

(3) For purposes of paragraph (c)(1)(ii) of this section, the term “applicable percentage” means 10 percent except where an increased applicable percentage is applied in paragraph (d) of this section.

(d) *Treatment of drugs that have unique circumstances.* For purposes of paragraph (c)(1)(ii) of this section, the term “applicable percentage” means

(1) 35 percent for drugs that are reconstituted with a hydrogel and have variable dosing based on patient-specific characteristics

(2) [Reserved]

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

(f) *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]

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) 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.

(3) A separate supplying fee is paid to a pharmacy for each prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

(b) *Supplying fees following transplant.* Beginning CY 2006—(1) A supplying fee of \$50 is paid to pharmacy for the initial supplied prescription of drugs and