

§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.

(a) *Provision of information to manufacturers*—(1) *In general.* For each calendar quarter beginning on or after January 1, 2023, CMS reports to each manufacturer (as defined in § 414.802) of a refundable single-dose container or single-use package drug the following for the calendar quarter:

(i) Information on the total number of billing units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined by the JW modifier (or any successor modifier that includes the same data).

(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (a)(3) of this section.

(iii) Reports will include information in paragraphs (a)(1)(i) and (ii) of this section for new refund quarters and updated refund quarters (as defined at § 414.902).

(iv) For purposes of this section, the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(2) *Exclusion of units of packaged drugs.* The total number of billing units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of paragraph (a)(1) of this section, and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (c)(2) of this section, shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

(3) *Report Timing.* Reports are sent once annually.

(b) *Manufacturer requirement.* For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, pay a refund that is equal to the amount determined in accordance with paragraph (c) of this section for such drug for such quarter.

(1) Refund amounts for which the manufacturer is liable, pursuant to

this paragraph, must be paid by December 31 of the year in which the report described in paragraph (a) of this section is sent, except that refund amounts for which the manufacturer is liable, pursuant to this paragraph, for amounts in the initial report for calendar quarters in 2023 must be paid no later than February 28, 2025.

(2) In the case that a disputed report results in a refund amount due, refund amounts that the manufacturer is liable for pursuant to this paragraph shall be paid no later than the dates specified in paragraph (b)(1) of this section or 30 days following the resolution of the dispute, whichever is later.

(3) Amounts paid as refunds pursuant to this paragraph shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act.

(c) *Refund amount.* The amount of the refund specified in this paragraph is with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code (except as provided in paragraph (c)(4) of this section) for:

(1) A new refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter;

(ii) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

(2) The refund amount owed by a manufacturer for an updated refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such updated refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

(ii) Exceeds the difference of:

(A) An amount equal to the applicable percentage of the estimated total allowed charges for such a drug during the updated refund quarter; and

(B) The refund amount already paid for such refundable drug for such quarter.

(3) Negative refund amount for an updated refund quarter. If the refund amount described in paragraph (c)(2) of this section 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.

(4) Exception when there are multiple manufacturers. If there is more than one manufacturer of a refundable single-dose container or single-use package drug for a quarter, the refund amount for which a manufacturer is liable is an amount equal to the estimated amount (if any) by which—

(i) The product of the amount calculated in paragraph (c)(1) of this section and the percentage of billing unit sales (of the applicable billing and payment code attributed to the National Drug Code; exceeds:

(ii) The product of the amount in paragraph (c)(2) of this section and percentage of billing unit sales of the applicable billing and payment code attributed to the National Drug Code.

(iii) The number of billing unit sales for each NDC is the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC.

(d) *Applicable percentage.* For purposes of paragraph (c) of this section, and except as provided in paragraph (e) of this section, the applicable percentage is:

(1) 10 percent, unless specified otherwise in this section.

(2) 35 percent for a drug that is constituted with a hydrogel and has variable dosing based on patient-specific characteristics.

(3) 90 percent for a drug with a low volume dose (as defined at §414.902) contained within 0.1 mL or less.

(4) 45 percent for a drug with a low volume dose (as defined in §414.902) contained within 0.11 mL up to 0.4 mL.

(5) 26 percent for a drug designated an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition (or diseases or conditions) and approved by the FDA only for one or more indications within such designated rare disease or condition (or diseases or conditions) and is furnished to fewer than 100 unique beneficiaries per calendar year. A drug is furnished to fewer than 100 unique beneficiaries per calendar year when one of the following two conditions is met:

(i) The number of unique beneficiaries to whom the drug is furnished is less than 100 during the calendar year in which the refund quarter occurs; or

(ii) Either:

(A) In the case of a drug for which 3 or more years of data is available, the average of unique beneficiaries per year to whom the drug is furnished during the calendar year in which the refund quarter occurs and the 2 previous calendar years is less than 100; or

(B) In the case of a drug for which at least 2 but less than 3 years of data is available, the average of unique beneficiaries per year to whom the drug is furnished during the calendar year in which the refund quarter occurs and the previous calendar year is less than 100.

(e) *Application process for increased applicable percentage.* Manufacturers may submit an application to CMS requesting consideration of an increased applicable percentage for purposes of paragraph (c) of this section because of the drug's unique circumstances. The process for submitting such an application is as follows:

(1) *Application.* An application must include:

(i) A written request that a drug be considered for an increased applicable percentage based on its unique circumstances;

(ii) FDA-approved labeling for the drug, or, if the drug is not approved by the February 1 application deadline described in paragraph (e)(2) of this section, documentation of FDA acceptance of the application for review;

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(iii) Justification for the consideration of an increased applicable percentage based on such unique circumstances; and

(iv) Justification for the requested applicable percentage.

(2) *Application timeline.* An application must be submitted in a form and manner specified by CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply. An application for a drug that is not FDA-approved by February 1 must have FDA approval by August 1 and the manufacturer must notify and submit the FDA-approved label to CMS by September 1 of the calendar year prior to the year the increased applicable percentage would apply.

(3) *Application processing.* Following a review of timely applications, CMS will summarize its analyses of applications and propose appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage for purposes of paragraph (c) of this section beginning as of the following January 1.

(f) *Dispute resolution.* Each manufacturer has an opportunity to dispute information in the report described in paragraph (a) of this section by submitting an error report as described in this paragraph.

(1) *Error report information.* To assert that there have been one or more errors in the report, a manufacturer must submit a dispute with each asserted error and provide the following information—

(i) Manufacturer name and address;

(ii) The name, telephone number, and email address of one or more employees or representatives of the manufacturer.

(iii) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation;

(iv) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of why the manufacturer believes that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

(2) *Form, manner, and timing of submission.* Each manufacturer asserting an

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error must submit its error report(s), in the form and manner specified by CMS, within 30-days after the issuance of the report.

(g) *Enforcement—(1) Manufacturer audits.* Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this section shall be subject to periodic audit with respect to such drug and such refunds.

(2) *Civil money penalty.* The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (b) of this section for such drug for a calendar quarter in an amount equal to the sum of—

(i) The amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

(ii) 25 percent of such amount.

[87 FR 70226, Nov. 18, 2022, as amended at 88 FR 15920, Mar. 15, 2023; 88 FR 79532, Nov. 16, 2023]

Subpart L—Supplying and Dispensing Fees

§ 414.1000 Purpose.

This subpart implements section 1842(o)(2) and section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, by specifying a supplying fee for drugs and biologicals covered under Part B of Title XVIII of the Act that are described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

[69 FR 66425, Nov. 15, 2004]

§ 414.1001 Basis of payment.

(a) *Supplying fees.* Beginning in CY 2006—

(1) A supplying fee of \$24 is paid to a pharmacy for the first prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(2) A supplying fee of \$16 is paid to a pharmacy for each prescription following the first prescription (as specified in paragraph (a)(1) of this section)