

§ 405.2164

42 CFR Ch. IV (10-1-99 Edition)

(3) *Conditions the patient or the patient's caregiver must meet.* The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions:

(i) Is trained by the facility to inject EPO and is capable of carrying out the procedure.

(ii) Is capable of reading and understanding the drug labeling.

(iii) Is trained in, and capable of observing, aseptic techniques.

(4) *Care and storage of drug.* The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

(h) *Use of EPO at home: Responsibilities of the physician or the dialysis facility.* The patient's physician or dialysis facility must—

(1) Develop a protocol that follows the drug label instructions;

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and

(3) Through the amounts prescribed, ensure that the drug "on hand" at any time does not exceed a 2-month supply.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 57 FR 7134, Feb. 28, 1992; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994; 59 FR 46513, Sept. 8, 1994; 61 FR 19743, May 2, 1996]

§ 405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§ 405.2130 through 405.2164, with the exception of §§ 405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under § 405.2137.

(c) The period of approval for a special purpose renal dialysis facility may

not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§ 405.2102) or a qualified physician-director (§ 405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 59 FR 46514, Sept. 8, 1994]

§ 405.2171 Condition: Minimal service requirements for a renal transplantation center.

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by HCFA as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff; if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator

and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician.

(a) *Standard: participation in recipient registry.* The renal transplantation center participates in a patient registry program with an OPO certified or recertified under part 485, subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.

(b) *Standard: social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(c) *Standard: dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietician (§405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(d) *Standard: Laboratory services:* (1) The renal transplantation center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter.

(2) Laboratory services for crossmatching of recipient serum and

donor lymphocytes for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis.

(e) *Standard: Organ procurement.* A renal transplantation center using the services of an organ procurement organization designated or redesignated under part 485, subpart D of this chapter to obtain donor organs has a written agreement covering these services. The renal transplantation center agrees to notify HCFA in writing within 30 days of the termination of the agreement.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 53 FR 6548, Mar. 1, 1988; 57 FR 7134, Feb. 28, 1992; 59 FR 46514, Sept. 8, 1994]

§ 405.2180 Termination of Medicare coverage.

(a) Except as provided in §405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this subpart U will result in termination of Medicare coverage of the services furnished by that supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required by §405.2134, coverage may be reinstated when HCFA determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in this subpart, coverage will not be reinstated until HCFA finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

[53 FR 36277, Sept. 19, 1988]

§ 405.2181 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* HCFA may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if HCFA finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass its geographic area; and