# Supporting Statement – Part A

## Negotiation Program Drug Selection for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (CMS-10844, OMB 0938-1443)

### Introduction

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (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 (each, a "selected drug"). Further, the Act instructs CMS to identify selected drugs eligible for renegotiation, as described in section 1194(f) of the Act. The purpose of this collection of information request is for CMS to collect information to implement the Medicare Drug Price Negotiation Program in accordance with the policies in the Medicare Drug Price Negotiation Program rule ("final rule") (CMS-4215-F).

For the purposes of this information collection request (ICR), qualifying single source drug has the same definition as it is given in 42 CFR 429.20. If a term included in this ICR Form is also included and defined in 42 CFR 429.20, the term's definition in this form is the same as in the final rule. Definitions otherwise included in this form are intended for purposes related to this form and the Medicare Drug Price Negotiation Program only. For the fourth year of the Negotiation Program, initial price applicability year 2029, and each subsequent year, thereafter, CMS will select for negotiation up to 20 high expenditure, single source drugs payable under Part B and/or covered under Part D. Additionally, section 1194(f)(3) of the Act directs CMS to select drugs for renegotiation from a list of renegotiation-eligible drugs. In accordance with section 1194(f)(2) of the Act and 42 CFR 429.20, CMS defines a "renegotiation-eligible drug" as a selected drug for which (1) a new indication is added to the drug, (2) the drug monopoly status was not that of an extended-monopoly or a long-monopoly drug and changes to that of an extended-monopoly drug, (3) the drug monopoly status was not that of a long-monopoly drug; and changes to that of a long-monopoly drug, or (4) the Secretary determines there has been a material change of any section 1194(e)(1) or (e)(2) factors.

This ICR addresses information for CMS to determine certain circumstances that impact the drugs selected for negotiation and renegotiation. First, this ICR addresses information for CMS to determine the applicability of a potential circumstance provided under the Act where certain drugs may be removed from negotiation eligibility if certain statutory requirements are met. Specifically, in accordance with section 1192(f)(1)(B) of the Act, CMS may delay the inclusion of a negotiation-eligible drug that includes the reference product for a biosimilar biological product

on the selected drug list for a given initial price applicability year if certain statutory requirements are met regarding the biosimilar's status of licensure and marketing (the "Biosimilar Delay") in accordance with section 1192(f) of the Act. Second, this ICR offers Primary Manufacturers[1] the voluntary option to submit information to CMS to inform CMS' determinations of which selected drugs qualify as a renegotiation-eligible drug and may be selected for renegotiation in accordance with section 1194(f)(3) of the Act. Specifically, section 1194(f)(2) of the Act instructs CMS to identify whether a selected drug is eligible for renegotiation because a new indication has been added to the selected drug (per section 1194(f)(2)(A)) or because there has been a material change to any of the factors listed in section 1194(e) of the Act (per section 1194(f)(2)(D)). In accordance with section 1194(f)(3)(C) of the Act, CMS will select drugs for renegotiation from among these renegotiation-eligible drugs if CMS expects renegotiation is "likely to result in a significant change" in the MFP. This applies to renegotiation-eligible drugs that are not automatically selected for renegotiation due to a change in monopoly status.

Within the Drug Selection ICR, CMS previously included the information collection for a manufacturer to request a Small Biotech Exception, which, in accordance with section 1192(d)(2) of the Act, provided for the exclusion of an otherwise "negotiation-eligible drug" with respect to initial price applicability years 2026, 2027, and 2028, for a qualifying single source drug that met the requirements for the exception for small biotech drugs (the "Small Biotech Exception"). However, since the statutory provision providing for a Small Biotech Exception does not apply to initial price applicability year 2029 and beyond, CMS has removed the Small Biotech Exception Form from the Drug Selection ICR. CMS is proposing to collect information necessary for eligibility related to the temporary floor for small biotech drugs within the Drug Price Negotiation for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (CMS-10844, OMB 0938-1443), which was published for a 60-day public comment period concurrently with the 60-day public comment period for this Drug Selection ICR. CMS incorporated revisions included with the final rule that are also applicable to this ICR via the final version of this ICR and will submit to OMB for approval.

Each of the two ICR forms for the Drug Selection ICR inform the selection of drugs covered under Medicare Part B and Part D for negotiation and renegotiation for an initial price applicability year and, therefore, are being advanced through the same Paperwork Reduction Act (PRA) review process. CMS will publish the list of drugs selected for renegotiation at the same time as the publication of the selected drug list for an initial price applicability year, as described in 42 CFR 429.100.

CMS intends to annually incorporate technical revisions in this ICR for references to a calendar year or other specific date. For example, these technical revisions would include references to initial price applicability year 2029 and calendar year 2027 for the first year of this revised ICR.

[1] To the extent that more than one entity meets the statutory definition of manufacturer (specified in section 1193(a)(1) of the Act) for a selected drug for purposes of an initial price applicability year, the manufacturer identified by CMS as the New Drug Application(s) (NDA(s)) holder or the Biologics License Application(s) (BLA(s)) holder for the selected drug to be "the manufacturer" of the selected drug (hereinafter the "Primary Manufacturer").

CMS would continue to provide any proposed substantive revisions and requests for renewal of the package for public comment consistent with the PRA.

If information within a section of this Supporting Statement applies to only the Biosimilar Delay or the Identification and Selection of Renegotiation-Eligible Drugs, a subtitle heading corresponding to the name of the applicable collection form will be listed before the applicable information.

## A. Background

*Biosimilar Delay:* In accordance with section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product ("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the statutorily-defined selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a "Reference Drug") on the selected drug list for a given initial price applicability year (the "Biosimilar Delay").

Section 1192(f) of the Act contemplates two potential requests under the Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year ("Initial Delay Request"), as stated in section 1192(f)(1)(B)(i)(I) of the Act; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year ("Additional Delay Request"), as stated in section 1192(f)(1)(B)(i)(II) of the Act. CMS did not grant any Initial Delay Requests for initial price applicability year 2028; therefore, no Reference Drugs would be the subject of an Additional Delay Request in initial price applicability year 2029. CMS includes requirements for Additional Delay Requests in 42 CFR 429.110(d); but information regarding collection of information for an Additional Delay Request will be addressed in a future revision of this information collection request, as applicable.

Note: This ICR only collects information relevant to a manufacturer's request for the Biosimilar Delay for one initial price applicability year, and is not determinative of a manufacturer's request for a subsequent initial price applicability year.

A determination by CMS that a given Reference Drug is removed from the list of negotiation eligible drugs due to an Initial Delay Request for one initial price applicability year does not mean that this Reference Drug will continue to qualify for the Biosimilar Delay for an Additional Delay Request for a second initial price applicability year.[2]

*Identification and Selection of Renegotiation-Eligible Drugs:* Section 1194(f) of the Act establishes the requirements governing the identification of renegotiation-eligible drugs, selection of drugs for renegotiation, and the renegotiation process. First, CMS will identify renegotiation-eligible drugs in accordance section 1194(f)(2) of the Act, as described in 42 CFR 429.605. Second, CMS will select for renegotiation certain renegotiation-eligible drugs in accordance with

[2] See 42 C.F.R. §429.110(d)

section 1194(f)(3) of the Act, as described in 42 CFR 429.610. Data specified in section 1194(e)(1) and section 1194(e)(2) of the Act inform the identification and selection of certain drugs for renegotiation.

Section 1194(f)(2) of the Act establishes the definition of a "renegotiation-eligible drug" as a selected drug for which (1) a new indication is added to the drug; (2) the drug monopoly status was not that of an extended-monopoly or a long-monopoly drug and changes to that of an extended-monopoly drug; (3) the drug monopoly status was not that of a long-monopoly drug and changes to that of a long-monopoly drug; or (4) the Secretary determines there has been a material change to any section 1194(e) factor. CMS will follow the procedure outlined in 42 CFR 429.605(e) to identify whether a new indication has been added to a selected drug for purposes of determining renegotiation eligibility and selection. As described in 42 CFR 429.615, CMS will only consider off-label use when identifying indications for renegotiation eligibility and selection if the Primary Manufacturer of a selected drug submits the off-label use through this voluntary ICR submission process.

## B. Justification

### 1. Need and Legal Basis

*Biosimilar Delay:* CMS will review a Biosimilar Delay request in accordance with section 1192(f)(1)(B) of the Act. A Biosimilar Delay request must be submitted to CMS before CMS establishes the selected drug list for an initial price applicability year. The deadline for submission of a Biosimilar Delay request will be specified by CMS. CMS anticipates sharing the submission opening and closing dates upon approval of the Drug Selection ICR from OMB. CMS anticipates providing a 30-day submission period.

Manufacturers who might benefit from submitting a Biosimilar Delay request for an initial price applicability year are those manufacturers of Biosimilars that anticipate that, in accordance with section 1192(f)(1)(A) of the Act:

(1) the Reference Drug including the reference product for the Biosimilar may be selected for an initial price applicability year;
(2) the Reference Drug would be an extended-monopoly drug, as defined in section 1194(c)(4) of the Act, included on the selected drug list for such initial price applicability year, absent the Biosimilar Delay;
(3) the Reference Drug includes the reference product identified in the Biosimilar's application for licensure under section 351(k) of the Public Health Service Act ("PHS Act") that has been approved by the Food and Drug Administration (FDA) or accepted for review, as described in 42 CFR 429.110(b)(1);
(4) more than one year has not elapsed since the licensure of the Biosimilar if marketing of the Biosimilar has not commenced;
(5) the Biosimilar Manufacturer is not the same as the Reference Manufacturer and is not treated as being the same pursuant to section 1192(f)(1)(C) of the Act;

(6) the Biosimilar Manufacturer and the Reference Manufacturer have not entered into an agreement that either:
   a. requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request; or
   b. directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time; and
(7) there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the statutorily-defined selected drug publication date for such initial price applicability year, based on the process described in 42 CFR 429.110(c).

*Identification and Selection of Renegotiation-Eligible Drugs:* Section 1194(f)(2) of the Act defines a renegotiation-eligible drug as a selected drug for which a new indication has been added, a selected drug for which there has been a material change to any of the factors listed in section 1194(e) of the Act, or a selected drug that has experienced a change in monopoly status to an extended monopoly or a long monopoly drug. Section 1194(f)(3) then instructs CMS to select all drugs with a change in monopoly status for renegotiation and to select from among the remaining renegotiation-eligible drugs those drugs for which CMS expects renegotiation is likely to result in a significant change to the MFP otherwise negotiated. CMS is offering Primary Manufacturers the voluntary option to submit new information to CMS that was not included in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data to CMS from the previous negotiation or renegotiation in which the selected drug's MFP was negotiated or renegotiated to inform renegotiation eligibility and selection through this ICR. Instructions in this ICR Form specify the applicable reporting time period by data element. The deadline for submission of information pertaining to the Identification and Selection of Renegotiation-Eligible Drugs will be specified by CMS. CMS anticipates sharing the submission opening and closing dates upon approval of the Drug Selection ICR from OMB. CMS anticipates providing a 30-day submission period.

CMS does not anticipate that Primary Manufacturers with a selected drug that qualifies as renegotiation-eligible due to a change in monopoly status as outlined in section 1194(f)(2)(B) and (C) of the Act will provide information via this ICR as such drugs will automatically be selected for renegotiation per section 1194(f)(3)(A) and (B) of the Act, and thus the information collected via this ICR will not inform CMS' determinations with regard to such drugs' eligibility or selection for renegotiation (in accordance with section 1194(f)(4) of the Act, and as described in 42 CFR 429.605(b), CMS will still consider voluntary submissions that may inform CMS in the renegotiation of the MFP for drugs selected for renegotiation). Once a renegotiation-eligible drug is selected for renegotiation, CMS will collect new information for all section 1194(e)(1) data elements from all Primary Manufacturers with a drug selected for renegotiation as described in 42 CFR 429.615(b). Additionally, once a renegotiation-eligible drug is selected for renegotiation, CMS will solicit new data for all section 1194(e)(2) factors from the Primary Manufacturer and other interested parties who choose to submit.

**2. Information Users**

*Biosimilar Delay:* The requirements for the Biosimilar Delay are specified in section 1192(f) of the Act. When the Biosimilar Manufacturer completes the ICR Form for the Biosimilar Delay and submits the form to CMS, CMS will use the submitted information to inform the agency's consideration and determination of whether the Biosimilar Manufacturer's request for a Biosimilar Delay may be granted. For example, CMS will use the submitted information to identify a negotiation-eligible drug as a Reference Drug; confirm that the Biosimilar Manufacturer is not the same or treated as the same entity as the Reference Manufacturer; determine whether an application for licensure of the Biosimilar has been accepted for review or approved by the FDA; confirm that the Biosimilar Manufacturer and the Reference Manufacturer have not entered into an agreement that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request, or directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time; and determine whether there is a high likelihood that the Biosimilar will be licensed and bona fide marketed within two years of the statutorily-defined selected drug publication date for initial price applicability year 2029 (additional information regarding this determination is included in 42 CFR 429.110(b) and (c)).

*Identification and Selection of Renegotiation-Eligible Drugs:* The requirements regarding determination and selection of renegotiation-eligible drugs are specified in section 1194(f) of the Act. When the Primary Manufacturer voluntarily submits the Identification and Selection of Renegotiation-Eligible Drugs ICR Form, CMS will use the information, in addition to the information as discussed in 42 CFR 429.605(c) and (d), to identify whether there has been a material change to any factor listed in section 1194(e) of the Act with respect to a selected drug or whether a new indication has been added for a selected drug for purposes of determining renegotiation eligibility for an initial price applicability year. Also, CMS will use the information from this information collection to help identify whether to select for renegotiation certain renegotiation-eligible drugs for which CMS expects renegotiation is likely to result in a significant change in the MFP otherwise negotiated.

**3. Use of Information Technology**

CMS will continue to use an automated tool within the existing information technology system, the Health Plan Management System (the CMS HPMS), for manufacturers to submit the Biosimilar Delay ICR Form.

Manufacturers of Medicare Part D drugs currently use the CMS HPMS system for other Part D program needs. Manufacturers of drugs covered under Medicare Part B currently use the CMS HPMS for the Medicare Prescription Drug Inflation Rebate Program.[3] Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting

[3] 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.

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.[4]

For submission of the Identification and Selection of Renegotiation-Eligible Drugs ICR Form, CMS will provide access to a Box[5] folder specific to the Primary Manufacturer if the Primary Manufacturer chooses to submit information for CMS' consideration. No parties other than the Primary Manufacturer and CMS and its contractors will have access to this folder. CMS currently uses secure, limited access Box folders for other components of the Negotiation Program with Primary Manufacturers. CMS will provide the Primary Manufacturer with a template of Word and/or Excel files that replicate only the questions and data field requirements in this ICR Form for the Primary Manufacturer to complete and submit to CMS. Primary Manufacturers will refer to the ICR Form for any additional instructions and/or definitions applicable to a section/question.

**4. Duplication of Efforts**

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

**5. Small Businesses**

This collection of information has been designed with a view towards minimizing the reporting burden for Biosimilar Manufacturers seeking a Biosimilar Delay and for Primary Manufacturers voluntarily submitting data for renegotiation eligibility and selection. The information is being collected once for an initial price applicability year, and only from each of, as applicable:

1) The Biosimilar Manufacturer seeking the Biosimilar Delay for a Reference Drug and includes those data items for CMS:
    a. to determine that a negotiation-eligible drug includes the reference product for the Biosimilar,
    b. to determine that the Biosimilar Manufacturer is not the same entity as the Reference Manufacturer,
    c. to determine the status of licensure for the Biosimilar under section 351(k) of the PHS Act,
    d. to determine that more than one year has not elapsed since the licensure of the Biosimilar if marketing of the Biosimilar has not commenced,
    e. to determine that the Biosimilar Manufacturer and the Reference Manufacturer have not entered into an agreement that either:
        i. requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request; or

[4] https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf.
[5] If CMS specifies an alternative secure location to Box, CMS will provide updated instructions and information to Primary Manufacturers. Access to this alternative location would also be limited consistent with the Box folders.

ii. directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time; and

f. to determine that there is a high likelihood of market entry of the Biosimilar within two years of the statutorily-defined selected drug publication date for such initial price applicability year.

2) The Primary Manufacturer of a selected drug and includes data items for CMS:

a. to identify if there has been a material change in a section 1194(e)(1) or (e)(2) data factor, for the purposes of identifying renegotiation-eligible drugs for an initial price applicability year, and for selecting drugs for renegotiation for an initial price applicability year, or

b. to identify a new indication for the selected drug for purposes of identifying renegotiation-eligible drugs for an initial price applicability year and for selecting drugs for renegotiation for an initial price applicability year.

Biosimilar Manufacturers and Primary Manufacturers may be entities that are considered to be a small business. The impacts of this collection on a Biosimilar Manufacturer or a Primary Manufacturer are estimated to be the same regardless of the size of the Biosimilar Manufacturer or Primary Manufacturer.

**6. Less Frequent Collection**

Less frequent collection would not be an option because a a Biosimilar Manufacturer is expected to submit the information only once per initial price applicability year for each drug or drugs for which the Biosimilar Manufacturer seeks the Biosimilar Delay. Additionally, the Primary Manufacturer may voluntarily submit this requested information no more than once per initial price applicability year for each selected drug.

**7. Special Circumstances**

There are no special circumstances that would require an 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**

CMS published a 60-day notice, in conjunction with a proposed rule (CMS-4215-P, RIN 0938–AV90), in the Federal Register on June 12, 2026. Comments were received and are responded to within the preamble of the subsequent final rule (CMS-4215-F). We have also attached a summary of the comments that were submitted and our responses that were in relation to this collection of information request, such as comments regarding the submission process and requirements for the biosimilar initial delay requests and the identification and selection of a renegotiation-eligible drug. A crosswalk document describing the changes from the currently approved version of this ICR to the revisions in this final package is included. There were no substantial changes to the submission form and no changes to the requirements/burden from the 60-day version to this final package.

*Outside Consultation*
In the development of the Drug Selection ICR, CMS sought input from other federal agencies. CMS consulted with the FDA, and the Internal Revenue Service (IRS) Office of Chief Counsel provided technical assistance related to subsections (a) and (b) of section 52 of the IRC.

**9. Payments/Gifts to Respondents**

No payments or gifts will be given to respondents for submission of the information requested. If CMS determines that the Biosimilar Delay applies for an initial price applicability year, then the qualifying single source drug(s) for which the Biosimilar Manufacturer sought a delay will be delayed from inclusion on the selected drug list, for that initial price applicability year. If CMS determines that a selected drug is a renegotiation-eligible drug, then CMS may include the drug on the selected drug list for renegotiation for that initial price applicability year.

**10. Confidentiality**

All information collected will be kept private to the extent required and permitted under applicable laws and regulations.

*Identification and Selection of Renegotiation-Eligible Drugs:* 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)).

As discussed in Negotiation Program NPRM, CMS is implementing a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information of Primary Manufacturers including Exemption 3 and/or Exemption 4 of FOIA, and that strikes an appropriate balance between (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating information that does not qualify for such protection as proprietary. CMS does not intend to include redacted information from any voluntary information submitted by a Primary Manufacturer to CMS in response to the Drug Selection ICR if the selected drug of the Primary Manufacturer is selected for renegotiation and there is an agreement for a renegotiated MFP, in accordance with 42 CFR 429.200 within the public explanation for each selected drug with a renegotiated MFP discussed in 42 CFR 429.620(k). If the selected drug is then selected for renegotiation and the Primary Manufacturer submits the same information the Primary Manufacturer provided in response to the Drug Selection ICR in response to the Drug Price Negotiation ICR, in accordance with 42 CFR 429.615(a), CMS may include the information provided in response to the Drug Price Negotiation ICR in the public explanation of a renegotiated MFP in accordance with 42 CFR 429.620(k) and in accordance with the confidentiality policy described in 42 CFR 429.300.

**11. Sensitive Questions**

*Biosimilar Delay*: The Biosimilar Manufacturer must provide its EIN(s), and the EIN(s) of the Reference Manufacturer. In addition, the Biosimilar Manufacturer must provide certain information about the status of licensure and marketing of the Biosimilar, in addition to certain financial and business information of the Biosimilar Manufacturer related to the manufacturing and marketing of the Biosimilar. The Biosimilar Manufacturer must also provide information about agreements between the Biosimilar Manufacturer and the Reference Manufacturer relating to requirements or incentives to submit an Initial Delay Request or direct or indirect restrictions on the quantity of the Biosimilar that may be sold in the United States over a specified period of time.

*Identification and Selection of Renegotiation-Eligible Drugs:* There are no sensitive questions associated with this collection.

**12. Burden Estimates (Hours & Wages)**

*Biosimilar Delay:* A Biosimilar Manufacturer must complete and submit the information requested on this form in order for a drug to be considered for the Biosimilar Delay for an initial price applicability year.

To identify wage estimates, we used data from the Bureau of Labor Statistics (shown below) to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for

estimating the burden associated with completing the ICR Form for a Biosimilar Delay, form submission, and recordkeeping.[6]

| Occupation Title | Hourly Median Wage | Fringe Benefits and Overhead per Hour | Adjusted Hourly Wage* |
|---|---|---|---|
| Lawyer (23-1011) | $142.57 | $142.57 | $285.14 |
| General and Operations Manager (11-1021) | $82.99 | $82.99 | $165.98 |
| Chief Executive (11-1011) | $177.65 | $177.65 | $355.30 |

*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.*

Table 1 presents total burden, and total cost (based on the adjusted hourly wage as shown above), to submit the data outlined in the justification section of this supporting statement and the information collection.

We estimate 10 total respondents in one year of submission of this ICR, for example using the base year of 2026 for initial price applicability year 2029. We have not revised this estimate compared to the prior initial price applicability years based on volume of requests received for one initial price applicability. We believe that collection of these data will be a one-time cost for each Biosimilar Manufacturer for each negotiation-eligible drug for which it is seeking the Biosimilar Delay for one initial price applicability year.

We estimate it will take a lawyer, on average, 20 hours, at a cost of $285.14 per hour, to gather and review the relevant IRC provisions (e.g., subsection (a) or (b) of section 52 of the IRC) and to identify any controlled group members that as of December 31, 2021 were treated as a single employer with the Biosimilar Manufacturer under subsection (a) or (b) of section 52 of the IRC, to identify and review any agreements between the Reference Manufacturer and the Biosimilar Manufacturer, and to identify and review FDA licensure documentation and manufacturing schedule, trade agreements, and Securities and Exchange disclosures related to the Biosimilar Drug. We estimate that it will take a general and operations manager, on average, 4 hours, at a cost of $165.98 per hour, to examine the gathered information and submit the ICR Form for a Biosimilar Delay to CMS. We also estimate that it will take a lawyer and a general and operations manager, on average, 30 minutes, or 0.5 hours, each to request technical assistance

[6] See May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 - Pharmaceutical and Medicine Manufacturing. Available at: https://www.bls.gov/oes/tables.htm.

from CMS (which is 20.5 hours in sum for a lawyer and 4.5 hours in sum for a general and operations manager). We estimate that it will take a chief executive, on average, 1 hour, at a cost of $355.30 per hour, to review the information prior to submission and to log in to CMS' existing information technology system to certify the submission. Certification must be done by an Authorized Representative of the Biosimilar Manufacturer as defined in 42 CFR 429.20.

The cost estimates for one-time costs are presented in Table 1. The estimate yields a total burden of 260 hours (26 hours * 10 total respondents) and total cost of $69,475.80 ($6,947.58 per respondent * 10 total respondents).

**TABLE 1: SUMMARY OF INFORMATION COLLECTION FOR BIOSIMILAR DRUGS FOR THE ONE TIME COST OVER THE ONE-YEAR PERIOD**

| Respondents' Occupational Title | # Of Hours per Respondent | # Of Respondents | Total Burden Hours | Total Cost |
|---|---|---|---|---|
| Lawyer (23-1011) | 20.5 | 10 | 205 | $58,453.70 |
| General and Operations Manager (11-1021) | 4.5 | 10 | 45 | $7,469.10 |
| Chief Executive (11-1011) | 1.0 | 10 | 10 | $3,553.00 |
| **Total** | **26.0** | **10** | **260** | **$69,475.80** |
| **Cost per Respondent** | | | | **$6,947.58** |

*Identification and Selection of Renegotiation-Eligible Drugs:* Primary Manufacturers that agreed to an MFP for a selected drug may voluntarily report certain information provided for in sections 1194(e)(1) and (e)(2) of the Act for purposes of CMS identifying and selecting renegotiation-eligible drugs as well as information on any new indication(s) added to the selected drug for purposes of CMS identifying and selecting renegotiation-eligible drugs. Table 2 presents the estimated hourly median 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. 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 2 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. Additionally, CMS is adding questions in this revised package within Section 4 (Question 12) and CMS has slightly expanded the date range for the data encompassed in Section 6 Section G, which may or may not require the Primary Manufacturer to gather additional information. Given these uncertainties, the burden estimate is provided along with a high estimate and low estimate in Table 3. CMS believes that the range is already sufficient to account for any additional time a Primary Manufacturer may need to spend preparing a response for the new question and Section 6 revised data period in this revised package, as well. CMS does not intend for the Primary Manufacturer to provide information in response to this ICR Form that the Primary Manufacturer provided in its most recent full submission of section 1194(e)(1) data to CMS. CMS has included specific instructions in this ICR Form to specify the beginning and end dates for the applicable reporting time periods for each data element.

CMS anticipates collecting data from all Primary Manufacturers for each selected drug with an agreed-upon MFP for prior initial price applicability years in response to the Identification and Selection of Renegotiation-Eligible Drugs ICR Form unless the selected drug has a change in monopoly status or a selected drug has been removed from the selected drug list by CMS consistent with section 1193(c) of the Act, which will be, at most, 36 responses for one initial price applicability year, using initial price applicability year 2029 as the base year. For purposes of this information collection, CMS assumes there will be up to 36 Primary Manufacturers, one for each selected drug, for the base year, but CMS cannot provide definitive assumptions about how many drugs may be selected for renegotiation. As additional drugs are selected for negotiation, such as for initial price applicability years 2029 and 2030, additional selected drugs may be eligible for renegotiation. However, due to removal from selection (consistent with 42 CFR 429.125(b)), some drugs selected for negotiation may be removed prior to submission of this ICR. Therefore, we estimate the respondent number based on data available to CMS prior to the base year of initial price applicability year 2029. Further, regardless of the total number of drugs eligible for selection 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 certain data on behalf of any Secondary Manufacturer(s) of a selected drug, if applicable.

CMS estimates it will take a business operations specialist or team of business operations specialists, on average, 25 hours, at a cost of $95.06 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 patent applications, 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, 75 hours, at a cost of $119.92 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.

Once these analyses are performed, CMS estimates that it will take a financial manager, on average, 6.25 hours, at a cost of $175.98 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 0.5 hours, on average, at a cost of $285.14 per hour, to review the compiled data submission.

CMS estimates that it will take a cost estimator, on average, 17.75 hours, at a cost of $82.82 per hour, to compile and report the required data to CMS, per the data element form instructions. Finally, CMS estimates that it will take a chief executive, on average, 0.5 hours, at $355.30 per hour, to review the data submission and log in to the CMS HPMS to certify the submission. Certification must be done by an Authorized Representative of the Primary Manufacturer as defined in 42 CFR 429.20.

The cost estimates for one-time costs are presented in Table 2. The estimate yields a total burden of 4,500 hours (125 hrs. per Primary Manufacturer per selected drug * 36 selected drugs) and total cost of $513,383.40 for all 36 selected drugs ($14,260.65 per respondent per selected drug * 36 selected drugs).

**TABLE 2: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR UP TO 36 SELECTED DRUGS FOR ONE INITIAL PRICE APPLICABILITY YEAR**

| Occupation Title | Hourly Median Wage | Cost per hour* | # Of Hours | # Of Respondents | Total Burden Hours | Total Cost |
|---|---|---|---|---|---|---|
| Financial Manager (11-3031) | $87.99 | $175.98 | 6.25 | 36 | 225 | $39,595.50 |
| Cost Estimator (13-1051) | $41.41 | $82.82 | 17.75 | 36 | 639 | $52,921.98 |
| Business Operations Specialists (13-1000) | $47.53 | $95.06 | 25.00 | 36 | 900 | $85,554.00 |
| Economist (19-3011)[7] | $59.96 | $119.92 | 75.00 | 36 | 2,700 | $323,784.00 |
| Lawyer (23-1011) | $142.57 | $285.14 | 0.50 | 36 | 18 | $5,132.52 |
| Chief Executive (11-1011) | $177.65 | $355.30 | 0.50 | 36 | 18 | $6,395.40 |
| **Total (36 Manufacturers)** | - | - | - | **36** | **4,500** | **$513,383.40** |
| **Total per Manufacturer** | - | - | - | **1** | **125** | **$14,260.65** |

[7] Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000 – Cross-industry. Available at: https://www.bls.gov/oes/tables.htm.

** As previously noted, this estimate assumes a 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 3 below to illustrate the possible variability for this burden estimate. To calculate the low estimate, the base estimate (Table 2 "Total Burden Hours" per 1 respondent) has been reduced by half for each labor category. For the high estimate, the required time associated with each labor category from the base estimate has been doubled.

**TABLE 3: COST RANGE ESTIMATES FOR PRIMARY MANUFACTURER FOR ONE INITIAL PRICE APPLICABILITY YEAR**

| | Hours per Respondent | Cost per Respondent | Total Cost |
|---|---|---|---|
| Low Estimate | 62.5 | $7,130.335 | $256,691.70 |
| Base Estimate (from Table 2) | 125.0 | $14,260.650 | $513,383.40 |
| High Estimate | 250.0 | $28,521.300 | $1,026,766.80 |

**TABLE 4: TOTAL BURDEN HOURS FOR ALL RESPONDENTS FOR THE BIOSIMILAR DELAY REQUEST AND THE IDENTIFICATION AND SELECTION OF RENEGOTIATION-ELIGIBLE DRUGS**

| Task | Total Burden Hours |
|---|---|
| Biosimilar Delay | 260 |
| Identification and Selection of Renegotiation-Eligible Drugs | 4,500 |
| **Total Hourly Burden Over 1 Year** | **4,760** |

### 13. Capital Costs

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

### 14. Cost to Federal Government

To generate salary estimates for the Tables 5 and 6 below, we used: the 2026 General Schedule (GS) Locality Pay Tables[8] published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region. In this regard, Tables 5 and 6 present the Full-Time Equivalent (FTE) of staff required for the task, the adjusted hourly wage, which is the hourly

[8] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2026/DCB_h.pdf.

basic rate plus the cost of fringe benefits (calculated at 100 percent of salary). Staffing estimates are based on CMS duties as follows:

*Biosimilar Delay:* We anticipate that one GS-13 Federal employee will spend approximately 80 hours, or one FTE approximately two weeks, one GS-14 Federal employee will spend approximately 10 hours, and one GS-15 Federal employee will spend approximately 2.5 hours, maintaining the ICR Form for a Biosimilar Delay and analyzing data collected through the Form. The adjusted hourly wage of $116.70 is the total of the hourly basic rate of $58.35 for one GS-13 step-1 plus 100 percent fringe benefit rate of $58.35, the adjusted hourly wage of $137.92 is the total of the hourly basic rate of $68.96 for one GS-14 step-1 plus 100 percent fringe benefit rate of $68.96, and the adjusted hourly wage of $162.22 is the total of the hourly basic rate of $81.11 for one GS-15 step-1 plus 100 percent fringe benefit rate of $81.11. We anticipate that one GS-13 Federal employee will spend approximately 16 hours handling communications with Biosimilar Manufacturers, including notifying each Biosimilar Manufacturer of CMS' determination regarding its Biosimilar Delay request and providing technical assistance with the CMS HPMS tool. We anticipate that other GS-13 Federal employees will spend a total of 120 hours, or the equivalent of one FTE approximately three weeks, to provide technical directions to a contractor that will revise the automated tool within the CMS HPMS for the Biosimilar Manufacturers to submit the ICR Form for a Biosimilar Delay. We anticipate that this contractor will spend a total of 720 hours at a cost of $249.59 per hour.

**TABLE 5. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF BIOSIMILAR DELAY REQUESTS**

| Staff | FTE Equivalent | Hourly Wage* | Total Burden Hours | Total Cost |
|---|---|---|---|---|
| Biosimilar Delay Review | | | | |
| GS-13, step 1 | 1 | $116.70 | 80.0 | $9,336.00 |
| GS-14, step 1 | 1 | $137.92 | 10.0 | $1,379.20 |
| GS-15, step 1 | 1 | $162.22 | 2.5 | $405.55 |
| Communicating with Biosimilar Manufacturers | | | | |
| GS-13, step 1 | 1 | $116.70 | 16.0 | $1,867.20 |
| Modification of the Existing CMS HPMS | | | | |
| GS-13, step 1 | 1 | $116.70 | 120.0 | $14,004.00 |
| Contractor | 1 | $249.59 | 720.0 | $179,704.80 |
| **Total Cost to Government Over One Year** | | | **$206,696.75** | |

*Identification and Selection of Renegotiation-Eligible Drugs:*

We anticipate that seven GS-13 Federal employees will spend approximately a total of 245 hours, three GS-14 Federal employees will spend approximately 105 hours, and one GS-15 Federal employee will spend approximately 35 hours, maintaining the Identification and Selection of Renegotiation-Eligible Drugs ICR Form, Box access for Primary Manufacturers, and analyzing data collected through the Form.

**TABLE 6. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF IDENTIFICATION AND SELECTION OF RENEGETIATION-ELIGIBLE DRUGS DATA**

| Staff | FTE Equivalent | Hourly Wage* | Total Burden Hours | Total Cost |
|---|---|---|---|---|
| Section 1194(e) Review | | | | |
| GS-13, step 1 | 7 | $116.70 | 245 | $28,591.50 |
| GS-14, step 1 | 3 | $137.92 | 105 | $14,481.60 |
| GS-15, step 1 | 1 | $162.22 | 35 | $5,677.70 |
| **Total Cost to Government Over One Year** | | | | **$48,750.80** |

** As previously noted, this estimate assumes a 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.*

**TABLE 7. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF THE BIOSIMILAR DELAY REQUEST AND THE REVIEW OF IDENTIFICATION AND SELECTION OF RENEGOTIATION-ELIGIBLE DRUG DATA**

| Task | Estimated Cost |
|---|---|
| Biosimilar Delay Review | $206,696.75 |
| Identification and Selection of Renegotiation-Eligible Drugs Data Review | $48,750.80 |
| **Total Cost to Government Over 1 Year** | **$255,447.55** |

**15. Changes to Burden**

This is a revision to a currently approved ICR.

In this final version, CMS includes the following:

CMS has removed burden associated with a Small Biotech Exception.

In the Biosimilar Delay ICR Form and the Identification and Selection of Renegotiation-Eligible Drugs Form, CMS replaced references to dates specific to a specific initial price applicability

year and replaced the reference with terms language to reference the requirement in the final rule. These revisions do not impact the burden.

Additionally, for the Identification and Selection of Renegotiation-Eligible Drugs ICR Form, CMS included other technical revisions to the ICR Form that do not impact burden, including, for example, CMS added instructions to Sections 2, 4 and 5 for Primary Manufacturers of drugs originally selected for initial price applicability year 2028 to answer the questions in each section. In addition, CMS clarified the instructions in Sections 1 and 3 regarding the applicability of submitting certain prior research and development (R&D) costs related to drugs selected originally for initial price applicability years 2026 and 2027. Finally, CMS slightly adjusted the applicable data time period for Section 6 from the date of the written or verbal final offer presented by either the Primary Manufacturer or CMS, whichever is later, as applicable, from the negotiation period in which the selected drug's MFP was negotiated through the due date of this ICR (consistent with 42 CFR 429.615(a)). The additional data that may be relevant for the period of time between the final offer and the agreed-to MFP is likely minimal to none, as is the potential for additional data from November 30 to the due date of this ICR if different than November 30. Therefore, CMS believes, any minimal impact is already accounted for in the range of burden estimate provided in this Supporting Statement.

In sum, the hourly burden difference and cost impact between the currently approved version and this final version are included in Table 8 below.

**TABLE 8. COMPARISON OF CURRENTLY APPROVED ICR TO THIS FINAL VERSION**

| Item | Total for Currently Approved ICR | Total for This Final Version | Total Difference |
|---|---|---|---|
| Total Number of Respondents | 65 | 46 | -19 |
| Total Hourly Burden | 3,677.50 | 4,760 | 1,082.50 |
| **Total Cost Per Respondent** | **$132,073.08** | **$21,208.23** | **-$110,864.85** |

Finally, CMS revised the burden estimate to the federal government to account for the removal of the Small Biotech Exception Request ICR Form and updated the wage amounts used for the staff, which account for the most up-to-date year that is available. In sum, the estimated cost differences between the currently approved version and the changes in this final version are included in Table 9 below.

**TABLE 9. COMPARISON OF CURRENTLY APPROVED ICR TO THE FINAL VERSION: TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF THE BIOSIMILAR DELAY REQUEST AND THE IDENTIFICATION AND SELECTION OF RENEGOTIATION-ELIGIBLE DRUGS**

| Task | Estimated Cost for Currently Approved ICR | Estimated Cost for This Final Version |
|---|---|---|
| Small Biotech Exception Review | $246,045.74 | ------ |
| Biosimilar Delay Review | $191,685.60 | $206,696.75 |
| Identification and Selection of Renegotiation-Eligible Drugs | $48,270.60 | $48,750.80 |
| **Total Cost to Government Over 1 Year** | **$486,001.94** | **$255,447.55** |
| **Total Difference in the Total Cost to Government Over 1 Year** | ------ | **-$230,554.39** |

**16. Publication/Tabulation Dates**

The results of this information collection will not be published.

**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.