CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(Amended After Comments)

902 KAR 20:490. Rural emergency hospitals.

RELATES TO: KRS 2.015, 42 C.F.R. 485.500—485.546, 42 C.F.R. 485.618, 45 C.F.R. Part 160, Part 164, 42 U.S.C. 1320d-2 – 1320d-8

STATUTORY AUTHORITY: KRS 216B.042

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes the minimum requirements for licensure as a rural emergency hospital.

Section 1. Definitions. "Rural emergency hospital (REH)" is defined by 42 C.F.R. 485.502 as an entity that:

(1) Operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the secretary of the U.S. Department of Health and Human Services in which the annual per patient average length of stay does not exceed twenty-four (24) hours; and

(2) Shall not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-REH or post-hospital extended care services.

Section 2. Licensure.

(1) A facility shall be eligible to apply for a license as an REH if the facility ~~**[is certified as an REH by the Centers for Medicare and Medicaid Services and]**~~was, as of December 27, 2020:

(a) Licensed as a critical access hospital pursuant to 906 KAR 1:110; or

(b)

1. Licensed as a general acute care hospital pursuant to 902 KAR 20:016;
2. Had fifty (50) or fewer beds; and
3. Was considered rural or treated as being located in a rural area in accordance with 42 C.F.R. 485.506(b) or (c).

(2) Except for beds the REH maintains in a distinct part unit licensed as a skilled nursing facility, the facility's inpatient beds shall be delicensed.

~~**[(3)] [A facility that converts to an REH shall not be relicensed to operate as a critical access hospital or acute care hospital without first obtaining certificate of need.]**~~

Section 3. Application and Fees.

(1) A facility that applies for initial licensure or annual renewal as an REH shall submit to the Office of Inspector General:

(a) A completed Application for Licensure to Operate a Rural Emergency Hospital; and

(b) An accompanying fee in the amount of $1,000, made payable to the Kentucky State Treasurer.

(2) As a condition of annual renewal, the application required by subsection (1) of this section shall be submitted to the cabinet at least sixty (60) days prior to the date of expiration of the REH's licensure.

Section 4. Change of Status.

(1) An REH shall report a change of:

(a) Name or location in accordance with the requirements of 902 KAR 20:008, Section 3(3); or

(b) Ownership in accordance with the requirements of 902 KAR 20:008, Section 2(16).

(2) Failure to renew a license by the annual renewal date shall result in a late penalty pursuant to 902 KAR 20:008, Section 3(4).

Section 5. Services and Basic Requirements.

(1) An REH shall comply with applicable federal, state, and local laws and regulations pertaining to the operation of the facility, including compliance with 42 C.F.R. 485.506 – 485.546.

(2) An REH shall:

(a) Provide emergency department services and observation care, including compliance with the requirements of:

1. 42 C.F.R. 485.516; and
2. 42 C.F.R. 485.618 with respect to:
   a. Twenty-four (24) hour availability of emergency services;
   b. Equipment, supplies, and medication;
   c. Blood and blood products;
   d. Personnel; and
   e. Coordination with emergency response systems;

(b) Provide basic laboratory services in accordance with 42 C.F.R. 485.518;

(c) Maintain, or have available, diagnostic radiologic services in accordance with 42 C.F.R. 485.520;

(d) Have pharmaceutical services that meet the needs of its patients in accordance with 42 C.F.R. 485.522; and

(e) In accordance with 42 C.F.R. 485.538, have in effect a transfer agreement with at least one (1) hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH.

(3) In accordance with 42 C.F.R. 485.524(a), an REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system, including:

(a) Therapeutic radiologic services;

(b) Laboratory services;

(c) Outpatient rehabilitation;

(d) Surgical services;

(e) Maternal health services; or

(f) Behavioral health services.

(4) An REH may provide skilled nursing facility services in a distinct part unit in accordance with 42 C.F.R. 485.546.

Section 6. Personnel. An REH shall assure that licensed personnel meet the applicable standards required by the appropriate professional licensing board and provide services within the applicable scope of practice.

Section 7. Patient Records.

(1) Ownership.

(a) Medical records shall be the property of the REH.

(b) The original medical record shall not be removed except by court order.

(c) Copies of medical records or portions thereof may be used and disclosed in accordance with the requirements established in this administrative regulation.

(2) Confidentiality and Security: Use and Disclosure.

(a) The REH shall maintain the confidentiality and security of patient 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.

(b) The REH may use and disclose patient 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.

(c) An REH may establish higher levels of confidentiality and security than those required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.

(d) Retention of records. After a patient's death or discharge, the completed medical record shall be placed in an inactive file and retained for at least:

1. Six (6) years; or

2. Three (3) years after the patient reaches the age of majority in accordance with KRS 2.015, whichever is longer.

(3) The REH shall:

(a) Designate a specific location for the maintenance and storage of the agency's medical records;

(b) Have provisions for storage of medical records in the event the agency ceases to operate; and

(c) Safeguard the record and its content against loss, defacement, or tampering.

Section 8. Incorporation by Reference.

(1) The form, OIG-20:490, "Application for Licensure to Operate a Rural Emergency Hospital", December 2022 edition, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. This material may also be viewed on the Office of Inspector General's Web site at: https://chfs.ky.gov/agencies/os/oig/dhc/Pages/ltcapplications.aspx. 902 KAR 20:490

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: April 10, 2023

FILED WITH LRC: April 12, 2023 at 8:00 a.m.

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:s: Kara Daniel; Stephanie Brammer-Barnes

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the minimum requirements for licensure as a rural emergency hospital (REH). REHs are a new provider type established by the Consolidated Appropriations Act of 2021. The REH designation provides an opportunity for critical access hospitals (CAHs) and certain rural hospitals to avert potential closure and continue to provide essential services for the communities they serve. Conversion to an REH allows for the provision of emergency services, observation care, and additional outpatient services, if elected by the REH, that do not exceed an annual per patient average of twenty-four (24) hours. Although REHs are prohibited from providing inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-REH or post-hospital extended care services, this level of care is intended to promote equity in health care for those living in rural communities by facilitating access to needed services.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to establish the REH licensure category and require compliance with the federal Conditions of Participation established by 42 C.F.R. 485.500—485.546.

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

This administrative regulation conforms to the content of KRS 216B.042 by establishing the minimum requirements for licensure as an REH.

(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 requirements for licensure as an REH.

(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 amended after comments regulation: 1. Clarifies that licensure as an REH shall be obtained prior to certification by the Centers for Medicare and Medicaid Services (CMS); and 2. Deletes the requirement for an REH to obtain certificate of need approval prior to converting back to a critical access hospital or acute care hospital.

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

This amended after comments regulation is necessary to clarify that licensure as an REH shall be obtained prior to certification from CMS.

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

This amended after comments regulation to the content of KRS 216B.042 by establishing the minimum requirements for licensure as an REH.

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

This amended after comments regulation assists in the effective administration of the statutes by establishing the minimum requirements for licensure as an REH.

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

This amended after comments regulation affects facilities seeking licensure and CMS certification as an REH in accordance with 42 C.F.R. 485.506. It is not known how many CAHs or rural hospitals will convert to an REH.

(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:

In accordance with this administrative regulation, entities seeking licensure as an REH will be required to submit an initial and annual application to the cabinet with accompanying documentation. REHs will have to comply with the federal requirements established by 42 C.F.R. 485.500—485.546 as a condition of state licensure.

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

This administrative regulation establishes an initial and annual renewal fee of $1,000. However, CAHs and other rural hospitals that convert to an REH already pay a higher licensure fee in accordance with 902 KAR 20:008, Section 3(2)(x) and (k) respectively.

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

CAHs and rural hospitals that convert to an REH may avert potential closure and continue to provide essential services for the communities they serve.

(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 administrative regulation.

(b) On a continuing basis:

There are no additional costs to the Office of Inspector General for implementation of this administrative regulation 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:

This administrative regulation establishes an initial and annual renewal fee of $1,000. However, CAHs and other rural hospitals that convert to an REH already pay a higher licensure fee in accordance with 902 KAR 20:008, Section 3(2)(x) and (k) respectively.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation establishes an initial and annual renewal fee of $1,000.

(9) TIERING: Is tiering applied?

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

FISCAL NOTE

(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 impacts rural emergency hospitals (REH) and 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 and 42 C.F.R. 485.500—485.546

(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 administrative regulation establishes an initial and annual renewal fee of $1,000. Because critical access hospitals (CAHs) and other rural hospitals that convert to an REH already pay licensure fees in accordance with 902 KAR 20:008, Section 3(2)(x) and (k) respectively, there is no increase in 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 administrative regulation establishes an initial and annual renewal fee of $1,000. Because CAHs and other rural hospitals that convert to an REH already pay licensure fees in accordance with 902 KAR 20:008, Section 3(2)(x) and (k) respectively, there is no increase in revenue.

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

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

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

There are no additional costs to the Office of Inspector General for implementation of this administrative regulation 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:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

By discontinuing infrequently used inpatient beds, this administrative regulation will generate cost savings for CAHs and rural hospitals that convert to an REH.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

By discontinuing infrequently used inpatient beds, this administrative regulation will generate cost savings for CAHs and rural hospitals that convert to an REH.

(c) How much will it cost the regulated entities for the first year?

This administrative regulation establishes an initial and annual renewal fee of $1,000. However, CAHs and other rural hospitals that convert to an REH already pay a higher licensure fee in accordance with 902 KAR 20:008, Section 3(2)(x) and (k) respectively.

(d) How much will it cost the regulated entities for subsequent years?

This administrative regulation establishes an initial and annual renewal fee of $1,000. However, CAHs and other rural hospitals that convert to an REH already pay a higher licensure fee in accordance with 902 KAR 20:008, Section 3(2)(x) and (k) respectively.

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

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] It is not known how many entities will convert to an REH. However, CAHs and rural hospitals that discontinue infrequently used inpatient beds and convert to an REH may avert potential closure and continue to provide essential services for the communities they serve.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.
42 C.F.R. 485.500—485.546, 42 C.F.R. 485.618, 45 C.F.R. Part 160, Part 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. 485.500—485.546 establish the federal conditions of participation for the certification of rural emergency hospitals. In accordance with 42 C.F.R. 485.516, rural emergency hospitals must meet the critical access hospital requirements of 42 C.F.R. 485.618 for emergency services. 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.