA and applications and approvals, and market data, and

¹⁶ The burden estimate assumes some coordination between the Primary Manufacturer and the Secondary Manufacturer, as necessary, to collect and submit the data.

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, 450 hours, at a cost of \$111.00 per hour, to perform necessary economic analyses, including of new R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped those costs, the selected drug's cost of production and distribution, and other data elements specified in the data element instructions. Although submitting evidence about therapeutic alternatives is optional, this burden estimate assumes that all Primary Manufacturers will choose to perform analyses related to new information on 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, 37.5 hours, at a cost of \$172.66 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 3 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, 106.5 hours, at a cost of \$66.42 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 CEO, on average, 3 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 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 3. The estimate yields a total burden of 18,750 hours (750 hrs. per Primary Manufacturer per selected drug * 25 selected drugs) and total cost of \$1,971,087.00 if a maximum of 25 selected drugs are selected for renegotiation (\$78,843.48 per respondent per selected drug * 25 selected drugs).

TABLE 3: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR UP TO 25 SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2028

Occupation Title	Median Hourly Wage	Cost per hour*	# Hours	# Respondents	Total Burden Hours	Total Cost
Financial Manager (11-3031)	\$86.33	\$172.66	37.5	25	937.5	\$161,868.75
Cost Estimator (13-1051)	\$33.21	\$66.42	106.5	25	2,662.5	\$176,843.25
Business Operations Specialists (13-1000)	\$46.55	\$93.10	150	25	3,750	\$349,125.00
Economist (19-3011). ¹⁷	\$55.50	\$111.00	450	25	11,250	\$1,248,750.00
Lawyer (23-1011)	\$115.00	\$230.00	3	25	75	\$17,250.00
Chief Executive (11-1011)	\$115.00	\$230.00	3	25	75	\$17,250.00
Total (25 Manufacturers)	-	-	18,750	25	18,750	\$1,971,087.00
Total per Manufacturer	-	-	750	1	750	\$78,843.48

** 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 are provided in Table 4 below to illustrate the possible variability for this burden estimate. To calculate the low estimate, the base estimate (Table 3 Total) has been reduced by half for each labor category. For the high estimate, the required time and cost associated with each labor category from the base estimate has been doubled.

¹⁷ Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2024 Occupational Employment and Wage Statistics data used. Available here: <https://data.bls.gov/oes/#/industry/000000>.

TABLE 4: COST RANGE ESTIMATES FOR PRIMARY MANUFACTURER

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	375	\$39,421.74	\$985,543.50
Base Estimate (from Table 3)	750	\$78,843.48	\$1,971,087.00
High Estimate	1,500	\$157,686.96	\$3,9542,174.00

B. Estimated Burden for General Public

To generate burden estimates for initial price applicability year 2028, CMS reviewed the public feedback that was received for the initial price applicability year 2027 negotiation period. CMS received 218 submissions from individuals and organizations for the section 1194(e)(2) data collection. Approximately 54% of these submissions were from a respondent self-selecting an organization-related category. Due to the inclusion of selected drugs for renegotiation and the year-over-year greater awareness around the public input process for the Drug Price Negotiation Program, CMS will maintain the total estimate of responses that may be received as the initial price applicability year 2027 burden estimate (325), which assumes it will receive approximately a 49 percent increase in the total volume of public submissions for initial price applicability year 2028 compared to initial price applicability year 2027. This results in approximately 325 total submissions, with approximately 150 individual respondents and 175 organizations because the proportion of individuals and organizations remained generally consistent across the first two initial price applicability years for which data has been collected thus far.

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. 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 \$271,320.00 dollars (5,700 hrs. * \$47.60), as displayed in Table 5.

TABLE 5: SUMMARY OF INFORMATION COLLECTION REQUEST FOR PUBLIC FEEDBACK FOR INITIAL PRICE APPLICABILITY YEAR 2028

Type of Respondent	Occupation Title	Median Hourly Wage*	# Respondents	Hours per response	Total hours	Total Cost
Individual	All Occupations 00-0000	\$47.60	150	3	450	\$21,420.00
Organization	All Occupations 00-0000	\$47.60	175	30	5,250	\$249,900.00
Total	-	-	325	17.54	5,700	\$271,320.00

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

An additional low estimate and high estimate is provided in Table 6 and Table 7 below to illustrate possible variability for this burden estimate. To calculate the low estimate, the base estimate (Table 5 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 6: COST RANGE ESTIMATES FOR AN INDIVIDUAL FOR PUBLIC FEEDBACK FOR INITIAL PRICE APPLICABILITY YEAR 2028

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	1.5	\$71.40	\$10,710.00
Base Estimate (from Table 3)	3	\$142.80	\$21,420.00
High Estimate	6	\$285.60	\$42,840.00

TABLE 7: COST RANGE ESTIMATES FOR AN ORGANIZATION FOR PUBLIC FEEDBACK FOR INITIAL PRICE APPLICABILITY YEAR 2028

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	15	\$714.00	\$124,950.00
Base Estimate (from Table 3)	30	\$1,428.00	\$249,900.00
High Estimate	60	\$2,856.00	\$499,800.00

Counteroffer ICR Form

A Primary Manufacturer must complete and submit the information requested on the Statutory Written Counteroffer ICR Form or the Renegotiation Written Counteroffer ICR Form, as applicable, 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. The Statutory Written Counteroffer ICR Form and the Renegotiation Written Counteroffer ICR Form are collectively referred to as the “Counteroffer ICR Form” due to CMS approximating the estimates for each form to be similar due to the questions on the forms requiring about the same amount of time for a manufacturer to collect and submit the information on the applicable form.

To derive wage estimates, CMS used data from the Bureau of Labor Statistics’ May 2024 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 ICR Form.¹⁸ When industry-specific wage estimates were not available, the Bureau of Labor Statistics’ May 2024 Occupational Employment and Wage Statistics data was used. Table 8 below presents the estimated median hourly wage, the cost of fringe benefits and overhead, total burden hours, and total cost to submit the form.

CMS will select up to 15 high expenditure, single source drugs payable under Medicare Part B and/or covered under Medicare Part D for negotiation for initial price applicability year 2028. Statutory written counteroffers will be submitted by Primary Manufacturers for up to 15 selected drugs, and completing the Statutory Written Counteroffer ICR 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 2028 will occur in 2026, as the statute instructs CMS to make a written initial offer to the

¹⁸ See May 2024 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 - Pharmaceutical and Medicine Manufacturing. Available at <https://data.bls.gov/oes/#/industry/325400>.

Primary Manufacturer with the proposal for the MFP for a selected drug no later than June 1, 2026, 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. Renegotiation written counteroffers will be submitted by Primary Manufacturers for a maximum of 25 selected drugs, and completing the Renegotiation Written Counteroffer ICR Form will be a one-time cost for each selected drug for which a Primary Manufacturer submits a renegotiation written counteroffer. Pursuant to section 1194(f)(4)(B) of the Act and section 130.4.3 of the final guidance, the deadlines for CMS to make a written initial offer to the Primary Manufacturer and for the Primary Manufacturer to submit a Counteroffer, if applicable, are the same for the renegotiation process as for the negotiation process for initial price applicability year 2028. 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 40 total respondents for initial price applicability year 2028. CMS chose this number because by statute only up to 15 drugs payable under Medicare Part B and/or covered under Medicare Part D can be selected for negotiation for 2028 and a maximum of 25 drugs can be selected for renegotiation for 2028, and for each selected drug CMS will undergo negotiation or renegotiation with only one Primary Manufacturer, so it is not possible that there would be more than 40 respondents for initial price applicability year 2028.

CMS expects the Primary Manufacturer will have a team preparing the Counteroffer ICR 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 ICR Form.

- CMS estimates it will take a business operation specialist, or a team of business operations specialists, 27 hours, on average, at \$93.10 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 \$128.24 per hour) for pharmacists, 5 hours (on average, at \$100.90 per hour) for nurses, and 5 hours (on average, at \$227.26 per hour) for doctors.

- CMS estimates it will take an economist, or team of economists, 64 hours, on average, at \$111.00 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 \$169.50 per hour, to review Counteroffer options and justifications and develop a Counteroffer proposal for the MFP.
- 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 Counteroffer ICR Form, and submit the Counteroffer ICR 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 for the MFP, 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 8 below. CMS estimates a total burden of 8,170 hours (204.25 hrs. * 40 respondents) and total cost of \$1,307,699.00 (\$32,692.46 per respondent * 40 respondents).

TABLE 8: SUMMARY OF INFORMATION COLLECTION FOR DEVELOPING A COUNTEROFFER ICR FORM 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 (13-1000)	\$46.55	\$93.10	27	40	1,080	\$100,548.00
Pharmacists (29-1051)	\$64.12	\$128.24	15	40	600	\$79,944.00
Registered Nurses (29-1141)	\$50.45	\$100.90	5	40	200	\$20,180.00

Occupation Title	Median Hourly Wage	Cost per hour**	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
General Internal Medicine Physicians (29-1216) ¹⁹	\$113.63	\$227.26	5	40	200	\$45,452.00
Economist (19-3011) ²⁰	\$55.50	\$111.00	64	40	2,560	\$284,160.00
General and Operations Managers (11-1021)	\$84.75	\$169.50	14.25	40	570	\$96,615.00
Lawyer (23-1011)	\$115.00	\$230.00	64	40	2,560	\$588,800.00
Chief Executive (11-1011)	\$115.00	\$230.00	10	40	400	\$92,000.00
Total	-	-	204.25	40	8,170	\$1,307,699.00
Cost per Respondent	-	-	-	-	-	\$32,692.46

***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.

¹⁹ Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2024 Occupational Employment and Wage Statistics data used.

²⁰ Industry-specific wage estimate not available, Bureau of Labor Statistics' May 2024 Occupational Employment and Wage Statistics data used.

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 and renegotiation processes

To generate salary estimates reflected in Table 9 below, CMS used the 2025 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region.²¹ In this regard, Table 9 presents the Full-Time Equivalent (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 ICR 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 ICR Form.

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

²¹ See: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2025/DCB_h.pdf

**TABLE 9. BURDEN ESTIMATE COST FOR CMS STAFF FOR INITIAL PRICE
APPLICABILITY YEAR 2028**

Staff	FTE Equivalent	Hourly Wage	Total Burden Hours	Total Cost
Section 1194(e) Review				
GS-13, step 1	8	115.56	1,566	\$1,447,735.68
GS-14, step 1	3	136.54	1,566	\$641,464.92
GS-15, step 1	2	160.62	398	\$127,853.52
Modification of the Existing CMS HPMS				
GS-13, step 1	2	115.56	100	\$23,112.00
Contractor	4.5	249.59	350	\$393,104.25
Total Cost to Government Over One Year				\$2,633,270.37

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 Counteroffer submissions from Primary Manufacturers.

To generate salary estimates for the table below, CMS used the 2025 GS Locality Pay Tables²² published by the OPM for the Washington-Baltimore-Arlington region. In this regard, Table 10 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 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 ICR Form to inform negotiations or renegotiations; 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 Counteroffer ICR Form.

²² See: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2025/DCB_h.pdf

TABLE 10. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT THE COUNTEROFFER PROCESS FOR SELECTED DRUGS

Staff	FTE Equivalent	Hourly Wage	Total Burden Hours	Total Cost
Counteroffer Review				
GS-13, step 1	5	115.56	638	\$368,636.40
GS-14, step 1	5	136.54	638	\$435,562.60
GS-15, step 1	2	160.62	172	\$55,253.28
Senior Executive Service	1	188.54	86	\$16,214.44
Modification of the Existing CMS HPMS				
GS-13, step 1	1	115.56	60	\$6,933.60
Contractor	2	249.59	100	\$49,918.00
Total Cost to Government Over One Year				\$932,518.32

15. Changes to Burden

This is a revision of a currently approved ICR.

In the 30-day proposed revisions, CMS included technical revisions to each of the ICR forms that are listed in the accompanying crosswalk of changes between the 60-day package and this 30-day package that did not result in changes to the burden estimate. CMS revised the character limit downwards for some Section I questions, which may reduce the time a respondent spends answering these questions. However, based on public comments received in response to the 60-day package and comments received on previous versions of this ICR for initial price applicability years 2026 and 2027, some commenters noted that a higher character limit reduces burden in preparing a response and completing the ICR because the respondent does not need to spend time prioritizing the information to be shared and editing the response to fit within the maximum character limit. Therefore, CMS does not believe the revisions to the character limits for certain questions in Section I result in a change to the burden estimate because, while some respondents may find the reduction reduces response time, other respondents may find no change or a slight increase in response time. Additionally, CMS revised Question 56 to align with the CMS HPMS to require an upload of a PDF of a list of citations included with a respondents Section I response only, and no longer will permit a respondent to manually enter each citation.

Based on a review of previous submissions and public comments, CMS believes the PDF upload is the preferred and least burdensome submission method for respondents; however, the process still requires respondents to manually compile a list of citations. Therefore, CMS does not believe the PDF upload functionality impacts the burden estimated for this step. Further, for both the character limit revisions and the citation functionality, CMS believes the current range of estimated burden still captures these considerations appropriately.

In the 60-day proposed revisions, CMS included:

CMS revised the burden estimates and cost to the federal government upwards to account for use of this ICR package to meet the statutory requirement for initial price applicability year 2028 to renegotiate the MFP for selected drugs because additional manufacturers and the public will use the Forms to submit information to CMS and the federal government will need to prepare and review additional information related to the Forms.

CMS also included revisions in the 60-day ICR package based on lessons learned from implementation of the Negotiation Program in initial price applicability year 2027 to improve clarity of instructions to ensure high quality and consistent data across Primary Manufacturer submissions and to improve CMS' ability to conduct compliance reviews of such submissions. CMS also reviewed the information collection and program requirements to identify any opportunities to reduce collection burden. For example, with respect to the Negotiation Data Elements ICR form, CMS streamlined Section C to simplify the categories of R&D costs, and has reduced the overall number of questions in Sections C and I. Additionally, CMS included clarifying instructions throughout Sections A through G. CMS incorporated other process improvements in streamlining the steps for providing evidence citations and visual information in Section I to simplify the submission process for respondents and remove any potential duplication across question responses by including one location for submission of visual information and evidence citations, in lieu of question by question, as applicable. CMS believes that all of these changes will result in a more efficient preparation process for Primary Manufacturers and the public in preparing to answer the Negotiation Data Elements ICR. The revisions may reduce burden for an individual response; however, as CMS has already factored a varying range of burden possibilities into the estimates, CMS did not believe these changes resulted in further impact to the ranges provided already.

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

16. Publication/Tabulation Dates

Pursuant to section 1195(a)(2) of the Act and sections 60.6 and 130.4.4 of the final guidance, CMS will publish an explanation for the MFP with respect to the 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.