

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Certificate of Need
(Amendment)

900 KAR 6:075. Certificate of need nonsubstantive review.

RELATES TO: KRS 216B.010, 216B.015, 216B.040, 216B.062, 216B.090, 216B.095, 216B.115, 216B.455, 216B.990

STATUTORY AUTHORITY: KRS 216B.040(2)(a)1., 216B.095

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1. requires the Cabinet for Health and Family Services to administer Kentucky's Certificate of Need Program and to promulgate administrative regulations as necessary for the program. KRS 216B.095 authorizes the review of certificate of need applications that are granted nonsubstantive status. This administrative regulation establishes the requirements necessary for consideration for nonsubstantive review of applications for the orderly administration of the Certificate of Need Program.

Section 1. Definitions.

- (1) "Ambulatory surgical center" is defined by KRS 216B.015(4).
- (2) "Cabinet" is defined by KRS 216B.015(6).
- (3) "Certificate of Need Newsletter" means the monthly newsletter that is published by the cabinet regarding certificate of need matters and is available on the Certificate of Need Web site at <https://chfs.ky.gov/agencies/os/oig/dcn/Pages/cn.aspx>.
- (4) "Days" means calendar days, unless otherwise specified.
- (5) "Formal review" means the review of an application for certificate of need that is reviewed within ninety (90) days from the commencement of the review as provided by KRS 216B.062(1) and that is reviewed for compliance with the review criteria set forth at KRS 216B.040 and 900 KAR 6:070.
- (6) "Nonsubstantive review" is defined by KRS 216B.015(18).
- (7) "Public notice" means notice given through the cabinet's Certificate of Need Newsletter.

Section 2. Nonsubstantive Review.

- (1) The cabinet shall grant nonsubstantive review status to an application to change the location of a proposed health facility or to relocate a licensed health facility only if:
 - (a) There is no substantial change in health services or bed capacity; and
 - (b)
 1. The change of location or relocation is within the same county; or
 2. The change of location or relocation is for a psychiatric residential treatment facility.
- (2) The cabinet shall grant nonsubstantive review status to an application that proposes to establish an ambulatory surgical center pursuant to the conditions specified in KRS 216B.095(7).
- (3) In addition to the projects specified in KRS 216B.095(3)(a) through (e), pursuant to KRS 216B.095(3)(f), the Office of Inspector General shall grant nonsubstantive review status to an application for which a certificate of need is required if:
 - (a) The proposal involves the establishment or expansion of a health facility or health service for which there is not a component in the State Health Plan;
 - (b) The proposal involves an application to re-establish a licensed healthcare facility or service that was provided at a hospital and was voluntarily discontinued by the applicant under the following circumstances:

1. The termination or voluntary closure of the hospital:
 - a. Was not the result of an order or directive by the cabinet, governmental agency, judicial body, or other regulatory authority;
 - b. Did not occur during or after an investigation by the cabinet, governmental agency, or other regulatory authority;
 - c. Did occur while the facility was in substantial compliance with applicable administrative regulations and was otherwise eligible for re-licensure; and
 - d. Was not an express condition of any subsequent certificate of need approval;
2. The application to re-establish the healthcare facility or service that was voluntarily discontinued is filed no more than one (1) year from the date the hospital last provided the service that the applicant is seeking to re-establish;
3. A proposed healthcare facility shall be located within the same county as the former healthcare facility and at a single location; and
4. The application shall not seek to re-establish any type of bed utilized in the care and treatment of patients for more than twenty-three (23) consecutive hours; ~~or~~

(c)

1. The proposal involves an application to establish an ambulatory surgical center that does not charge its patients and does not seek or accept commercial insurance, Medicare, Medicaid, or other financial support from the federal government; and
2. The proposed ambulatory surgical center shall utilize the surgical facilities of an existing licensed ambulatory surgical center during times the host ambulatory surgical center is not in operation;

(d) The proposal involves an application by a licensed health facility to establish a Class I ground ambulance service operating at the Advanced Life Support (ALS) or Basic Life Support (BLS) level to provide nonemergency transport of individuals if the applicant agrees to the following restrictions to be placed on its proposed certificate of need and ground ambulance license:

1. The applicant shall only transport individuals who are patients of the licensed health facility or a health facility under common ownership; and
2. The applicant shall only transport individuals to or from its health facility or a health facility under common ownership and another licensed health facility, the individual's place of residence, or other community-based setting; or

(e) The proposal involves an application to transfer acute care beds from one (1) or more existing Kentucky-licensed hospitals to establish a new hospital under the following circumstances:

1. The existing hospital and new facility shall be under common ownership and located in the same county;
2. The existing hospital's overall rating by the Centers for Medicare and Medicaid Services Hospital Compare was three (3) stars or higher for three (3) out of the last four (4) reported quarters preceding the date the application was filed; and
3. No more than fifty (50) percent of the existing hospital's acute care beds shall be transferred to the new facility.

(4) A certificate of need approved for an application submitted under subsection (3)(c) of this section shall state the limitations specified under subsection (3)(c)1. and 2. of this section.

(5) If an application is denied nonsubstantive review status by the Office of Inspector General, the application shall automatically be placed in the formal review process.

(6) If an application is granted nonsubstantive review status by the Office of Inspector General, notice of the decision to grant nonsubstantive review status shall be given to the applicant and all known affected persons.

(7)

- (a) If an application is granted nonsubstantive review status by the Office of Inspector General, any affected person who believes that the application is not entitled to nonsubstantive review status or who believes that the application should not be approved may request a hearing by filing a request for a hearing within ten (10) days of the notice of the decision to conduct nonsubstantive review.
- (b) The provisions of 900 KAR 6:090 shall govern the conduct of all nonsubstantive review hearings.
- (c)
1. Except as provided in subparagraph 2. of this paragraph, nonsubstantive review applications shall not be comparatively reviewed.
 2. If the capital expenditure proposed involves the establishment or expansion of a health facility or health service for which there is a component in the State Health Plan, the nonsubstantive review applications shall be comparatively reviewed.
- (d) Nonsubstantive review applications may be consolidated for hearing purposes.
- (8) If an application for certificate of need is granted nonsubstantive review status by the Office of Inspector General, there shall be a presumption that the facility or service is needed and a presumption that the facility or service is consistent with the State Health Plan.
- (9) If each applicable review criterion in the State Health Plan has been met, there shall be a presumption that the facility or service is needed unless the presumption of need has been rebutted by clear and convincing evidence by an affected party.
- (10) Unless a hearing is requested pursuant to 900 KAR 6:090, the Office of Inspector General shall approve each application for a certificate of need that has been granted nonsubstantive review status if the exception established in subsection (11)(a) of this section does not apply.
- (11) The cabinet shall disapprove an application for a certificate of need that has been granted nonsubstantive review if the cabinet finds that the:
- (a) Application is not entitled to nonsubstantive review status; or
 - (b) Presumption of need or presumption that the facility or service is consistent with the State Health Plan provided for in subsection (8) of this section has been rebutted by clear and convincing evidence by an affected party.
- (12) In determining whether an application is consistent with the State Health Plan, the cabinet, in making a final decision on an application, shall apply the latest criteria, inventories, and need analysis figures maintained by the cabinet and the version of the State Health Plan in effect at the time of the public notice of the application.
- (13) In determining whether an application is consistent with the State Health Plan following a reconsideration hearing pursuant to KRS 216B.090 or a reconsideration hearing that is held by virtue of a court ruling, the cabinet shall apply the latest criteria, inventories, and need analysis figures maintained by the cabinet and the version of the State Health Plan in effect at the time of the reconsideration decision or decision following a court ruling.
- (14) A decision to approve or disapprove an application that has been granted nonsubstantive review status shall be rendered within thirty-five (35) days of the date that nonsubstantive review status has been granted, as required by KRS 216B.095(1). A hearing officer shall prioritize rendering decisions regarding applications granted nonsubstantive review status pursuant to Section 2(3)(d) of this administrative regulation.
- (15) If a certificate of need is disapproved following nonsubstantive review, the applicant may:
- (a) Request that the cabinet reconsider its decision pursuant to KRS 216B.090 and 900 KAR 6:065;
 - (b) Request that the application be placed in the next cycle of the formal review process; or

(c) Seek judicial review pursuant to KRS 216B.115.

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: January 25, 2022

FILED WITH LRC: January 27, 2022 at 11 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on April 28, 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 April 21, 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 April 30, 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

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes procedures for the nonsubstantive review of certificate of need applications. Nonsubstantive review is an expedited review process granted to certain applications pursuant to KRS 216B.095. This administrative regulation expands upon the types of applications that qualify for nonsubstantive review per the statute.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to comply with the content of the authorizing statutes, specifically KRS 216B.010, 216B.015(18), 216B.040, and 216B.095.

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

This administrative regulation conforms to the content of the authorizing statutes by adding types of certificate of need applications that qualify for nonsubstantive review status, setting forth the procedure for granting nonsubstantive review status, and setting forth the procedure for affected parties to request a hearing to dispute the review status or application.

(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 adding types of certificate of need applications that qualify for nonsubstantive review status, setting forth the procedure for granting nonsubstantive review status, and setting forth the procedure for affected parties to request a hearing to dispute the review status or application.

(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 grants nonsubstantive review status to certificate of need applications submitted by licensed health facilities seeking to establish a Class I ground ambulance service operating at the Advanced Life Support (ALS) or Basic Life Support (BLS) level to provide nonemergency transport of individuals who are patients of the licensed health facility or a health facility under common ownership and the applicant agrees to the placement of restrictions as established by Section 2(3)(d) of this administrative regulation on its proposed certificate of need and ground ambulance license. This amendment also adds a cross-reference to KRS 216B.095(1) to emphasize the 35-day statutory time limit to issue a decision on applications assigned nonsubstantive review and requires hearing officers to prioritize decisions on nonemergency ground ambulance applications. Additionally, this amendment grants nonsubstantive review status to certificate of need applications for acute care hospitals that wish to transfer existing acute care beds to a new facility under common ownership if: - The facilities are located within the same county; - The existing hospital's overall rating by the Centers for Medicare and Medicaid Services Hospital Compare was three (3) stars or higher for three (3) of the last four (4) reported quarters preceding the date the application was filed; and -

No more than fifty (50) percent of the existing hospital's acute care beds are transferred to the new facility.

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

This amendment is being proposed pursuant to KRS 216B.095(3)(f), which permits the cabinet to grant nonsubstantive review status to a certificate of need application in accordance with circumstances prescribed by the cabinet via administrative regulation.

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

This amendment conforms to KRS 216B.095(3)(f), which permits the cabinet to grant nonsubstantive review status to a certificate of need application in accordance with circumstances prescribed by the cabinet via administrative regulation.

(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 procedures for review of certificate of need applications granted nonsubstantive review status.

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

This administrative regulation affects entities that submit certificate of need applications subject to the nonsubstantive review process. The number of entities that submit certificate of need applications subject to nonsubstantive review varies.

(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:

This amendment will permit nonsubstantive review of certificate of need applications for health facility-based Class I ground ambulance service operating at the ALS or BLS level to provide nonemergency transport in accordance with the circumstances prescribed by Section 2(3)(d) of this administrative regulation. This amendment will also permit nonsubstantive review of certificate of need applications for acute care hospitals that wish to transfer existing acute care beds to a new facility under common ownership located in the same county and in accordance with additional criteria proposed in Section 2(3)(e) of this administrative regulation.

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

. The certificate of need application filing fee is the same for nonsubstantive review and formal review and is established in a separate administrative regulation, 900 KAR 6:020.

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

The proposed amendment will help improve access to services without a duplication of acute care beds as well as enhance patient care in an effort to address ongoing delays in nonemergency ambulance transportation.

(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:

State general funds and agency monies are used to implement and enforce this administrative regulation.

(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 used as certificate of need applications are reviewed under a formal review process (900 KAR 6:070) or nonsubstantive review process (this administrative regulation). The list of applications granted nonsubstantive review is being amended to add two (2) new categories.

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 entities that are subject to the certificate of need program's nonsubstantive review process. 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.010, 216B.015(8), 216B.040, 216B.095

(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 does not generate additional revenue for state or local government.

(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 does not generate additional revenue for state or local government during 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: