

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.

EFFECTIVE DATE NOTE: At 75 FR 49199, Aug. 12, 2010, § 413.196 was amended by adding paragraphs (c) and (d), effective January 1, 2011. For the convenience of the user, the added text is set forth below:

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

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(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.

**§ 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 413.200, Reimbursement of OPAs and histocompatibility laboratories;

(iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and

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(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]

### **§ 413.200 Payment of independent organ procurement organizations and histocompatibility laboratories.**

(a) *Principle.* Covered services furnished after September 30, 1978 by organ procurement organizations (OPOs) and histocompatibility laboratories in connection with kidney acquisition and transplantation will be reimbursed under the principles for determining reasonable cost contained in this part. Services furnished by freestanding OPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, will be reimbursed by making an interim payment to the transplant hospitals using these services and by making a retroactive adjustment, directly with the OPO or laboratory, based upon a cost report filed by the OPO or laboratory. (The reasonable costs of services furnished by hospital based OPOs or laboratories will be reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* For purposes of this section:

*Freestanding* refers to an OPO or a histocompatibility laboratory that is not—

(1) Subject to the control of the hospital with respect to the hiring, firing, training, and paying of employees; and

(2) Considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

*Histocompatibility laboratory* means a laboratory meeting the standards and providing the services for kidneys or other organs set forth in § 413.2171(d) of this chapter.

*OPO* means an organization defined in § 486.302 of this chapter.

(c) *Agreements with independent OPOs and laboratories.* (1) Any freestanding

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OPO or histocompatibility laboratory that wishes to have the cost of its pretransplant services reimbursed under the Medicare program must file an agreement with CMS under which the OPO or laboratory agrees—

(i) To file a cost report in accordance with § 413.24(f) within three months after the end of each fiscal year;

(ii) To permit CMS to designate an intermediary to determine the interim reimbursement rate payable to the transplant hospitals for services provided by the OPO or laboratory and to make a determination of reasonable cost based upon the cost report filed by the OPO or laboratory;

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;

(iv) To pay to CMS amounts that have been paid by CMS to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the OPO or laboratory; and

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1861 of the Act.

(2) The initial cost report due from an OPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c) (1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Hospitals eligible to receive Medicare reimbursement for renal transplantation will be paid for the pretransplantation services of a freestanding OPO or histocompatibility laboratory that has an agreement with the Secretary under paragraph (c) of this section, on the basis of an interim rate established by an intermediary for that OPO or laboratory.

(2) The interim rate will be based on the average cost per service incurred by an OPO or laboratory, during its previous fiscal year, associated with procuring a kidney for transplantation. This interim rate may be adjusted if necessary for anticipated cost changes. If there is not adequate cost data to determine the initial interim rate, it will