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]

BILLING CODE 4120–01–P

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* 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://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]

BILLING CODE 4120–01–P

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