

(c) Establishing procedures that a facility must follow to appeal its payment amount under the prospective payment system.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70330, Nov. 21, 2005; 73 FR 20474, Apr. 15, 2008]

EFFECTIVE DATE NOTE: At 75 FR 49198, Aug. 12, 2010, §413.170 was amended by revising the introductory text and paragraphs (a) and (b), effective January 1, 2011. For the convenience of the user, the revised text is set forth as follows:

§413.170 Scope.

This subpart implements sections 1881(b)(2), (b)(4), (b)(7), and (b)(12) through (b)(14) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis services in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in §413.171(c).

(b) Providing procedures and criteria under which a pediatric ESRD facility (an ESRD facility with at least a 50 percent pediatric patient mix as specified in §413.184 of this subpart) may receive an exception to its prospective payment rate prior to January 1, 2011; and

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§413.171 Definitions.

For purposes of this subpart, the following definitions apply:

Base rate. The average payment amount per-treatment, standardized to remove the effects of case-mix and area wage levels and further reduced for budget neutrality and the outlier percentage. The base rate is the amount to which the patient-specific case-mix adjustments and any ESRD facility adjustments, if applicable, are applied.

Composite Rate Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

ESRD facility. An ESRD facility is an independent facility or a hospital-based provider of services (as described in §413.174(b) and (c) of this chapter),

including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in §494.10 of this chapter and meets the supervision requirements described in part 494 of this chapter, and that furnishes institutional dialysis services and supplies under §410.50 and §410.52 of this chapter.

New ESRD facility. A new ESRD facility is an ESRD facility (as defined above) that is certified for Medicare participation on or after January 1, 2011.

Pediatric ESRD Patient. A pediatric ESRD patient is defined as an individual less than 18 years of age who is receiving renal dialysis services.

Renal dialysis services. Effective January 1, 2011, the following items and services are considered “renal dialysis services,” and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

(1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;

(3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form),

(4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.

(5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis.

Separately billable items and services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act.

[75 FR 49198, Aug. 12, 2010]

§413.172

EFFECTIVE DATE NOTE: At 75 FR 49198, Aug. 12, 2010, §413.171 was added, effective January 1, 2011.

§413.172 Principles of prospective payment.

(a) Payments for outpatient maintenance dialysis are based on rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered outpatient maintenance dialysis. Approved ESRD facility means—

(1) Any independent or hospital-based facility (as defined in accordance with §§413.174(b) and 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

(c) CMS publishes the methodology used to establish payment rates and the changes specified in §413.196(b) in the FEDERAL REGISTER.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008]

EFFECTIVE DATE NOTE: At 75 FR 49198, Aug. 12, 2010, §413.172 was amended by revising paragraph (a), (b) introductory text and paragraph (b)(1), effective January 1, 2011. For the convenience of the user, the revised text is set forth as follows:

§413.172 Principles of prospective payment.

(a) Payment for renal dialysis services as defined in §413.171 and home dialysis services as defined in §413.217 of this chapter are based on payment rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in §413.171 or home dialysis services. Approved ESRD facility means—

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(1) Any independent ESRD facility or hospital-based provider of services (as defined in §413.174(b) and §413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

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

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using the following methodology:

(1) For dialysis services furnished prior to January 1, 2009, the methodology differentiates between hospital-based and independent ESRD facilities;

(2) For dialysis services furnished on or after January 1, 2009—

(i) The composite rate paid to hospital-based facilities for dialysis services shall be the same as the composite rate paid for such services furnished by independent renal dialysis facilities.

(ii) When applying the geographic index to hospital-based facilities, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.

(3) Effectively encourages efficient delivery of dialysis services; and

(4) 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 §498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under §498.3 of this chapter. 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