

Dated: April 13, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10849]

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 (the 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 June 20, 2023.

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 <http://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 website 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-10849 Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

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 Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB Control Number); *Title of Information Collection:* Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA); *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 (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") with manufacturers, defined at section 1191(c)(3) of the Act, for certain high expenditure, single source drugs covered under Medicare Part B and Part D ("selected drugs"). For the first year of the Negotiation Program, CMS will select up to ten Part D high expenditure, single source drugs for negotiation, which will be published September 1, 2023. The MFPs that are negotiated for these drugs will apply beginning in initial price applicability year 2026. The negotiation period for initial price applicability year 2026 begins October 1, 2023, or on the date when the manufacturer of a selected drug enters into a Medicare Drug Price Negotiation Program Agreement with CMS if that date is prior to October 1, 2023.

The statute provides that, after receiving CMS' written initial offer, the Primary Manufacturer may, in accordance with section 1194(b)(2)(C) of the Act, submit an optional written counteroffer (if CMS' written initial offer is not accepted by the Primary Manufacturer) that must be submitted no later than 30 days after the date of receipt of the written initial offer. If the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS' written initial offer during the drug price negotiation process for initial price applicability year 2026, the Primary Manufacturer must submit the Counteroffer Form. *Form Number:* CMS-10849 (OMB control number: 0938-New); *Frequency:* Once; *Affected Public:* Private Sector and Business or other for-profits; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 793. For policy questions regarding this collection contact Lara Strawbridge at (410) 786-6880.

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