

§ 405.2139

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

in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§ 405.2139 **Condition: Medical records.**

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) *Standard: medical record.* Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see § 405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in § 405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures;

and discharge summary including final diagnosis and prognosis.

(b) *Standard: protection of medical record information.* The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(c) *Standard: medical records supervisor.* A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

(d) *Standard: Completion of medical records and centralization of clinical information.* Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

(e) *Standard: retention and preservation of records.* Medical records are retained for a period of time not less than that determined by the State statute governing records retention or

statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

(f) *Standard: location and facilities.* The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

(g) *Standard: transfer of medical information.* The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 52 FR 36934, Oct. 2, 1987]

§ 405.2140 Condition: Physical environment.

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(a) *Standard: building and equipment.* The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.

(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.

(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(3) The areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.

(4) [Reserved]

(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in "Hemodialysis Systems," second edition, which is incorporated by reference.

(ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2, Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

(iii) Incorporation by reference of the AAMI's "Hemodialysis Systems," second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.¹ If any changes in "Hemodialysis Systems," second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(b) *Standard: favorable environment for patients.* The facility is maintained and equipped to provide a functional sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items which conform to requirements for reuse in § 405.2150.

¹The publication entitled "Hemodialysis Systems," second edition, 1992, is available for inspection at the HCFA Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244-1850 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.