Supporting Statement – Part A

Small Biotech Exception and Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027 (CMS-10844, OMB 0938-1443)

Introduction

CMS is requesting the revision of one Office of Management and Budget (OMB) currently approved Medicare ICR Form: Small Biotech Exception (CMS-10844, OMB 0938-1443[1]).

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"). 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 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (expected to be issued in Fall 2024 concurrently with this ICR; referenced hereinafter as "final guidance")[2]. Terms used in this ICR have the meaning set forth in the final guidance. For the second year of the Negotiation Program, initial price applicability year 2027, CMS will select for negotiation up to 15 high expenditure, single source drugs covered under Part D.

The Act provides certain exceptions and exclusions for otherwise negotiation-eligible drugs. This ICR addresses information necessary 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

1 Available for viewing at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=2023040938016#https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016#.

2 Available at: https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-andmanufacturer-effectuation-mfp-2026-2027.pdf.

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.

This ICR was formerly titled "Small Biotech Exception" and has been revised to "Small Biotech Exception and Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027". This title revision reflects the addition of an information collection to this package pertaining to the Biosimilar Delay. CMS is authorized to collect information pertaining to the Biosimilar Delay under the authority in sections 11001 and 11002 of the IRA. For clarity, the currently approved information collection pertaining to the SBE will continue with revisions reflected in this 30-day notice.

Pursuant to the above, CMS is requesting the revision of one Office of Management and Budget (OMB) currently approved Medicare ICR Form: Small Biotech Exception (CMS-10844, OMB 0938-1443[3]). For purposes of recognition, CMS is requesting to include the information collection for the Biosimilar Delay within the collection of CMS-10844, OMB 0938-1443. Revising the currently approved ICR package for the SBE to include the information collection for the Biosimilar Delay will streamline the review process for the pharmaceutical industry and other interested parties when reviewing Paperwork Reduction Act (PRA) renewals for this notice.

For initial price applicability year 2026, CMS provided the process and submission form for a request for a Biosimilar Delay within the initial policy guidance published by CMS for initial price applicability year 2026.[4] Because the increased number of qualifying single source drugs for initial price applicability year 2027 is likely to increase the number of Biosimilar Delay requests for initial price applicability year 2027, CMS is submitting the ICR process and submission questions for consideration by OMB.

Both of the information collection request forms for the Small Biotech Exception and Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027 inform the selection of drugs covered under Medicare Part D for negotiation for initial price applicability year 2027 and therefore are being advanced through the same PRA review process.

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

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3 Available for viewing at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=2023040938016#https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016#.

4 Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (see section 30.3.1 and Appendix B, available at https://www.cms.gov/files/document/medicare-drugprice-negotiation-programinitialguidance.pdf) (hereinafter, Initial Program Applicability Year 2026 Initial Negotiation Program Guidance).

A. Background

Small Biotech Exception: In accordance with section 1192(d)(2) of the Act, the manufacturer of a small biotech drug ("Submitting Manufacturer") may submit a request with respect to initial price applicability years 2026, 2027, and 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.

Among other requirements for the SBE, the statute requires that CMS consider, for Part D drugs: Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures for the qualifying single source drug under Part D during 2021, and Total Expenditures under Part D for all covered Part D drugs for which the manufacturer that had the Coverage Gap Discount Program (CGDP) Agreement in effect for the qualifying single source drug during 2021. To identify and exclude such small biotech drugs, CMS will consider whether, for dates of service in calendar year 2021, the Total Expenditures under Part D for the qualifying single source drug (1) were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and (2) were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer of the qualifying single source drug had a CGDP Agreement in effect during 2021.

In order to accurately identify, at the request of a manufacturer, whether a given qualifying single source drug qualifies for the SBE for initial price applicability year 2027 in accordance with section 1192(d)(2) of the Act, CMS needs to collect information to identify the entity that had a CGDP Agreement under section 1860D-14A for the drug in effect on December 31, 2021 (the "2021 Manufacturer"), including all other entities that, as of December 31, 2021, were treated as a single employer with that entity under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC) of 1986 and had a Medicare CGDP Agreement in effect on December 31, 2021. Accordingly, for the purpose of the SBE, "controlled group" of the 2021 Manufacturer means all corporations or partnerships, sole proprietorships, and other entities that were treated as a single employer with the 2021 Manufacturer under subsection (a) or (b) of section 52 of the IRC and the Department of the Treasury regulations thereunder.

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 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.[5] Because the earliest effective date for this limitation is January 1, 2025 for acquisitions prior to January 1,

5 *See* section 50.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, dated November 17, 2023, 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.

2025, this requirement applies to requests for the SBE starting in initial price applicability year 2027. Therefore, beginning with initial price applicability year 2027, in order for the Submitting Manufacturer to have its qualifying single source drug considered for an SBE, CMS must consider whether the Submitting Manufacturer was acquired after 2021, and if so, whether the acquiring entity is a manufacturer that is not a specified manufacturer on January 1, 2025.[6] For purposes of implementing the 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 became the New Drug Application (NDA) / Biologics License Application (BLA) holder.

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

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 2026; therefore, no Reference Drugs would be the subject of an Additional Delay Request in initial price applicability year 2027.

Note: This ICR only collects information relevant to a manufacturer's request for the Biosimilar Delay for initial price applicability year 2027.

6 In future years, CMS shall also consider whether the acquiring entity is a manufacturer that will not meet the definition of specified manufacturer at the beginning of the plan year immediately following the acquisition.

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 2027 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 2028). The process for submitting an Initial Delay Request for initial price applicability year 2028 and for submitting Additional Delay Requests will be addressed in future guidance or rulemaking, as applicable, and future ICR(s), as applicable.

B. Justification

1. Need and Legal Basis

Small Biotech Exception: CMS currently does not have information necessary to determine whether manufacturers of Medicare Part D drugs and biological products were treated as a single employer 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 are excluded from the term "negotiation-eligible drug," a Submitting Manufacturer must submit information to CMS about the 2021 Manufacturer's controlled group in 2021 in order for the drug to be considered for the SBE.

Additionally, to implement the limitation at section 1192(d)(2)(B)(ii) of the Act, CMS needs information from the Submitting Manufacturer to assess whether this 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 covered under Medicare Part D for negotiation for initial price applicability year 2027. 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 SBE and Biosimilar Delay ICR from the Office of Management and Budget. CMS anticipates providing a 30-day submission period.

Manufacturers who might benefit from submitting an SBE for initial price applicability year 2027 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 will be described in the forthcoming Medicare Drug Price Negotiation Program Draft Guidance and, (2) absent such a request, the drug will be considered a negotiation-eligible drug for initial price applicability year 2027 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 qualifying single source drug may not solely consist of a new formulation of another drug that is also 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 2027. 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 SBE and Biosimilar Delay ICR from the Office of Management and Budget. CMS anticipates providing a 30-day submission period.

Manufacturers who might benefit from submitting a Biosimilar Delay request for initial price applicability year 2027 are those manufacturers of Biosimilars that anticipate that, in accordance with section 1192(f)(1)(A) of the Act:

(1) the Reference Drug for the Biosimilar may be selected for initial price applicability year 2027;

(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 2027, 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 30.3.1.2 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 2027, based on the process described in section 30.3.1.2 of the final guidance.

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 2021 Manufacturer and assess whether the drug meets the statutory requirements for the SBE. In addition, for initial price applicability year 2027, 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 the licensure status of the Biosimilar; 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 2027 (additional information regarding this determination is included in section 30.3.1 of the final guidance).

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 ICR Form.

Similarly, CMS intends to develop an automated tool within the CMS HPMS for manufacturers to submit the Biosimilar Delay ICR Form. The new automated tool for the Biosimilar Delay is scheduled to be available by Fall 2024. In the event that its completion is delayed, CMS will use the submission process deployed for initial price applicability year 2026 for initial price

applicability year 2027. If repeating the process used for Biosimilar Delay requests in initial price applicability year 2026, a Biosimilar Manufacturer would take the following steps:

1) The Biosimilar Manufacturer would email IRARebateandNegotiation@cms.hhs.gov with the subject line "Biosimilar Delay Information Collection Request Form Submission" to submit a completed Biosimilar Delay ICR Form, except for the required attachments.
2) Within 5 business days of receipt, CMS would respond by email to provide the Biosimilar Manufacturer with access to a Box folder specific to the Biosimilar Manufacturer's Initial Delay Request in order to provide the required attachments. No parties other than the Biosimilar Manufacturer and CMS and its contractors would have access to this folder.

Manufacturers of Medicare Part D drugs currently use the CMS HPMS system for other Part D program needs. Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)" PDF. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.[7]

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 and for Biosimilar Manufacturers seeking a Biosimilar Delay. The information is being collected once for initial price applicability year 2027, and only from either:

1) The Submitting Manufacturer seeking an SBE for its qualifying single source drug and includes those data items necessary 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 Medicare 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 Medicare expenditures meet the specified thresholds.

2) The Biosimilar Manufacturer seeking the Biosimilar Delay for a Reference Drug and includes those data items necessary for CMS:

7 https://www.cms.gov/about-cms/information-systems/hpms/user-id-process

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 2027.

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

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

A 60-day Federal Register Notice (89 FR 36821) published May 3, 2024 and the public comment period closed on July 2, 2024. CMS received three public submissions: one from a professional trade association and two from pharmaceutical manufacturers. CMS includes summaries of the timely public comments received and responses to those comments in the document titled "Centers for Medicare and Medicaid Services Response to Public Comments Received for CMS-10844, OMB 0938-1443", available with the 30-day public notice materials for this ICR.

A 30-day Federal Register Notice (89 FR 80249) published October 2, 2024.

Outside Consultation
In the development of the SBE and Biosimilar Delay ICR Forms, 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.

10. Confidentiality

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

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 the SBE, the Submitting Manufacturer must provide its Employer Identification Number(s) (EIN(s)), and the EIN(s) of any members of its controlled group that had a Medicare CGDP Agreement in effect on December 31, 2021. If the Submitting Manufacturer did not have a CGDP Agreement in effect for such qualifying single source drug on December 31, 2021, the Submitting Manufacturer must provide the EIN(s) of the entity that had a Medicare CGDP Agreement for the qualifying single source drug on December 31, 2021, and the EIN(s) of any members of that entity's controlled group that had a Medicare CGDP Agreement in effect on December 31, 2021. Finally, 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.

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 2027. 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.

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 an SBE, form submission, and recordkeeping.[8] Tables 1 through 4 present the median hourly wage, the cost of fringe benefits and overhead, the adjusted hourly wage, along with total burden and total cost.

Occupation Title	**Median Hourly Wage**	**Fringe Benefits and Overhead ($/hr)**	**Adjusted Hourly Wage ($/hr)**
Lawyer (23-1011)	$70.08	$70.08	$140.16
General and Operations Manager (11-1021)	$48.69	$48.69	$ 97.38
Chief Executive (11-1011)	$99.37	$99.37	$198.74

We estimate 15 total respondents in 2024: nine that are Submitting Manufacturers that had a CGDP Agreement in effect for the qualifying single source drug on December 31, 2021 and were not acquired after 2021, three Submitting Manufacturers that had a CGDP Agreement in effect for the qualifying single source drug on December 31, 2021 and were acquired after 2021, two Submitting Manufacturers that did not have the CGDP Agreement for the qualifying single source drug on December 31, 2021 and were not acquired after 2021, and one Submitting Manufacturer that did not have the CGDP Agreement for the qualifying single source drug on December 31, 2021 and was acquired after 2021. We believe that 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 2027.

We estimate that nine Submitting Manufacturers will have had a CGDP Agreement in effect for qualifying single source drug on December 31, 2021, and were not acquired after 2021 and will therefore provide information only about their own entity. We estimate it will take a lawyer, on average, five hours, at a cost per hour of $140.16, 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

8 See May 2023 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at https://www.bls.gov/oes/current/oes_stru.htm.

group members that as of December 31, 2021 were treated as a single employer with the Submitting Manufacturer under subsection (a) or (b) of section 52 of the IRC and had a Medicare CGDP Agreement in effect on December 31, 2021, and therefore must be counted together by CMS when calculating 2021 Medicare expenditures for all covered Part D drugs for which the entity has an agreement under the Medicare CGDP. We estimate that it will take a general and operations manager, on average, two hours, at $97.38 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 five and one-half hours for a lawyer in sum and two and one-half 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 $198.74 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) chief executive officer (CEO) of the Submitting Manufacturer, (2) 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 74.25 hours (8.25 hrs.* 9 respondents) and total cost $9,576.14 ($1,064.02 per respondent * 9 respondents).

TABLE 1: SUMMARY OF INFORMATION COLLECTION FOR SMALL BIOTECH DRUGS FOR A SUBMITTING MANUFACTURER WITH A CGDP AGREEMENT FOR THE QUALIFYING SINGLE SOURCE DRUG ON DECEMBER 31, 2021, AND THE SUBMITTING MANUFACTER WAS NOT ACQUIRED AFTER 2021 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)	5.5	9	49.5	$6,937.92
General and Operations Manager (11-1021)	2.5	9	22.5	$2,191.05
Chief Executive (11-1011)	0.25	9	2.25	$447.17

Total	8.25	9	74.25	$9,576.14
Cost per Respondent				$1,064.02

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.

We estimate that three Submitting Manufacturers had a CGDP Agreement in effect for the qualifying single source drug as of December 31, 2021 and were acquired after 2021, and will therefore provide information only about their own entity but may need to obtain information about the acquiring entity. We estimate it will take a lawyer, on average, six hours, at a cost per hour of $140.16, 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 Submitting Manufacturer under subsection (a) or (b) of section 52 of the IRC and had a Medicare CGDP Agreement in effect on December 31, 2021, and therefore must be counted together by CMS when calculating 2021 Medicare expenditures for all covered Part D drugs for which the entity has an agreement under the Medicare CGDP. We estimate that it will take a general and operations manager, on average, three hours, at $97.38 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 and one-half 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 $198.74 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 Submitting Manufacturer, (2) the CFO of the Submitting Manufacturer, (3) an individual other than a CEO or CFO of the Submitting Manufacturer, 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).

We have presented the cost estimates in Table 2. We estimate a total burden of 30.75 hours (10.25 hrs.* 3 respondents) and total cost $3,904.67 ($1,301.56 per respondent * 3 respondents).

TABLE 2: SUMMARY OF INFORMATION COLLECTION FOR SMALL BIOTECH DRUGS FOR A SUBMITTING MANUFACTURER WITH A CGDP AGREEMENT FOR THE QUALIFYING SINGLE SOURCE DRUG ON DECEMBER 31, 2021, AND THE SUBMITTING MANUFACTER WAS ACQUIRED AFTER 2021 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)	6.5	3	19.5	$2,733.12
General and Operations Manager (11-1021)	3.5	3	10.5	$1,022.49
Chief Executive (11-1011)	0.25	3	.75	$149.06
Total	10.25	3	30.75	$3,904.67
Cost per Respondent				$1,301.56

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.

We estimate that two Submitting Manufacturers will not have had the CGDP Agreement for the qualifying single source drug on December 31, 2021, and the Submitting Manufacturer was not acquired after 2021 and will have to obtain the relevant information from the entity that had the CGDP Agreement for the qualifying single source drug in effect on December 31, 2021. We estimate it will take a lawyer, on average, 12 hours, at a cost per hour of $140.16, to gather and review the relevant IRC provisions, including contacting, if applicable, the entity that had the CGDP Agreement for the qualifying single source drug in effect on 2021 to identify any controlled group members that as of December 31, 2021 were treated as a single employer under subsection (a) or (b) of section 52 of the IRC and had a Medicare CGDP Agreement in effect on December 31, 2021, and therefore must be counted together by CMS when calculating 2021 Medicare expenditures for all covered Part D drugs for which that entity had an agreement under the Medicare CGDP. We estimate that it will take a general operations manager, on average, two

hours and 30 minutes, or 2.5 hours, at $97.34 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 and operations manager, on average, 30 minutes, or 0.5 hours, each to request technical assistance from CMS (totaling 12.5 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, 30 minutes, or 0.5 hours, at $198.74 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 Submitting Manufacturer, (2) the 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 3. We estimate a total burden of 32 hours (16 hrs.* 2 respondents) and total cost $4,287.02 ($2,143.51 per respondent * 2 respondents).

TABLE 3: SUMMARY OF INFORMATION COLLECTION FOR SMALL BIOTECH DRUGS FOR WHICH THE SUBMITTING MANUFACTURER DID NOT HAVE A CGDP AGREEMENT FOR THE QUALIFYING SINGLE SOURCE DRUG ON DECEMBER 31, 2021 AND THE SUBMITTING MANUFACTURER WAS NOT ACQUIRED AFTER 2021, 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)	12.5	2	25	$3,504
General and Operations Manager (11-1021)	3	2	6	$584.28
Chief Executive (11-1011)	0.5	2	1	$198.74
Total	16	2	32	$4,287.02
Cost per Respondent				$2,143.51

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.

We estimate that one Submitting Manufacturer will not have had the CGDP Agreement for the qualifying single source drug on December 31, 2021, and the Submitting Manufacturer was acquired after 2021 and will have to obtain the relevant information from the entity that had the CGDP Agreement for the qualifying single source drug in effect on December 31, 2021 and about the acquiring entity. We estimate it will take a lawyer, on average, 13 hours, at a cost per hour of $140.16, to gather and review the relevant IRC provisions, including, if applicable, contacting the entity that had the CGDP Agreement for the qualifying single source drug in effect on 2021 to identify any controlled group members that as of December 31, 2021 were treated as a single employer under subsection (a) or (b) of section 52 of the IRC and had a Medicare CGDP Agreement in effect on December 31, 2021, and therefore must be counted together by CMS when calculating 2021 Medicare expenditures for all covered Part D drugs for which that entity had an agreement under the Medicare CGDP. In addition, within this estimated time, a lawyer would need to identify if a CGDP Agreement was in effect on December 31, 2021 for a post2021 acquiring manufacturer, if this entity is distinct from the entity that owned the qualifying single source drug as of December 31, 2021, and the corresponding controlled group members. We estimate that it will take a general operations manager, on average, three hours and 30 minutes, or 3.5 hours, at $97.34 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 and operations manager, on average, 30 minutes, or 0.5 hours, each to request technical assistance from CMS (totaling 13.5 hours for a lawyer in sum and four hours for a general and operations manager in sum). We estimate that it will take a chief executive, on average, 30 minutes, or 0.5 hours, at $198.74 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 Submitting Manufacturer, (2) the 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 4. We estimate a total burden of 18 hours (18 hrs.* 1 respondent) and total cost $2,381.06 ($2,381.05 per respondent * 1 respondent).

TABLE 4: SUMMARY OF INFORMATION COLLECTION FOR SMALL BIOTECH DRUGS FOR WHICH THE SUBMITTING MANUFACTURER DID NOT HAVE A CGDP AGREEMENT FOR THE QUALIFYING SINGLE SOURCE DRUG ON DECEMBER 31, 2021 AND THE SUBMITTING MANUFACTURER WAS ACQUIRED AFTER 2021, FOR THE ONE TIME COST OVER THE ONE-YEAR PERIOD

Respondents'	# Of Hours per	# Of Respondents	Total	Total Cost

Occupation Title	Respondents	Responses	Burden Hours	
Lawyer (23-1011)	13.5	1	13.5	$1,892.16
General and Operations Manager (11-1021)	4	1	4	$389.52
Chief Executive (11-1011)	0.5	1	0.5	$99.37
Total	18	1	18	$2,381.05
Cost per Respondent				$2,381.05

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.

For the estimated 15 respondents, we estimate a total burden of 155 hours and total cost of $20,148.88.

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 2027.

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 5 presents the median hourly wage, the cost of fringe benefits and overhead, the adjusted hourly wage, along with total burden and total cost.

We estimate 10 total respondents in 2024. We believe that collection of these data will be a onetime cost for each Biosimilar Manufacturer for each negotiation-eligible drug for which it is seeking the Biosimilar Delay for initial price applicability year 2027.

9 See May 2023 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at https://www.bls.gov/oes/current/oes_stru.htm.

We estimate it will take a lawyer, on average, 20 hours, at a cost per hour of $140.16, 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 Drug and the Biosimilar Drug, 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 $97.38 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 $198.74 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 $35,102.23.

TABLE 5: 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	$28,732.80
General and Operations Manager (11-1021)	4.5	10	45	$4,382.10
Chief Executive (11-1011)	1	10	10	$1,987.40
Total	26	10	260	$35,102.30

Cost per Respondent				$3,510.23

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies.

13. Capital Costs

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

14. Cost to Federal Government

To generate salary estimates for the table below, we used: the 2024 General Schedule (GS) Locality Pay Tables[10] 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 $113.04 is the total of the hourly rate of $56.52 for one GS-13 step-1 plus 100 percent fringe benefit rate of $56.52. The adjusted hourly wage of $133.58 is the total of the hourly rate of $66.79 for one GS-14 step-1 plus 100 percent fringe benefit rate of $66.79 and the adjusted hourly wage of $157.12 is the total of the hourly rate of $78.56 for one GS-15 step-1 plus 100 percent fringe benefit rate of $78.56. 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 720 hours at a cost of $246.97 per hour.

10 https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB_h.pdf

TABLE 6. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF THE SBE REQUESTS

Task	Estimated Cost
SBE Review GS-13 (step 1): (1 x $113.04 x 60 hours) GS-14 (step 1): (1 x $133.58 x 16 hours) GS-15 (step 1): (1 x $157.12 x 4 hours)	$6,782.40 + $2,137.28 + $628.48 = $9,548.16
Communicating with Submitting Manufacturers GS-13 (step 1): (1 x $113.04 x 16 hours) GS-14 (step 1): (1 x $133.58 x 4 hours) GS-15 (step 1): (1 x $157.12 x 1 hour)	$1,808.64 + $534.32 + 157.12 = $2,500.08
Modification of existing system GS-13 (step 1): (1 x $113.04 x 120 hours) Contractor: (1 x $246.97 x 720 hours)	$13,564.80 + $177,818.40 = $191,383.20
Total Cost to Government Over 1 Year	$203,431.44

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 $113.04 is the total of the hourly rate of $56.52 for one GS-13 step1 plus 100 percent fringe benefit rate of $56.52, the adjusted hourly wage of $133.58 is the total of the hourly rate of $66.79 for one GS-14 step-1 plus 100 percent fringe benefit rate of $66.79, and the adjusted hourly wage of $157.12 is the total of the hourly rate of $78.56 for one GS-15 step-1 plus 100 percent fringe benefit rate of $78.56. 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 200 hours, or the equivalent of one FTE approximately five weeks, to provide technical direction to a contractor that will develop an automated tool within an existing information technology system for the Biosimilar Manufacturers to submit the ICR Form for a Biosimilar Delay. We anticipate that this contractor will spend a total of 1,120 hours at a cost of $246.97 per hour.

TABLE 7. 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 $113.04 x 80 hours) GS-14 (step 1): (1 x $133.58 x 10 hours) GS-15 (step 1): (1 x $157.12 x 2.5 hours)	$9,043.20 + $1,335.80 + $392.80 = $10,771.80
Communicating with Biosimilar Manufacturers GS-13 (step 1): (1 x $113.04 * 16 hours)	$1,808.64
Modification of existing system GS-13 (step 1): (1 x $113.04 x 200 hours) Contractor: (1 x $246.97 x 1,120 hours)	$22,608 + $276,606.40 = $299,214.40
Total Cost to Government Over 1 Year	$311,794.84

In total, we anticipate the total cost to the government over 1 year as $515,226.28.

TABLE 8. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF THE SBE AND BIOSIMILAR DELAY REQUESTS

Task	Estimated Cost
SBE Review	$203,431.44
Biosimilar Delay Review	$311,794.84
Total Cost to Government Over 1 Year	$515,226.28

15. Changes to Burden

This is a revision of the currently approved ICR.

In the 30-day proposed revisions:
All technical revisions included in the 30-day proposed revisions are described in the crosswalk that is included in the materials available for the 30-day comment period and are included in the redline copy of the 30-day proposed ICR Forms document. For example, CMS includes a

technical revision to the introduction information included with the collection instruction to revise the reference to the draft guidance (which is being finalized concurrent with the publication of this 30-day package). In addition, CMS proposes revisions to clarify the instructions and Question 2a related to whether the Submitting Manufacturer holding the NDA/BLA for the drug was acquired by another entity after 2021. Finally, CMS proposes technical revisions to the Biosimilar Delay ICR Form to clarify the instructions to Questions 3 when a BLA has not yet been submitted to the FDA for a Biosimilar and to the instructions in Questions 8 and 10 to regarding the 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 2027 consistent with the final guidance. Technical revisions are also included in the Supporting Statement.

In the 60-day proposed revisions:
With respect to the ICR form for an SBE, CMS removed previous question 3 to remove requests for the NDC-11s for the qualifying single source drug for which the Submitting Manufacturer seeks the SBE, and added new questions (Questions 2a and 2b) related to an acquisition of the Submitting Manufacturer after December 31, 2021. CMS believes that CMS has sufficient information to identify NDC-11s for the qualifying single source drug for which the Submitting Manufacturer seeks the SBE. CMS added Questions 2a and 2b in order to capture information necessary to consider the application of the limitation language at section 1192(d)(2)(B)(ii) of the Act, which states that a qualifying single source drug is not eligible for an SBE if the Submitting Manufacturer is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act.[10] The addition of the new question and removal of previous Question 3 results in reordering of the questions.

CMS added the ICR Form to request a Biosimilar Delay in this ICR package. The ICR Form for a
Biosimilar Delay includes revisions to format the fillable template that was included as Appendix B in the Initial Program Applicability Year 2026 Initial Negotiation Program Guidance for inclusion in the CMS HPMS for initial price applicability year 2027. CMS also revised Question 3 to clarify requests for information about the status of certain FDA drug applications. CMS reduced the information requested in Questions 4 and 5 regarding the Reference Drug and the Reference Manufacturer because CMS believes that the Questions, as revised, will provide information sufficient for CMS to identify the Reference Drug and the Reference Manufacturer.

CMS adjusted the burden estimates to manufacturers and the federal government to include the addition of the Biosimilar Delay request for information to this ICR package.

CMS slightly revised the burden estimate upwards for manufacturers to respond to the SBE ICR Form when technical assistance in completion of the necessary information may be needed by the manufacturer. CMS revised the burden estimate for small biotech drugs owned by a manufacturer when the manufacturer was acquired after 2021 to account for the additional time needed to gather the information needed for CMS determine if the acquisition renders the

Submitting Manufacturer's drug ineligible for the SBE. CMS also revised the burden estimate to the federal government to account for the reduction in time needed to maintain the CMS HPMS tool in its second year of implementation of the SBE. Finally, CMS increased the burden estimate to the federal government to include additional review by a GS-14 and a GS-15 and to include additional hours for a GS-13 based on lessons learned from CMS review of submissions received for initial price applicability year 2026.

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.