

902 KAR 20:018. Operation and services; renal dialysis facilities.

RELATES TO: KRS 216B.010, 216B.015, 216B.040, 216B.042, 216B.045, 216B.050, 216B.055, 216B.075, 216B.085, 216B.105-216B.125, 216B.990(1), (2), 314.035, 314.137

STATUTORY AUTHORITY: KRS 216B.042(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 requires the cabinet to promulgate administrative regulations necessary for the proper administration of licensure of health services and facilities. This administrative regulation establishes licensure requirements for the operation and services of renal dialysis facilities.

Section 1. Definitions. (1) "Administrator" means a person who:

- (a) Holds a baccalaureate degree or its equivalent; and
- (b) Has at least one (1) year of experience in an ESRD unit.

(2) "Anti-HBs" means the antibody to the hepatitis B virus conferred either by vaccination or infection.

(3) "Dialysis technician" means a person credentialed by the Board of Nursing as a dialysis technician.

(4) "End stage renal disease" or ESRD" means that stage of renal impairment which:

- (a) Is irreversible and permanent; and
- (b) Requires dialysis or kidney transplantation to ameliorate uremic symptoms and maintain life.

(5) "Facility" means renal dialysis facility, as included in the definition of "health facility" at KRS 216B.015(10).

(6) "HBsAg" means the hepatitis B antigen, present in the blood of persons who are infected by the hepatitis B virus.

(7) "HBV negative" means the absence of the hepatitis B virus, the hepatitis B antigen, and the antibody to the hepatitis B virus.

(8) "Medical director" means a licensed physician who is a board eligible or certified nephrologist, internist, or pediatrician with at least twelve (12) months experience or training in the treatment and management of ESRD patients.

(9) "Qualified dietician" means a person licensed pursuant to KRS 310.021.

(10) "Qualified medical record practitioner" means a person who has graduated from a program for medical record administrators or technicians accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and who is certified as a registered records administrator or an accredited record technician by the American Medical Record Association.

(11) "Qualified registered nurse" means a person licensed to engage in registered nursing practice pursuant to KRS 314.041, who has at least:

(a) Twelve (12) months experience in clinical nursing plus six (6) months of experience in nursing care of ESRD patients; or

(b) Eighteen (18) months experience in nursing care of ESRD patients.

(12) "Qualified social worker" means a social worker licensed to practice in Kentucky, who has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education.

(13) "Renal dialysis center" means a hospital unit approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients:

- (a) Including inpatient dialysis furnished directly or under arrangement; and
- (b) Excluding renal transportation.

(14) "Renal transplantation center" means a hospital unit approved to provide transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients,

including inpatient dialysis furnished directly or under arrangement. A renal transplantation center may also be a renal dialysis center.

(15) "Self-care dialysis training" means a program to train an ESRD patient or helper, or both, to perform dialysis.

Section 2. Requirement for Service. A facility shall not be licensed or relicensed as a renal dialysis facility unless it provides the services required in Section 4 of this administrative regulation.

Section 3. Administration and Operation. (1) Licensee.

(a) The licensee shall be legally responsible for the operation of the facility and for compliance with federal, state, and local laws and regulations pertaining to the operation of the facility.

(b) The licensee shall develop and enforce written policies for the administration and operation of the facility. Policies shall include:

1. Personnel practices and procedures;
2. Job descriptions for each level of personnel, including authority and responsibilities of each classification;
3. Qualifications for medical staff membership;
4. Medical care practices and procedures;
5. Prevention and control of hepatitis, peritonitis, and other infections, including appropriate procedures for:
 - a. Surveillance and reporting of infections;
 - b. Housekeeping;
 - c. Handling and disposal of waste and contaminants;
 - d. Sterilization and disinfection; and
 - e. Sterilization and maintenance of equipment; and
6. Procedures to be followed in an emergency, including fire, natural disaster, and equipment failure.

(2) Administrator. The facility shall have an administrator responsible for the management of the facility, including enforcement of written policies and protection of patients' personal and property rights.

(3) The facility shall:

- (a) Have a permanent site of operation; and
- (b) Maintain regularly scheduled hours during which dialysis services are available.

(4) Affiliation agreements. A renal dialysis facility shall have affiliation agreements or arrangements, in writing, with renal dialysis centers and renal transplantation centers which provide the following:

(a) A renal transplantation centers agreement shall provide for medical and surgical specialty services required for the care of ESRD patients, including transplantation and inpatient dialysis furnished directly or under arrangement.

(b) A renal dialysis centers agreement shall provide for working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed, as follows:

1. Timely transfer or referral of patients between the renal dialysis facility and the renal dialysis center shall be effected if it is determined to be medically appropriate by the physicians at the facility and the center.

2. The following information shall be provided to the recipient facility within one (1) working day of a patient's transfer or referral:

- a. Patient care plan;
- b. Medical information;

c. Other information necessary or useful in the care and treatment of the patient.

(5) Personnel. An adequate number of personnel shall be present to meet the needs of patients, including medical and nonmedical emergencies.

(a) Medical staff. The facility shall have an organized medical staff responsible for the:

1. Quality of all medical care provided to patients in the facility; and
2. Ethical and professional practices of its staff.

(b) There shall be a medical director responsible for supervising the staff of the facility. The medical director shall be a full or part-time staff member. In the medical director's absence a similarly qualified medical staff member shall be either in the unit or immediately available in the community when a patient is being dialyzed.

(c) The facility shall employ at least one (1) full-time qualified registered nurse to be responsible for nursing services. If a patient is undergoing dialysis, a qualified registered nurse shall be on duty to oversee patient care.

(d) The facility shall employ or have contracts for services with the following ancillary personnel:

1. A qualified dietician;
2. A qualified medical records practitioner;
3. A qualified social worker.

(6) Incident and accident reports.

(a) A facility shall submit an incident report to the Cabinet for Health Services, Office of the Inspector General, within three (3) days of the occurrence of a reportable event.

(b) A facility shall retain a copy of the report for inspection by the cabinet.

(c) Reportable events include:

1. An incident requiring emergency treatment or hospitalization;
2. A cleaning agent left in a machine that is subsequently used on a patient;
3. Contamination of the water supply;
4. Development of infection or communicable disease; and
5. An accident or other event having a direct or immediate bearing on the health, safety, or security of a patient or staff member.

Section 4. Services. (1) Each patient is admitted on the medical authority of, and is under the supervision of, the medical director. When absent from the facility the medical director shall designate a qualified physician to be responsible for admission and supervision of patients.

(2) Laboratory services. A renal dialysis facility shall have access to laboratory facilities and services to meet the needs of each ESRD patient, with the exception of tissue pathology and histocompatibility testing. The services shall be performed by:

(a) A laboratory in a licensed hospital; or

(b) A laboratory licensed by the Department for Health Services pursuant to KRS Chapter 333.

(3) Medical records.

(a) A current and complete medical record shall be maintained for each patient.

(b) Organization. The supervisor of medical records shall be responsible for the proper documentation, completion and preservation of all the facility's medical records.

(c) Indexing. Medical records shall be properly indexed and systematically filed.

(d) Ownership. A patient's record shall not be removed from the facility's custody except in compliance with a court order or subpoena.

(e) Confidentiality. A patient's record shall be available for inspection only to members of the professional staff, the patient, or an authorized individual acting in behalf of the patient. Patient records may be used for research or statistical investigation, if each patient's anonymity is protected.

(f) Content. A complete medical record shall be prepared for each patient admitted to the facility, to include at least the following information:

1. Name and address of the patient, and guardian or committee, if any;
2. Patient identity data:
 - a. Name;
 - b. Address;
 - c. Date of birth;
 - d. Gender; and
 - e. Marital status;
3. Date of admission;
4. Date of transfer to renal transplantation center, if applicable;
5. Referring and attending physicians' names;
6. History and physical examination record prior to the initial treatment;
7. Treatment plans;
8. Records of special examinations, consultations, and clinical, laboratory, and x-ray services;
9. Doctors' orders, dated and signed;
10. Nurses' notes;
11. Dialysis chart including pulse, respiration and blood pressure;
12. Social evaluation and plan developed by the social worker; and
13. Orders for medication and treatment written in ink and signed by the prescribing practitioner acting within the scope of practice;
14. A record of each medication administered, to include:
 - a. Date and time of administration;
 - b. Type of medication administered;
 - c. Amount of medication administered;
 - d. Method of administration;
 - e. Name of practitioner prescribing medication; and
 - f. Name of the person who administered the medication.
- (g) Retention of records.
 1. After the death or discharge of an adult patient, the completed medical record shall be placed in an inactive file and retained for five (5) years;
 2. After the death or discharge of a minor patient, the record shall be placed in an inactive file and retained for five (5) years from the date of the event, or three (3) years after the patient reaches the age of majority, whichever is longer.
- (4) Pharmaceutical services.
 - (a) The facility shall have provisions for promptly obtaining prescribed drugs and biologicals from licensed pharmacies.
 - (b) The facility shall provide appropriate methods and procedures for storage, control and administering of drugs and biologicals.
 - (c) A medication shall be administered by one (1) of the following professionals, acting within the relevant statutory scope of practice:
 1. A physician;
 2. A physician's assistant;
 3. An advanced nurse registered practitioner;
 4. A registered nurse;
 5. A licensed practical nurse; or
 6. A dialysis technician.
 - (5) Social services. The qualified social worker shall be responsible for:
 - (a) Each patient's social evaluation and treatment;
 - (b) Participating in team review of patient progress and recommending changes in treatment based on the patient's current social needs;

- (c) Providing casework and group work services to patients and their families;
- (d) Financial advice;
- (e) Referrals for vocational rehabilitation; and
- (f) Identifying community social agencies and other resources and assisting patients and their families to utilize them.

(6) Dietetic services. The nutritional needs of each patient shall be evaluated by the attending physician and the qualified dietician. The dietician, in consultation with the attending physician, shall be responsible for:

- (a) Assessing the nutritional and dietetic needs of each patient;
 - (b) Recommending therapeutic diets;
 - (c) Counseling patients and their families on prescribed diets; and
 - (d) Monitoring adherence and response to diets.
- (7) Self-care dialysis support services.

(a) A renal dialysis facility offering self-care dialysis training shall make the following services available either directly, under agreement, or by arrangement with another ESRD facility, upon completion of patient training:

1. Monitoring the patient's home adaptation, including provisions for visits to the home or the facility;
 2. Consultation for the patient with a qualified social worker and a qualified dietician;
 3. A recordkeeping system which assures continuity of care;
 4. Installation and maintenance of dialysis equipment;
 5. Testing and appropriate treatment of the dialysis water;
 6. Ordering of supplies as needed; and
 7. Infection control, including hepatitis and peritonitis;
- (b) A nurse responsible for self-care dialysis training shall have at least three (3) months of experience in training patients for self-care dialysis.

Section 5. Physical Environment. (1) Building and equipment.

(a) Equipment used in the facility shall be maintained free of a condition posing a potential hazard to patients or personnel. There shall be a program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(b) Water used for dialysis purposes shall be analyzed periodically and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Records of test results and equipment maintenance shall be maintained at the facility.

(2) Routine disease testing and infection control.

(a) The licensee shall establish and enforce routine disease testing and infection control policies which are consistent with the most recent guidelines established by the Centers for Disease Control and Prevention for preventing the transmission of infection among chronic hemodialysis patients.

(b) A facility using a central-batch delivery system shall provide, on the premises or through affiliation agreements, sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(3) Contamination prevention. A facility shall employ appropriate techniques to prevent cross contamination between the unit and adjacent hospital or public areas including food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal shall be carried out in accordance with applicable law and acceptable public health standards. (8 Ky.R. 219; eff. 11-5-1981; 12 Ky.R. 62; eff. 8-13-1985; 18 Ky.R. 811; eff. 10-16-1991; 23 Ky.R. 199; eff. 8-21-1996; 2859; eff. 2-19-1997; 28 Ky.R. 1697; 2040;

eff. 3-14-2002; Crt eff. 1-11-2019.)