



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4210-N2]

Medicare Program; Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Final 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' final guidance for the third cycle of the Medicare Drug Price Negotiation Program (hereafter the “Negotiation Program”), the first cycle of renegotiation, and manufacturer effectuation of the maximum fair price (MFP) in 2026, 2027, and 2028 for the implementation of the Inflation Reduction Act of 2022 (IRA) ([Pub. L. 117-169](#)). This and other IRA-related guidance can be viewed on the dedicated IRA section of the CMS website at

<https://www.cms.gov/inflation-reduction-act-and-medicare/>

ADDRESSES: Inquiries related to the final guidance should be sent to IRAREbateandNegotiation@cms.hhs.gov with the subject line, “Medicare Drug Price Negotiation Program Final Guidance.”

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

The IRA was signed into law on August 16, 2022. Sections 11001 and 11002 of the IRA established the Negotiation Program to negotiate 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 (the Act) as added by sections 11001 and 11002 of the IRA. On July 4, 2025, the “Working Families Tax Cuts Act” (Pub. L. 119-21) was

signed into law. Section 71203 of the “Working Families Tax Cuts Act” expanded protections for orphan drugs in section 1192(e) of the Act. The final guidance describes how CMS will implement the Negotiation Program for Initial Price Applicability Year (IPAY) 2028 (January 1, 2028 to December 31, 2028), which includes renegotiation, and specifies the requirements for manufacturer effectuation of the MFPs in 2026, 2027, and 2028.

To obtain copies of this Negotiation Program final guidance and other IRA-related documents, please access the CMS IRA 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 IRA updates by email, individuals may sign up for CMS IRA's email updates at *<https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates>*.

The Administrator of CMS, Dr. Mehmet Oz, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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