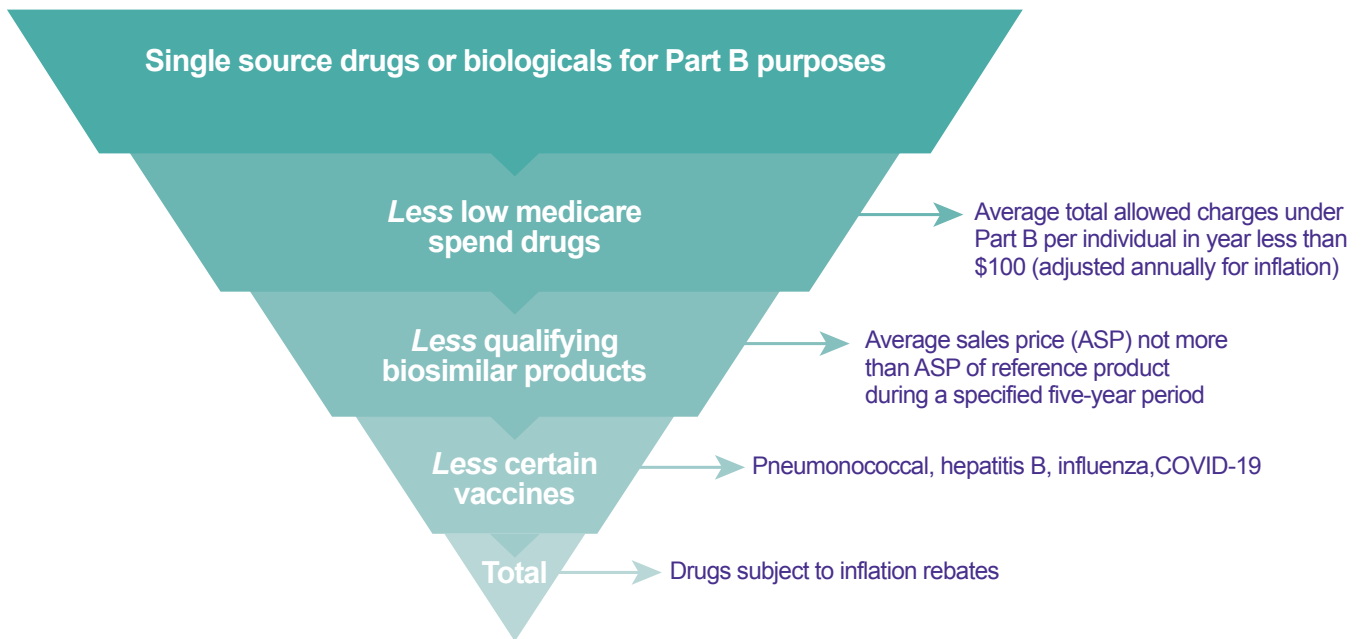


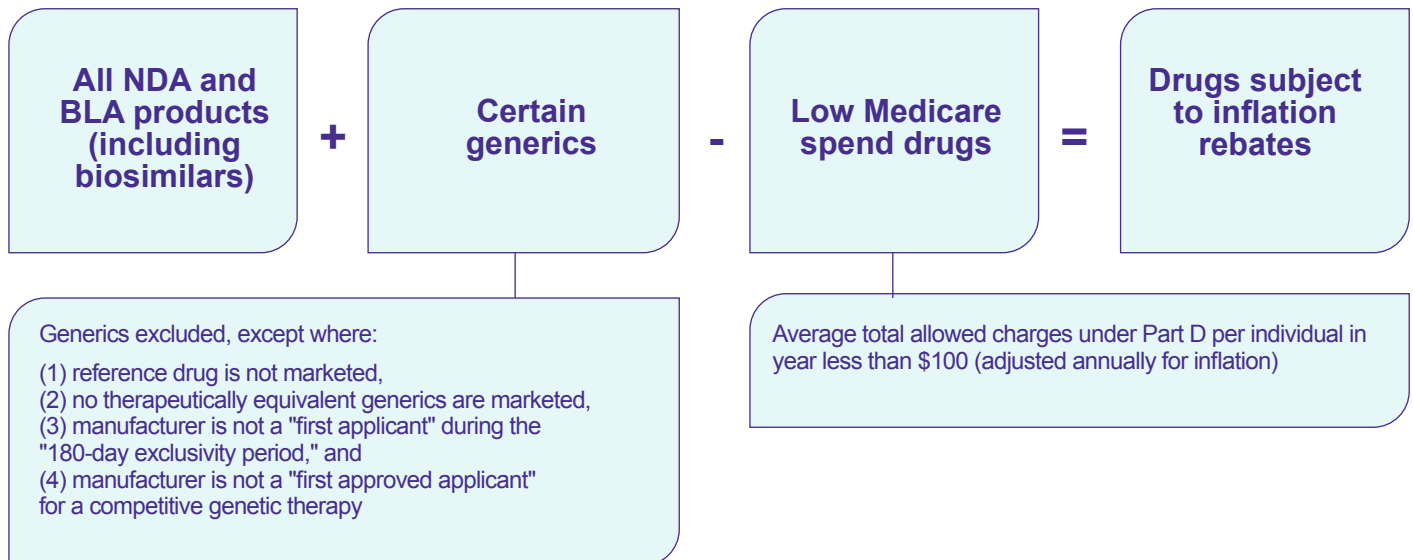
## INFLATION REDUCTION ACT: DRUG REBATES

The Inflation Reduction Act (IRA) of 2022 requires biopharmaceutical companies to pay rebates to the government if the price for drugs in Medicare Part B or Part D increase faster than the rate of inflation.






### What drugs are subject to Part B Inflation Rebates?



### What drugs are subject to Part D Inflation Rebates?



## Timeline for Initial Round of Rebates

Action	Part B	Part D
 <b>Start Date for Rebate Process</b>	Quarter beginning <b>January 1, 2023</b>	Year beginning <b>October 1, 2022</b>
 <b>Rebate Calculation</b>	How ASP changed compared to inflation-adjusted ASP from <b>Q3 2021</b> (Jan 2021 CPI benchmark)	How volume-weighted average annualized average manufacturer price (AMP) changed compared to inflation-adjusted volume-weighted average annualized AMP for <b>Q1 through Q3 2021</b> (Jan 2021 CPI benchmark)
 <b>HHS Deadline to Inform Company of Rebate Owed</b>	<b>September 30, 2023</b> <i>For initial year, HHS may delay the timeframe for reporting until September 30, 2025.</i>	<b>June 30, 2024</b> <i>For initial year, HHS may delay the timeframe for reporting until December 31, 2025</i>
 <b>Rebate Due to HHS</b>	<b>30 days</b> after invoice receipt	<b>30 days</b> after invoice receipt
 <b>Beneficiary Protection</b>	Inflation growth cap applied to Part B co-insurance beginning <b>April 1, 2023</b>	N/A

Note: Part B rebate timeline is quarterly. Part D is yearly.

## How do Part B and Part D rebates differ on key issues?

Civil Monetary Penalties (CMPs)	CMS Rulemaking	Utilization Subject to Inflation Rebates
<p><b>Part B Rebates:</b> A manufacturer that does not pay a rebate will be subject to a CMP, which shall be equal to <b>at least 125%</b> of the rebate amount.</p> <p><b>Part D Rebates:</b> A manufacturer that does not pay a rebate will be subject to a CMP, which shall be an amount <b>equal to 125%</b> of the rebate amount.</p>	<p><b>Part B Rebates:</b> CMS is not expressly directed to implement the Part B inflation rebates through guidance for initial years.</p> <p><b>Part D Rebates:</b> CMS is directed to implement the Part D inflation rebates through guidance for years 2022, 2023, and 2024.</p>	<p><b>Part B Rebates:</b> Units reimbursed by Part B are packaged units, 340B units, and Medicaid units.</p> <p><b>Part D Rebates:</b> Units reimbursed by Part D are 340B units, starting in 2026.</p> <p><b>Both:</b> The Secretary is required to waive or reduce the rebate amount for products on the 506E shortage list and on biosimilars experiencing severe supply chain disruptions.</p>