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ALERT

Initial Guidance Regarding the Inflation Reduction Act Medicare Prescription Drug Inflation Rebate Program

February 13, 2023

The Inflation Reduction Act of 2022 (IRA) establishes the Medicare Prescription Drug Inflation Rebate Program, which requires drug companies to pay rebates, referred to as inflation rebates, to Medicare if they raise their prices for certain Medicare Part B and Medicare Part D drugs faster than the rate of inflation. On February 9, 2023, the Centers for Medicare & Medicaid Services (CMS) released initial guidance specifying the initial requirements and procedures for implementation of the Medicare Prescription Drug Inflation Rebate Program for Medicare Part B and Medicare Part D.

CMS is seeking public comment on a number of aspects of its initial guidance, set forth below. Comments are due to CMS on March 11, 2023.

With respect to the implementation of Part D inflation rebates, CMS is seeking comment on the following:

- 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;

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- 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;
- The process CMS intends to use to impose Civil Monetary Penalties (CMPs) on manufacturers that fail to pay rebates; and
- Penalties on manufacturers that fail to pay rebates.

With respect to the implementation of Part B inflation rebates, CMS is seeking comment on the following topics:

- 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.

More information about the initial guidance can be found on CMS's recently published fact sheet and on the dedicated IRA section of the CMS website.

Wiley's multidisciplinary team of legal experts on the Medicare Prescription Drug Inflation Rebate Program is closely monitoring IRA developments and is available to assist with any questions that may arise. For more information about the Medicare Prescription Drug Inflation Rebate Program or the IRA generally, please contact one of the attorneys listed in this alert.