

**STATEMENT OF EMERGENCY**  
**900 KAR 6:075E**

This emergency administrative regulation is being promulgated in accordance with KRS 13A.190(1)(a), to prevent a loss of federal or state funds. The previous administration declared that a public health crisis existed in counties without adequate ambulance services to treat medical emergencies with urgency and with respect to patient choice. However, there is not a lack of access or issue with patient choice. The formal review process is more appropriate than the nonsubstantive review process for applications to establish a Class I ground ambulance service. If the prior action is not reversed by this emergency administrative regulation, there will be a loss of state funds due to litigation regarding that prior action. This emergency administrative regulation will be replaced by an ordinary administrative regulation. The ordinary administrative regulation is identical to this emergency administrative regulation.

ANDY BESHEAR, Governor  
ERIC FRIEDLANDER, Acting Secretary

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

**900 KAR 6:075E. 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[, 344A.030(1)(b)]

STATUTORY AUTHORITY: KRS 216B.040(2)(a)1, 216B.095[, EO 2018-325]

EFFECTIVE: January 2, 2019

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. [~~EO 2018-325 abolished the Office of Health Policy and created the Division of Certificate of Need within the Office of Inspector General.~~] 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) [~~"Base station" means the primary physical location of an ambulance service.~~

~~(3)~~] "Cabinet" is defined by KRS 216B.015(6).

~~(3)~~[(4)] "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)~~[(5)] "Days" means calendar days, unless otherwise specified.

~~(5)~~[(6)] "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)~~[(7)] "Nonsubstantive review" is defined by KRS 216B.015(18).

~~(7)~~~~(8)~~ "Public notice" means notice given through the cabinet's Certificate of Need Newsletter.

~~(9) "Satellite location" means a physical location with a street address from where an ambulance is based on a twenty-four (24) hour basis.~~

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; ~~or~~

~~(d)1. The proposal involves an application to establish a Class I ground ambulance service;~~

~~2. The applicant's proposed service area is limited to a county with a population of 50,000 or more;~~

~~3. There is no more than one (1) licensed Class I ground ambulance service that has both a license to serve the entire county that the applicant is proposing to serve and that has a base station or a satellite location, or both, located in the county that the applicant is proposing to~~

serve; and

~~4. The current Class I ground ambulance service provider serving the county as specified in subparagraph 3. of this paragraph is not owned or operated by a public organization].~~

(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 nonsubstan-

tive review status shall be rendered within thirty-five (35) days of the date that nonsubstantive review status has been granted.

(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 D. MATHER, Inspector General

ERIC FRIEDLANDER, Acting Secretary

APPROVED BY AGENCY: December 30, 2019

FILED WITH LRC: January 2, 2020 at 4 p.m.

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## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Persons: Stephanie Brammer-Barnes and Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation addresses the nonsubstantive review of certificate of need applications. Nonsubstantive review is an expedited review process granted to certain applications pursuant to KRS 216B.095. 900 KAR 6:075 expands upon the types of applications qualified 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), 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 and setting forth the procedure for granting nonsubstantive review status and performing the expedited review as well as 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 qualified for nonsubstantive review status and setting forth the procedure for granting nonsubstantive review status and performing the expedited review as well as 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: The amendment adds statutory citations to the RELATES TO paragraph to comply with KRS 13A.220(4)(e); removes references to EO 2018-325, which was codified by 2019 Ky. Acts ch. 90 (Senate Bill 167); deletes the definitions of "base station" and "satellite location"; and removes the authorization for nonsubstantive review for proposals involving an application to establish a Class I ground ambulance service.

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

necessary to reverse action taken by the prior administration, which claimed there was a public health emergency created by lack of access to Class I ambulances in Kentucky's larger counties and patient choice. There is not a lack of access or issue with patient choice, and the formal review process is more appropriate than the nonsubstantive review process for applications to establish a Class I ground ambulance service.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statute by revising the list of nonsubstantive review categories established by the cabinet in accordance with KRS 216B.095(3)(f).

(d) How the amendment will assist in the effective administration of the statutes: The amendment will assist in the effective administration of the statutes by reversing a prior determination that there was a public health emergency created by a lack of access and issues with patient choice.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: This administrative regulation affects certificate of need applicants proposing Class I ambulance services and affected parties. It is not known how many applicants will propose a Class I ambulance service.

(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: A certificate of need application proposing to establish a Class I ambulance service in certain counties will no longer be permitted to use the nonsubstantive review process. Instead, those applications will be reviewed by the formal review process governed by 900 KAR 6:060, Certificate of need considerations for formal review.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to entities to comply with this amendment other than the certificate of need application filing fee, which is determined using a methodology calculated using the capital expenditure of the proposed service. 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): Returning the proposals to establish a Class I ground ambulance service to the formal review process will ensure that the nonsubstantive review process is reserved for a very limited number of exceptions authorized by KRS 216B.095. There is not a public health emergency or a lack of access to, or issue of patient choice with, Class I ambulances in Kentucky's larger counties. The formal review process is more appropriate than the nonsubstantive review process for applications to establish a Class I ground ambulance service.

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

(a) Initially: No additional costs will be incurred to implement this administrative regulation.

(b) On a continuing basis: No additional costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: There is no source of funding needed to implement 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: Neither an increase in fees nor funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any

fees.

(9) Tiering: Is tiering applied? Tiering is used as certificate of need applications are reviewed using either a formal review process (under 900 KAR 6:070) or nonsubstantive review process (this administrative regulation). The applications that qualify for nonsubstantive review are being amended to remove one category of applications previously authorized to proceed under the nonsubstantive category.

### 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 impacts the Cabinet for Health and Family Services, Office of Inspector General, and any government owned or operated ambulance providers.

2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.010, 216B.015(18), and 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 administrative regulation is not expected to generate 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 administrative regulation is not expected to generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year? This administrative regulation is not expected to have any costs for its administration.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation is not expected to have any costs for its administration.

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: \_\_\_\_\_