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TITLE 42--PUBLIC HEALTH
HUMAN SERVICES

PART 413--PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

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Subpart H--Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

Sec. 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that--

- (1) Differentiates between hospital-based facilities and independent ESRD facilities;
- (2) Effectively encourages efficient delivery of dialysis services; and
- (3) Provides incentives for increasing the use of home dialysis.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, CMS considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under Sec. 498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under Sec. 498.3 of this chapter. For purposes of rate-setting and payment under this section, CMS determines that a facility is hospital-based if the--

- (1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;
- (2) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;
- (3) Facility personnel policies and practices conform to those of the hospital;
- (4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and
- (5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, CMS does not consider--

- (1) An agreement between a facility and a hospital concerning patient referral;
- (2) A shared service arrangement between a facility and a hospital; or
- (3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in Sec. 414.313(c) of this chapter), the prospective rate

(as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in Sec. 414.313.

(f) *Erythropoietin/Epoietin (EPO)*. (1) When EPO is furnished to an ESRD patient by a Medicare-approved ESRD facility or a supplier of home dialysis equipment and supplies, payment is based on the amount specified in paragraph (f)(3) of this section.

(2) The payment is made only on an assignment basis, that is, directly to the facility or supplier, which must accept, as payment in full, the amount that CMS determines.

(3) CMS determines the payment amount in accordance with the following rules:

(i) The amount is prospectively determined, as specified in section 1881(b)(11)(B)(ii) of the Act, reviewed and adjusted by CMS, as necessary, and paid to hospital-based and independent dialysis facilities and to suppliers of home dialysis equipment and supplies, regardless of the location of the facility, supplier, or patient.

(ii) If CMS determines that an adjustment to the payment amount is necessary, CMS publishes a Federal Register notice proposing a revision to the EPO payment amount and requesting public comment.

(iii) Any increase in this amount for a year does not exceed the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(iv) The Medicare payment amount is subject to the Part B deductible and coinsurance.

(g) *Additional payment for certain drugs*. In addition to the prospective payment described in this section, CMS makes an additional payment for certain drugs furnished to ESRD patients by a Medicare-approved ESRD facility. CMS makes this payment directly to the ESRD facility. The facility must accept the allowance determined by CMS as payment in full. Payment for these drugs is made as follows:

(1) *Hospital-based facilities*. CMS makes payments in accordance with the cost reimbursement rules set forth in this part.

(2) *Independent facilities*. CMS makes payment in accordance with the methodology set forth in Sec. 405.517 of this chapter for paying for drugs that are not paid on a cost or prospective payment basis.