IRA Inflation Rebates

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The Inflation Reduction Act (IRA) of 2022 (the Act) enables the Centers for Medicare and Medicaid Services (CMS) to negotiate drug prices with manufacturers, while also implementing an inflation cap on drug prices and reducing out-of-pocket expenses on prescription medications for Medicare recipients. This article will explore the Medicare Part B and Part D inflation rebates and their calculation methods, and the potential impact of these changes on pharmaceutical manufacturers as various provisions of the Act take effect.

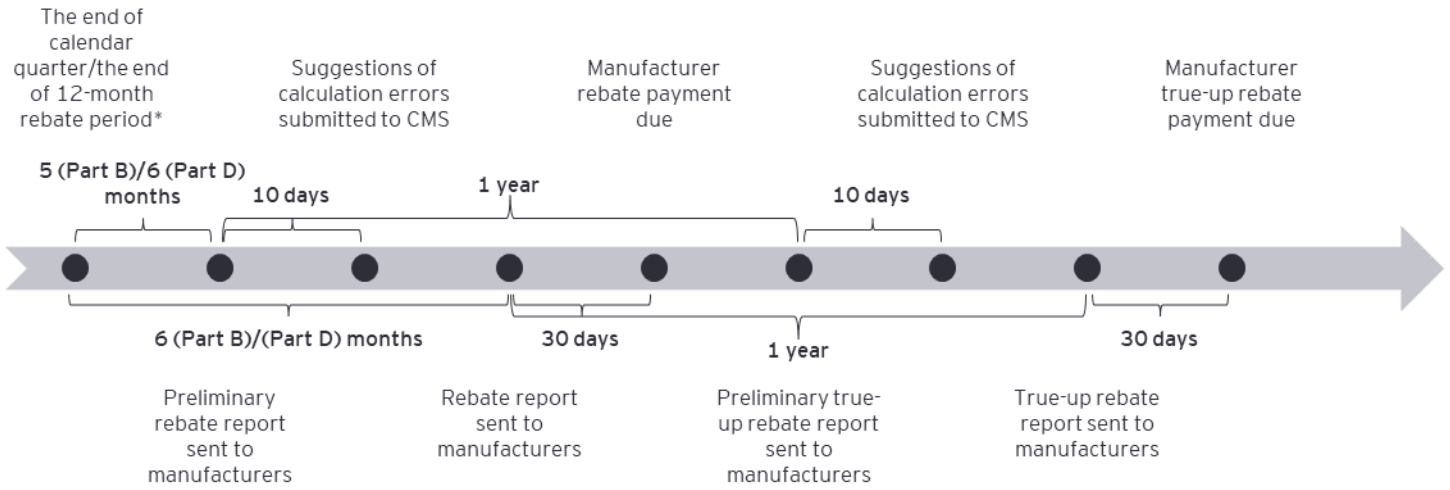
Medicare Part B and Part D inflation rebates

Key takeaways:

- Manufacturers need to monitor the pricing of their Medicare Part B and D drugs and be aware that they are required to pay quarterly rebates to Health & Human Services (HHS) for certain drugs covered under Medicare Part B and D if the payment amount rises faster than inflation. Failure to pay rebates on time may result in civil monetary penalties.
- Manufacturers should understand the calculation methodology for inflation rebates, specifically the timing of the benchmark values. This includes understanding that the Medicare Part B inflation rebates are calculated at the Healthcare Common Procedure Coding System (HCPCS) code level and Medicare Part D inflation rebates at the NDC-9 level.

The IRA requires pharmaceutical manufacturers to pay quarterly rebates to HHS for certain drugs and biologics covered under Medicare Parts B and D if the payment amount for their drug rises faster than inflation. Though the rebate provisions took effect in October 2022 for Part D and January 2023 for Part B, the CMS has until December 31, 2025 (Part D) and September 30, 2025 (Part B), to invoice manufacturers. For each drug with an associated IRA rebate, manufacturers must pay rebates within 30 days of receiving the invoice. The CMS is required to include on invoices the total number of units for which manufacturers must pay rebates, the difference between the payment amount and the inflation-adjusted payment amount (i.e., the inflation-adjusted payment amount in the benchmark quarter), and the rebate amount.

Medicare Part B and Part D inflation rebate program timeline



*The first applicable calendar quarter for Part B inflation rebates is Q1 2023. The first applicable 12-month period for Part D inflation rebates begins October 1, 2022.

The IRA defines a "Part B rebatable drug" to mean a single-source drug or biological product, including biosimilar biological products but excluding a qualifying biosimilar biological product (for which payment is made under Part B). The selection of a Part B drug for the Drug Price Negotiation Program does not impact the inflation rebate applicability of the drug. The IRA excludes a drug or biologic from the definition if the average total allowed charges under Part B per patient is less than $100 in 2023, or in future years, $100 increased by a formula based on a percentage increase. The IRA also expressly excludes vaccines from the definition.

The IRA defines a "Part D rebatable drug" to mean a covered Part D drug that, as of the first day of the applicable period, is approved under a new application under the Federal Food, Drug, and Cosmetic Act (FDCA), a biologic licensed under the Public Health Service Act (PHSA) or a drug approved under an abbreviated new drug application under the FDCA (if certain criteria are met).[1] The selection of a Part D drug for the Drug Price Negotiation Program does not impact the inflation rebate applicability of the drug. The IRA excludes from the definition a drug or biologic if the average annual cost under Part D per patient is less than $100 for the applicable period beginning October 1, 2022. The $100 amount increases by a percentage for subsequent applicable periods.

[1] 42 CFR 423.100 defines "covered Part D drug."

The calculation of the rebate amounts for both Medicare Part B and Part D is similar to Medicaid additional rebate, using consumer price index values and benchmark periods.	
	The inflation rebate for Part B drugs will be calculated at the HCPCS code level and the resulting rebate will be allocated based on sales volume if there are multiple manufacturers with drugs with same HCPCS codes. *The Part B inflation rebate amount is determined by multiplying the total number of units sold in Medicare Part B by the difference between the drug's ASP*106% in a given quarter and the inflation-adjusted ASP*106% of the benchmark quarter*. For Part B drugs approved before or on December 1, 2020, the benchmark quarter is Q3 2021 and benchmark period CPI-U is the January 2021 CPI-U. For Part B drugs approved after December 1, 2020 benchmark quarter is the third full quarter after drug was first marketed and benchmark period CPI-U is the CPI-U for the first month of first full calendar quarter after drug was first marketed.
	The inflation rebate for Part D drugs occurs at the NDC-9 level and is based on volume weighted annual average manufacturer price (AMP). Volume weighted annual AMP is calculated by aggregating the multiplication of the quarterly AMP by a ratio calculated by dividing AMP units for the quarter by the annual AMP units for each quarter. The Part D inflation rebate amount is determined by multiplying the total number of units sold in Medicare Part D by the difference between the drug's volume weighted annual AMP in a given year and the inflation-adjusted volume weighted annual AMP of the benchmark period. For Part D drugs approved before or on October 1, 2021, the benchmark period is Q1–Q3 2021 and benchmark period CPI-U is January 2021 CPI-U. For Part D drugs approved after October 1, 2021, the benchmark period is the first calendar year after drug was marketed and CPI-U is the CPI-U for January of that calendar year.

The Act restricts administrative and judicial review of various determinations, including rebate units, qualification as a rebatable drug, calculation of rebate amounts, or payment amount for Part B rebatable drugs. Manufacturers failing to pay inflation rebates may be subject to civil monetary penalties equivalent to at least 125% of the rebate amount.

Impacts on the manufacturers and the industry

Stakeholder collaboration and internal connectivity are crucial for effectively managing risk and achieving business goals in the era of the IRA. Key departments such as legal, compliance, contracting/market access, government affairs, member management, and government pricing should work together closely to navigate the complexities of the IRA and foster organizational success. The following are some implications that may impact manufacturers' financial accruals, business, and pricing strategy.

Implication category	Medicare Part B and D inflation rebates
Product portfolio management	▸ Manufacturers should employ strategic timing for product launches and price adjustments, aligning them with the benchmark periods and inflation rebates, to effectively mitigate the overall amount of rebate payments.
Gross-to-net and accruals	▸ Manufacturers should employ strategic timing for product launches and price adjustments, aligning them with the benchmark periods and inflation rebates, to effectively mitigate the overall amount of rebate payments. ▸ Manufacturers should collaborate closely with relevant stakeholders to prevent the issuance of overlapping discounts for Medicare and 340B programs on the same purchase
Commercial strategy and pricing	▸ Manufacturers should consider assessing their commercial arrangements and be prepared for negotiations with commercial customers in light of the IRA provisions. ▸ Manufacturers should thoroughly analyze pricing strategies and potential price concessions during product launches, ensuring a clear understanding of their financial implications in relation to the requirements imposed by the IRA. ▸ Manufacturers contemplating mergers and acquisitions should carefully evaluate the impact of the IRA provisions on the assets and overall business being acquired.

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