

may immediately file another exception request. Any subsequent exception request must address and document the issues cited in CMS' denial letter.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70331, Nov. 21, 2005]

§ 413.182 Criteria for approval of exception requests.

(a) CMS may approve exceptions to a pediatric ESRD facility's prospective payment rate if the pediatric ESRD facility did not have an approved exception rate as of October 1, 2002.

(b) The pediatric ESRD facility must demonstrate, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(1) Pediatric patient mix, as specified in § 413.184.

(2) Self-dialysis training costs in pediatric facilities, as specified in § 413.186.

[70 FR 70331, Nov. 21, 2005]

§ 413.184 Payment exception: Atypical service intensity (patient mix).

(a) *Qualifications.* To qualify for an exception to its prospective payment rate based on its pediatric patient mix a facility must demonstrate that—

(1) At least 50 percent of its patients are individuals under 18 years of age;

(2) Its nursing personnel costs are allocated properly between each mode of care;

(3) The additional nursing hours per treatment are not the result of an excess number of employees;

(4) Its pediatric patients require a significantly higher staff-to-patient ratio than typical adult patients; and

(5) These services, procedures, or supplies and their per treatment costs are clearly prudent and reasonable when compared to those of pediatric facilities with a similar patient mix.

(b) *Documentation.* (1) A pediatric ESRD facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed and filed cost report (in accordance with cost re-

porting requirements under § 413.198) showing—

(i) Age of patients and percentage of patients under the age of 18;

(ii) Individual patient diagnosis;

(iii) Home patients and ages;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Diabetic patients; and

(vi) Patients isolated because of contagious disease.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing—

(A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70331, Nov. 21, 2005]

§ 413.186 Payment exception: Self-dialysis training costs in pediatric facilities.

(a) *Qualification.* To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the pediatric ESRD facility must establish that it incurs per treatment costs for furnishing self-dialysis and