

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;

(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 to establish an industrial ambulance service;

(e) Prior to July 1, 2026, the proposal involves an application by:

1. An ambulance service that is owned by a city or county government seeking to provide ambulance transport services pursuant to KRS 216B.020(9)(a)1. or 2.; or
2. A licensed hospital seeking to provide transport from a location that is not a health care facility pursuant to KRS 216B.020(9)(a)3. and (b);

(f) 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. No more than fifty (50) percent of the existing hospital's acute care beds shall be transferred to the new facility; and
- 3.

- a. If the existing hospital is a state university teaching hospital, the existing hospital exceeded, by at least one (1), the minimum number of quality measures required to receive supplemental university directed payments from Kentucky Medicaid for the state fiscal year preceding the date the application was filed; or
- b. If the existing hospital is not a state university teaching hospital, the existing hospital's overall rating by the Centers for Medicare and Medicaid Services Hospital Compare was three (3) stars or higher on the most recent annual update to the overall star ratings preceding the date the application was filed; ~~{or}~~

(g)

1. The proposal involves an application from a Program of All-Inclusive Care for the Elderly (PACE) program that:
 - a. Has met the requirements of the State Readiness Review (SRR) according to a report submitted by the Department for Medicaid Services (DMS) to the Centers for Medicare and Medicaid Services (CMS);
 - b. Seeks to provide, directly to its members, a health service that is not exempt from certificate of need (CON) under KRS 216B.020(1); and

- c. Ensures that all services authorized under the PACE agreement are provided exclusively to its members who reside within the service area. The service area shall be:
 - (i) Located within the Commonwealth of Kentucky; and
 - (ii) Approved by both CMS and DMS.
- 2. Only an approved PACE program operating within the applicant's service area shall qualify as an affected person for the purpose of opposing a PACE program application.
- 3. A PACE program shall not be required to obtain certificate of need (CON) approval if the program:
 - a. Provides direct patient health services that are exempt from CON under KRS 216B.020(1) and provides other services subject to CON approval through contracts with licensed providers; or
 - b. Has already obtained CON approval within the approved PACE service area to provide a health service that is not exempt from CON;
- (h) The proposal involves an application to establish an inpatient psychiatric unit in an existing licensed acute care hospital under the following conditions:
 - 1. The hospital is located in a county that has no existing, freestanding psychiatric hospital;
 - 2. The occupancy of acute care beds in the applicant's facility is less than seventy (70) percent according to the most recent edition of the Kentucky Annual Hospital Utilization and Services Report;
 - 3.
 - a. All of the proposed psychiatric beds are being converted from licensed acute care beds; and
 - b. No more than twenty-five (25) acute care beds will be converted to psychiatric beds;
 - 4. All of the psychiatric beds will be implemented on-site at the applicant's existing licensed facility; and
 - 5. All of the psychiatric beds shall be dedicated exclusively to the treatment of adult patients, aged eighteen (18) to sixty-four (64);
- (i) The proposal involves an application to provide megavoltage radiation therapy by an applicant that is majority owned by a Kentucky-licensed acute care hospital accredited by the American College of Surgeons Commission on Cancer;
- (j) The proposal involves an application to provide positron emission tomography services;
- (k) The proposal involves an application to provide magnetic resonance imaging services by an applicant that will be accredited by the American College of Radiology within twelve (12) months of licensure; or
- (l) The proposal involves an application by a Kentucky-licensed acute care hospital, critical access hospital, or nursing facility proposing to establish or expand a home health service to serve exclusively patients discharged from its 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)(g) 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.

Section 3. Exemption from Certificate of Need.

(1) A city or county government-owned ambulance service that meets the criteria established by KRS 216B.020(8) shall not be required to obtain a certificate of need to provide emergency ambulance transport services.

(2) A hospital-owned ambulance service shall not be required to obtain a certificate of need to provide non-emergency or emergency transport that originates from its hospital pursuant to KRS 216B.020(7).

(3)

(a) If a hospital-owned ambulance service has certificate of need approval prior to the most recent effective date of this administrative regulation to provide transport services from another health facility to its hospital, the service shall not be required to obtain authorization in accordance with paragraph (b) of this subsection.

(b) A hospital-owned ambulance service that is exempt from certificate of need under KRS 216B.020(7) may provide transport services from another health facility to its hospital if authorized as set out in KRS 311A.025(4).

(c)

1. As used in paragraph (b) of this subsection, a hospital is authorized to provide inter-facility transport of a patient if:

a. The hospital contacts by phone at least one (1) ground ambulance provider with jurisdiction in the territory in which the other health facility is located, using contact information from the most recent edition of the agency directory maintained by the Kentucky Board of Emergency Medical Services at the following link (<https://kbems.kctcs.edu/legal/EMS%20Directory.aspx>); and

b. The ground ambulance provider:

(i) Declines the hospital's request for patient transport; or

(ii) Is not able to initiate the patient's transport within four (4) hours of receiving the hospital's request.

2. For purposes of this paragraph, a provider initiates transport when it arrives at the hospital to transport the patient.

3. The hospital shall document the ambulance service contacted and the reason for authorization to provide transport from another health facility to its hospital.

(4)

(a) In accordance with KRS 216B.020(12)(a), the provisions of this section and Section 2(3)(e) of this administrative regulation shall expire on July 1, 2026.

(b) In accordance with KRS 216B.020(12)(b), a certificate of need exemption granted to an ambulance service under this section of this administrative regulation shall remain in effect on and after July 1, 2026.

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: March 10, 2023

FILED WITH LRC: March 15, 2023 at 8:00 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on May 22, 2023, 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 May 15, 2023, 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 May 31, 2023. 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 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 adds the following types of certificate of need applications to those that are granted nonsubstantive review status: 1. Applications by licensed hospitals to convert existing acute care beds to psychiatric beds for adult patients if certain criteria are met; 2. Applications by a licensed hospital to provide megavoltage radiation therapy; 3. Applications to provide positron emission tomography services; 4. Applications to provide magnetic resonance imaging services; and 5. Applications by a licensed acute care hospital, critical access hospital, or nursing facility proposing to establish or expand a home health service to serve patients discharged from its 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. These changes were requested by providers to allow them to add needed health care services more quickly and efficiently in response to their patient's changing needs. This amendment is needed to expand access to health services

throughout the state, including in rural areas, to enhance immediate access to resources.

(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 the applicants and healthcare services added in Section 2(3)(h) – (l) 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 health care services by making it easier to obtain a certificate of need to provide these services. This will increase access to services that are closer to home for many patients, particularly in rural areas of the state.

(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 establishes any fees or directly or indirectly increases 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

(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:

(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?

This administrative regulation will not generate cost savings for regulated entities during the first year.

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

This administrative regulation will not generate cost savings for regulated entities during subsequent years.

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

This administrative regulation imposes no additional costs on regulated entities.

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

This administrative regulation imposes no additional costs on regulated entities during subsequent years.

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)] This new administrative regulation is not expected to have a major economic impact on the regulated entities.