



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1800-NC3]

Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Draft Guidance; Comment Request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The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' draft guidance for the second cycle of the Medicare Drug Price Negotiation Program and manufacturer effectuation of the maximum fair price for 2026 and 2027 for the implementation of the Inflation Reduction Act. This and other Inflation Reduction Act-related guidance can be viewed on the dedicated Inflation Reduction Act section of the CMS website at <https://www.cms.gov/inflation-reduction-act-and-medicare/>.

DATES: Comments must be received by July 2, 2024.

ADDRESSES: Written comments should be sent to IRAREbateandNegotiation@cms.hhs.gov with the relevant subject line, “Medicare Drug Price Negotiation Program Draft Guidance.”

FOR FURTHER INFORMATION CONTACT: Elizabeth Daniel,
Elizabeth.daniel@cms.hhs.gov or (667) 290-8793.

SUPPLEMENTARY INFORMATION: The Inflation Reduction Act (IRA) ([Pub. L. 117-169](#)) was signed into law on August 16, 2022. Sections 11001 and 11002 of the IRA 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 as added by sections 11001 and 11002 of the IRA. The draft guidance describes how CMS intends to implement the Negotiation Program for Initial Price Applicability Year (IPAY) 2027 (January 1, 2027 to December 31, 2027), and specifies the requirements for manufacturer effectuation of the MFPs for 2026 and 2027.

To obtain copies of the Negotiation Program draft guidance and other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act website by copying and pasting the following web address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: April 30, 2024.

Evell J. Barco Holland,

Federal Register Liaison,

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