(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 hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, CMS does not consider—

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in §414.313(c) of this chapter), the prospective rate (as described in paragraph (a) 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 uncollectable 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 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;