



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10844]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <https://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA web site by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10844	Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request
-----------	---

Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR

1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Revision with of a currently approved collection; *Title of Information Collection:* Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request; *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act). The information collection request forms for the Small Biotech Exception, the Biosimilar Delay, and the Selection of Renegotiation-Eligible Drugs for initial price applicability year 2028 must be submitted to CMS before CMS establishes the selected drug list for initial price applicability year 2028.

Small Biotech Exception: In accordance with section 1192(d)(2) of the Act, the term “negotiation-eligible drug” excludes, with respect to the 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”). This information is required in order for CMS to accurately identify whether a given drug meets the criteria for the Small Biotech Exception in accordance with section 1192(d)(2) of the Act. To ensure that drugs payable under Part B and/or drugs covered under Part D that meet the requirements for the SBE are excluded from the term “negotiation-eligible drug,” a manufacturer that seeks the SBE for its drug payable under Part B and/or covered under Part D (“Submitting Manufacturer”) must

submit information to CMS about the company and its products in order for the drug to be considered for the exception. If the Submitting Manufacturer seeks the SBE for a drug payable under Part B and/or covered under Part D it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021, for drugs covered under Part D and information related to the holder of the New Drug Application(s) (NDA)(s) or Biologics License Applications(s) (BLA)(s) as of December 31, 2021 for drugs payable under Part B. If the Submitting Manufacturer was acquired by another entity after December 31, 2021, the Submitting Manufacturer must provide information regarding that acquiring entity for CMS to assess whether the acquisition triggers the limitation at section 1192(d)(2)(B)(ii) of the Act.

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 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”). This information is required in order for CMS to accurately determine if a drug meets the criteria for the Biosimilar Delay for initial price applicability year 2028 in accordance with section 1192(f) of the Act. To ensure that the delay of selection and negotiation of biologics is only applied if there is a high likelihood that the Biosimilar will be licensed and marketed, a Biosimilar Manufacturer that seeks the Biosimilar Delay must submit information to CMS related to the Biosimilar. This information includes identifying information for the Biosimilar and the Reference Drug; the licensure status of the Biosimilar; attestations that the Biosimilar Manufacturer is not the same or treated as the same entity as the Reference Manufacturer, that the Biosimilar Manufacturer and the Reference Manufacturer (who is the manufacturer of the Reference Drug) have not entered into an

agreement that requires or incentivizes the Biosimilar Manufacturer to submit the Biosimilar Delay, 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 documentation specified under section 1192(f)(3) of the Act to demonstrate there is a high likelihood that the Biosimilar will be licensed and marketed within two years of the statutorily-defined selected drug publication date for initial price applicability year 2028.

Selection of Renegotiation-Eligible Drugs: Section 1194(f) of the Act establishes the requirements governing the identification of renegotiation-eligible drugs and selection of drugs for renegotiation. CMS will offer Primary Manufacturers¹ 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)(D) 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 and based on a material change to any of the factors listed in section 1194(e) of the Act. *Form Number:* CMS-10844 (OMB control number 0938-1443); *Frequency:* Once; *Affected Public:* Private Sector, Business, and Not-for Profits; *Number of Respondents:* 65; *Number of Responses:* 65; *Total Annual Hours:* 3,677.50. (For questions regarding this collection contact Elisabeth Daniel at 667-290-8793.)

William N. Parham, III

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025-08423 Filed: 5/9/2025 8:45 am; Publication Date: 5/13/2025]

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").