

§ 414.1000

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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

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)

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 biologicals described in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a patient during the first 30-day period following a transplant.

(2) A supplying fee of \$16 is paid to a pharmacy for each prescription following an initial prescription after a transplant (as specified in paragraph (b)(1) of this section) of drugs and biologicals describe in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(c) *30-day dispensing fees.* Beginning CY 2006—(1) A dispensing fee of \$57 is paid to a supplier to the extent that the prescription is for the initial dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(2) Except for supplied inhalation drugs that meet criteria described in paragraph (c)(1) of this section, a dispensing fee of \$33 is paid for each dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(d) *90-day dispensing fee.* Beginning CY 2006, a dispensing fee of \$66 is paid to a supplier for each dispensed 90-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 90-day supply.

[70 FR 70334, Nov. 21, 2005]

Subpart M—Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services

SOURCE: 72 FR 66404, Nov. 27, 2007, unless otherwise noted.

§414.1100 Basis and scope.

This subpart implements sections 1834(k)(1) and (k)(3) of the Act by specifying the payment methodology for comprehensive outpatient rehabilitation facility services covered under Part B of Title XVIII of the Act that are described at section 1861(cc)(1) of the Act.

§414.1105 Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) services.

(a) *Payment under the physician fee schedule.* Except as otherwise specified under paragraphs (b), (c), (d), and (e) of this section payment for CORF services, as defined under §410.100 of this chapter, is paid the lesser of 80 percent of the following:

(1) The actual charge for the item or service; or

(2) The nonfacility amount determined under the physician fee schedule established under section 1848(b) of the Act for the item or service.

(b) *Payment for physician services.* No separate payment for physician services that are CORF services under §410.100(a) of this chapter will be made.

(c) *Payment for supplies and durable medical equipment, prosthetic and orthotic devices, and drugs and biologicals.* Supplies and durable medical equipment that are CORF services under §410.100(l) of this chapter, prosthetic device services that are CORF services under §410.100(f), orthotic devices that are CORF services under §410.100(g) of this chapter and drugs and biologicals that are CORF services under §410.100(k) of this chapter are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (d); or

(2) The amount determined under the DMEPOS fee schedule established