CMS Issues Revised Program Guidance on the Medicare Inflation Rebate Program

On December 14, 2023, the Centers for Medicare and Medicaid Services (CMS) issued revised guidance on the Inflation Reduction Act's requirements for a Medicare Inflation Rebate Program (Revised Guidance). Among the revisions, the Revised Guidance discusses:

- Key requirements and procedures for calculating rebates and invoicing manufacturers under the Medicare Prescription Drug Inflation Rebate Program under Medicare Part B and Part D.

- The list of 48 prescription drugs for which Part B beneficiary coinsurances may be lower between January 1, 2024 – March 31, 2024.

- How CMS will handle the identification of generic Part D rebatable drugs and exclude from the rebate calculation any units dispensed on or after the date that a generic drug no longer meets the definition of a Part D rebatable drug.

- How CMS will calculate the reduction in rebate amount for a rebatable drug that is described as "currently in shortage" by the Food and Drug Administration (FDA) or when there is a severe supply chain disruption, such as that caused by a natural disaster or other unique or unexpected event.

- The process CMS will use to report the rebate amount and adjustments to the manufacturer of a Part D rebatable drug.

- That manufacturers that do not pay the Part D drug inflation rebate amount owed for an applicable period for a Part D rebatable drug within 30 calendar days of receiving the Rebate Report may be subject to a Civil Monetary Penalty (CMP).

- The notice and appeals procedures for CMPs.

- Example data and calculations to illustrate how CMS will calculate the Part D drug inflation rebate amount.

CMS continues to evaluate different options for identifying 340B units and will finalize a policy for excluding 340B units by plan year 2026.

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More on This Topic:

- [Revised Guidance](#)
- [Notice](#)
- [Fact Sheet](#)

For questions, please reach out to [Vicky Jucelin](#).