

Negotiation Process for Medicare Part D Drugs

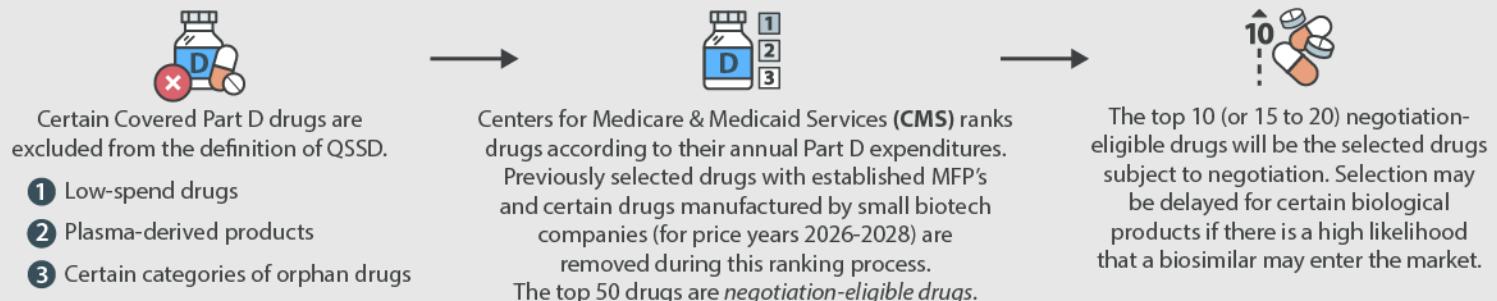
P.L. 117-169, also known as the Inflation Reduction Act (IRA), established the Medicare Drug Price Negotiation Program. The program authorizes the Secretary of Health and Human Services (Secretary) to negotiate prices for certain high expenditure single-source chemical drugs and biological products under Medicare Part B or Part D. For the first two years (2026 and 2027), the program applies only to Part D drugs; the negotiation process for those drugs is described below.

Implementation Timeline



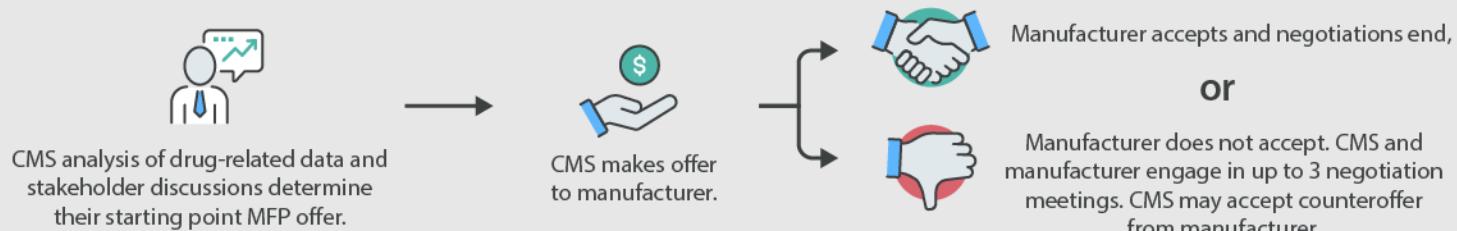
Drug Selection Process

To be selected, a drug must be a covered drug under Medicare Part D. Qualifying single-source drugs (**QSSDs**) are prescription drugs and biological products that have been approved and marketed for 7 years, if a chemical drug, and 11 years, if a biological product.



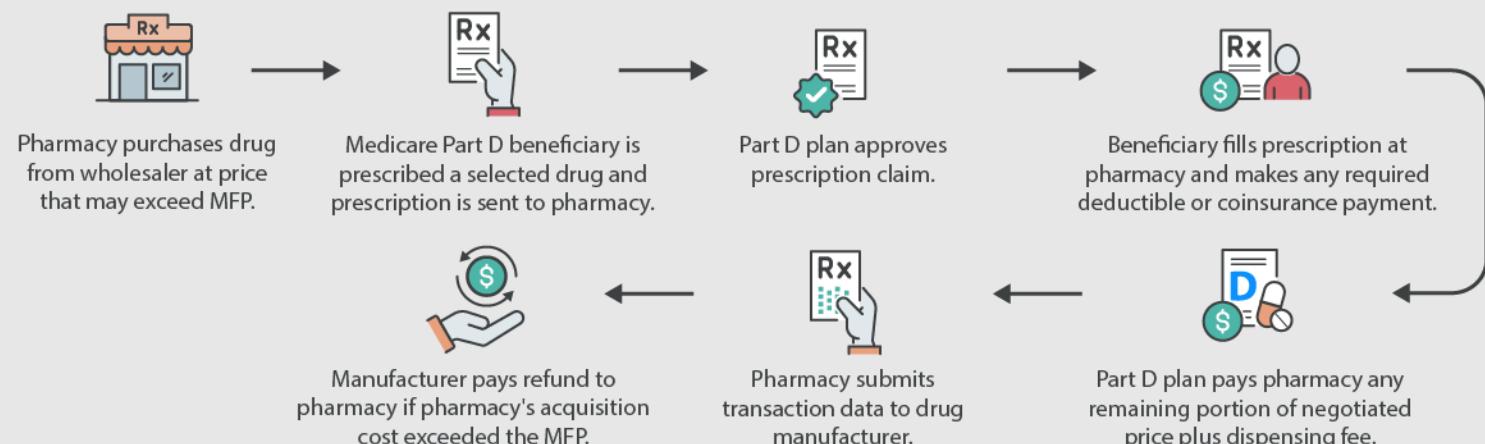
Negotiation Process

During the negotiation period, as specified in statute, the Secretary uses both federal and manufacturer-submitted data to examine research and development (**R&D**) costs as well as production and distribution costs for the selected drug, the drug's revenue and sales volume, and any federal financial support for its development, as well as information on existing and pending patents and therapeutic alternatives. The Maximum Fair Price (**MFP**) is subject to a statutory ceiling. Some drugs may be subject to a renegotiation process in subsequent years. The products of manufacturers who do not participate in the negotiation or fail to effectuate CMS's final MFP offer will not be eligible for coverage under Part D or federal funding under the Medicaid program.



Application of MFP

Manufacturers of selected drugs must provide access to the MFP to Medicare beneficiaries enrolled in a Part D plan and to pharmacies and other dispensing entities. Part D plans are required to include selected drugs on their formularies, and a Part D plan's negotiated payment for each selected drug must not exceed the MFP plus a dispensing fee. A beneficiary's payment for the drug, either in the deductible phase or through coinsurance, must be based on that negotiated payment.



Sources: SSA §1191-1198 (42 U.S.C. §§1320f-1320f-7); Centers for Medicare and Medicaid Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 (May. 12, 2025), <https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf>; For more information, see CRS Report R47872, Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Responses and Potential Effects, by Kevin J. Hickey, Laura A. Wreschnig, and Hannah-Alise Rogers (2023).

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