

date of the decision on which review is sought.

(2) The facility may not submit to the reviewing entity, whether it is the contractor or the PRRB, any additional information or cost data that had not been submitted to CMS at the time CMS evaluated the exception request.

(d) *Determining amount in controversy.* For purposes of determining PRRB jurisdiction under subpart R of part 405 of this chapter for the appeals described in paragraph (b) of this section—

(1) The amount in controversy per treatment is determined by subtracting the amount of program payment from the amount the facility requested under § 413.180; and

(2) The total amount in controversy is calculated by multiplying the amount in controversy per treatment by the projected number of treatments for the exception request period.

[62 FR 43668, Aug. 15, 1997, as amended at 81 FR 77965, Nov. 4, 2016]

§ 413.195 Limitation on Review.

Administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following is prohibited: The determination of payment amounts under section 1881(b)(14)(A) of the Act, the establishment of an appropriate unit of payment under section 1881(b)(14)(C) of the Act, the identification of renal dialysis services included in the bundled payment, the adjustments under section 1881(b)(14)(D) of the Act, the application of the phase-in under section 1881(b)(14)(E) of the Act, and the establishment of the market basket percentage increase factors under section 1881(b)(14)(F) of the Act.

[75 FR 49199, Aug. 12, 2010]

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

(a) CMS or the facility's contractor notifies each facility of changes in its payment rate. This notice includes changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(b) Changes in payment rates resulting from incorporation of updated cost data or general revisions of geographic labor cost adjustment factors are announced by notice published in the FEDERAL REGISTER without opportunity for prior comment. Revisions of the rate-setting methodology are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

(c) Effective for items and services furnished on or after January 1, 2011 and before January 1, 2012, CMS adjusts the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor.

(d) Effective for items and services furnished on or after January 1, 2012, CMS updates on an annual basis the following:

(1) The per-treatment base rate and the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor.

(2) The wage index using the most current hospital wage data.

(3) The fixed dollar loss amount as defined in § 413.237 of this part to ensure that outlier payments continue to be 1.0 percent of total payments to ESRD facilities.

[62 FR 43668, Aug. 15, 1997, as amended at 75 FR 49199, Aug. 12, 2010]

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and Scope.* This section implements section 1881(b)(2)(B)(i) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities under part 494 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate CMS-approved cost report in accordance with §§ 413.20 and 413.24, which

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).