Supporting Statement – Part A

Information Collection Request (ICR) for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10847, OMB 0938-NEW)

A. Background

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program ("the Negotiation Program"), codified in sections 1191 through 1198 of the Social Security Act ("the Act"). The Act establishes the Negotiation Program to negotiate a maximum fair price ("MFP"), 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 drug").[1] For the first year of the Negotiation Program, CMS will select 10 Part D high expenditure, single source drugs for negotiation. The MFPs that are negotiated for these drugs will apply beginning in initial price applicability year 2026. The negotiation period for initial price applicability year 2026 begins October 1, 2023, or when the manufacturer of a selected drug enters into a Medicare Drug Price Negotiation Program Agreement (an "Agreement") with CMS, whichever is sooner. Section 1194(e) of the Act requires CMS to consider two sets of factors as the basis for determining the offer and counteroffer throughout the negotiation process: (1) certain data that must be submitted by the manufacturer of each drug selected for negotiation; and (2) evidence about alternative treatments, as available, with respect to each selected drug and therapeutic alternative(s) for each selected drug.

In accordance with section 1193(a)(4) and section 1194(b)(2) 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 offers and counteroffers. In addition, manufacturers and the public may submit information on the factors outlined in section 1194(e)(2) of the Act, which describe evidence about the selected drug and its therapeutic alternative(s).

For the purposes of this Information Collection Request (ICR), a selected drug for initial price applicability year 2026 is defined as a drug included on the selected drug list published by CMS by September 1, 2023. 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. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS 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 "Primary Manufacturer").

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

Likewise, for initial price applicability year 2026, CMS will refer to any other entity that meets the statutory definition of manufacturer for a drug product included on the selected drug list 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." Secondary Manufacturers would include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug that meet these criteria.

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.

Note: This ICR focuses on information required for selected drugs for initial price applicability year 2026.

B. Justification

1. Need and Legal Basis

Manufacturer-Specific Data

The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. These data include the data required to calculate non-FAMP for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A) of the Act, and the negotiation factors outlined in section 1194(e)(1) of the Act for the purpose of formulating offers and counteroffers process pursuant to section 1193(a)(4)(B) of the Act. Some of these data are held by the Primary Manufacturer and are not currently available to CMS. The Primary Manufacturer must submit the applicable data required in these sections of the Act. Data described in sections 1194(e)(1) and 1193(a)(4) of the Act must be submitted by the Primary Manufacturer. Section 1194(e)(1) data submitted by Primary Manufacturers must include data from Secondary Manufacturers, as applicable.

Completing this form requires the Primary Manufacturer to provide the following information:

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 Food and Drug Administration (FDA), and applications and approvals under section 505(c) of the Food, Drug, and Cosmetic Act (FD&C Act) or section 351(a) of the Public Health Service (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) (with the exception of costs related to the acquisition of the selected drug, which would be reported only for the Primary Manufacturer).

Evidence About Alternative Treatments

Section 1194(e)(2) of the Act requires CMS to consider certain data on alternative treatments to the selected drug. Because the statute does not specify where these data come from, CMS will allow for optional submissions from Primary Manufacturers and the public (e.g., clinicians, patients or patient organizations, caregivers, and/or academic experts). CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in 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, including Secondary Manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, patients or patient organizations, and other interested parties, may optionally submit evidence about alternative treatments.

The Negotiation Data Elements ICR Form for manufacturer-submitted data elements and evidence about alternative treatments must be submitted to CMS not later than October 2, 2023, for initial price applicability year 2026.

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

- The extent to which such selected drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives;
- Prescribing information approved by the FDA for such selected drug and therapeutic alternatives to such drug;
- Comparative effectiveness of such selected drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations; and
- The extent to which such selected drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

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 with the Primary Manufacturer to achieve the lowest MFP for each selected drug.

3. Use of Information Technology

Manufacturer-Specific Data

CMS intends to develop an automated tool within an existing information technology system, the CMS Health Plan Management System (CMS HPMS), for Primary Manufacturers to provide manufacturer-specific data. Manufacturers of Medicare Part D drugs currently use this system for other Part D program needs. The new tool is scheduled to be available by September 1, 2023 (the first day that data about each selected drug and alternative treatments may be submitted). Instructions for manufacturers to gain access to CMS HPMS are available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.

To the extent the CMS HPMS tool is available by September 1, 2023, this ICR form must be submitted in the CMS HPMS. In the event that completion of the CMS HPMS tool is delayed, submission of responses to this ICR via the CMS HPMS tool will be optional and encouraged when the tool becomes available after September 1, 2023 for initial price applicability year 2026. If CMS HPMS is not used for submission because the CMS HPMS tool is delayed, responses to this ICR should sent by email to IRARebateandNegotiation@cms.hhs.gov with the subject line "[Drug Name]: Manufacturer-Submitted Evidence" by October 2, 2023 for initial price applicability year 2026.

Evidence About Alternative Treatments

The Primary Manufacturer of a selected drug may optionally submit any evidence about alternative treatments as part of their larger data submission in CMS HPMS. Instructions for manufacturers to gain access to CMS HPMS are available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.

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.

This publicly available tool is scheduled to be available by September 1, 2023 (the first day that data about each selected drug and alternative treatments may be submitted). To the extent the public tool is available by September 1, 2023, responses to questions in sections I and J of this ICR form must be submitted via the publicly available web link. In the event that completion of the public tool is delayed, submission of responses to questions in sections I and J of this ICR via the publicly available web link will be optional and encouraged when the tool becomes available after September 1, 2023 for initial price applicability year 2026. If the publicly available web

link is not used for submission because the public tool is delayed, responses to questions in sections I and J of this ICR should be sent by e-mail to IRARebateandNegotiation@cms.hhs.gov with the subject line "[Drug Name]: Evidence About Alternative Treatments" by October 2, 2023 for initial price applicability year 2026.

4. Duplication of Efforts

Manufacturer-Specific Data

Some manufacturer-specific data described in sections 1193(a)(4) and 1194(e)(1) of the Act 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-Federal Average Manufacturer Price on an annual basis to the Department of Veterans Affairs (VA). The Federal Supply Schedule and the Big Four 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. As noted elsewhere, CMS has removed or revised certain requests for information from the draft ICR to reduce burden. Ultimately, CMS believes that 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.

Evidence About Alternative Treatments

The information collection of evidence about alternative treatments required by section 1194(e)(2) of the Act may be obtained through multiple sources, such as a literature search or review of clinical guidelines, and is optional for the Primary Manufacturer and public to submit. CMS intends to consider clinical evidence available through literature searches, widely accepted treatment guidelines, subject matter experts, and clinical experts (e.g., Medicare beneficiaries, academic experts, clinicians, caregivers, patients or patient organizations, and other interested parties), and data analyses.

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 data. Only drugs with the highest total expenditures under Medicare Part D will be selected for negotiation for initial price applicability year 2026. Because of this basis for selection Primary Manufacturers with selected drugs to which this ICR applies are manufacturers with high expenditures, reducing the likelihood that the information collection imposes a burden on small businesses. There is additionally an exception for small biotech drugs (the Small Biotech

Exception; OMB 0938-NEW) that excludes from selection certain qualifying covered Part D drugs based on Part D total expenditures from selection in initial price applicability year 2026. 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

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.

Pursuant to section 1197(c) of the Act, any Primary Manufacturer of a selected drug that has entered into an Agreement with CMS may be subject to a civil monetary penalty of $1,000,000 for each day of a violation, including, but not limited to, failure to submit data required under section 1194(e)(1) of the Act, including failure to engage in requested corrective action to mitigate such failures. As described in 26 U.S.C. § 5000D, a Primary Manufacturer may be subject to an excise tax for failure to meet certain Negotiation Program requirements. Alternatively, the Primary Manufacturer may opt out of the Negotiation Program and avoid the excise tax on sales of the selected drug during the period for which the manufacturer does not have applicable agreements with the Medicare and Medicaid programs and none of their drugs are covered by an agreement under section 1860D-14A or section 1860D-14C of the Act (see section 40.6 of Medicare Drug Price Negotiation Program: Revised Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (the "revised guidance")).

Evidence About Alternative Treatments

Submission of information about 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 Manufacturers, 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 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.

7. Special Circumstances

Manufacturer-Submitted Data

Non-FAMP data are proprietary, as are certain other data required under section 1194(e)(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).

Evidence About Alternative Treatments

While CMS neither requests nor requires protected health information (PHI) or personal identifying information (PII) in this information request, interested parties may potentially submit information considered to be PHI or PII.

For both the manufacturer-submitted data and the evidence on alternative treatments, there are no special circumstances that would require this information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

A 60-day notice was published in the Federal Register on March 21, 2023 (88 Fed. Reg. 16983) for the public to submit written comment on the information collection requirements. CMS received comments from 24 entities in response to the 60-day notice. The comments identified issues/themes/concerns that included but were not limited to: the deadline to submit the information requested, the burden on respondents to report the mandatory and optional information requested, the process and format for submitting the requested information, and requests for clarification and other revisions to instruction and question language specific to each

section of the ICR. Attached as a supplemental document in this ICR is CMS responses to the comments.

A 30-day notice was published in the Federal Register on XXXX for the public to submit written comment on the information collection requirements.

9. Payments/Gifts to Respondents

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

10. Confidentiality

Information that is deemed proprietary shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. Proprietary information, including trade secrets and confidential commercial or financial information, will also be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(3), (4)).[2]

As discussed in section 40.2.1 of the revised guidance, CMS will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information including Exemptions 3 and/or 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 2026, CMS will treat information on non-FAMP (as defined in 38 U.S.C. § 8126(h)(5)) as proprietary.

For initial price applicability year 2026, 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 applications and approvals 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, 2025, for initial price applicability year 2026 (described in section 60.6.1 of the revised guidance). In this public explanation and any other public documents discussing the MFP, CMS will make public the section 1194(e)(1) and section 1194(e)(2) data submitted by the

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

Primary Manufacturer and the public that are determined to be non-proprietary. 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.

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimates (Hours & Wages)

A Primary Manufacturer must complete and submit the information requested on the 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)(A) and 1194(e)(1) of the Act. 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 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.

Wage estimates are derived from Bureau of Labor Statistics Occupational and Employment Wage Statistics data,[3] including national average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with collecting manufacturer-specific data and information collection from the public related to evidence about alternative treatments.

Manufacturer-Specific Data

Some manufacturer-specific data described in sections 1193(a)(4) and 1194(e)(1) of the Act 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. For purposes of calculating the federal ceiling price, drug manufacturers also report the quarterly and annual non-Federal Average Manufacturer Price on an annual basis to the Department of Veterans Affairs (VA). The Federal Supply Schedule and the Big Four 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. As noted elsewhere, CMS has removed or revised certain requests for information from the draft ICR to reduce burden. Ultimately, CMS believes that the Primary Manufacturer is best positioned to

[3] Retrieved from https://www.bls.gov/oes/tables.htm.

provide the requested data and the statute provides that manufacturers participating in the Negotiation Program will submit the requested data.

Thus, Primary Manufacturers have experience providing information similar to the negotiation factors outlined in sections 1193(a)(4)(A) and 1194(e) of the Act. Table 1 presents the estimated mean hourly wage, the cost of fringe benefits and overhead, the adjusted hourly wage (inclusive of fringe benefits and overhead), total burden, and total cost to submit these data. 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.

Evidence About Alternative Treatments

As previously noted, information on 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)(A) 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 for 10 selected drugs for initial price applicability year 2026, which will be collected in 2023. For purposes of this information collection, CMS assumes there will be 10 Primary Manufacturers, one for each selected drug. 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 Primary Manufacturer would require the same time and effort to submit data for each selected drug.

CMS estimates it will take a business operations specialist or team of business operations specialists, on average, 100 hours, at a cost of $77.28 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, 300 hours, at a cost of $116.18 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 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, 25 hours, at a cost of $147.56 per hour. to review the results of all the analyses and cost estimates prior to submission to CMS. Finally, CMS estimates that it will take a cost estimator, on average, 75 hours, at a cost of $70.90 per hour, to compile and report the required data to CMS, per the data element form instructions. The cost estimates for one-time costs are presented in Table 1. The estimate yields a total burden of 5,000 hours (500 hrs. per Primary Manufacturer per selected drug * 10 selected drugs) and total cost of $515,885.00 for all 10 selected drugs ($51,588.50 per respondent per selected drug * 10 selected drugs).

TABLE 1: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR 10 SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2026

Occupation Title	Mean Hourly Wage	Cost per hour*	# Hours	# Respondents	Total Burden Hours	Total Cost
Financial Manager (11-3031)	$73.78	$147.56	25	10	250	$36,890.00
Cost Estimator (13-1051)	$35.45	$70.90	75	10	750	$53,175.00
Business Operations Specialists (13-1000)	$38.64	$77.28	100	10	1,000	$77,280.00
Economist (19-3011)	$58.09	$116.18	300	10	3,000	$348,540.00
Total (10 Manufacturers)	**-**	**-**	**5,000**	**10**	**5,000**	**$515,885.00**
Total per Manufacturer	**-**	**-**	**500**	**1**	**500**	**$51,588.50**

** 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.

TABLE 2: COST RANGE ESTIMATES FOR PRIMARY MANUFACTURER

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	250	$25,794.25	$257,942.50
Base Estimate (from Table 1)	500	$51,588.50	$515,885.00
High Estimate	1,000	$103,177.00	$1,031,770.00

B. Estimated Burden for General Public

To generate burden estimates CMS reviewed the public feedback that was received for the International Pricing Index Model for Medicare Part B Drugs advance notice of proposed rulemaking (ANPRM) (83 C.F.R. § 54546). The ANPRM sought public comment on potential options CMS would consider for testing changes to payment for certain separately payable Part B drugs and biologicals. CMS received 3,946 timely comments related to the International Pricing Index Model. Of the comments received, 3,686 were received from individual commenters, the remaining 260 comment letters were received from organizations. Given the similar subject matter of the International Pricing Index Model and the information collection related to drug therapeutic advances and alternatives and other information listed in section 1194(e)(2), CMS will use these comment counts as the basis to reasonably estimate the number of responses expected for the submission of section 1194(e)(2) of the Act data for a selected drug.

This estimate assumes as many as 3,000 individual respondents may spend, on average, 2 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 300 organizations may take, on average, 20 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 overhead and fringe benefits at 100 percent of the hourly wage. This estimate yields a total burden of 12,000 hours (3.63 hrs. * 3,300 respondents) and total cost of $672,240.00 dollars (12,000 hrs. * $56.02), as displayed in Table 3.

TABLE 3: SUMMARY OF INFORMATION COLLECTION REQUEST FOR PUBLIC FEEDBACK FOR 10 SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2026

Type of Respondent	Occupation Title	Mean Hourly Wage*	# Respondents	Hours per response	Total hours	Total Cost
Individual	All Occupations 00-0000	$56.02	3,000	2	6,000	$336,120.00
Organization	All Occupations 00-0000	$56.02	300	20	6,000	$336,120.00
Total	**-**	**-**	**3,300**	**3.63**	**12,000**	**$672,240.00**

**Includes fringe benefits and overhead of 100 percent of mean 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 2026

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	**1**	**$56.02**	**$168,000.00**
Base Estimate (from Table 3)	**2**	**$112.04**	**$336,120.00**
High Estimate	**4**	**$224.08**	**$672,240.00**

TABLE 5: COST RANGE ESTIMATES FOR AN ORGANIZATION FOR PUBLIC FEEDBACK FOR INITIAL PRICE APPLICABILITY YEAR 2026

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	**10**	**$560.20**	**$168,000.00**
Base Estimate (from Table 3)	**20**	**$1,120.40**	**$336,120.00**
High Estimate	**40**	**$2,240.80**	**$672,240.00**

Total burden estimates are displayed in Table 6.

TABLE 6: SUMMARY OF BURDEN FOR INITIAL PRICE APPLICABILITY YEAR 2026

Occupation Title	Total Burden Hours	Total Cost
Primary Manufacturers (n=10)	5,000	$515,885.00
Individuals (n=3,000)	6,000	$336,120.00
Organizations (n=300)	6,000	$336,120.00
Total	**17,000**	**$1,188,125.00**

13. Capital Costs

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

14. Cost to Federal Government

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.

Estimates

To generate salary estimates reflected in Table 7 below, CMS used the 2022 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the

Washington-Baltimore-Arlington region.[4] In this regard, Table 7 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage for one year of information collection covered by this information collection. Staffing estimates are based on CMS duties as follows:

- CMS will develop policies and procedures for determining the maximum fair price and the negotiation process; and
- Review and analyze the data that drug manufacturers and the public submit.

TABLE 7. BURDEN ESTIMATECOST FOR CMS STAFF FOR INITIAL PRICE APPLICABILITY YEAR 2026

Staff	Salary	Benefits	FTE Equivalent	Total
GS-13, step 4	$117,505	$117,505	7	$1,645,070.00
GS-14, step 4	$138,856	$138,856	3	$833,136.00
GS-15, step 4	$163,333	$163,333	2	$653,332.00
-	-	-	-	**$3,131,538.00**

In addition, CMS staff and one contractor will complete work in the CMS HPMS to accommodate this ICR. The same GS locality as Table 7 is used in Table 8.

TABLE 8. BURDEN ESTIMATE COST FOR CMS STAFF AND CONTRACTORS FOR INITIAL PRICE APPLICABILITY YEAR 2026 TO BUILD CMS HPMS

Staff	Rate	Hours	FTE Equivalent	Total
GS-13, step 1	$107.34	80	2.5	$21,468.00
Contractor	$245.54	200	6	$294,648.00
-	-	-	-	**$316,116.00**

[4] See: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/DCB.pdf.

15. Changes to Burden

This a new ICR. The burden has been revised to include federal costs for system work on the CMS HPMS. Non-burden-related changes incorporated in the 30-day public notice are included in the 60- to 30-Day Negotiation Data Elements Cross Walk.

16. Publication/Tabulation Dates

As required by section 1195(a)(2) of the Act, CMS will publish an explanation for the MFP with respect to the negotiation factors in section 1194(e) of the Act, therefore summarized 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 revised 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.