



Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10849]

Agency Information Collection Activities: Submission for OMB Review; 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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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 Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

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 10 high expenditure, single

source drugs covered by Medicare Part D 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 begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement or, for initial price applicability year 2026, 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:* 2,043. (For policy questions regarding this collection contact Lara Strawbridge at 410-786-6880.)

Dated: July 20, 2023.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

[FR Doc. 2023-15713 Filed: 7/24/2023 8:45 am; Publication Date: 7/25/2023]