

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

**DATES:** Written PRA comments should be submitted on or before September 1, 2023. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicole Ongele, FCC, via email [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [nicole.ongele@fcc.gov](mailto:nicole.ongele@fcc.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Nicole Ongele, (202) 418-2991.

**SUPPLEMENTARY INFORMATION:**

*OMB Control Number:* 3060-0057.

*Title:* Application for Equipment Authorization, FCC Form 731.

*Form Number:* FCC Form 731.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit.

*Number of Respondents and Responses:* 11,305 respondents; 24,873 responses.

*Estimated Time per Response:* 0.1-40 hours.

*Frequency of Response:* On occasion and other ongoing reporting requirements.

*Obligation to Respond:* Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154(i), 301, 302a, 303, 309(j), 312, 316, and the Secure Equipment Act of 2021, Public Law 117-55, 135 Stat. 423.

*Total Annual Burden:* 206,863 hours.

*Total Annual Cost:* \$50,155,140.

*Needs and Uses:* The Commission will submit this information collection to the Office of Management and Budget (OMB) after this 60-day comment period to obtain the three-year clearance. The information will be used by the Commission to fulfill its statutory mandate under the Secure Equipment Act of 2021, Public Law 117-55, 135 Stat. 423 (2021) to implement prohibitions in its equipment authorization program that will protect the nation's telecommunications systems from equipment that has been determined to pose an unacceptable risk to national security or the safety of U.S. persons.

Federal Communications Commission.

**Marlene Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2023-14012 Filed 6-30-23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10847]

#### 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 August 2, 2023.

**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](http://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 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 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:* Negotiation Data

Elements under Sections 11001 and 11002 of the Inflation Reduction Act; *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 maximum fair prices (“MFPs”), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D. For the first year of the Negotiation Program, the Secretary of Health and Human Services (the “Secretary”) will select 10 Part D high expenditure, single source drugs for negotiation.

The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. These data include the data required to calculate non-FAMP for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A), and the negotiation factors outlined in section 1194(e)(1) for the purpose of formulating offers and counteroffers process pursuant to section 1193(a)(4)(B). Some of these data are held by the Primary Manufacturer and are not currently available to CMS. Data described in section 1194(e)(1) and 1193(a)(4) must be submitted by the Primary Manufacturer.

Section 1194(e)(2) requires CMS to consider certain data on alternative treatments to the selected drug. Because the statute does not specify where these data come from, CMS will allow for optional submission from Primary Manufacturers and the public. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in 1194(e)(2) to ensure consideration of such factors. Manufacturers may optionally submit this information as part of their Negotiation Data Elements Information Collection Request Form. The public may optionally submit evidence about alternative treatments. *Form Number:* CMS–10847 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Individuals and Households, Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 3,300; *Total Annual Responses:* 3,000; *Total Annual Hours:* 17,000. (For policy questions regarding this collection

contact Lara Strawbridge at 410–786–6880.)

Dated: June 29, 2023.

**William N. Parham, III,**

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

[FR Doc. 2023–14176 Filed 6–30–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS–1800–N]

#### Inflation Reduction Act (IRA) Revised Program Guidance

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

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing the availability of CMS’ revised guidance for the Medicare Drug Price Negotiation Program for the implementation of the Inflation Reduction Act. CMS will be releasing additional Inflation Reduction Act-related guidance; all can be viewed on the dedicated Inflation Reduction Act section of the CMS website.

**ADDRESSES:** Inquiries related to the revised guidance should be sent to [IRAREbateandNegotiation@cms.hhs.gov](mailto:IRAREbateandNegotiation@cms.hhs.gov) with the relevant subject line, “Medicare Drug Price Negotiation Program Guidance.”

**SUPPLEMENTARY INFORMATION:** The Inflation Reduction Act was signed into law on August 16, 2022. Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (Pub. L. 117–169), signed into law on August 16, 2022, established the Medicare Drug Price Negotiation Program (hereafter the “Negotiation Program”) to negotiate Maximum Fair Prices (MFPs) for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereafter “the Act”) as added by sections 11001 and 11002 of the Inflation Reduction Act.

To obtain copies of the revised guidance and the responses to comments from the initial guidance, as well as other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act website by copying and pasting the following web address into your web browser: [https://](https://www.cms.gov/inflation-reduction-act-and-medicare)

[www.cms.gov/inflation-reduction-act-and-medicare](https://www.cms.gov/inflation-reduction-act-and-medicare). If interested in receiving CMS Inflation Reduction Act updates by email, individuals may sign up for CMS Inflation Reduction Act’s email updates at <https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates>.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: June 28, 2023.

**Evell J. Barco Holland,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2023–14097 Filed 6–30–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–N–2440]

#### Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cardiovascular and Renal Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on September 13, 2023, from 9 a.m. to 4 p.m. Eastern Time.

**ADDRESSES:** All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The