Supporting Statement – Part A

Negotiation Program Drug Selection for Initial Price Applicability Year 2028 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. For the purposes of this information collection request (ICR), qualifying single source drug has the same definition as it is given in section 30.1 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027, and 2028 (expected to be issued in Fall 2025 concurrently with this ICR; referenced hereinafter as "final guidance"). Terms used in this ICR have the meaning set forth in the final guidance. For the third year of the Negotiation Program, initial price applicability year 2028, CMS will select for negotiation up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D. 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 section 130.1 of the final guidance, 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 two potential circumstances 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(d)(2) of the Act, the term "negotiation-eligible drug" excludes, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the "Small Biotech Exception," or "SBE"). Additionally, 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.

We are revising this ICR's title as follows, "Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request" (hereinafter, the "Drug Selection ICR"). This title revision reflects the addition of an information collection to this package pertaining to CMS' determinations regarding eligibility and selection of selected drugs for renegotiation. CMS is authorized to collect information pertaining to eligibility and selection of selected drugs for renegotiation under the authority in sections 11001 and 11002 of the IRA. For clarity, the currently approved information collections pertaining to the SBE and Biosimilar Delay will continue with revisions reflected in this 30-day notice.

CMS is requesting to include the information collection for the Identification and Selection of Renegotiation-Eligible Drugs within the currently approved collection of CMS-10844, OMB 0938-1443. Revising the currently approved ICR package to include three information collections that inform CMS' determinations of the lists of selected drugs for negotiation and renegotiation will streamline the review process for the pharmaceutical industry and other interested parties when reviewing Paperwork Reduction Act (PRA) renewals for this notice.

Each of the three 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 initial price applicability year 2028 and therefore are being advanced through the same 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 initial price applicability year 2028, as described in sections 30.4 and 130.2.2 of the final guidance.

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 initial price applicability year 2028, CMS will designate the entity that holds the New Drug Application(s) (NDA(s)) / Biologics License Application(s) (BLA(s)) for the selected drug to be "the manufacturer" of the selected drug (hereinafter the "Primary Manufacturer").

If information within a section of this Supporting Statement applies to only the SBE, 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

Small Biotech Exception: In accordance with section 1192(d)(2) of the Act, the Primary Manufacturer of a small biotech drug ("Submitting Manufacturer") may submit a request with respect to initial price applicability years 2026, 2027, and/or 2028 for CMS' consideration to exclude a qualifying single source drug that meets the requirements for the exception for small biotech drugs from the list of "negotiation-eligible drugs" for a given initial price applicability year.

For initial price applicability year 2028, section 1192(d) of the Act requires CMS to evaluate whether a qualifying single source drug qualifies for the SBE based on Total Expenditures under Part B or Part D. CMS will make separate determinations with respect to the Part B criteria pursuant to section 1192(d)(2)(A)(ii) of the Act (the "Part B Track"), and the Part D criteria pursuant to section 1192(d)(2)(A)(i) of the Act (the "Part D Track"). For initial price applicability year 2028, the term "negotiation-eligible drug" will exclude any qualifying single source drug that meets either the Part B or Part D criteria to qualify for the SBE.

For the purposes of the SBE, in accordance with section 30.2.1 of the final guidance, CMS needs to collect information to accurately identify: the "Part D 2021 Manufacturer," which is the entity that had the Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D-14A in effect for the qualifying single source drug on December 31, 2021; and the "Part B 2021 Manufacturer," which is the entity that held the New Drug Application(s) or Biologics License Application(s) (NDA(s)/BLA(s)) for the qualifying single source drug on December 31, 2021. In addition, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all corporations or partnerships, sole proprietorships, and other entities that, on December 31, 2021, were treated as a single employer (i.e., part of the same controlled group) under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 (IRC) with the Part B 2021 Manufacturer or Part D 2021 Manufacturer. The controlled group of the Part D 2021 Manufacturer comprises all entities that, as of December 31, 2021, were treated as a single employer with the Part D 2021 Manufacturer and had a CGDP Agreement in effect on December 31, 2021. To accurately identify whether a drug meets the SBE criteria in accordance with section 1192(d)(2)(A)(i) of the Act, CMS collects the name, address, Employer Identification Number (EIN), unique identifier assigned by CMS (P Number), and labeler code(s) owned by the Part D 2021 Manufacturer and the entity(ies) in the Part D 2021 Manufacturer's controlled group. The controlled group of the Part B 2021 Manufacturer comprises all entities that, as of December 31, 2021, were treated as a single employer with the Part B 2021 Manufacturer. To accurately identify whether a drug meets the SBE criteria in accordance with

section 1192(d)(2)(A)(ii) of the Act, CMS collects the name, address, EIN, and unique identifier assigned by CMS (P Number) for the Part B 2021 Manufacturer and the entity(ies) in the Part B 2021 Manufacturer's controlled group. CMS also collects the NDA(s) and/or BLA(s) held by the Part B 2021 Manufacturer and all entity(ies) in the Part B 2021 Manufacturer's controlled group.

In applying the Part D Track of the SBE, the statute requires that CMS consider Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures under Part D for the qualifying single source drug during 2021, and Total Expenditures under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021.[2] To identify and exclude drugs eligible for the SBE, CMS will consider whether, for dates of service in calendar year 2021, the Total Expenditures during 2021 under Part D for the qualifying single source drug were: (1) equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs during 2021; and (2) equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs during 2021 for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021. [3]

In applying the Part B Track of the SBE, the statute requires that CMS consider Total Expenditures under Part B in 2021 for all qualifying single source drugs, Total Expenditures under Part B during 2021 for the qualifying single source drug, and Total Expenditures under Part B in 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group. To identify and exclude drugs eligible for the SBE, CMS will consider whether, for Medicare Fee-for-Service (FFS) Part B claims data and Medicare Advantage (MA) encounter data for Part B items and services (hereinafter collectively referred to as "Part B data") with dates of service in calendar year 2021, the Total Expenditures under Part B, as determined using Part B data as described in the final guidance, during 2021 for the qualifying single source drug were: (1) equal to or less than one percent of the Total Expenditures under Part B for all qualifying single source drugs paid under Part B during 2021; and (2) equal to at least 80 percent of the Total Expenditures under Part B during 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group for which payment may be made under Part B.

Additionally, the limitation at section 1192(d)(2)(B)(ii) of the Act states that a qualifying single source drug is not eligible for the SBE if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section

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2 As stated in section 50.1.1 of the Revised Medicare Part D Manufacturer Discount Program Final Guidance, dated December 20, 2024, available at https://www.cms.gov/files/document/manufacturer-discount-program-finalguidance.pdf (hereinafter, the "Manufacturer Discount Program Final Guidance"): "A manufacturer that participated in the CGDP in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer's
CGDP Agreement would be considered to have had an agreement in effect during 2021."

3 As explained in section 30.2.1 of the final guidance, for purposes of identifying the qualifying single source drugs that comprise the ratios described in 1192(d)(2)(A), CMS will identify drugs that meet the definition of a qualifying single source drug for initial price applicability year 2028 based on the aggregation policies set forth in section 30.1 of final guidance.

1860D–14C(g)(4)(B)(ii) effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025, or January 1,

2026, for acquisitions occurring during 2025.[4] For purposes of implementing this limitation, CMS will use the determination made under the Medicare Part D Manufacturer Discount Program (the "Manufacturer Discount Program") as to whether the acquiring entity met the definition of specified manufacturer in the applicable period. CMS will consider an acquiring entity to have met the Manufacturer Discount Program definition of specified manufacturer for purposes of this limitation if the acquiring entity is identified by CMS under the Manufacturer Discount Program as either a specified manufacturer under section 1860D-14C(g)(4)(B)(ii) or a specified small manufacturer under section 1860D-14C(g)(4)(C)(ii) of the Act. For an acquisition of a manufacturer to be relevant to the limitation, and therefore to potentially preclude a drug from being considered a qualifying single source drug that could be eligible for an SBE, the transaction must occur after 2021 and must involve the acquisition of the Submitting Manufacturer after the Submitting Manufacturer held the NDA(s)/BLA(s) for the qualifying single source drug.

Note: This ICR only collects information relevant to a manufacturer's request for the SBE for initial price applicability year 2028. To request the SBE for initial price applicability year 2028, a Submitting Manufacturer must submit a request for an SBE for initial price applicability year 2028 regardless of whether the manufacturer submitted a request for initial price applicability years 2026 and/or 2027.

A determination by CMS that a given qualifying single source drug qualifies for the SBE for initial price applicability year 2028 does not determine if the drug will qualify for the temporary floor for a small biotech drug that is selected for initial price applicability years 2029 or 2030 as described in section 1194(d) of the Act. CMS will provide information about section 1194(d) in future rulemaking.

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

4 *See* section 50.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, dated December 20, 2024, available at https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf, and, *see also*, the November 17, 2023 HPMS memorandum titled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers", available at https://www.cms.gov/files/document/manufacturer-discount-program-specified-and-specified-smallmanufacturermethodology.pdf, for more information.

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 2027; therefore, no Reference Drugs would be the subject of an Additional Delay Request in initial price applicability year 2028. CMS includes information about Additional Delay Requests in the final guidance; but information regarding collection of information for an Additional Delay Request will be addressed in future information collection requests, as applicable.

Note: This ICR only collects information relevant to a manufacturer's request for the Biosimilar Delay for initial price applicability year 2028.

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 initial price applicability year 2028 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 (initial price applicability year 2029). The process for submitting an Initial Delay Request for initial price applicability year 2029 and for submitting Additional Delay Requests will be addressed in future rulemaking, as applicable, and future ICR(s), as applicable.

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 renegotiationeligible drugs in accordance section 1194(f)(2) of the Act, as described in section 130.1 of the final guidance. Second, CMS will select for renegotiation certain renegotiation-eligible drugs in accordance with section 1194(f)(3) of the Act, as described in section 130.2 of the final guidance. 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 section 130.1.3 of the final guidance to identify whether a new indication has been added to a selected drug for purposes of determining renegotiation eligibility and selection. As discussed in section 130.1.3 of the final guidance, 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

Small Biotech Exception: CMS currently does not have information to determine whether manufacturers of drugs and biological products payable under Part B and/or covered under Part D were treated as a single employer with other entities under subsection (a) or (b) of section 52 of the IRC as of December 31, 2021. This information is required in order for CMS to accurately identify whether a given drug meets the criteria for the SBE in accordance with section 1192(d)(2) of the Act. To ensure that only qualifying single source drugs that meet the requirements for the SBE Part D Track are excluded from the term "negotiation-eligible drug," a Submitting Manufacturer must submit to CMS information for the Part D 2021 Manufacturer and the Part D 2021 Manufacturer's controlled group such as the Employer Identification Number(s) (EIN(s)), P number(s), labeler code(s) owned by each entity that are associated with the entity's unique identifier (P number), and labeler code(s) owned by each entity that are associated with unique identifier(s) (P number(s)) owned by other entities. To ensure that only qualifying single source drugs that meet the requirements for the SBE Part B Track are excluded from the term "negotiation-eligible drug," a Submitting Manufacturer must submit to CMS the EIN(s) and NDA(s) and/or BLA(s) held by the Part B 2021 Manufacturer and the Part B 2021 Manufacturer's controlled group on December 31, 2021.

Finally, to implement the limitation at section 1192(d)(2)(B)(ii) of the Act, CMS needs information from the Submitting Manufacturer to assess whether the Submitting Manufacturer was the subject of an acquisition which would render the Submitting Manufacturer's qualifying single source drug to be ineligible for consideration under the SBE.

The SBE informs the selection of drugs payable under Part B and/or covered under Part D for negotiation for initial price applicability year 2028. The deadline for submission of an SBE will be specified by CMS. CMS anticipates sharing the submission opening and closing dates upon approval of the Drug Selection ICR from the Office of Management and Budget (OMB). CMS anticipates providing a 30-day submission period.

Manufacturers who might benefit from submitting an SBE for initial price applicability year 2028 are those manufacturers of a qualifying single source drug who believe that (1) the drug meets the criteria for the SBE as set forth in section 1192(d)(2) of the Act and as described in the final guidance and, (2) absent such a request and a determination by CMS that the drug qualifies for the SBE, the drug will be considered a negotiation-eligible drug for initial price applicability year 2028 based on the criteria and process specified in section 1192(d) of the Act and the final guidance.

As described in section 30.2.1 of the final guidance, to the extent that more than one entity meets the statutory definition of a manufacturer of a qualifying single source drug, only the holder of the NDA(s)/BLA(s) for the qualifying single source drug may be the Submitting Manufacturer. In accordance with section 1192(d)(2)(C) of the Act, for purposes of applying the SBE, a new

formulation of a qualifying single source drug is not considered a separate qualifying single source drug; consistent with section 30.1 of the final guidance, new formulations aggregated as part of the qualifying single source drug would not disqualify the qualifying single source drug from consideration for the SBE.

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 initial price applicability year 2028. 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 initial price applicability year 2028 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 initial price applicability year 2028;
(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 initial price applicability year 2028, 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 section 30.3.1.1 of the final guidance;
(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 initial price applicability year 2028, based on the process described in section 30.3.1.3 of the final guidance.

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 original full submission of section 1194(e)(1) data to CMS for the negotiation period in which the selected drug's MFP was negotiated to inform renegotiation eligibility and selection through this ICR. Instructions in this ICR Form specify the applicable reporting time period by data element.

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 section 130.4 of the final guidance 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 section 130.3.2 of the final guidance. 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

Small Biotech Exception: The requirements for the SBE are specified in section 1192(d)(2) of the Act. When the Submitting Manufacturer completes the ICR Form for the SBE and submits the form to CMS, CMS will use the submitted information to inform the agency's consideration and determination of whether the Submitting Manufacturer's qualifying single source drug qualifies for the SBE. For example, CMS will use the submitted information to identify and verify the entity that is the Part B 2021 Manufacturer or Part D 2021 Manufacturer and assess whether the drug meets the statutory requirements for the SBE. In addition, for initial price applicability year 2028, CMS will use information submitted in response to the ICR Form to determine if the limitation based on acquisition of the Submitting Manufacturer has been triggered such that its drug cannot be considered for the SBE.

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 2028 (additional information regarding this determination is included in section 30.3.1.3 of the final guidance).

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 section 130.1 of final guidance, 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 initial price applicability year 2028. 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 SBE and Biosimilar Delay ICR Forms.

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.[5] Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (CMS HPMS) for the Medicare Drug Price Negotiation Program" PDF. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.[6]

For submission of the Identification and Selection of Renegotiation-Eligible Drugs ICR Form, CMS will provide access to a Box[7] folder specific to the Primary Manufacturer if the Primary

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

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

7 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.

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

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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 Submitting Manufacturers seeking an SBE, 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 initial price applicability year 2028, and only from each of, as applicable:

1) The Submitting Manufacturer seeking an SBE for its qualifying single source drug(s) and includes those data items for CMS:
    a. to determine whether the Submitting Manufacturer was acquired by another entity after 2021, and if so, whether that acquisition precludes the manufacturer's qualifying single source drug from being eligible for the SBE; and
    b. to identify the applicable Total Expenditures for purposes of implementing the SBE. In accordance with section 1192(d)(2) of the Act, the SBE applies to drugs for which 2021 Total Expenditures meet the specified thresholds.

2) 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 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 initial price applicability year 2028.

3) 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 initial price applicability year 2028 and for selecting drugs for renegotiation for initial price applicability year 2028, or
   b. to identify a new indication for the selected drug for purposes of identifying renegotiation-eligible drugs for initial price applicability year 2028 and for selecting drugs for renegotiation for initial price applicability year 2028.

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

6. Less Frequent Collection

Less frequent collection would not be an option because a Submitting Manufacturer or a Biosimilar Manufacturer is expected to submit the information only once per initial price applicability year for each drug or drugs for which the Submitting Manufacturer or the Biosimilar Manufacturer seeks either the SBE or the Biosimilar Delay, respectively. 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 posted this package for a 60-day public comment period. The 60-day Federal Register notice published in the Federal Register (90 FR 20305) on May 13, 2025. CMS reviewed the three public comments received. CMS responses to in-scope, timely public comments are available in the "Summary of Public Comments and Responses" document included with this 30day package. CMS is posting this package for a 30-day public comment period. CMS will review the public comments received and address in-scope, timely public comments as part of the final materials submitted with the request for OMB approval of this ICR.

The 30-day Federal Register notice published in the Federal Register (90 FR 46895) on September 30, 2025

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 SBE and/or the Biosimilar Delay applies for an initial price applicability year, then the qualifying single source drug(s) for which the Submitting Manufacturer or Biosimilar Manufacturer sought an exception or delay, respectively, will be excluded from the term "negotiation-eligible drug" or 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 final guidance, 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 section 130.3.1 of this final guidance within the public explanation for each selected drug with a renegotiated MFP discussed in section 130.4.5 of the final guidance. 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 section 130.3.2 of this final guidance, 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 section 60.6.1 of the final guidance and in accordance with the confidentiality policy described in sections 40.2.1 and 50.2 of the final guidance.

11. Sensitive Questions

Small Biotech Exception: In order to ensure that all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC are treated as one manufacturer for purposes of applying the Part D Track of the SBE, the Submitting Manufacturer must provide the EIN(s) of the entity that had a CGDP Agreement in effect for the qualifying single source drug on December 31, 2021 (that is, the Part D 2021 Manufacturer) (regardless of whether such entity is the Submitting Manufacturer or another entity), and the EIN(s) of any members of that entity's controlled group that had a CGDP Agreement in effect on December 31, 2021. If the Submitting Manufacturer was acquired after December 31, 2021, the Submitting Manufacturer must provide the EIN(s) for the acquiring entity.

In order to ensure that all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC are treated as one manufacturer for purposes of applying the Part B Track of the SBE, the Submitting Manufacturer must provide the EIN(s) of the entity that held the NDA(s) or BLA(s) for the qualifying single source drug as of December 31, 2021 (that is, the Part B 2021 Manufacturer) (regardless of whether such entity is the Submitting Manufacturer or another entity), and the EIN(s) of any members of that entity's controlled group on December 31, 2021. Additionally, if the Submitting Manufacturer was acquired after December 31, 2021, the Submitting Manufacturer must provide the EIN(s) for the acquiring entity.

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)

Small Biotech Exception: A Submitting Manufacturer must complete and submit the information requested on this form in order for the drug to be considered for the SBE for initial price applicability year 2028. If the Submitting Manufacturer that seeks an SBE for a qualifying single source drug was acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the acquiring entity. A Submitting Manufacturer may submit the SBE for drugs payable under Part B, covered under Part D, or both payable under Part B and covered under Part D.

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 an SBE, form submission, and recordkeeping.[8]

Occupation Title	Median Hourly Wage	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)*

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

Lawyer (23-1011)	$115.00	$115.00	$230.00
General and Operations Manager (11-1021)	$84.75	$84.75	$169.50
Chief Executive (11-1011)	$115.00	$115.00	$230.00

**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.*

Tables 1 and 2 present the total burden and total cost (based on the adjusted hourly wage as shown above). 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. Although CMS expects Submitting Manufacturers to have some of the data readily available for submission, there is some uncertainty as to the estimate in Table 1 as some of the data required may not be readily available and may take time to compile and there may be potential variations in burden between a Submitting Manufacturer submitting an SBE depending on whether the qualifying single source drug is solely payable under Part B, solely covered under Part D, or is both payable under Part B and covered under Part D.

Additionally, some Submitting Manufacturers will have to submit additional material based on whether the Submitting Manufacturer was acquired after December 31, 2021, whether the Submitting Manufacturer had a CGDP Agreement in effect for the qualifying single source drug on December 31, 2021, and whether the Submitting Manufacturer held the NDA(s) and/or BLA(s) for the qualifying single source drug on December 31, 2021. Given this variability, the burden estimate is provided along with a high estimate and low estimate in Table 2.

CMS estimates 30 total respondents will submit for an SBE in 2025. We believe that the collection of these data will be a one-time cost for each Submitting Manufacturer for each qualifying single source drug for which it is seeking the SBE for initial price applicability year 2028.

CMS estimates it will take a lawyer, on average, six hours, at a cost per hour of $230.00, to gather and review the relevant IRC provisions (e.g., subsection (a) or (b) of section 52 of the IRC), to identify any controlled group members that as of December 31, 2021, were treated as a single employer with the Part B 2021 Manufacturer and/or the Part D 2021 Manufacturer under subsection (a) or (b) of section 52 of the IRC, and to report the relevant information for these entities. Under the Part B Track of the SBE, such information includes the list of NDA(s) and/or BLA(s) held by the Part B 2021 Manufacturer and any member of its controlled group as of

December 31, 2021. Under the Part D Track of the SBE, such information includes the unique identifier assigned by CMS (P number) and labeler code(s) owned by the Part D 2021 Manufacturer and any member of its controlled group that had a CGDP Agreement in effect on December 31, 2021. This information must be utilized by CMS when calculating Total Expenditures under Part B during 2021 for the qualifying single source drugs of the Part B 2021 Manufacturer and any member of its controlled group, or when calculating Total Expenditures under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer and its controlled group had a CGDP agreement in effect on December 31, 2021. We estimate that it will take a general and operations manager, on average, two and one-half hours, at $169.50 per hour, to examine the gathered information and submit the ICR Form for an SBE to CMS. We also estimate that it will take a lawyer and a general operations manager, on average, 30 minutes, or 0.5 hours, each to request technical assistance from CMS (totaling six and one-half hours for a lawyer in sum and three hours for a general and operations manager in sum). We estimate that it will take a chief executive, on average, 15 minutes, or 0.25 hours, at $230.00 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 (1) the chief executive officer (CEO) of the Submitting Manufacturer, (2) the chief financial officer (CFO) of the Submitting Manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO of the Submitting Manufacturer, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

We have presented the cost estimates in Table 1. We estimate a total burden of 292.5 hours (9.75 hrs. * 30 respondents) and total cost of $61,830.00 ($2,061.00 per respondent * 30 respondents).

TABLE 1: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR SMALL BIOTECH DRUGS FOR A SUBMITTING MANUFACTURER FOR THE ONE TIME COST OVER THE ONE-YEAR PERIOD FOR INITIAL PRICE APPLICABILITY YEAR 2028

Respondents' Occupation Title	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
Lawyer (23-1011)	6.5	30	195	$44,850.00
General and Operations Manager (11-1021)	3	30	90	$15,255.00

Chief Executive (11-1011)	0.25	30	7.5	$1,725.00
Total	9.75	30	292.5	$61,830.00
Cost per Respondent				$2,061.00

An additional low estimate and high estimate is provided in Table 2 below to illustrate the possible variability for this burden estimate based on the amount of research and review required to answer the collection for a particular drug and based on which scenarios apply to a specific drug (e.g., acquisition). The high and low estimates are intended to capture the varying amount of time that may be needed for a submission that includes a drug solely payable under Part B or solely covered under Part D, or that is both payable under Part B and covered under Part D. To calculate the low estimate, the base estimate (Table 1 "# of hours per 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 2: COST RANGE ESTIMATES OF BURDEN FOR SUBMITTING MANUFACTURER FOR THE ONE TIME COST FOR SMALL BIOTECH DRUGS OVER THE ONE-YEAR PERIOD FOR INITIAL PRICE APPLICABILITY YEAR 2028

	Hours per Respondent	**Cost per Respondent**	**Total Cost**
Low Estimate	4.875	$1,030.50	$30,915.00
Base Estimate (from Table 1)	9.75	$2,061.00	$61,830.00
High Estimate	19.5	$4,122.00	$123,660.00

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 initial price applicability year 2028.

To identify wage estimates, we used data from the Bureau of Labor Statistics 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.[9] Table 3 presents total burden and total cost (based on the adjusted hourly wage as shown above).

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

We estimate 10 total respondents in 2025. We have not revised this estimate compared to the prior initial price applicability year based on volume of requests received for initial price applicability year 2027. 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 initial price applicability year 2028.

We estimate it will take a lawyer, on average, 20 hours, at a cost per hour of $230.00, 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, four hours, at $169.50 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 from CMS (which is 20.5 hours in sum for a lawyer and four and one-half hours in sum for a general and operations manager). We estimate that it will take a chief executive, on average, one hour, at $230.00 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 (1) the CEO of the Biosimilar Manufacturer, (2) the CFO of the Biosimilar Manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO of the Biosimilar Manufacturer, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

We have presented the cost estimates in Table 3. For all 10 respondents, we estimate a total burden of 260 hours and total cost of $57,077.50.

TABLE 3: SUMMARY OF INFORMATION COLLECTION FOR BIOSIMILAR DRUGS FOR THE ONE TIME COST OVER THE ONE-YEAR PERIOD

Respondents' Occupation Title	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
Lawyer (23-1011)	20.5	10	205	$47,150.00
General and Operations Manager (11-1021)	4.5	10	45	$7,627.50

Chief Executive (11-1011)	1	10	10	$2,300
Total	26	10	260	$57,077.50
Cost per Respondent				$5,707.75

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 4 presents the estimated median hourly wage, the adjusted hourly wage (inclusive of fringe benefits and overhead), total burden, and total cost to submit the data outlined in the justification section of this supporting statement and the information collection. 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 4 as some of the data required may not be readily available and may take time to compile, such as R&D costs that manufacturers have incurred since the periods reflected in their prior submissions required under section 1194(e)(1) of the Act. Given this uncertainty, the burden estimate is provided along with a high estimate and low estimate in Table 5. CMS does not intend for the Primary Manufacturer to provide information in response to this ICR Form that the Primary Manufacturer provided in its original full submission of section 1194(e)(1) data to CMS. 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 is soliciting comment on these instructions as to whether the information provided is sufficient to make clear the time period(s) for which the information is requested by CMS in response to this ICR Form.

CMS anticipates collecting data from all Primary Manufacturers for each selected drug with an agreed-upon MFP for initial price applicability years 2026 and 2027 in response to the Identification and Selection of Renegotiation-Eligible Drugs ICR Form unless the selected drug has a change in monopoly status, which will be, at most, 25 responses for initial price applicability year 2028. For purposes of this information collection, CMS assumes there will be up to 25 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 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 $93.10 per hour, to gather cost data and compile required information, as specified in the data elements instructions, such as data on prior Federal financial support, pending 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 $111.00 per hour, to perform necessary economic analyses, including the R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs, the selected drug's cost of production and distribution, and other data elements specified in the data element instructions.

Once these analyses are performed, CMS estimates that it will take a financial manager, on average, 6.25 hours, at a cost of $172.66 per hour, to review the results of all the analyses and cost estimates prior to submission to CMS. CMS estimates it will take a lawyer one-half hour, on average, at $230.00 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 $66.42 per hour, to compile and report the required data to CMS, per the data element form instructions. Finally, CMS estimates that it will take a chief executive, on average, one-half hour, at $230.00 per hour, to review the data submission and log in to the CMS HPMS to certify the submission. Certification must be done by (1) the CEO, (2) the CFO, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

The cost estimates for one-time costs are presented in Table 4. The estimate yields a total burden of 3,125 hours (125 hrs. per Primary Manufacturer per selected drug * 25 selected drugs) and total cost of $329,139.51 for all 25 selected drugs ($13,165.58 per respondent per selected drug * 25 selected drugs).

TABLE 4: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR UP TO 25 SELECTED DRUGS FOR INITIAL PRICE APPLICABILITY YEAR 2028

Occupation Title	Median Hourly Wage	Cost per hour*	# Hours	# Respondents	Total Burden Hours	Total Cost
Financial Manager (11-3031)	$86.33	$172.66	6.25	25	156.25	$27,603.13
Cost Estimator (13-1051)	$33.21	$66.42	17.75	25	443.75	$29,473.88
Business Operations Specialists (13-1000)	$46.55	$93.10	25	25	625	$58,187.50
Economist (19-3011)[10]	$55.00	$111.00	75	25	1,875	$208,125.00

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

Lawyer (23-1011)	$115.00	$230.00	.5	25	12.5	$2,875.00
Chief Executive (11-1011)	$115.00	$230.00	.5	25	12.5	$2,875.00
Total (25 Manufacturers)	-	-	-	25	**3,125**	$329,139.51
Total per Manufacturer	-	-	125	1	125	$13,165.58

** 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 5 below to illustrate the possible variability for this burden estimate. To calculate the low estimate, the base estimate (Table 4 "Total Burden Hours") 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 5: COST RANGE ESTIMATES FOR PRIMARY MANUFACTURER FOR INITIAL PRICE APPLICABILITY YEAR 2028

	Hours per Respondent	**Cost per Respondent**	**Total Cost**
Low Estimate	62.5	$6,582.79	$164,569.76
Base Estimate (from Table 4)	125	$13,165.58	$329,139.51
High Estimate	250	$26,331.16	$658,279.02

TABLE 6: TOTAL BURDEN HOURS FOR ALL RESPONDENTS FOR THE SMALL BIOTECH EXCEPTION, BIOSIMILAR DELAY REQUEST, AND THE IDENTIFICATION AND SELECTION OF RENEGOTIATION-ELIGIBLE DRUGS

Task	**Total Burden Hours**
Small Biotech Exception	292.5
Biosimilar Delay	260
Identification and Selection of Renegotiation-Eligible Drugs	3,125
Total Hourly Burden Over 1 Year	**3,677.50**

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 table below, we used: the 2025 General Schedule (GS) Locality Pay Tables[11] published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region. In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. Staffing estimates are based on CMS duties as follows:
Small Biotech Exception: We anticipate that one GS-13 Federal employee will spend approximately 60 hours, one GS-14 Federal employee will spend approximately 16 hours, and one GS-15 Federal employee will spend four hours maintaining the SBE ICR Form and analyzing data collected through the Form. The adjusted hourly wage of $115.56 is the total of the hourly rate of $57.78 for one GS-13 step-1 plus 100 percent fringe benefit rate of $57.78. The adjusted hourly wage of $136.54 is the total of the hourly rate of $68.27 for one GS-14 step-1 plus 100 percent fringe benefit rate of $68.27 and the adjusted hourly wage of $160.62 is the total of the hourly rate of $80.31 for one GS-15 step-1 plus 100 percent fringe benefit rate of $80.31. We anticipate that one GS-13 Federal employee will spend approximately 16 hours, one GS-14 Federal employee will spend approximately four hours, and one GS-15 Federal employee will spend approximately one hour handling communications with Submitting Manufacturers, including notifying each Submitting Manufacturer of CMS' determination regarding its SBE 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 direction to a contractor that will revise the automated tool, the CMS HPMS, for the Submitting Manufacturers to submit the ICR Form for an SBE. We anticipate that this contractor will spend a total of 920 hours at a cost of $249.59 per hour.

TABLE 7. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF THE SMALL BIOTECH EXCEPTION

Task	Estimated Cost
SBE Review GS-13 (step 1): (1 x $115.56 x 60 hours) GS-14 (step 1): (1 x $136.54 x 16 hours) GS-15 (step 1): (1 x $160.62 x 4 hours)	$6,933.60 + $2,184.64 + $642.48 = $9,760.72

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

Communicating with Submitting Manufacturers GS-13 (step 1): (1 x $115.56 x 16 hours) GS-14 (step 1): (1 x $136.54 x 4 hours) GS-15 (step 1): (1 x $160.62 x 1 hour)	$1,848.96 + $546.16 + 160.62 = $2,555.74
Modification of existing system GS-13 (step 1): (1 x $115.56 x 120 hours) Contractor: (1 x $249.59 x 920 hours)	$13,867.20 + $229,622.80= $243,490.00
Total Cost to Government Over 1 Year	$246,045.74

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 $115.56 is the total of the hourly rate of $57.78 for one GS-13 step1 plus 100 percent fringe benefit rate of $57.78, the adjusted hourly wage of $136.54 is the total of the hourly rate of 68.27 for one GS-14 step-1 plus 100 percent fringe benefit rate of $68.27, and the adjusted hourly wage of $160.62 is the total of the hourly rate of $80.31 for one GS-15 step-1 plus 100 percent fringe benefit rate of $80.31. 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 direction 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 8. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF BIOSIMILAR DELAY REQUESTS

Task	Estimated Cost
Biosimilar Delay Review GS-13 (step 1): (1 x $115.56 x 80 hours) GS-14 (step 1): (1 x $136.54 x 10 hours) GS-15 (step 1): (1 x $160.62 x 2.5 hours)	$9,244.80 + $1,365.40 + $321.24 = $10,931.44
Communicating with Biosimilar Manufacturers GS-13 (step 1): (1 x $115.56 * 16 hours)	$1,848.96

Modification of existing system GS-13 (step 1): (1 x $113.04 x 120 hours) Contractor: (1 x $249.59 x 720 hours)	$13,867.20 + $179,704.80 = $191,685.60
Total Cost to Government Over 1 Year	$193,572.00

Identification and Selection of Renegotiation-Eligible Drugs:
We anticipate that five GS-13 Federal employees will spend approximately a total of 175 hours, two GS-14 Federal employees will spend approximately 40 hours, and one GS-15 Federal employee will spend approximately 20 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 9. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF IDENTIFICATION AND SELECTION OF RENEGETIATION-ELIGIBLE DRUG DATA

Staff	FTE Equivalent	Hourly Wage	Total Burden Hours	Total Cost
Section 1194(e) Review				
GS-13, step 1	7	115.56	245	$28,312.20
GS-14, step 1	3	136.54	105	$14,336.70
GS-15, step 1	1	160.62	35	$5,621.70
Total Cost to Government Over One Year				**$48,270.60**

In total, we anticipate the total cost to the government over 1 year as $48,270.60.

TABLE 10. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF THE SMALL BIOTECH EXCEPTION, THE BIOSIMILAR DELAY REQUEST AND THE REVIEW OF IDENTIFICATION AND SELECTION OF RENEGOTIATION-ELIGIBLE DRUG DATA

Task	Estimated Cost
SBE Review	$246,045.74
Biosimilar Delay Review	$191,685.60
Renegotiation-Eligible Drugs Data Review	$48,270.60
Total Cost to Government Over 1 Year	$486,001.94

15. Changes to Burden

This is a revision of the currently approved ICR.

In these 30-day proposed revisions, CMS updated the burden estimates using Bureau of Labor Statistics' May 2024 Occupational Employment and Wage Statistics data. CMS also included technical revisions to each of the ICR forms that are listed in an accompanying document of changes between the 60-day package and this 30-day package that did not result in changes to the burden estimate.

In the 60-day proposed revisions, CMS included:

With respect to the ICR form for an SBE request, CMS revised the questions in sections that are applicable regardless of which Medicare program(s) (Part B and/or Part D) cover the drug and in sections that are applicable specifically to a drug payable under Part B and/or covered under Part D. CMS also included technical revisions throughout the ICR based on lessons learned from submissions received in initial price applicability year 2027 in order to clarify the terms used and questions asked. CMS also added questions specific to drugs payable under Part B based on the new statutory requirement for initial price applicability year 2028 to permit drugs payable under Part B to request an SBE. Additionally, CMS presented the burden estimate for an SBE request with a high, low, and middle estimate to capture the varied scenarios that may lead to a difference in time to prepare and submit the request based on a specific drug's ownership history and Medicare coverage. CMS does not believe the technical revisions in the SBE ICR Form impacted the manufacturer burden estimates.

With respect to the ICR form for a Biosimilar Delay request, CMS included technical revisions throughout the ICR based on lessons learned from submissions received in initial price applicability year 2027 in order to clarify the terms used and questions asked. CMS does not believe that these minor revisions impacted the burden estimate for Biosimilar Manufacturers, and therefore there was no difference between the currently approved ICR compared to the 60-day proposed changes.

CMS included a new burden estimate for a Primary Manufacturer's voluntary completion of the identification and selection of renegotiation-eligible drugs form.

In sum, the hourly burden difference and cost impact between the currently approved version and the changes in this 30-day proposed revision (which are revised with updated Bureau of Labor Statistics' data compared to the 60-day proposed version) are included in Table 11 below.

TABLE 11. COMPARISON OF CURRENTLY APPROVED ICR COMPARED TO THE 30-DAY PROPOSED REVISIONS

Item	Total for Currently	Total for 30-Day	Total Difference

	Approved ICR	Proposed Revisions	
Total Number of Respondents	25	65	40
Total Hourly Burden	415	**3,677.50**	3,262.5
Total Cost Per Respondent	$55,251.18	$132,073.08	$76,821.90

Finally, CMS revised the burden estimate to the federal government to account for the additional time needed to incorporate drugs payable under Part B into the HPMS module, for the reduction in time needed to maintain the CMS HPMS tool in its second year of implementation of the Biosimilar Delay, and for the time needed to review the voluntary submissions of the identification and selection of renegotiation-eligible drugs information. In sum, the estimated cost differences between the currently approved version and the changes in this 30-day proposed revision (which are same as the 60-day proposed version) are included in Table 12 below.

TABLE 12. COMPARISON OF CURRENTLY APPROVED ICR COMPARED TO THE 30-DAY PROPOSED REVISIONS: TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF THE SMALL BIOTECH REQUEST, BIOSIMILAR DELAY REQUEST, AND THE IDENTIFICATION AND SELECTION OF RENEGOTIATION-ELIGIBLE DRUGS

Task	Estimated Cost for Currently Approved ICR	Estimated Cost for 30-Day Proposed Revisions
SBE Review	$203,431.44	$246,045.74
Biosimilar Delay Review	$311,794.84	$191,685.60
Identification and Selection of Renegotiation-Eligible Drugs	--	$48,270.60
Total Cost to Government Over 1 Year	$515,226.28	$486,001.94
Total Difference in the Total Cost to the Government Over 1 Year	------	-$29,224.34

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.