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?**

**Single source drugs or biologicals for Part B purposes**

- **Less low medicare spend drugs**
  - Average total allowed charges under Part B per individual in year less than $100 (adjusted annually for inflation)

- **Less qualifying biosimilar products**
  - Average sales price (ASP) not more than ASP of reference product during a specified five-year period

- **Less certain vaccines**
  - Pneumonococcal, hepatitis B, influenza, COVID-19

**Total**

Drugs subject to inflation rebates

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

**All NDA and BLA products (including biosimilars) + Certain generics - Low Medicare spend drugs = Drugs subject to inflation rebates**

Generics excluded, except where:

1. reference drug is not marketed,
2. no therapeutically equivalent generics are marketed,
3. manufacturer is not a "first applicant" during the "180-day exclusivity period," and
4. manufacturer is not a "first approved applicant" for a competitive genetic therapy

Average total allowed charges under Part D per individual in year less than $100 (adjusted annually for inflation)
### Timeline for Initial Round of Rebates

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

**Part B Rebates**: A manufacturer that does not pay a rebate will be subject to a CMP, which shall be equal to **at least 125%** of the rebate amount.

**Part D Rebates**: A manufacturer that does not pay a rebate will be subject to a CMP, which shall be an amount **equal to 125%** of the rebate amount.

**CMS Rulemaking**

**Part B Rebates**: CMS is not expressly directed to implement the Part B inflation rebates through guidance for initial years.

**Part D Rebates**: CMS is directed to implement the Part D inflation rebates through guidance for years 2022, 2023, and 2024.

**Utilization Subject to Inflation Rebates**

**Part B Rebates**: Units reimbursed by Part B are packaged units, 340B units, and Medicaid units.

**Part D Rebates**: Units reimbursed by Part D are 340B units, starting in 2026.

**Both**: 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.