

provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with § 413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis service, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

- (i) Are not related to patient care for outpatient maintenance dialysis;
- (ii) Are for services or items specifically not reimbursable under the program;
- (iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or
- (iv) Are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

- (i) Section 413.157, Return on equity capital of proprietary providers;
- (ii) Section 413.420, Payment to independent organ procurement organizations and to histocompatibility laboratories for kidney acquisition costs;
- (iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and
- (iv) Sections 413.64, Payments to providers, and §§ 413.13, 413.30, 413.35, 413.40,

413.74, and §§ 415.55 through 415.70, § 415.162, and § 415.164 of this chapter, Principles of reimbursement for services by hospital-based physicians.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008; 87 FR 72287, Nov. 23, 2022]

#### § 413.200 [Reserved]

#### § 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in § 486.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal contractors. Medicare costs are based on the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The OPO must submit a request to the contractor for review and approval of these arrangements.

[62 FR 43668, Aug. 15, 1997, as amended at 71 FR 31046, May 31, 2006]

#### § 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

(a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in § 486.302 (only covered organs will be paid for on a reasonable cost basis).

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(b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal contractors.

(c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

### **§ 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.**

Except as noted in § 413.174(f), items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in § 413.217 of this part, are paid under the ESRD prospective payment system described in § 413.215 through § 413.235 of this part.

(a) *Qualifications for payment.* To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.

(b) *Payment for items and services.* CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and services defined in § 413.217 of this part either directly or under arrangements.

[75 FR 49199, Aug. 12, 2010]

### **§ 413.215 Basis of payment.**

(a) Except as otherwise provided under § 413.235 or § 413.174(f) of this part, effective January 1, 2011, ESRD facilities receive a predetermined per treatment payment amount described in § 413.230 of this part, for renal dialysis services, specified under section 1881(b)(14) of the Act and as defined in § 413.217 of this part, furnished to Medicare Part B fee-for-service beneficiaries.

(b) In addition to the per-treatment payment amount, as described in paragraph (a) of this section, the ESRD facility may receive payment for bad

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debts of Medicare beneficiaries as specified in § 413.89(h)(3).

[75 FR 49200, Aug. 12, 2010, as amended at 81 FR 77965, Nov. 4, 2016]

### **§ 413.217 Items and services included in the ESRD prospective payment system.**

The following items and services are included in the ESRD prospective payment system effective January 1, 2011:

(a) Renal dialysis services as defined in § 413.171; and

(b) Home dialysis services, support, and equipment as identified in § 410.52 of this chapter.

[75 FR 49200, Aug. 12, 2010]

### **§ 413.220 Methodology for calculating the per-treatment base rate under the ESRD prospective payment system effective January 1, 2011.**

(a) *Data sources.* The methodology for determining the per treatment base rate under the ESRD prospective payment system utilized:

(1) Medicare data available to estimate the average cost and payments for renal dialysis services.

(2) ESRD facility cost report data capturing the average cost per treatment.

(3) The lowest per patient utilization calendar year as identified from Medicare claims is calendar year 2007.

(4) Wage index values used to adjust for geographic wage levels described in § 413.231 of this part.

(5) An adjustment factor to account for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by ESRD facilities.

(b) *Determining the per treatment base rate for calendar year 2011.* Except as noted in § 413.174(f), the ESRD prospective payment system combines payments for the composite rate items and services as defined in § 413.171 of this part and the items and services that, prior to January 1, 2011, were separately billable items and services, as defined in § 413.171 of this part, into a single per treatment base rate developed from 2007 claims data. The steps to calculating the per-treatment base rate for 2011 are as follows:

(1) *Per patient utilization in CY 2007, 2008, or 2009.* CMS removes the effects