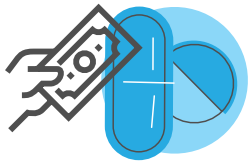
Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Policies in the Calendar Year 2025 Physician Fee Schedule Final Rule



In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) into law. Among many other provisions, this landmark law will require drug companies that raise their drug prices faster than the rate of inflation to pay Medicare a rebate. This will lead to a stronger Medicare for current and future enrollees and discourage unreasonable price increases by drug companies.

The prescription drug law makes improvements to Medicare that will expand benefits, lower drug costs, keep prescription drug plan premiums stable, and improve the sustainability of the Medicare program. The law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare both now and in the long run.

Q: What is the Medicare Prescription Drug Inflation Rebate Program?

The prescription drug law requires drug companies to pay a rebate if they raise their prices for certain drugs faster than the rate of inflation. This rebate is paid to Medicare and will be calculated and invoiced by the Centers for Medicare & Medicaid Services (CMS). The law establishes Medicare Part B prescription drug inflation rebates for single-source drugs and biologicals with prices increasing faster than the rate of inflation and provides for lower Part B beneficiary coinsurance on these drugs and biologicals. In addition, the law establishes Medicare Part D prescription drug inflation rebates for certain drugs and biologicals with prices increasing faster than the rate of inflation. Collectively, the program to implement these rebates is referred to as the Medicare Prescription Drug Inflation Rebate Program or the Inflation Rebate Program.

Q: How will this program improve Medicare?

The Medicare Prescription Drug Inflation Rebate Program will lead to a stronger Medicare program for current and future beneficiaries and discourage runaway price increases by drug companies. The rebates paid by drug companies will be deposited in the Federal Supplementary Medical Insurance Trust Fund, which will help ensure long-term sustainability of the Medicare program for future generations.

Q: How will people with Medicare benefit from the Medicare Prescription Drug Inflation Rebate Program?

The Medicare Prescription Drug Inflation Rebate Program may discourage drug companies from increasing their prices faster than the rate of inflation. Beginning April 1, 2023, people with Medicare started to see lower out-of- pocket costs for certain Part B drugs and biologicals with prices that have increased faster than the rate of inflation. For these drugs and biologicals, the beneficiary coinsurance is 20 percent of the inflation-adjusted payment amount, which is less than what the beneficiary would pay in coinsurance otherwise.

Q: What changed in the Medicare Prescription Drug Inflation Rebate Program between the 2023 revised guidance and this final rule?

CMS is codifying policies established in the revised guidance documents for the Part B Drug Inflation Rebate Program and the Part D Drug Inflation Rebate Program, both published December 14, 2023. In addition to codifying these policies, we are finalizing new and revised policies for the Inflation Rebate Program in the Calendar Year (CY) 2025 Physician Fee Schedule (PFS) final rule.[1]

[1] CY 2025 Medicare Physician Fee Schedule Final Rule. **https://www.federalregister.gov/public-inspection/current**.
[2] Under the Infrastructure Investment and Jobs Act of 2021 (P.L. 117-58), section 90004, manufacturers are required to provide a refund to CMS for certain discarded amounts from separately payable single-dose container or single-use package drugs beginning January 1, 2023.

For the Part B Drug Inflation Rebate Program, CMS finalized new policies to:

- Compare the payment amount in the quarterly pricing files published by CMS to the inflation-adjusted payment amount for a given quarter when determining whether the criteria for a coinsurance adjustment are met;
- Identify a benchmark quarter for drugs first approved or licensed by the FDA on or before December 1, 2020 but with a first marketed date after December 1, 2020;
- Remove 340B units for professional claims with dates of service during 2024 (in addition to 2023) submitted by Medicare suppliers that are 340B covered entities;
- Establish a method and process for reconciliation of a rebate amount to account for revised information, calculation error, or misreporting, including the circumstances that may trigger such a reconciliation;
- Exclude units of refundable single dose container or single use package drugs subject to discarded drug refunds from the calculation of rebate amounts in the reconciliation process; and
- Establish a civil money penalty process for when a manufacturer of a Part B rebatable drug fails to pay the rebate amount in full by the payment deadline for such drug for such applicable calendar quarter.

For the Part D Drug Inflation Rebate Program, CMS finalized new policies to:

- Identify the payment amount benchmark period for a Part D rebatable drug in certain instances of missing manufacturer reported Average Manufacturer Price (AMP) data;
- Establish a method and process for reconciliation of a rebate amount to account for revised information, calculation error, or misreporting, including the circumstances that may trigger such a reconciliation; and
- Establish a civil money penalty process for when a manufacturer of a Part D rebatable drug fails to pay the rebate amount in full by the payment deadline for such drug for such applicable period.

CMS also stated that it will explore establishing a Medicare Part D claims data repository to comply with the statutory obligation for removal of 340B units from Part D drug inflation rebate calculations starting January 1, 2026. CMS plans to continue exploring the development of detailed policies and requirements related to any such repository for future rulemaking related to this topic and the exclusion of 340B units.

The provisions in the final rule will apply with respect to applicable calendar quarters beginning on or after January 1, 2023 (for Part B) and applicable periods beginning on or after October 1, 2022 (for Part D).

Q: Why is CMS using rulemaking instead of program guidance to make changes to the rebate program?

CMS is using rulemaking because the IRA allows for the implementation of the Medicare Part D Drug Inflation Rebate Program through program instruction or other forms of program guidance only through 2024, and CMS seeks to set forth policies for both the Part B and Part D inflation rebates in regulations.

Q: Will CMS continue to accept public input on the Medicare Prescription Drug Inflation Rebate Program?

Yes. Public feedback is critical to the success of the Inflation Rebate Program and implementation of all the Medicare provisions of the prescription drug law. CMS is using many tools to ensure interested parties' voices are heard on implementation of the program. CMS is engaging and will continue to engage interested parties through national stakeholder calls, quarterly strategic meetings, and monthly technical calls with CMS staff. One tool CMS used to solicit feedback from interested parties was through notice-and-comment rulemaking on newly proposed policies, as well as existing policies, for both the Medicare Part B and Part D Drug Inflation Rebate Programs. CMS also will continue to solicit feedback from interested parties on any future policymaking.

In addition, CMS previously voluntarily sought comments during the comment period for the initial guidance. Commenters represented a wide range of views, including academic experts and thought leaders, consumer and patient organizations, data vendors/ software technology entities, health plans,

health care providers, health systems, individuals, drug companies, and pharmacies. CMS posted copies of the timely comment letters that CMS received on the Inflation Reduction Act website at https://www.cms.gov/inflation-reduction-act-and-medicare. CMS considered these comments when drafting the proposed rule and the revised Part B and Part D guidance.

Q: How will CMS remove 340B units from the calculation of Part D rebates?

In the proposed rule, CMS proposed an estimation methodology to fulfill the statutory requirement to remove 340B units from Part D inflation rebate calculations beginning on January 1, 2026. After further consideration and taking into account the public comments received on the proposed estimation methodology, CMS did not finalize the estimation policy for the applicable period that begins on October 1, 2025.

CMS stated in the final rule that it instead will explore establishing a Medicare Part D claims data repository for removal of 340B units from Part D drug inflation rebate calculations starting January 1, 2026. CMS plans to continue exploring the development of detailed policies and requirements related to any such repository for future rulemaking related to this topic and the exclusion of 340B units starting January 1, 2026. CMS will also continue to explore requiring that covered entities and their contracted 340B third party administrators (340B TPAs) report retrospectively at a minimum the 4 elements we described and solicited comment on in the proposed rule. Specifically, we solicited comment on requiring covered entities to submit the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); and (4) Dispensing Pharmacy NPI. We welcome engagement with interested parties as we develop specific policies and requirements related to the potential repository.

Q: How is CMS calculating inflation rebates for drugs currently in shortage, facing a severe supply chain disruption, or likely to be in shortage?

To calculate the reduction in the inflation rebate amount for a Part B or Part D rebatable drug currently in shortage, CMS will first determine the number of days such drug is described as "currently in shortage" on an FDA shortage list during the period for which the rebate is being assessed (i.e., calendar quarter for Part B or 12-month applicable period for Part D). CMS will then divide that number by the total number of days in the calendar quarter or applicable period. CMS will multiply that amount by a percentage that is decreased over time. The table below provides the reduction percentages for rebatable Part B or Part D drugs "currently in shortage" on an FDA shortage list.

For a Part B or Part D rebatable biosimilar or a generic Part D rebatable drug facing a severe supply chain disruption or a generic Part D rebatable drug likely to be in shortage, the drug company will be required to submit to CMS a request for a rebate reduction. The table below provides the reduction percentages for Part B and Part D rebatable biosimilars and generic Part D rebatable drugs when CMS determines there is a severe supply chain disruption and for generic Part D rebatable drugs that CMS determines are likely to be in shortage.

Q: What is the process for a drug company to request a rebate reduction for a Part B or Part D rebatable biosimilar or generic Part D rebatable drug when there is a severe supply chain disruption or for a generic Part D rebatable drug that is likely to be in shortage?

A drug company that seeks a reduction of the rebate amount for a Part B or Part D rebatable biosimilar or generic Part D rebatable drug when it believes there is a severe supply chain, or for a generic Part D rebatable drug that is likely to be in shortage will be required to submit to CMS a request for a reduction along with supporting documentation. To request a rebate reduction, a manufacturer should first email **IRARebateandNegotiation@cms.hhs.gov** to indicate its intention to submit a request for a reduction in the rebate amount. CMS will then provide the manufacturer with the relevant request form(s) and access to a secure

submission process. The table below describes the process and deadlines for requesting a rebate reduction when a manufacturer believes there is a severe supply chain disruption or likely shortage.

The collection of information approved under OMB control number 0938-1474 includes further instructions for drug companies to submit rebate reduction requests. CMS has also provided additional information about the process and deadlines for receiving a rebate reduction in the Frequently Asked Questions: Rebate Reductions under the Medicare Prescription Drug Inflation Rebate Program at **https://www.cms.gov/files/document/rebate-reductions-under-medicare-prescription-drug-inflation-rebate-program-faq.pdf**.

If a drug company submits a timely and complete request and CMS determines that a reduction should be granted based on its review of the request and supporting documentation, CMS will reduce the rebate amount by 75 percent for one year regardless of whether the drug subsequently goes on an FDA shortage list during that year. If a severe supply chain disruption or likely shortage is not resolved in the first year, the drug company may apply for an extension of the rebate reduction for a second year. Reductions for a severe supply chain disruption or likely shortage are limited to two consecutive years.

Q: Why is there a reconciliation process?

Per statute, CMS must provide a method and process to adjust the calculation of the rebate amount for a Part D rebatable drug for an applicable period to account for revisions to the number of units dispensed submitted by a PDP sponsor of a prescription drug plan or a Medicare Advantage (MA) organization offering an MA-PD plan. The statute specifies that, CMS must reconcile any underpayments in the rebate amount paid by the manufacturer of the applicable Part D rebatable drug due to such an adjustment. To fulfill this statutory obligation and to address the accuracy of the rebate amount, CMS will conduct regular reconciliations under the Part D Drug Inflation Rebate Program. CMS also believes conducting a reconciliation for the Part B Drug Inflation Rebate Program is important to ensure the accuracy of the rebate amount and for programmatic alignment with the Part D Drug Inflation Rebate Program.

Q: What will be reconciled?

CMS will reconcile the rebate amount for Part B and Part D inflation rebates. For Part B inflation rebates, CMS will reconcile the rebate amount to include updated information about key data elements included in the calculation of the rebate amount. Twelve months after the receipt of the Rebate Report, CMS will provide to the manufacturers a reconciled rebate amount with restatements, as applicable, of the data elements included in the rebate calculation and the reconciled total rebate amount.

For Part D inflation rebates, CMS will provide two regular reconciliations of the rebate amount to occur 12 months and 36 months after CMS issues the Rebate Report. In these reconciliations, CMS will provide manufacturers with restatements, as applicable, of the data elements included in the rebate calculation. The updated calculation will reflect the reconciled rebate amount.

Determination of Rebate Reduction Amount for Part B or Part D Rebatable Drugs

	Drug Shortage	Severe Supply Chain Disruption	Likely to be in Shortage
Eligibility for a Rebate Reduction	Part B or Part D rebatable drug	Part B or Part D rebatable biosimilar or generic Part D rebatable drug for which a drug company submits a request to CMS	Generic Part D rebatable drug for which a drug company submits a request to CMS
Process to Request a Rebate Reduction	No request required. CMS will monitor the FDA shortage lists	A drug company must email CMS and submit a Severe Supply Chain Disruption Rebate Reduction Request, or Extension Request, with supporting documentation in accordance with the information collection request approved under OMB control number 0938-1474	A drug company must email CMS and submit a Likely to be in Shortage Rebate Reduction Request, or Extension Request, with supporting documentation in accordance with the information collection request approved under OMB control number 0938-1474
Deadline for Initial Request		Within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began for a natural disaster or other unique or unexpected event occurring on or after August 2, 2024	Before the start of the applicable period in which the generic Part D rebatable drug is likely to be in shortage
Deadline for Extension Request		At least 60 calendar days before the start of the second applicable period or fifth calendar quarter in which the Part B or Part D rebatable biosimilar or generic Part D rebatable drug continues to be affected by the severe supply chain disruption	At least 60 calendar days before the start of the second applicable period in which the generic Part D rebatable drug is likely to be in shortage
Duration of Reduction	Indefinite for as long as drug is “currently in shortage” on an FDA shortage list; the reduction is based on the amount of time a drug is “currently in shortage” and decreases over time	One year; drug company may request an extension of the reduction for an additional year for up to two consecutive years total	

[3] In cases where the initial request for a generic Part D rebatable drug or Part D rebatable biosimilar is made less than 60 calendar days before the end of an applicable period such that the initial rebate reduction applied to the next applicable period rather than the applicable period in which the event that caused the severe supply chain disruption occurred or began, the Extension Request must be submitted at least 60 calendar days prior to the end of that next applicable period in which the initial reduction applied

Determination of Rebate Reduction Amount for Part B or Part D Rebatable Drugs

	Drug Shortage		Severe Supply Chain Disruption	Likely to be in Shortage
First year[4]	25%	75%	75%	75%
Second year	10%	50%	75%	75%
Subsequent years	2%	25%	N/A	N/A
Application of Reduction[5]	For a Part B rebatable drug, CMS will apply the rebate reduction to all of the NDCs under the relevant HCPCS code(s) if any NDC-10 assigned to the HCPCS code(s) is currently in shortage For a Part D rebatable drug, CMS will apply the rebate reduction to the entire Part D rebatable drug at the NDC-9 level if any NDC-10 for a Part D rebatable drug is currently in shortage[6]		For a Part B rebatable biosimilar, CMS will apply the rebate reduction to all the NDC-11s under the relevant HCPCS code if CMS grants a drug company's request for an NDC-11 For a generic Part D rebatable drug or biosimilar, CMS will apply the rebate reduction to the entire generic Part D rebatable drug or biosimilar at the NDC-9 level if CMS grants a drug company's request for an NDC-11	For a generic Part D rebatable drug, CMS will apply the rebate reduction to the entire generic Part D rebatable drug at the NDC-9 level if CMS grants a drug company's request for an NDC-11

Note: Generic drugs are not Part B rebatable drugs. The scope of generic drugs subject to Part D drug inflation rebates is limited to sole-source generic drugs. Multi-source generic drugs are not Part D rebatable drugs.

[4] As clarified in the final rule, CMS will apply the greatest rebate reduction to the first calendar quarter or applicable period that a covered Part B or Part D drug is currently in shortage, regardless of whether the drug meets the definition of a Part B or Part D rebatable drug or is subject to the rebate amount, starting with the calendar quarter that begins January 1, 2023, or applicable period that begins October 1, 2022. Similarly, CMS will apply a severe supply chain disruption or likely to be in shortage rebate reduction beginning with the calendar quarter or applicable period for which the reduction request was granted, regardless of whether the drug meets the definition of a Part B or Part D rebatable drug or is subject to a rebate amount in that calendar quarter or applicable period.

[5] Although the NDC information used for rebate reductions for drugs currently in shortage are applied based on the NDC-10 level, a drug company requesting a rebate reduction based on a severe supply chain disruption or likely shortage should submit information at the NDC-11 level.

[6] For the purposes of this Fact Sheet, CMS uses the term "currently in shortage" to refer to Part B or Part D rebatable drugs that are in the status of "currently in shortage" on the CDER shortage list, as well as biological products listed on CBER's current shortages list.

Q: What are the key dates for implementation of this program?

- **October 1, 2022 –** The start of the first 12-month applicable period for which drug companies will be required to pay rebates to Medicare if their prices for certain Part D drugs increase faster than the rate of inflation over the 12-month period.
- **December 20, 2022 –** CMS issued its first inflation rebate guidance for Medicare providers and suppliers regarding reporting the 340B modifier for the Part B inflation rebates.
- **January 1, 2023 –** The start of the first quarter for which drug companies will be required to pay rebates to Medicare if prices for certain Part B drugs increase faster than the rate of inflation
- **February 9, 2023 –** CMS issued initial guidance with a 30-day comment period on key topics to implement the Medicare Prescription Drug Inflation Rebate Program.
- **March 11, 2023 –** The 30-day comment period on key topics to implement the Medicare Prescription Drug Inflation Rebate Program closed.
- **April 1, 2023 –** Beginning on this date, people with Traditional Medicare and Medicare Advantage started paying a lower coinsurance for certain Part B drugs if the drug's price increased faster than the rate of inflation in a benchmark quarter.
- **December 14, 2023 –** CMS issued revised guidance to implement the Medicare Prescription Drug Inflation Rebate Program and issued revised guidance for Medicare providers and suppliers regarding reporting the 340B modifier for the Part B inflation rebates.
- **July 10, 2024 –** CMS issued a proposed rule to codify policies established in the revised Medicare Prescription Drug Inflation Rebate Program Guidance and propose new and revised policies to further implement the program.
- **September 9, 2024 –** The date the comment period closes for interested parties to comment on the proposed rule.
- **November 1, 2024 –** CMS issued a final rule to codify policies established in the revised Medicare Prescription Drug Inflation Rebate Program Guidance, as well as new and revised policies to further implement the program.
- **September 30, 2025 –** The date by which CMS must invoice drug companies for the Part B inflation rebates they owe Medicare for applicable calendar quarters in calendar years 2023 and 2024.
- **December 31, 2025 –** The date by which CMS must invoice drug companies for the Part D inflation rebates they owe Medicare for the 12-month applicable periods beginning October 1, 2022 and October 1, 2023.

More information on the Medicare Prescription Drug Inflation Rebate Program:
https://www.cms.gov/inflation-reduction-act-and- medicare/inflation-rebates-medicare