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 labeled amount of the product. Section 1847A(h) of the Social Security Act (the Act) requires manufacturers to pay a refund to CMS (to be deposited into the Federal Supplementary Medical Insurance Trust Fund) for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter referred to as a refundable drug). As stated in 87 FR 69711, the refund amount is generally the amount of the discarded drug that exceeds an applicable percentage (required to be at least 10 percent) of total charges for the drug in a given calendar quarter.

Criteria

Manufacturers subject to the discarded drug refund are those that manufacture a refundable drug, which is defined in Section 1847A(h)(8) of the Act and at 42 CFR § 414.902, as a single-source drug, biological, or biosimilar biological product for which payment has been made under Medicare Part B and that are furnished from a single-dose container or single-use package based on the Food and Drug Administration (FDA)-approved labeling or product information.

The following are excluded from the definition of refundable drug:

- 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 National Drug Codes (NDCs) of such drug
- A drug approved or licensed by FDA on or after November 15, 2021 and for which the date the drug was first marketed (as reported to CMS) does not adequately approximate the date of first payment under Part B due to an applicable national coverage determination, until the last day of the sixth full quarter for which the drug has been covered and paid under Medicare Part B for the first NDC assigned to the billing and payment code of such drug

Reporting Discarded Amounts

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, which are separately payable under Part B. In submitting claims to Medicare, providers must indicate the number of billing units of the drug that were discarded using the JW modifier on a claim line along with a claim line with the number of billing units of the drug that were administered (without a 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 of discarded drug 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. The estimated total allowed charges for a given quarter are determined by multiplying the total number of units of the drug paid during the quarter (excluding units that were packaged for payment), and the ASP-based payment limit effective during that quarter. Medicare Part B drug payment limits are published and effective on a quarterly basis and CMS uses the ASP-based payment limits to calculate the discarded drug refund due for each quarter.

New Refund Quarters

For new refund quarters, as defined at 42 CFR § 414.902, CMS calculates the refund amount due 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).

Updated Refund Quarters

To account for any lagged claims processed after refund amounts were calculated for new refund quarters, CMS calculates the refund amount due for an updated refund quarter, as defined at 42 CFR § 414.902, by completing steps 1 through 3 listed above and then:

- Step (4): Subtracting the refund amount already paid for such refundable drug for such quarter.

If the resulting refund amount due is negative, the amount will be netted from refunds owed for other updated and new refund quarters included in the same report as such updated refund quarter.

Note: Section 1847A(h)(3) of the Act specifies that the applicable percentage is 10 percent, but authorizes CMS to increase this percentage as appropriate, through notice and comment rulemaking, in the case that a refundable drug has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act. Products with an increased applicable percentage 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 page on the ASP website.

Timing and Report Content

Discarded drug refund 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 (1) the total number of units discarded based on the JW modifier and (2) the refund amount due for each quarter. Manufacturers have an opportunity to submit an error report to CMS within 30 days after issuance 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. 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, as stated at 42 CFR § 414.940(b).

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 the CMS Discarded Drugs webpage.
Contact us at DiscardedDrugs.cms.hhs.gov
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