



## 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 web site.

**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 web site 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.

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