

(2) End of the period during which the announced rate was to apply.

(k) *Period of approval: Payment exception request under §§ 413.182(c) and 413.188.* A prospective exception payment rate approved by CMS under §§ 413.182(c) and 413.188 applies from the date of the extraordinary event until the end of the period during which the prospective announced rate was to apply, unless CMS determines that another date is more appropriate. If CMS does not extend the exception period and the facility believes that it continues to require an exception to its rate, the facility must reapply in accordance with the procedures in this section.

(l) *Denial of an exception request.* CMS denies exception requests submitted without the documentation specified in § 413.182 and the applicable regulations cited there.

(m) *Criteria for refiling a denied exception request.* A facility that has been denied an exception request during the 180 days may file another exception request if all required documentation is filed with the intermediary by the 180th day.

§ 413.182 Criteria for approval of exception requests.

CMS may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates, 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:

- (a) Atypical service intensity (patient mix), as specified in § 413.184.
- (b) Isolated essential facility, as specified in § 413.186.
- (c) Extraordinary circumstances, as specified in § 413.188.
- (d) Self-dialysis training costs, as specified in § 413.190.
- (e) Frequency of dialysis, as specified in § 413.192.

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

(a) To qualify for an exception to the prospective payment rate based on

atypical service intensity (patient mix)—

(1) A facility must demonstrate that a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients. Examples that may qualify under this criterion are more intense dialysis services that are medically necessary for patients such as—

(i) Patients who have been referred from other facilities on a temporary basis for more intense care during a period of medical instability and who return to the original facility after stabilization;

(ii) Pediatric patients who require a significantly higher staff-to-patient ratio than typical adult patients; or

(iii) Patients with medical conditions that are not commonly treated by ESRD facilities and that complicate the dialysis procedure.

(2) The facility must demonstrate clearly that these services, procedures, or supplies and its per treatment costs are prudent and reasonable when compared to those of facilities with a similar patient mix.

(3) A facility must demonstrate that—

(i) Its nursing personnel costs have been allocated properly between each mode of care; and

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

(b) *Documentation.* (1) A facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed fiscal or calendar year showing—

(i) Patients who received transplants, including the date of transplant;

(ii) Patients awaiting a transplant who are medically able, have given consent, and are on an active transplant list, and projected transplants;

(iii) Home patients;

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

(v) Individual patient diagnosis;

(vi) Diabetic patients;

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- (vii) Patients isolated because of contagious disease;
 - (viii) Age of patients;
 - (ix) Mortality rate, by age and diagnosis;
 - (x) Number of patient transfers, reasons for transfers, and any related information; and
 - (xi) Total number of hospital admissions for the facility's patients, reason for, and length of stay of each session.
- (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.

§413.186 Payment exception: Isolated essential facility.

- (a) *Qualifications.* To qualify for an exception to the prospective payment rate based on being an isolated essential facility—
 - (1) The facility must be the only supplier of dialysis in its geographical area;
 - (2) The facility's patients must be unable to obtain dialysis services else-

where without substantial additional hardship; and

(3) The facility's excess costs must be justifiable.

(b) *Criteria for determining qualifications.* In determining whether a facility qualifies for an exception based on its being an isolated essential facility, CMS considers—

- (1) Local, permanent residential population density;
- (2) Typical local commuting distances from medical services;
- (3) Volume of treatments; and
- (4) The extent that other dialysis facilities are used by area residents (other than the applying facility's patients).

(c) *Documentation.* (1) *Isolated.* Generally, to be considered isolated, the facility must document that it is located outside an established Metropolitan Statistical Area and provides dialysis to a permanent patient population, as opposed to a transient patient population.

(2) *Essential.* To be considered essential, the facility must document—

- (i) That a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship; and
- (ii) The additional hardship the patients will incur in travel time and cost.

(3) *Cost per treatment.* The facility must—

- (i) Document that its cost per treatment is reasonable; and
- (ii) Explain how the facility's cost per treatment in excess of its composite rate relates to the isolated essential facility criteria specified in paragraph (b) of this section.

(4) *Additional information.* The facility must also furnish the following information in a format that concisely explains the facility's cost and patient data to support its request:

- (i) A list of current and requested payment rates for each modality.
- (ii) An explanation of how the facility's costs in excess of its composite rate payment are attributable to its being an isolated essential facility.
- (iii) An explanation of any unusual geographic conditions in the area surrounding the facility.