

**OVERVIEW OF DRUG PRICING PROVISIONS IN
THE INFLATION REDUCTION ACT**

AUGUST 9, 2022

Democrats’ latest reconciliation package contains two key health care policies aimed at lowering the cost of health care and reforming how the Medicare program purchases prescription drugs. The central component of the proposal requires Medicare to negotiate prices for certain high-cost drugs. Additionally, the bill would penalize manufacturers for raising the cost of Medicare drugs in excess of inflation and incorporates changes to reduce cost sharing for Medicare beneficiaries.

Medicare Drug Price Negotiation Program

The bill requires the Secretary of Health and Human Services (HHS) to establish a drug price negotiation program for selected high cost Medicare Part B and Part D drugs. Under the program, the Secretary must:

- 1) Select and publish a list of Medicare Part B and D drugs eligible for negotiation;
- 2) Enter into agreements with manufacturers; and
- 3) Negotiate a price for each drug, which would become effective beginning 2026

Timeline of Drug Negotiation Program

Applicable Year	Number of Drugs	Eligible Drug Categories	Selected Drug Publication Deadline	Negotiated Max Price Deadline
2026	10	Part D drugs only	Feb 1, 2024	Nov 1, 2024
2027	15	Part D drugs only	Feb 1, 2025	Nov 1, 2025
2028	15	Part B and D drugs	Feb 1, 2026	Nov 1, 2026
2029	20	Part B and D drugs	Feb 1, 2027	Nov 1, 2027

Selection of Drugs

- By February 1st two years before the applicable year, the Secretary must rank eligible Part B and Part D drugs¹ by total expenditure² in the most recent twelve months
- The Secretary must then select the requisite amount of highest cost drugs for that year (refer to table above)
- The selection of these drugs is not subject to administrative or judicial review

Agreements with Manufacturers

- The Secretary must enter into agreements with manufacturers to negotiate (and re-negotiate) a maximum fair price for those selected drugs effective beginning 2026 (first applicable year)

¹ Certain small biotech and orphan drugs would be excluded.

- The Secretary must first provide the manufacturer a written initial offer and include justification based on the following factors:
 - Manufacturer-specific data
 - market data,
 - cost of production,
 - pending applications/market exclusivities, etc.
 - Evidence about alternative treatments
 - Extent to which drug represents a therapeutic advance
 - Prescribing information
 - Comparative effectiveness to alternatives, etc.

Negotiating the Maximum Fair Price

- The Secretary must strive to achieve the lowest maximum price and cannot agree to any price that exceeds the specified price ceiling or is less than the specified price floor
 - The price ceiling and floor differ for Medicare Part B and Part D drugs, and are based on formulas that incorporate the non-federal manufacturer price and/or weighted payment amounts for prior plan years
- Once the manufacturer receives the Secretary’s offer, the manufacturer must either accept or propose a counteroffer in writing justified by the factors outlined above
- Manufacturers will then be required to provide the maximum fair price to eligible individuals (beneficiaries enrolled in Medicare Part B or Part D)
- This agreement will be in place as long as the drug is designated as a “selected drug”
- The Secretary must also set up a process for renegotiation of selected drugs when applicable (i.e. addition of a new indication)

Drug Inflation Rebates

- Beginning January 1, 2023, the Secretary must provide manufacturers with information on the number of drugs billed, any excess price increases, and the rebate amount owed by a manufacturer for each eligible Part B and D drug
- Within 30 days of receipt, manufacturers must pay the Secretary a rebate equal to the dollar amount in excess of inflation charged for Medicare Part B and D drugs for a given quarter
- Manufacturers who fail to comply will be subject to a civil penalty of at least 125% of the owed rebate amount

Medicare Improvements

- Beginning 2025, would cap out of pocket drug costs for Medicare beneficiaries at \$2,000/year. Beneficiaries will have the option to spread their cost sharing over the year in capped monthly installments
- Beginning 2025, requires the Secretary to establish a manufacturer discount program that offers discounted prices for *non-selected* Part D drugs for certain Medicare beneficiaries
- Expands premium and co-payment assistance for Medicare Part D beneficiaries from 135% of the federal poverty level (FPL) to 150% (FPL)