

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(Amendment)

902 KAR 20:018. Operation and services; ~~end-stage renal disease~~~~[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), 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~~[314.035, 314.137]~~

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~~[of]~~ health services and health facilities. This administrative regulation establishes the minimum licensure requirements for the operation of and services provided by end-stage~~[of]~~ renal disease (ESRD)~~[dialysis]~~ facilities.

Section 1. Definitions.

- (1) "Administrator" means an individual~~[a person]~~ who:
 - (a) Holds a baccalaureate degree or its equivalent; ~~[and]~~
 - (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) ~~["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.
- (3) ~~[(4)]~~ "End-~~[st]~~age 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~~[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].
- (4) ~~[(5)]~~ "ESRD facility" means a facility or entity that provides outpatient maintenance dialysis services, home dialysis training and support, or both.
- (5) ~~[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 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) Has ~~[is a board-eligible or certified nephrologist, internist, or pediatrician with]~~ at least twelve (12) months of experience providing care to patients receiving dialysis; or
 - (d) If the physician does not meet the requirements of paragraphs (a) – (c) of this subsection, has received approval in accordance with 42 C.F.R. 494.140(a)(2) to direct an ESRD facility ~~[training in the treatment and management of ESRD patients].~~
- (6) ~~[(9)]~~ "Qualified dietitian" means an individual who:
 - (a) Is ~~[a person]~~ 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) ~~((10))~~ "Qualified medical record ~~technician~~~~[practitioner]~~" means an individual who:
- (a) ~~[a person who]~~ Has graduated from a program for medical record ~~[administrators or]~~ technicians that is accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association;~~;~~ and
 - (b) ~~[who]~~ Is certified as ~~[a registered records administrator or]~~ an accredited record technician by the American Medical Record Association.
- (8) ~~((11))~~ "Qualified registered nurse manager" means a nurse manager responsible for nursing services who:
- (a) Is ~~[person]~~ licensed to practice as a registered nurse under~~[to engage in registered nursing practice pursuant to]~~ KRS 314.041;
 - (b) Is a full-time employee of the ESRD facility; and
 - (c) Has ~~[, who has]~~ at least:
 1. ~~((a))~~ Twelve (12) months of experience in clinical nursing; and
 2. ~~[plus]~~ Six (6) months of experience in providing nursing care to~~[of ESRD]~~ patients on maintenance dialysis~~;~~ or
 - ~~((b))~~ Eighteen (18) months experience in nursing care of ESRD patients.
- (9) ~~((12))~~ "Qualified social worker" means a clinical social worker licensed and practicing in accordance with KRS 335.100~~[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].~~
- (10) ~~((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. Services include~~;~~
- ~~((a))~~ Including inpatient dialysis furnished directly or under arrangement~~;~~ and do not include
 - ~~((b))~~ Excluding renal transplants~~[transportation]~~.
- (11) ~~((14))~~ "Renal transplantation center" means a hospital unit approved to provide kidney transplants~~[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.~~
- (12) ~~((15))~~ "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~~[A]~~ facility shall not be licensed or relicensed as an ESRD~~[a renal dialysis]~~ facility unless the facility meets the requirements~~[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 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~~[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. An ESRD~~[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) An ESRD ~~[The]~~ facility shall:
- (a) Demonstrate compliance with the requirements of 42 C.F.R. 494.1—494.180, except for an ESRD facility that is state-licensed only. ~~[Have a permanent site of operation];~~ and
 - (b) Maintain regularly scheduled hours during which dialysis services are available.
- (4) Affiliation agreements. An ESRD~~[A renal dialysis]~~ facility shall have a written affiliation agreement or arrangement with a~~[agreements or arrangements, in writing, with]~~ renal transplantation center and a renal dialysis center that establishes~~[centers and renal transplantation centers which provide]~~ the following:
- (a) The agreement between an ESRD facility and a renal transplantation center~~[centers agreement]~~ shall ensure the delivery of~~[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) The agreement between an ESRD facility and a renal dialysis center~~[centers agreement]~~ shall ensure that~~[provide for working relationships under which]~~ inpatient hospital care or other hospital services are available promptly to the ESRD~~[dialysis]~~ facility's patients as~~[when]~~ needed. The agreement shall delineate the following~~[, as follows]:~~
 1. Timely transfer or referral of patients between the ESRD~~[renal dialysis]~~ facility and the renal dialysis center shall occur if~~[be effected if it is]~~ determined to be medically appropriate by the physicians at both 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, including the:
 - a. Patient care plan;
 - b. Medical information; and
 - c. Any 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 at all times, including emergency situations~~[, including medical and nonmedical emergencies]~~.
- (a) Medical staff. An ESRD~~[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 the facility's~~[its]~~ 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~~[similarly qualified medical staff member]~~ shall be ~~[either]~~ in the unit or immediately available ~~[in the community]~~ when a patient is being dialyzed.

(c)

1. The ESRD facility shall employ at least one (1) full-time qualified registered nurse ~~manager~~~~[to be]~~ responsible for nursing services.

2. If a patient is undergoing dialysis, a qualified registered nurse ~~manager~~ shall be on duty to oversee patient care.

(d) The ESRD facility shall employ ~~[or have contracts for services with]~~ the following ancillary personnel directly or by contract:

1. A qualified dietician;

2. A qualified medical records technician~~[practitioner]~~; and

3. A qualified social worker.

(6) Incident and accident reports.

(a) An ESRD ~~[A]~~ facility shall submit an incident report to the cabinet no later than~~[Cabinet for Health Services, Office]~~~~[of the Inspector General, within]~~ three (3) days after~~[of the occurrence of]~~ a reportable event as described by paragraph (c) of this subsection.

(b) An ESRD ~~[A]~~ facility shall retain a copy of the incident report for inspection by the cabinet.

(c) A reportable event shall~~[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; or~~[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)

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

(2) Laboratory services.

(a) An ESRD ~~[A renal dialysis]~~ facility shall have access to laboratory facilities and services (except tissue pathology and histocompatibility) to meet the needs of each ESRD patient~~[, with the exception of tissue pathology and histocompatibility testing]~~.

(b) The laboratory that provides services shall be ~~[performed by]~~:

1. Located

~~[(a)]~~ ~~[A laboratory]~~ in a licensed hospital; or

2.

~~[(b)]~~ ~~[A laboratory]~~ Licensed in accordance with~~[by the Department for Health Services pursuant to]~~ KRS Chapter 333.

(3) Medical records.

(a) An ESRD facility shall maintain complete, accurate, and accessible records on ~~[A current and complete medical record shall be maintained 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~~all the facility's medical 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 to 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 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation. ~~[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 ESRD facility and ~~[, to]~~ include ~~[at least]~~ the following information:

1. Name and address of the person or agency responsible for the patient, if applicable~~[and guardian or committee, if any];~~

2. Patient identification information, including the patient's~~[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, including~~[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 the prescribing practitioner~~[prescribing medication]~~; 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.
- ~~[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) An ESRD ~~[The]~~ facility shall have provisions for promptly obtaining prescribed drugs and biologicals from a licensed pharmacy~~[pharmacies]~~.
 - (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~~~~[professionals,]~~ acting within the individual's professional~~[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 ESRD facility shall have a qualified social worker ~~[shall be]~~ responsible for:
- (a) Evaluation of each patient's psychosocial needs~~[social evaluation and treatment]~~;
 - (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~~[social]~~ 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~~[and group work]~~~~[services to patients and their families]~~;
 - (d) ~~[Financial advice;]~~
 - ~~[(e)]~~ Referrals for vocational rehabilitation services; and
 - ~~[(f)]~~ Identifying community social agencies and other resources and assisting patients and their families to utilize those resources~~[them]~~.
- (6) Dietetic services.
- ~~[(a)]~~ The nutritional needs of each patient shall be evaluated by the:
 - 1. Attending physician; and
 - 2. ~~[the]~~ Qualified dietician.
 - ~~[(b)]~~ The dietician, in consultation with the attending physician, shall be responsible for:
 - 1. ~~[(a)]~~ Assessing the nutritional status~~[and dietetic needs]~~ of each patient;
 - 2. ~~[(b)]~~ Recommending therapeutic diets;
 - 3. ~~[(c)]~~ Counseling patients and their families on prescribed diets; and
 - 4. ~~[(d)]~~ Monitoring adherence and response to diets.
- (7) Self-care dialysis support services.
- (a) An ESRD facility that offers ~~[A renal dialysis facility offering]~~ self-care dialysis training shall make the following services available ~~[either]~~ directly, or through

~~an~~~~[under]~~ agreement~~[,]~~ or ~~[by]~~ 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~~[provisions for visits to the]~~~~[home or the facility];~~
2. Patient consultation as needed~~[for the patient]~~ with a member of the ESRD facility's interdisciplinary team, e.g., a qualified social worker ~~or~~~~[and a]~~ qualified dietician;
3. A recordkeeping system to assure~~[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 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 ~~[responsible for self-care dialysis training shall have]~~ at least three (3) months of experience in the specific modality for which the nurse will provide self-care training~~[patients for self-care dialysis].~~

(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 follows:

(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) website 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 website _____ 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 delineate 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 is maintained and operated in accordance with the manufacturer's recommendations~~[used in the facility shall be maintained free of a condition posing a potential hazard to patients or personnel].~~
 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) Routine disease testing and infection control.
- (a) The licensee shall establish and enforce routine disease testing and infection control policies ~~that~~~~[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) An ESRD ~~[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) An ESRD ~~[A]~~ facility shall ~~use~~~~[employ]~~ 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, ~~[Waste storage and disposal shall be carried out]~~ in accordance with applicable law and accepted~~[acceptable]~~ 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 ~~[standards].~~

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: November 10, 2021

FILED WITH LRC: December 13, 2021 at 2:00 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on February 21, 2022, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by February 14, 2022, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until February 28, 2022. Send written notification of

intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Kara Daniel; Stephanie Brammer-Barnes, Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the minimum licensure requirements for the operation of and services provided by end-stage renal disease (ESRD) facilities.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to comply with the requirements of KRS 216B.042(1), which requires the Cabinet for Health and Family Services to establish licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

This administrative regulation conforms to the content of KRS 216B.042(1) by establishing the minimum licensure requirements for the operation of and services provided by ESRD facilities.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation assists in the effective administration of the statutes by establishing the minimum licensure requirements for the operation of and services provided by ESRD facilities.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

This amendment aligns with revisions to the Centers for Medicare and Medicaid Services State Operations Manual (SOM) which allows Medicare-certified ESRD facilities to provide dialysis services to long-term care residents in Medicare-certified nursing facilities. In addition, this amendment makes technical changes to conform to the administrative regulation drafting requirements of KRS Chapter 13A to improve clarity and flow, and also makes changes to ensure alignment with 42 C.F.R. 491.1 – 491.180.

(b) The necessity of the amendment to this administrative regulation:

This amendment is needed to align with federal guidance, please refer to SOM, chapter 2, section 2271A Dialysis in Nursing Homes: <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c02.pdf>

(c) How the amendment conforms to the content of the authorizing statutes:

This amendment conforms to the content of KRS 216B.042(1) by establishing the minimum licensure requirements for the operation of and services provided by ESRD facilities.

(d) How the amendment will assist in the effective administration of the statutes:

This amendment will assist in the effective administration of the statutes by establishing the minimum licensure requirements for the operation of and services provided by ESRD facilities.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

This amendment affects the 150 ESRD facilities licensed in Kentucky.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

Medicare-certified ESRD facilities may provide dialysis services to residents in a Medicare-certified nursing facility.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

. This amendment does not impose additional costs on ESRD facilities.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Patients in Medicare-certified nursing facilities will benefit from receiving dialysis treatments in the facility where they reside without need for off-site transportation to an ESRD facility.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

There are no additional costs to the Office of Inspector General for implementation of this amendment.

(b) On a continuing basis:

There are no additional costs to the Office of Inspector General for implementation of this amendment on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

The source of funding used for the implementation and enforcement of the licensure function is from federal funds and state matching funds of general and agency appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

No increase in fees or funding is necessary to implement this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees:

This amendment does not establish or increase any fees.

(9) TIERING: Is tiering applied?

Tiering is not applicable as compliance with this administrative regulation applies equally to all critical access hospitals regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

This administrative regulation affects ESRD facilities. This administrative regulation also impacts the Cabinet for Health and Family Services, Office of Inspector General.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 216B.042

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This amendment will not generate additional revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This amendment will not generate additional revenue in subsequent years.

(c) How much will it cost to administer this program for the first year?

This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years?

This amendment imposes no additional costs on the administrative body during subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.

42 C.F.R. 494.1 – 494.180, 45 C.F.R. 160, 164, 42 U.S.C. 1320d-2 - 1320d-8

(2) State compliance standards.

KRS 216B.042

(3) Minimum or uniform standards contained in the federal mandate.

42 C.F.R. 494.1 – 494.180 establish the federal conditions of participation for the certification of ESRD facilities. 45 C.F.R. 160, 164, and 42 U.S.C. 1320d-2 – 1320d-8 establish the HIPAA privacy rules to protect individuals' medical records and other personal health information.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

This administrative regulation does not impose requirements that are more strict than federal laws or regulations.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

Not applicable.