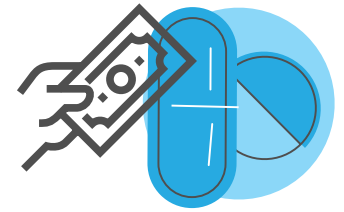


Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Revised Guidance



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 lower the cost of health insurance for American families and give peace of mind to 50 million seniors and people with disabilities by placing an annual out-of-pocket cap on Medicare prescription drug costs.

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, this 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 new program improve Medicare?

The Medicare Prescription Drug Inflation Rebate Program will lead to a stronger Medicare program for current and future enrollees 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 under 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 between the initial guidance and revised guidance for the Medicare Prescription Drug Inflation Rebate Program?

The initial program guidance published on February 9, 2023, voluntarily sought public comment on aspects of the requirements and procedures for implementing the Medicare Prescription Drug Inflation Rebate Program for Part B and Part D. On December 14, 2023, CMS published revised guidance with changes from the initial guidance to provide clarification, improve understanding of operational processes, and foster an effective inflation rebate program, such as:

- Additions to describe how CMS will reduce the inflation rebate amount for a Part B or Part D rebatable drug on a Food and Drug Administration (FDA) drug shortage list (e.g., CMS clarified that the inflation rebate for a drug in shortage will be reduced based on how long the drug is in shortage, with a greater reduction for plasma-derived products and sole-source Part D rebatable generic drugs);

- Revisions to reflect that CMS will apply a time-limited, standard reduction in the rebate amount when there is a severe supply chain disruption for a Part B or Part D rebatable biosimilar or Part D rebatable generic drug or when a Part D rebatable generic drug is likely to be in shortage;
- Additions to describe that CMS may consider a policy to exclude from Part B inflation rebate calculations units of discarded drugs or biologicals for which drug companies separately owe a discarded drug refund in future rulemaking;
- Clarifications to the methods CMS will use to calculate inflation rebate amounts in cases where certain data are not reported by drug companies;
- Clarifications to the process CMS will use to report the inflation rebate amount to drug companies;
- Additional detail on the process CMS will implement to issue Rebate Reports for calendar quarters in 2023 and 2024 for Part B rebatable drugs and for the 12-month applicable periods starting October 1, 2022, and October 1, 2023, for Part D rebatable drugs; and
- Additions of example calculations to illustrate how CMS will calculate inflation rebate amounts.

Q: Will CMS provide any additional information on implementation of the Inflation Rebates Program?

CMS may supplement this guidance with further program instruction or engage in rulemaking to explain how these policies will be implemented.

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 Medicare Prescription Drug 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 new program. One tool used by CMS to solicit feedback from interested parties was the 30-day comment period for the initial guidance, which concluded on March 11, 2023. CMS received 37 timely comment letters in response to the initial Part B guidance and 54 timely comment letters in response to

the initial Part D 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 will post 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> by December 15, 2023.

CMS considered these comments when drafting the revised Part B and Part D guidance. CMS intends to address certain policies in future rulemaking, which will allow for additional public comment.

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 rebatable Part B or Part D 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 12-month 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 Part D generic drug facing a severe supply chain disruption or a generic Part D rebatable drug likely to be in shortage, the drug company may request a rebate reduction. The Table below provides the reduction percentages for Part B and Part D rebatable biosimilars and generic Part D rebatable drugs that face a severe supply chain disruption and generic Part D rebatable drugs that are likely to be in shortage. CMS will not apply any rebate reduction for drugs that are not in actual or likely shortage or experiencing a severe supply chain disruption.

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

	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 rebatable 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	Part D rebatable generic drug
First year	25%	75%	75%	75%
Second year	10%	50%	75%	75%
Subsequent years	2%	25%	N/A	N/A

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.

Q: What is the process for a drug company to request a rebate reduction for a Part B or Part D rebatable biosimilar or Part D rebatable generic drug when there is a severe supply chain disruption or for a Part D rebatable generic 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 Part D rebatable generic drug when there is a severe supply chain disruption or when a Part D rebatable generic drug is likely to be in shortage will be required to submit to CMS a request for a reduction along with supporting documentation. In accordance with the Paperwork Reduction Act of 1995 (PRA), CMS intends to propose a collection of information addressing information that must be submitted by a drug company in order to receive consideration for a rebate reduction under these policies, including the process steps for that submission.

If the drug company submits a timely and complete request and CMS determines, based on its review of the request and supporting documentation, that a reduction should be granted, then 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. The 75 percent rebate reduction is limited to two consecutive years total. Upon completion of the PRA process for the information collection, CMS intends to announce the deadline for manufacturers to submit their rebate reduction extension requests.

Q: What are the key dates for implementation of this new 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.

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 revised rebate guidance:

<https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare>