

cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in § 405.2150.

(d) *Standard: emergency preparedness.* Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case of an emergency.

(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

(5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or non-medical emergency occurs.

(Secs. 1102, 1871, 1881(b), Social Security Act; 42 U.S.C. 1302, 1395hh, 1395rr(b))

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 45 FR 24839, Apr. 10, 1980; 52 FR 36934, Oct. 2, 1987; 60 FR 48043, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

**§ 405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.**

An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) *Standard: Hemodialyzers.* If the ESRD facility reuses hemodialyzers, it conforms to the following:

(1) *Reuse guidelines.* Voluntary guidelines adopted by the AAMI ("Reuse of Hemodialyzers," second edition). Incorporation by reference of the AAMI's "Reuse of Hemodialyzers," second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.<sup>1</sup> If any changes in "Reuse of Hemodialyzers," second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(2) *Procedure for chemical germicides.* To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(3) *Surveillance of patient reactions.* In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility—

(i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

<sup>1</sup>The publication entitled "Reuse of Hemodialyzers," second edition, 1993, is available for inspection at the CMS Information Resources Center, 7500 Security Boulevard, Baltimore, MD 21244-1850 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

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(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.

(b) *Standard: Transducer filters.* To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.

(c) *Standard: Bloodlines.* If the ESRD facility reuses bloodlines, it must—

(1) Limit the reuse of bloodlines to the same patient;

(2) Not reuse bloodlines labeled for “single use only”;

(3) Reuse only bloodlines for which the manufacturer’s protocol for reuse has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act; and

(4) Follow the FDA-accepted manufacturer’s protocol for reuse of that bloodline.

[52 FR 36935, Oct. 2, 1987, as amended at 55 FR 18335, May 2, 1990; 60 FR 48044, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

**§ 405.2160 Condition: Affiliation agreement or arrangement.**

(a) A renal dialysis facility and a renal dialysis center (see § 405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility’s patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and

(3) Security and accountability for patients’ personal effects are assured.

**§ 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.**

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See § 405.2102.)

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and