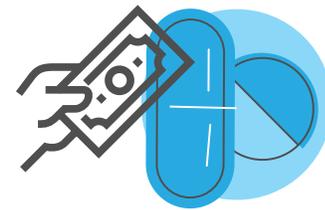


Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Initial Guidance



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 new 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 new 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 biologics with prices increasing faster than the rate of inflation, and provides for lower Part B beneficiary cost sharing on these drugs and biologics. In addition, the law establishes Medicare Part D prescription drug inflation rebates for certain drugs and biologics 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. The Inflation Rebate Program was authorized under the Inflation Reduction Act, which

lowers out-of-pocket drug costs for people with Medicare and improves the sustainability of the Medicare program for current and 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 may see lower out-of-pocket costs for certain Part B drugs and biologics with prices that have increased faster than the rate of inflation. For these drugs and biologics, the beneficiary coinsurance will be 20% of the inflation-adjusted payment amount, which will be less than what the beneficiary would pay in coinsurance otherwise.

Q: What's included in the initial program guidance for the Medicare Prescription Drug Inflation Rebate Program?

The initial program guidance issued on February 9, 2023 specifies the initial requirements and procedures for implementation of the new Medicare Prescription Drug Inflation Rebate Program.

CMS is seeking comment for the implementation of the Part B inflation rebates on topics such as:

- the process CMS intends to use to determine the number of drug units for calculating rebates;
- the process CMS intends to use to identify and remove 340B units for calculating rebates;
- the process CMS intends to use to identify and remove units for which a Medicaid drug rebate was paid for a covered outpatient drug;
- operational considerations related to the inclusion of units furnished to beneficiaries who are enrolled in Medicare Advantage plans;
- the processes CMS intends to use to reduce or waive the rebate amount in the case of a drug shortage or severe supply chain disruption;
- the process CMS intends to use to allocate the financial responsibility for the rebate amount for a calendar quarter where there is more than one manufacturer of the Part B rebatable drug; and

- the process CMS intends to use to ensure the integrity of the rebate determination process.

CMS is seeking comment for the implementation of the Part D inflation rebates on topics such as:

- options to identify the Part D rebatable drug billing units on the prescription claim and PDE file to assure that manufacturers are being accurately billed for Part D drug inflation rebates;
- options for methods to identify 340B units to exclude them from Part D rebatable drug units beginning in 2026;
- options to bill manufacturers in the future for Part D inflation rebates for Part D rebatable drugs of manufacturers that do not have an agreement in effect under the Medicaid Drug Rebate Program (MDRP), as well as Part D rebatable drugs that are not covered outpatient drugs under the MDRP;
- the processes CMS intends to use to reduce or waive the rebate amount in the case of a drug shortage or severe supply chain disruption;
- the mechanisms CMS intends to use to ensure integrity of the Part D drug inflation rebate invoicing process, including the use of Preliminary Rebate Reports and Preliminary True-Up Reports; and
- the process CMS intends to use to impose Civil Monetary Penalties (CMPs) on manufacturers that fail to pay rebates
- penalties on manufacturers that fail to pay rebates.

More information on how to submit comments can be found in the initial guidance. Comments received by March 11, 2023, will be considered.

Q: Can the public provide input on this new program?

Public feedback is critical to the success of the Medicare Prescription Drug Inflation Rebate Program, and this initial guidance is one tool, among many, CMS will use to ensure interested parties know when and how they can make their voices heard on implementation of the new drug law.

More information:

[CMS.gov/inflation-reduction-act-and-medicare](https://www.cms.gov/inflation-reduction-act-and-medicare)

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

- **October 1, 2022** – The start of the first 12-month 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 issues 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 closes.
- **April 1, 2023** – Beginning on this date, people with Traditional Medicare and Medicare Advantage may pay a lower coinsurance for certain Part B drugs if the drug’s price increased faster than the rate of inflation in a benchmark quarter.
- **Q4 2023** – CMS expects to issue revised guidance to implement the Medicare Prescription Drug Inflation Rebate Program. Timing may be adjusted as necessary.
- **September 30, 2025** – The date by which CMS must invoice drug companies for the Part B inflation rebates they owe Medicare for calendar quarters in 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 periods beginning October 1, 2022 and October 1, 2023.

