## §413.171

(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

(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; 75 FR 49198, Aug. 12, 2010]

## § 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

 $[75~\mathrm{FR}~49198,~\mathrm{Aug}.~12,~2010]$ 

## § 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—
- (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