

of this section) paid to that facility is increased by an add-on amount as described in § 414.313.

(f) *Erythropoietin/Epoietin (EPO)*. (1) When EPO is furnished to an ESRD patient by a Medicare-approved ESRD facility or a supplier of home dialysis equipment and supplies, payment is based on the amount specified in paragraph (f)(3) of this section.

(2) The payment is made only on an assignment basis, that is, directly to the facility or supplier, which must accept, as payment in full, the amount that CMS determines.

(3) CMS determines the payment amount in accordance with the following rules:

(i) The amount is prospectively determined, as specified in section 1881(b)(11)(B)(ii) of the Act, reviewed and adjusted by CMS, as necessary, and paid to hospital-based and independent dialysis facilities and to suppliers of home dialysis equipment and supplies, regardless of the location of the facility, supplier, or patient.

(ii) If CMS determines that an adjustment to the payment amount is necessary, CMS publishes a FEDERAL REGISTER notice proposing a revision to the EPO payment amount and requesting public comment.

(iii) Any increase in this amount for a year does not exceed the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(iv) The Medicare payment amount is subject to the Part B deductible and coinsurance.

(g) *Additional payment for certain drugs*. In addition to the prospective payment described in this section, CMS makes an additional payment for certain drugs furnished to ESRD patients by a Medicare-approved ESRD facility. CMS makes this payment directly to the ESRD facility. The facility must accept the allowance determined by CMS as payment in full. Payment for these drugs is made as follows:

(1) *Hospital-based facilities*. CMS makes payments in accordance with

the cost reimbursement rules set forth in this part.

(2) *Independent facilities*. CMS makes payment in accordance with the methodology set forth in § 405.517 of this chapter for paying for drugs that are not paid on a cost or prospective payment basis.

§ 413.176 Amount of payments.

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary pays the facility 80 percent of its prospective payment rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary subtracts the amount applicable to the deductible from the facility's prospective rate and pays the facility 80 percent of the remainder, if any.

§ 413.178 Bad debts.

(a) CMS will reimburse each facility its allowable Medicare bad debts, as defined in § 413.80(b), up to the facility's costs, as determined under Medicare principles, in a single lump sum payment at the end of the facility's cost reporting period.

(b) A facility must attempt to collect deductible and coinsurance amounts owed by beneficiaries before requesting reimbursement from CMS for uncollectible amounts. Section 413.80 specifies the collection efforts facilities must make.

(c) A facility must request payment for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list that specifically enumerates all uncollectible amounts related to covered services under the composite rate.

§ 413.180 Procedures for requesting exceptions to payment rates.

(a) *Outpatient maintenance dialysis payments*. All payments for outpatient maintenance dialysis furnished at or by facilities are made on the basis of prospective payment rates.

(b) *Criteria for requesting an exception*. If a facility projects on the basis of prior year costs and utilization trends that it will have an allowable cost per

§413.180

42 CFR Ch. IV (10-1-02 Edition)

treatment higher than its prospective rate set under §413.174, and if these excess costs are attributable to one or more of the factors in §413.182, the facility may request, in accordance with paragraph (d) of this section, that CMS approve an exception to that rate and set a higher prospective payment rate. However, a facility may only request an exception or seek to retain its previously approved exception rate when authorized under the conditions specified in paragraphs (d) and (e) of this section.

(c) *Application of deductible and coinsurance.* The higher payment rate is subject to the application of deductible and coinsurance in accordance with §413.176.

(d) *Payment rate exception request.* A facility must request an exception to its payment rate within 180 days of—

(1) The effective date of its new composite payment rate(s);

(2) The effective date that CMS opens the exceptions process; or

(3) The date on which an extraordinary cost-increasing event occurs, as specified (or provided for) in §§413.182(c) and 413.188.

(e) *Criteria for retaining a previously approved exception rate.* A facility may elect to retain its previously approved exception rate in lieu of any composite rate increase or any other exception amount if—

(1) The conditions under which the exception was granted have not changed;

(2) The facility files a request to retain the rate with its fiscal intermediary during the 30-day period before the opening of an exception cycle; and

(3) The request is approved by the fiscal intermediary.

(f) *Documentation for a payment rate exception request.* If the facility is requesting an exception to its payment rate, it must submit to CMS its most recently completed cost report as required under §413.198 and whatever statistics, data, and budgetary projections as determined by CMS to be needed to adjudicate each type of exception. CMS may audit any cost report or other information submitted. The materials submitted to CMS must—

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in §413.182;

(4) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(5) Specify that the facility has compared its most recently completed cost report with cost reports from (at least 2) prior years. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request.

(g) *Completion of requirements and criteria.* The facility must demonstrate to CMS's satisfaction that the requirements of this section and the criteria in §413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

(h) *Approval of an exception request.* An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary.

(i) *Determination of an exception request.* In determining the facility's payment rate under the exception process, CMS excludes all costs that are not reasonable or allowable under the reasonable cost principles set forth in this part.

(j) *Period of approval: Payment exception request.* Except for exceptions approved under §§413.180(e), 413.180(k), 413.182(c), and 413.188, a prospective exception payment rate approved by CMS applies for the period from the date the complete exception request was filed with its intermediary until the earlier of the—

(1) Date the circumstances justifying the exception rate no longer exist; or

(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;