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(i) Hospitalized and the physician elects to bill separately for services furnished during hospitalization; or

(ii) Not attended by the physician or his or her substitute for any reason, including when the physician is not available to furnish patient care or when the patient is not available to receive care.

(c) *Determination of payment amount.* The amount of payment for the MCP is determined under the Medicare physician fee schedule described in this part 414.

[55 FR 23441, June 8, 1990, as amended at 59 FR 63463, Dec. 8, 1994; 62 FR 43674, Aug. 15, 1997]

§ 414.316 Payment for physician services to patients in training for self-dialysis and home dialysis.

(a) For each patient, the carrier pays a flat amount that covers all physician services required to create the capacity for self-dialysis and home dialysis.

(b) CMS determines the amount on the basis of program experience and reviews it periodically.

(c) The payment is made at the end of the training course, is subject to the deductible and coinsurance provisions, and is in addition to any amounts payable under the initial or MCP methods set forth in §§ 414.313 and 414.314, respectively.

(d) If the training is not completed, the payment amount is proportionate to the time spent in training.

§ 414.320 Determination of reasonable charges for physician renal transplantation services.

(a) *Comprehensive payment for services furnished during a 60-day period.* (1) The comprehensive payment is subject to the deductible and coinsurance provisions and is for all surgeon services furnished during a period of 60 days in connection with a renal transplantation, including the usual preoperative and postoperative care, and for immunosuppressant therapy if supervised by the transplant surgeon.

(2) Additional sums, in amounts established on the basis of program experience, may be included in the comprehensive payment for other surgery performed concurrently with the transplant operation.

(3) The amount of the comprehensive payment may not exceed the lower of the following:

(i) The actual charges made for the services.

(ii) Overall national payment levels established under the ESRD program and adjusted to give effect to variations in physician's charges throughout the nation. (These adjusted amounts are the maximum allowances in a carrier's service area for renal transplantation surgery and related services by surgeons.)

(4) Maximum allowances computed under these instructions are revised at the beginning of each calendar year to the extent permitted by the lesser of the following:

(i) Changes in the economic index as described in § 405.504(a)(3)(i) of this chapter.

(ii) Percentage changes in the weighted average of the carrier's prevailing charges (before adjustment by the economic index) for—

(A) A unilateral nephrectomy; or

(B) Another medical or surgical service designated by CMS for this purpose.

(b) *Other payments.* Payments for covered medical services furnished to the transplant beneficiary by other specialists, as well as for services by the transplant surgeon after the 60-day period covered by the comprehensive payment, are made under the reasonable charge criteria set forth in § 405.502 (a) through (d) of this chapter. The payments for physicians' services in connection with renal transplantations are changed on the basis of program experience and the expected advances in the medical art for this operation.

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) *Equipment and supplies*—(1) *Basic rule.* Except as provided in paragraph (a)(2) of this section, Medicare pays for home dialysis equipment and supplies only under the prospective payment rates established at § 413.210.

(2) *Exception for equipment and supplies furnished prior to January 1, 2011.* If the conditions in subparagraphs (a)(2)(i) through (iv) of this section are met, Medicare pays for home analysis equipment and supplies on a reasonable

charge basis in accordance with subpart E (Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians) of part 405, but the amount of payment may not exceed the limit for equipment and supplies in paragraph (c)(2) of this section.

(i) The patient elects to obtain home dialysis equipment and supplies from a supplier that is not a Medicare approved dialysis facility.

(ii) The patient certifies to CMS that he or she has only one supplier for all home dialysis equipment and supplies. This certification is made on CMS Form 382 (the ''ESRD Beneficiary Selection'' form).

(iii) In writing, the supplier—

(A) Agrees to receive Medicare payment for home dialysis supplies and equipment only on an assignment-related basis; and

(B) Certifies to CMS that it has a written agreement with one Medicare approved dialysis facility or, if the beneficiary is also entitled to military or veteran's benefits, one military or Veterans Administration hospital, for each patient. (See part 494 of this chapter for the requirements for a Medicare approved dialysis facility.) Under the agreement, the facility or military or VA hospital agrees to the following:

(*1*) To furnish all home dialysis support services for each patient in accordance with part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. (§ 410.52 sets forth the scope and conditions of Medicare Part B coverage of home dialysis services, supplies, and equipment.)

(*2*) To furnish institutional dialysis services and supplies. (§ 410.50 sets forth the scope and conditions for Medicare Part B coverage of institutional dialysis services and supplies.)

(*3*) To furnish dialysis-related emergency services.

(*4*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are covered under the composite rate established at § 413.170 and to arrange for the laboratory to seek payment from the facility. The facility then includes these laboratory services in its claim for payment for home dialysis support services.

(*5*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are not covered under the composite rate established at § 413.170 and for which the laboratory files a Medicare claim directly.

(*6*) To furnish all other necessary dialysis services and supplies (that is, those which are not home dialysis equipment and supplies).

(*7*) To satisfy all documentation, recordkeeping and reporting requirements in part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. This includes maintaining a complete medical record of ESRD related items and services furnished by other parties. The facility must report, on the forms required by CMS or the ESRD network, all data for each patient in accordance with subpart U.

(iv) The facility with which the agreement is made must be located within a reasonable distance from the patient's home (that is, located so that the facility can actually furnish the needed services in a practical and timely manner, taking into account variables like the terrain, whether the patient's home is located in an urban or rural area, the availability of transportation, and the usual distances traveled by patients in the area to obtain health care services).

(C) Agrees to report to the ESRD facility providing support services, at least every 45 days, all data (meaning information showing what supplies and services were provided to the patient and when each was provided) for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

(b) *Support services*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, Medicare pays for support services only under the prospective payment rates established in § 413.210 of this chapter.

(2) *Exception for home support services furnished prior to January 1, 2011.* If the patient elects to obtain home dialysis equipment and supplies from a supplier that is not an approved ESRD facility, Medicare pays for support services, other than support services furnished

by military or VA hospitals referred to in paragraph (a)(2)(iii)(B) of this section, under paragraphs (b)(2) (i) and (ii) of this section but in no case may the amount of payment exceed the limit for support services in paragraph (c)(1) of this section:

(i) For support services furnished by a hospital-based ESRD facility, Medicare pays on a reasonable cost basis in accordance with part 413 of this chapter.

(ii) For support services furnished by an independent ESRD facility, Medicare pays on the basis of reasonable charges that are related to costs and allowances that are reasonable when the services are furnished in an effective and economical manner.

(c) Payment limits for support services, equipment and supplies, and notification of changes to the payment limits apply prior to January 1, 2011 as follows:

(1) *Support services.* The amount of payment for home dialysis support services is limited to the national average Medicare-allowed charge per patient per month for home dialysis support services, as determined by CMS, plus the median cost per treatment for all dialysis facilities for laboratory tests included under the composite rate, as determined by CMS, multiplied by the national average number of treatments per month.

(2) *Equipment and supplies.* Payment for home dialysis equipment and supplies is limited to an amount equal to the result obtained by subtracting the support services payment limit in paragraph (c)(1) of this section from the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent) of the national median payment as determined by CMS that would have been made under the prospective payment rates established in §413.170 of this chapter for hospital-based facilities.

(3) *Notification of changes to the payment limits.* Updated data are incorporated into the payment limits when the prospective payment rates established at §413.170 of this chapter are updated, and changes are announced by notice in the FEDERAL REGISTER without a public comment period. Revisions of the methodology for determining the limits are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[57 FR 54187, Nov. 17, 1992, as amended at 73 FR 20474, Apr. 15, 2008; 75 FR 49202, Aug. 12, 2010]

§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Prior to January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies. Effective January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to a Medicare-approved ESRD facility in accordance with the per treatment payment as defined in §413.230.

(b) After January 1, 2011, a home and self training amount is added to the per treatment base rate for adult and pediatric patients as defined in §413.230

[75 FR 49202, Aug. 12, 2010]

Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

§ 414.400 Purpose and basis.

This subpart implements competitive bidding programs for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

[72 FR 18084, Apr. 10, 2007]

§ 414.402 Definitions.

For purposes of this subpart, the following definitions apply:

Affected party means a contract supplier that has been notified that their DMEPOS CBP contract will be terminated for a breach of contract.

Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

Bidding entity means the entity whose legal business name is identified in the ''Form A: Business Organization Information'' section of the bid.