Discarded Drug Program Overview

Generally, when a separately payable drug from a single-dose container or single-use package is administered to an individual enrolled in Medicare Part B, Medicare pays the provider or facility for both administered and discarded amounts of the drug, up to the full labeled amount of the product. Section 90004 of the Infrastructure Investment and Jobs Act (IIJA) (Pub. L. 117–58, November 15, 2021) amended section 1847A of the Social Security Act (the Act) by adding provisions that require manufacturers to provide a refund to CMS for certain discarded amounts from a single-dose container or single-use package drug. Generally, the refund amount is the amount of payment for discarded amounts of a refundable drug (described below) that exceeds an applicable percentage, which is required to be at least 10 percent of total charges for the drug in a given calendar quarter. For specific calculations for new refund quarters and updated refund quarters, refer to 42 CFR § 414.940(c).

Criteria

Manufacturers required to refund CMS for discarded amounts are those that manufacture refundable single-dose container or single-use package drugs (hereinafter referred to as refundable drugs), which are defined as single-source drugs, biologicals, or biosimilar biological products for which payment has been made under Medicare Part B and that are furnished from a single-dose container or single-use package. Exclusions from the definition of refundable drugs, as described in 42 CFR § 414.902, and 87 FR 69719, include:

- Radiopharmaceuticals (therapeutic or diagnostic) or imaging agents
- Certain drugs or biologicals requiring filtration during the preparation process (prior to dilution and administration) for which unused portions must be discarded after the filtration process
- Drugs approved or licensed by FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first reported sale for any NDCs of such drug

Reporting

CMS requires providers and suppliers to use the JW modifier on all claims for separately payable drugs with discarded drug amounts from single-use containers or single-use packages separately payable under Part B to identify and monitor billing and payment for discarded amounts of drugs. In submitting claims to Medicare, providers must indicate the number of billing units of the drug that were discarded using the JW modifier. Use of the JZ modifier is required on claims for drugs from single-dose containers or single-use packages separately payable under Part B when there are no discarded amounts. For more information on the JZ and JW modifiers, please review the JW - JZ Modifiers FAQ (PDF) document.

Calculation

The refund amount is the amount by which the product of the number of discarded units and the payment limit exceeds the applicable percentage of the estimated total allowed charges for the drug for a given quarter, which is required to be at least 10 percent of total charges for the drug in a given calendar quarter (42 CFR § 414.940). Medicare Part B drug payment limits are published and effective on a quarterly basis. CMS uses the published payment limits to calculate the refund due for each new refund quarter by:

- Step (1): Multiplying the total number of discarded drug units based on the JW modifier submitted on all applicable claims for the quarter and the drug's payment limit, as determined under section 1847A(b)(1)(B) or (C) of the Act, for the quarter,
- Step (2): Multiplying the applicable percentage by the total allowed charges for the drug for the quarter, and
- Step (3): Subtracting the product calculated in step (2) from the product calculated in step (1).

Please note: Applicable percentages may vary based on refundable drugs' unique circumstances and are described further in 42 CFR § 414.940(d). Manufacturers may apply for an adjustment to their drug's applicable percentage. Application instructions are provided on the CMS Discarded Drugs website.

Billing

Manufacturer reports will be issued through the Manufacturer Payment Portal (MPP). CMS will issue an annual report to all manufacturers of refundable drugs, which will include the total number of units discarded based on the JW modifier and the refund amount calculated for each quarter. Manufacturers have an opportunity to submit an error report to CMS within 30 days after receipt of their report.

Payment

Manufacturers will be able to pay any refunds due through the MPP. Payment for refund amounts specified in the refund report is due by December 31 of the year in which the report is sent, except for the Initial Report for calendar quarters in 2023, which is due no later than February 28, 2025. If an error report is pending, payment will be due on the due date of the initial report or no later than 30 days after the error report has been resolved, whichever is later. (42 CFR § 414.940(b)(1) and (2)).

Enforcement and Penalty

Manufacturers of refundable drugs who do not comply with the requirement set forth at 42 CFR § 414.940(b) are subject to a civil money penalty of 125 percent of the assessed refund obligation as described in 42 CFR § 414.940(g).

For more information visit: CMS Discarded Drugs Website
Contact us at: DiscardedDrugs@cms.hhs.gov
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