

Inflation Reduction Act

Overview of Key Provisions: Drug Pricing, Tax, and Climate



Key Components of the Drug Pricing Reforms

Drug Price “Negotiation”

Eligibility for “negotiation”: Drugs will be eligible if, at the drug selection publication date, at least seven years (small molecule) or eleven years (biologics) have passed since FDA approval, and a generic or biosimilar has not been approved and marketed at that point. Maximum fair prices (“MFPs”) will be implemented at nine years (small molecule) and thirteen years (biologics) after FDA approval.

Selection & formulary placement: Drugs will be selected for “negotiation” based on a ranking of Medicare sales under Part B or Part D; however, drugs must have a minimum of \$200M in Medicare sales, adjusted for CPI and during a specified look-back period, to be eligible. Once “negotiated,” Part D drugs will have a guaranteed place on Part D formularies (though a plan will have the discretion to remove “negotiated” drugs from formularies if that plan adds a therapeutically equivalent generic drug to the formulary, subject to regulatory requirements).

Drug selection:

Year	Part B	Part D	Number
2026		✓	10
2027		✓	15
2028	✓	✓	15
2029+	✓	✓	20

2026 timeline: Ten Part D drugs will be selected by September 1, 2023. Manufacturers will have to submit data/dossiers by October 2, 2023. MFPs will be finalized in August 2024, with publication on September 1, 2024 (current Administration). MFP goes into effect on January 1, 2026.

2027+ timeline: Fifteen Part D drugs will be selected on February 1, 2025. Manufacturers will have to submit information by March 2025. MFPs will be finalized November 2025, effective January 1, 2027. Subsequent years will follow this basic schedule, with Part B drugs added to the “negotiation” process for 2028 and the number of drugs “negotiated” increasing to 20 per year (Parts B and D) starting in 2029.

Pricing:

Category	Years Post Approval	Rate Not to Exceed*
Short Monopoly	9-12	75% of average nonFAMP**
Extended Monopoly	12-15	65% of average nonFAMP**
Long Monopoly	16+	40% of average nonFAMP**

* The ceiling price for the “negotiation” is the lesser of a specified net price of the product after rebates (net “negotiated” for Part D/ASP for Part B), or a specified percentage of non-FAMP depending on date post-approval; MFP can be lower than ceiling price (no floor)

** NonFAMP = non-federal average manufacturer price

Generics and Biosimilars: A drug or biologic will be excluded from “negotiation” if, before or during the “negotiation” period, the Secretary determines a generic/biosimilar for the product has been approved and marketed. A drug or biologic already subject to MFP will no longer be subject to MFP if the Secretary makes that determination of generic or biological approval/licensing and marketing, with exemption beginning the first year after at least nine months have passed since the determination. The Secretary may delay MFP application to a biologic for one or two years upon the Secretary’s determination that there is a high likelihood of the introduction of a biosimilar within two years of what would otherwise be the publication date for the biologic’s MFP. Such delay must be requested by the biosimilar manufacturer.

Inflation Rebates

- The Inflation Reduction Act requires drug manufacturers to pay rebates on price increases above inflation for Medicare Part D and Medicare Part B sales, with 2021 as the base year to measure inflation.
- Part D inflation rebates will be calculated based on increases in Average Manufacturer Price above CPI-U starting October 2022. Part B rebates will be calculated based on increases in Average Sales Price above CPI-U starting in January 2023. Rebates will not be owed on commercial sales.
- The Secretary may delay the initial timeline for collecting and reporting rebate amounts until September 30, 2025 for Part B drugs and December 31, 2025 for Part D drugs.

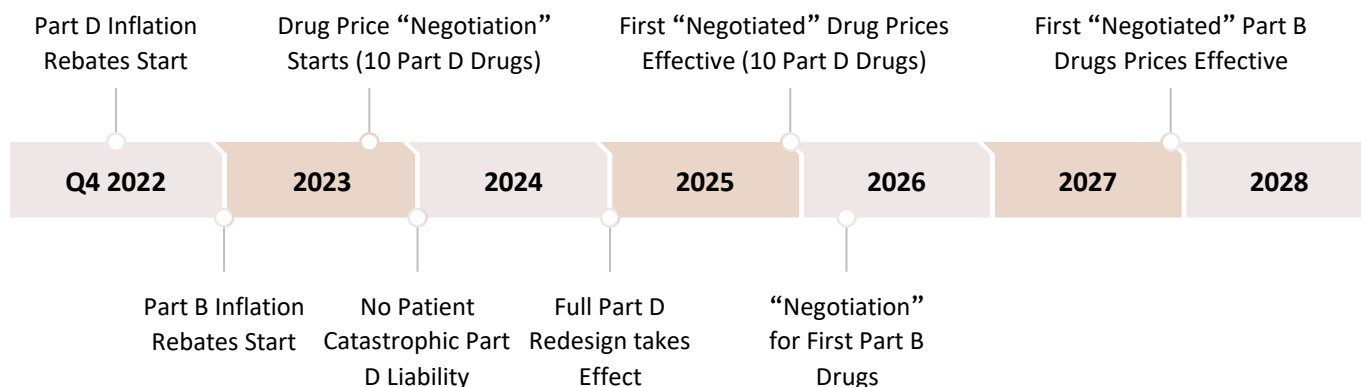
Restructured Part D Benefit

The Inflation Reduction Act includes a substantial redesign of the Part D Program to make it less expensive for Part D beneficiaries with higher drug utilization. It would also allow beneficiaries to spread costs more evenly across the year. The following changes are effective for 2025:

- **Out-of-Pocket (OOP) cap:** Sets an annual OOP cap at \$2,000, which can be spread monthly throughout the year.
- **Eliminates Coverage Gap:** Coverage gap phase is eliminated.
- **Reforms catastrophic phase:** Eliminates patient liability and increases plan liability in the catastrophic phase of the benefit from 15% to 60%. Manufacturer liability increases from 0% to 20%.
- **Controls premium increases:** The bill restricts increases in the base beneficiary premium to no more than 6% starting in 2024, through 2029. CMS may make a one-time permanent adjustment to premium contribution percentages in 2030.
- **Increases Low-Income-Subsidy (LIS) population:** Expands the Part D LIS income threshold from 135% to 150% of the federal poverty level.

Medicare Part D coverage phase	Current benefit	Inflation Reduction Act
Initial coverage	Plan: 75% Beneficiary: 25% Manufacturer: 0%	Plan: 65% Beneficiary: 25% Manufacturer: 10%
Coverage gap	Plan: 5% Beneficiary: 25% Manufacturer: 70%	Coverage gap removed
Catastrophic coverage	Plan: 15% Beneficiary: 5% Medicare: 80% Manufacturer: 0%	Plan: 60% Beneficiary: 0% Medicare: 20% Manufacturer: 20%
Out-of-pocket annual limit	None	\$2,000

Implementation timeline



Other Select Health Care Provisions: ACA Subsidies

In addition to drug pricing, the Inflation Reduction Act also extends enhanced Affordable Care Act (ACA) subsidies for three years through 2025 for individuals buying coverage through ACA Marketplaces.



Key Components of Tax Reform

The Inflation Reduction Act includes several tax provisions intended for deficit reduction.

- **Corporate Alternative Minimum Tax:** Imposes a new alternative minimum tax of 15% on corporations with over \$1 billion in average annual earnings in the previous three years, with some exceptions. This provision will apply to taxable years beginning after December 31, 2022.
- **Excise Tax on Repurchase of Corporate Stock:** Imposes a non-deductible 1% excise tax on the repurchase of stock by a publicly traded corporation. The tax does not apply if repurchases are less than \$1 million or are contributed to an employee pension or similar plan. This provision will apply to repurchases after December 31, 2022.
- **Selected Drug Manufacturer Excise Tax:** Imposes a new excise tax on drug manufacturers who fail to enter into Medicare “negotiation” agreements for selected drugs. The excise tax will be some percentage of the selected drug’s price, based on the period of noncompliance, and can be suspended should a manufacturer terminate all applicable Medicare agreements, including the Medicaid Drug Rebate Program agreement.



Key Components of Climate Reform

The Inflation Reduction Act climate provisions target consumers, low-middle income communities, and industries focused on the generation of energy and/or those who are the highest emitters of carbon emissions.

- **American Energy Security and Domestic Manufacturing:** Production tax credits to accelerate U.S. manufacturing of solar panels, wind turbines, batteries, and critical minerals processing, estimated to invest \$30 billion; \$10 billion investment tax credit to build clean technology manufacturing facilities, like facilities that make electric vehicles, wind turbines, and solar panels.
- **Decarbonize the Economy:** Tax credits for clean sources of electricity and energy storage and roughly \$30 billion in targeted grant and loan programs for states and electric utilities to accelerate the transition to clean electricity; tax credits and grants for clean fuels and clean commercial vehicles to reduce emissions from all parts of the transportation sector.