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CMS Issues Revised Guidance Implementing Medicare Inflation Rebates Under the Inflation Reduction Act

Article By:

Stephanie Trunk

The Centers for Medicare and Medicaid Services (CMS) continues to take steps implementing the Inflation Reduction Act of 2022 (IRA). Newly revised guidance issued on December 14, 2023, makes notable changes and clarifications to CMS' previous guidance released earlier this year.

As we previously reported back in September 2022, the IRA was signed into law by President Biden on August 16, 2022. The IRA made sweeping changes to drug reimbursement and coverage under Medicare. See our previous alert summarizing such changes: Drug Pricing Reform Finally Becomes Law: What the Inflation Reduction Act Means for Pharma. One such change is to charge and collect rebates on Medicare utilization of certain drugs to the extent Average Sales Price (ASP) in the case of Medicare Part B drugs or Average Manufacturer Price (AMP) in the case of Medicare Part D drugs rises faster the inflation. CMS previously published guidance implementing the inflation rebates under the IRA, which we discussed in our previous alert: CMS and OIG Issue Guidance on Implementation of the Inflation Reduction Act.

On December 14, 2023, CMS issued revised guidance available here: Inflation Rebates in Medicare | CMS. Below we summarize some key and interesting provisions in the revised guidance.

Key Dates for IRA Implementation

October 1, 2022	First 12-month period for which manufacturers are required to pay rebates to Medicare for AMPs rising faster than inflation on certain Part D drug utilization. **Note that CMS will not begin collecting inflation rebates on such utilization until 2025.**
January 1, 2023	First quarterly period for which manufacturers are required to pay rebates if ASP rises faster than inflation on certain Part B drug utilization. **Note**

	that CMS will not begin collecting inflation rebates on such utilization until 2025.
April 1, 2023	Medicare beneficiaries began paying a lower co-insurance for certain Part B drugs with ASPs rising faster than inflation.
September 30, 2025	Deadline for CMS to send first invoices to manufacturers for inflation rebates on Part B drug utilization in 2023 and 2024.
December 31, 2025	Deadline for CMS to send first invoices to manufacturers for inflation rebates on Part D drugs for the 12-month period beginning October 1, 2022, and the 12-month period beginning October 1, 2023.

Reprieve for Drugs in Shortage and for Certain Drugs with Supply Chain Disruptions

CMS provided additional guidance concerning how it plans to reduce inflation rebates due under the IRA for drugs in shortage or, in the case of biosimilars and generics drugs, that are experiencing a severe supply chain disruption. For drugs in shortage, CMS plans to divide the timeframe in which the drug is in shortage by the total applicable days in the relevant quarter for Part B drugs or the relevant 12-month period for Part D drugs and apply the applicable reduction percentage in the table below, which was re-published from the CMS fact sheet and guidance.

In the case of a severe supply chain disruption for a biosimilar or generic drug, the manufacturer may request that CMS provide an inflation rebate reduction. If CMS grants the request, the applicable reduction percentage in the table below will apply.

DRUG SHORTAGE		SEVERE SUPPLY CHAIN DISRUPTION	LIKELY TO BE IN SHORTAGE
Duration of Reduction	Indefinite for as long as drug is “currently in shortage” on an FDA shortage list		One year; manufacturer may request an extension of the reduction for an additional year for up to two consecutive years total
Percent Reduction in Rebate Owed	Part B or Part D rebateable drug other than a plasma-derived product or Part D rebatable generic drug	Part B or Part D plasma-derived product or Part D rebatable generic drug	Part B or Part D rebatable biosimilar or Part D rebatable generic drug
First year	25%	75%	75%
Second year	10%	50%	75%

Subsequent years	2%	25%	N/A

Excluding Drugs Purchased Under 340B Program

Beginning in 2024, 304B Covered Entities billing Medicare for Part B drugs are required to include a “JG” or “TB” modifier on Medicare claims to identify drugs purchased under the 340B program. This will be the mechanism for excluding 340B utilization from inflation rebates. In 2023, CMS will remove all Medicare units from suppliers that are listed in Health Resources and Services Administration Office of Pharmacy Affairs Information System (OPAIS) as Covered Entities.

There is no exclusion of Medicare Part D utilization where the dispensed drug was purchased under the 340B Program until January 1, 2026. CMS continues to evaluate how to identify this utilization and has suggested mandating the use of a modifier by dispensing pharmacies to identify drug stock dispensed to Medicare patients originally purchased under the 340B Program.

No “Double Dip” for Drugs Subject to Wastage Rebate Under Part B

The Infrastructure Investment and Jobs Act of 2021 requires manufacturers of single-dose or single-use vials reimbursed under Medicare Part B to pay a rebate on discarded amounts above a 10% threshold. Physicians and hospitals are required to identified discarded amounts using the JW billing modifier and to use the JZ modifier to attest to the discarded amount. The rebate went into effect the first quarter of 2023.

CMS may consider exempting Medicare Part B drugs units of single-dose vials on which a pharmaceutical manufacturer already paid a wastage rebate related to discarded product under the Infrastructure Investment and Jobs Act of 2021 from the IRA inflation rebate. CMS is seeking comments from stakeholders on this proposal.

Invoices

As noted above, by September 30, 2025, CMS must invoice manufacturers for inflation rebates on Part B drug utilization incurred in 2023 and 2024. Likewise, by December 31, 2025, CMS must invoice manufacturers for inflation rebates on Part D drugs utilization for the 12-month period beginning October 1, 2022, and the 12-month period beginning October 1, 2023.

CMS plans to issue each manufacturer a separate Preliminary Rebate Report for inflation rebates for Part B and Part D drugs. Manufacturers will have 10 calendar days to review the preliminary report and can submit a Suggestion of Calculation Error to CMS at that time. CMS plans to issue guidance with additional information and the draft Preliminary Rebate Report and Suggestion of Calculation Error forms at a later time. For the initial 2023 and 2024 timeframe for Part B drugs and the 12-month periods from October 1, 2022, and October 1, 2023, respectively for Part D drugs, manufacturers will have 30 calendar days to review the Preliminary Rebate Report for these time periods. Manufacturers must pay inflation rebates within 30 calendar days of receipt of the Preliminary Rebate Report or may be subject to Civil Monetary Penalties of 125% of the rebate amount.

Units for Part D Inflation Rebates

For Medicare Part D inflation rebates, CMS plans to use the units from the Medicare Part D claims, known as Prescription Drug Event data. In certain instances, the units may not match those used in the AMP calculations under the Medicaid Drug Rebate Program (MDRP) and CMS will attempt to convert the units as needed. This should be an area manufacturers should scrutinize closely, particularly related to drugs that might have a unit type of “each,” milliliters, grams, or inner and outer National Drug Codes (NDCs).

Additional Clarifications

- CMS made crystal clear that Medicare Part B drugs that are generic and sold pursuant to an Abbreviated New Drug Application (ANDA) are excluded from the inflation rebates as are older, branded, single-source drugs or biologics that share the same Healthcare Common Procedural Coding System (HCPCS) code as of October 1, 2003, under the Medicare Modernization Act of 2003 (codified at Section 1847A(c)(6)(C)(ii) of the Social Security Act). In addition, separately reimbursable radiopharmaceuticals are excluded from the Part B inflation rebate.
- CMS will not apply sequestration in Medicare Part B inflation rebates.
- Medicare Part B inflation rebates are not due on utilization by individuals with both Medicare and Medicaid coverage (known as “dual eligibles”) if Medicaid provided reimbursement for some or all of the patient Medicare cost-sharing obligations and, therefore, the manufacturer has already paid a rebate under the MDRP.
- To identify Medicare Part D drugs that are sold under an ANDA that might be single-source and subject to the Medicare Part D inflation rebate, CMS plans to rely on the reference listed drug designation in the US Food and Drug Administration’s (FDA) Orange Book as well as the listings in the FDA’s NDC directory to determine which products are currently be sold in the United States market. CMS notes that the rebate will only apply while such generic drug is single-source and would no longer be rebatable on the first day of the applicable period in which the generic drug is no longer single-source.
- CMS reiterated that a drug would not be a Part D rebatable drug if the manufacturer did not have a MDRP agreement in effect and, therefore, did not report AMP. CMS continues to assess other means to collect the needed information to subject these drugs to Medicare Part D inflation rebates.

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