

CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Health Care

(Amended at ARRS Committee)

902 KAR 20:018. Operation and services; End Stage Renal Disease (ESRD) 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), 310.021, 314.041, KRS Chapter 333, 335.100, 42 C.F.R. 494.1 – 494.180, 45 C.F.R. Part 160, Part 164, 42 U.S.C. 1320d-2 – 1320d-8

STATUTORY AUTHORITY: KRS 216B.042(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042(1) requires the cabinet to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensing standards and procedures to ensure safe, adequate, and efficient health services and health facilities. This administrative regulation establishes the minimum licensure requirements for the operation of and services provided by End Stage Renal Disease (ESRD) facilities.

Section 1. Definitions.

- (1) "Administrator" means an individual who:
 - (a) Holds a baccalaureate degree or its equivalent;
 - (b) Has at least one (1) year of experience working in an ESRD unit; and
 - (c) Is responsible for the management of the ESRD facility.
- (2) "Dialysis technician" means a person credentialed by the Board of Nursing as a dialysis technician.
- (3) "End Stage Renal Disease" or "ESRD" means a medical condition in which a person's kidneys cease functioning on a permanent basis leading to the need for long-term dialysis or a kidney transplant to maintain life.
- (4) "ESRD facility" means a facility or entity that provides outpatient maintenance dialysis services, home dialysis training and support, or both.
- (5) "Medical director" means a Kentucky-licensed physician who:
 - (a) Is board-certified in internal medicine or pediatrics;
 - (b) Has completed a board-approved training program in nephrology; and
 - (c)
 1. Has at least twelve (12) months of experience providing care to patients receiving dialysis; or
 2. If the physician does not meet the requirements of paragraphs (a) through (c) of this subsection, has received approval in accordance with 42 C.F.R. 494.140(a)(2) to direct an ESRD facility.
- (6) "Qualified dietitian" means an individual who:
 - (a) Is licensed pursuant to KRS 310.021; and
 - (b) Has a minimum of one (1) year professional work experience in clinical nutrition as a registered dietitian.
- (7) "Qualified medical record technician" means an individual who:
 - (a) Has graduated from a program for medical record technicians that is accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association; and
 - (b) Is certified as an accredited record technician by the American Medical Record Association.
- (8) "Qualified registered nurse manager" means a nurse manager responsible for nursing services who:

- (a) Is licensed to practice as a registered nurse under KRS 314.041;
- (b) Is a full-time employee of the ESRD facility; and
- (c) Has at least:
 - 1. Twelve (12) months of experience in clinical nursing; and
 - 2. Six (6) months of experience in providing nursing care to patients on maintenance dialysis.
- (9) "Qualified social worker" means a clinical social worker licensed and practicing in accordance with KRS 335.100 .
- (10) "Renal transplantation center" means a hospital unit approved to provide kidney transplants and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis provided directly or under arrangement.
- (11) "Self-care dialysis training" means a program to train an ESRD patient or the patient's helper, or both, to perform dialysis.

Section 2. Requirement for Service. An ESRD facility shall not be licensed or relicensed as an ESRD facility unless the facility meets the requirements of this administrative regulation.

Section 3. Administration and Operation.

- (1) Licensee.
 - (a) The licensee shall be legally responsible for the operation of the ESRD facility and for compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the facility.
 - (b) The licensee shall develop and enforce written policies for the administration and operation of the ESRD facility. Policies shall include:
 - 1. Personnel practices and procedures;
 - 2. Job descriptions for each level of personnel, including authority and responsibilities for 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. An ESRD facility shall have an administrator responsible for the management of the facility, including enforcement of written policies and protection of patients' rights.
- (3) An ESRD facility shall:
 - (a) Demonstrate compliance with the requirements of 42 C.F.R. 494.1 through 494.180, except for an ESRD facility that is state-licensed only; and
 - (b) Maintain regularly scheduled hours during which dialysis services shall be available.
- (4) Emergency coverage.
 - (a) An ESRD facility's governing body shall ensure that the facility shall provide each patient and facility staff member with written instructions for obtaining emergency medical care.
 - (b) An ESRD facility shall have available at the nursing station, a roster with:
 - 1. The names of physicians who may be called for emergencies;

2. When the physicians may be called; and
 3. How the physicians may be reached.
- (c) An ESRD facility shall have an agreement with a hospital that can provide the following services twenty-four (24) hours per day, seven (7) days per week:
1. Inpatient care;
 2. Routine and emergency dialysis;
 3. Other hospital services; and
 4. Emergency medical care.
- (d) The agreement shall:
1. Ensure that hospital services shall be available to the ESRD facility's patients as needed; and
 2. Include reasonable assurances that each patient from the ESRD facility shall be accepted and treated in an emergency.
- (5) Personnel. An adequate number of personnel shall be present to meet the needs of patients at all times, including emergency situations.
- (a) Medical staff. An ESRD 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 the facility's staff.
- (b)
1. There shall be a medical director responsible for supervising the staff of the ESRD facility.
 2. The medical director shall be a full- or part-time staff member.
 3. In the medical director's absence, a physician meeting the qualifications of a medical director or a physician who has received approval in accordance with 42 C.F.R. 494.140(a)(2) to direct an ESRD facility shall be in the unit or immediately available while a patient is being dialyzed.
- (c)
1. The ESRD facility shall employ at least one (1) full-time qualified registered nurse manager responsible for nursing services.
 2. If a patient is undergoing dialysis, a qualified registered nurse manager shall be on duty to supervise patient care.
- (d) The ESRD facility shall employ the following ancillary personnel directly or by contract:
1. A qualified dietician;
 2. A qualified medical records technician; and
 3. A qualified social worker.
- (6) Incident and accident reports.
- (a) An ESRD facility shall submit an incident report to the cabinet no later than three (3) days after a reportable event as established by paragraph (c) of this subsection.
- (b) An ESRD facility shall retain a copy of the incident report for inspection by the cabinet.
- (c) A reportable event shall 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; or
 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)

(a) Except as established in paragraph (b) of this subsection, each patient shall be admitted under the medical authority and supervision of the medical director.

(b) In the absence of the medical director, a physician meeting the qualifications of a medical director or a physician who has received approval in accordance with 42 C.F.R. 494.140(a)(2) to direct an ESRD facility shall be responsible for patient admissions and supervision.

(2) Laboratory services.

(a) An ESRD facility shall have access to laboratory facilities and services (except tissue pathology and histocompatibility) to meet the needs of each ESRD patient.

(b) The laboratory that provides services shall be:

1. Located in a licensed hospital; or
2. Licensed in accordance with KRS Chapter 333.

(3) Medical records.

(a) An ESRD facility shall maintain complete, accurate, and accessible records for each patient, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

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

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

(d) Ownership.

1. Medical records shall be the property of the ESRD facility.
2. The original medical record shall not be removed from the facility, except by court order or subpoena.
3. Copies of a medical record or portions of the record may be used and disclosed. Use and disclosure shall be as established by paragraph (e) of this subsection.

(e) Confidentiality and security; use and disclosure.

1. The ESRD facility shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 through 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.
2. The facility may use and disclose medical records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 through 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.

(f) Content. A complete medical record shall be prepared for each patient admitted to the ESRD facility and include the:

1. Name and address of the person or agency responsible for the patient, if applicable;
2. Patient identification information, including the patient's:
 - 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; and
 14. A record of each medication administered, including:
 - a. Date and time of administration;
 - b. Type of medication administered;
 - c. Amount of medication administered;
 - d. Method of administration;
 - e. Name of the prescribing practitioner; and
 - f. Name of the person who administered the medication.
- (g) Retention of records. Medical records shall be retained for at least six (6) years from the date of the patient's discharge, transfer, or death.
- (4) Pharmaceutical services.
- (a) An ESRD facility shall have provisions for promptly obtaining prescribed drugs and biologicals from a licensed pharmacy .
 - (b) The ESRD 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 practitioners acting within the individual's professional 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 ESRD facility shall have a qualified social worker responsible for:
- (a) Evaluation of each patient's psychosocial needs ;
 - (b) Participating in the ESRD facility's interdisciplinary team review of patient progress and recommending any changes, if needed, in treatment based on the patient's current psychosocial needs;
 - (c) Providing casework, counseling services, and referrals for other social services to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker ;
 - (d) Referrals for vocational rehabilitation services; and
 - (e) Identifying community social agencies and other resources and assisting patients and their families to utilize those resources.
- (6) Dietetic services.
- (a) The nutritional needs of each patient shall be evaluated by the:
 1. Attending physician; and
 2. Qualified dietician.
 - (b) The dietician, in consultation with the attending physician, shall be responsible for:
 1. Assessing the nutritional status of each patient;
 2. Recommending therapeutic diets;
 3. Counseling patients and their families on prescribed diets; and
 4. Monitoring adherence and response to diets.
- (7) Self-care dialysis support services.

(a) An ESRD facility that offers self-care dialysis training shall make the following services available, directly or through an agreement or arrangement with another ESRD facility, upon completion of patient training:

1. Monitoring the patient's home adaptation, including visits to the patient's home by ESRD facility personnel in accordance with the patient's plan of care ;
2. Patient consultation as needed with a member of the ESRD facility's interdisciplinary team (a qualified social worker or qualified dietician);
3. A recordkeeping system to assure 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 self-care and home dialysis training nurse shall:

1. Be a registered nurse licensed in accordance with KRS 314.041; and
2. Have at least twelve (12) months of experience in clinical nursing care and at least three (3) months of experience in the specific modality for which the nurse will provide self-care training.

(8) Dialysis services in a Medicare-certified nursing facility. A Medicare-certified ESRD facility or entity may provide dialysis services to a long-term care resident within a designated area of a Medicare-certified nursing facility as established in paragraphs (a) through (d) of this subsection.

(a)

1. Prior to providing dialysis in the nursing facility, the ESRD facility or entity shall submit a Form CMS-3427 to the cabinet, completing Section 22 and all other applicable fields.
2. Form CMS-3427 is available for download from the Centers for Medicare and Medicaid Services (CMS) Web site at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-3427>.

(b)

1. The ESRD facility or entity shall comply with the guidance established in the CMS State Operations Manual (SOM), chapter 2, section 2271A Dialysis in Nursing Homes.
2. The SOM, Chapter 2, section 2271A is available for download from the CMS Web site at: <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c02.pdf>.

(c)

1. The ESRD facility shall enter into a written agreement with each Medicare-certified nursing facility for which the ESRD facility will provide dialysis services.
2. The written agreement shall state the responsibilities of the ESRD facility and the nursing facility regarding the care of the resident before, during, and after dialysis treatments.

(d) The ESRD facility shall be responsible for the safe delivery of dialysis to the nursing facility resident, including:

1. Review of ESRD staff qualifications, training, and competency evaluation; and
2. Monitoring of all ESRD personnel who:
 - a. Administer dialysis treatments in the nursing facility; and
 - b. Provide on-site supervision of dialysis treatments.

Section 5. Physical Environment.

(1) Building and equipment.

(a)

1. An ESRD facility shall implement and maintain a program to ensure that all equipment shall be maintained and operated in accordance with the manufacturer's recommendations.
2. There shall be a program of preventive maintenance of equipment used in dialysis and related procedures in the ESRD facility.

(b)

1. 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.
2. Records of test results and equipment maintenance shall be maintained at the ESRD facility.

(2) Infection control.

(a) The licensee shall provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the ESRD unit and any adjacent hospital or other public areas pursuant to 42 C.F.R. 494.30.

(b) An ESRD 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) An ESRD facility shall use appropriate techniques to prevent cross contamination between the unit and adjacent hospital or public areas including:

1. Food service areas;
2. Laundry;
3. Disposal of solid waste and blood-contaminated equipment; and
4. Disposal of contaminants into sewage systems.

(b) An ESRD facility shall maintain procedures, in accordance with applicable law and accepted public health procedures for the:

1. Handling, storage, and disposal of potential infectious waste; and
2. Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

Section 6. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "End Stage Renal Disease Application and Survey and Certification Report", Form CMS-3427, February 2022; and

(b) "CMS State Operations Manual (SOM), Chapter 2, Section 2271A, Dialysis in Nursing Homes", September 2018.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of the Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

(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; Cert eff. 1-11-2019; 48 Ky.R. 2123, 49 Ky.R. 63; eff. 8-25-2022.)

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