

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Inspector General

3 Division of Certificate of Need

4 (Amendment)

5 900 KAR 6:075. Certificate of need nonsubstantive review.

6 RELATES TO: KRS 216B.010, 216B.015, 216B.090, 216B.455, 216B.990,

7 311A.030(1)(b)

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

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the
10 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need
11 Program and to promulgate administrative regulations as necessary for the program. KRS
12 216B.095 authorizes the review of certificate of need applications that are granted
13 nonsubstantive status. EO 2018-325 abolished the Office of Health Policy and created
14 the Division of Certificate of Need within the Office of Inspector General. This
15 administrative regulation establishes the requirements necessary for consideration for
16 nonsubstantive review of applications for the orderly administration of the Certificate of
17 Need Program.

18 Section 1. Definitions. (1) "Ambulatory surgical center" is defined by KRS
19 216B.015(4).

20 (2) "Cabinet" is defined by KRS 216B.015(6).

21 (3) "Certificate of Need Newsletter" means the monthly newsletter that is published

1 by the cabinet regarding certificate of need matters and is available on the Certificate of
2 Need Web site at <https://chfs.ky.gov/agencies/os/oig/dcn/Pages/cn.aspx>
3 [~~http://chfs.ky.gov/ohp/cen~~].

4 (4) "Days" means calendar days, unless otherwise specified.

5 (5) "Formal review" means the review of an application for certificate of need that is
6 reviewed within ninety (90) days from the commencement of the review as provided by
7 KRS 216B.062(1) and that is reviewed for compliance with the review criteria set forth at
8 KRS 216B.040 and 900 KAR 6:070.

9 (6) "Nonsubstantive review" is defined by KRS 216B.015(18).

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

12 Section 2. Nonsubstantive Review. (1) The cabinet shall grant nonsubstantive review
13 status to an application to change the location of a proposed health facility or to relocate
14 a licensed health facility only if:

15 (a) There is no substantial change in health services or bed capacity; and

16 (b)1. The change of location or relocation is within the same county; or

17 2. The change of location or relocation is for a psychiatric residential treatment facility.

18 (2) The cabinet shall grant nonsubstantive review status to an application that
19 proposes to establish an ambulatory surgical center pursuant to the conditions specified
20 in KRS 216B.095(7).

21 (3) In addition to the projects specified in KRS 216B.095(3)(a) through (e), pursuant
22 to KRS 216B.095(3)(f), the Office of Inspector General~~[Health Policy]~~ shall grant
23 nonsubstantive review status to an application for which a certificate of need is required

1 if:

2 (a) The proposal involves the establishment or expansion of a health facility or health
3 service for which there is not a component in the State Health Plan;

4 ~~(b) [The proposal involves an application to relocate or transfer licensed acute care
5 beds, not including neonatal Level III or Level IV beds, from one (1) existing licensed
6 hospital to another existing licensed hospital within the same area development district
7 and the requirements established in this paragraph are met.~~

8 ~~1.a. There shall not be an increase in the total number of licensed acute care beds in
9 that area development district; and~~

10 ~~b. The hospital from which the licensed beds are relocated delicensures those beds.~~

11 ~~2. If neonatal Level II beds are relocated or transferred pursuant to this paragraph:~~

12 ~~a. The receiving hospital shall have an existing licensed Level II, Level III, or Level IV
13 neonatal unit;~~

14 ~~b. A minimum of four (4) beds shall be relocated; and~~

15 ~~c. The relocation shall not leave the transferring hospital with less than four (4)
16 neonatal Level II beds unless the relocated beds represent all of its neonatal Level II
17 beds;~~

18 ~~(c) The proposal involves an application by an existing licensed acute care hospital
19 to:~~

20 ~~1. Convert licensed psychiatric or chemical dependency beds to acute care beds, not
21 including special purpose acute care beds such as neonatal Level II beds, Level III beds,
22 or Level IV beds;~~

23 ~~2. Convert and implement the beds on-site at the hospital's existing licensed facility;~~

1 and

2 ~~3. Delicense the same number of psychiatric or chemical dependency beds that are~~
3 ~~converted;~~

4 ~~(d) The proposal involves an application by an existing licensed hospital providing~~
5 ~~inpatient psychiatric treatment to:~~

6 ~~1. Convert psychiatric beds licensed for use with geriatric patients to acute care beds,~~
7 ~~not including special purpose acute care beds such as neonatal Level II beds, Level III~~
8 ~~beds, or Level IV beds;~~

9 ~~2. Convert and implement the beds on-site at the existing licensed hospital; and~~

10 ~~3. Delicense the same number of converted beds;~~

11 ~~(e)] The proposal involves an application to re-establish a licensed healthcare facility~~
12 ~~or service that was provided at a hospital and was voluntarily discontinued by the~~
13 ~~applicant under the following circumstances:~~

14 1. The termination or voluntary closure of the hospital:

15 a. Was not the result of an order or directive by the cabinet, governmental agency,
16 judicial body, or other regulatory authority;

17 b. Did not occur during or after an investigation by the cabinet, governmental agency,
18 or other regulatory authority;

19 c. Did occur while the facility was in substantial compliance with applicable
20 administrative regulations and was otherwise eligible for re-licensure; and

21 d. Was not an express condition of any subsequent certificate of need approval;

22 2. The application to re-establish the healthcare facility or service that was voluntarily
23 discontinued is filed no more than one (1) year from the date the hospital last provided

1 the service ~~that~~~~which~~ the applicant is seeking to re-establish;

2 3. A proposed healthcare facility shall be located within the same county as the former
3 healthcare facility and at a single location; and

4 4. The application shall not seek to re-establish any type of bed utilized in the care
5 and treatment of patients for more than twenty-three (23) consecutive hours;

6 ~~(c)~~~~(f)~~1. The proposal involves an application to establish an ambulatory surgical
7 center that does not charge its patients and does not seek or accept commercial
8 insurance, Medicare, Medicaid, or other financial support from the federal government;
9 and

10 2. The proposed ambulatory surgical center shall utilize the surgical facilities of an
11 existing licensed ambulatory surgical center during times the host ambulatory surgical
12 center is not in operation; or

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

15 2. The applicant's proposed service area is limited to a county with a population of
16 50,000 or more;

17 3. There is no more than one (1) licensed Class I ground ambulance service in the
18 county that the applicant is proposing to serve; and

19 4. The current Class I ground ambulance service provider serving the county is not
20 owned or operated by a public organization.

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

1 (5) If an application is denied nonsubstantive review status by the Office of Inspector
2 General~~[Health Policy]~~, the application shall automatically be placed in the formal review
3 process.

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

7 (7)(a) If an application is granted nonsubstantive review status by the Office of
8 Inspector General~~[Health Policy]~~, any affected person who believes that the application
9 is not entitled to nonsubstantive review status or who believes that the application should
10 not be approved may request a hearing by filing a request for a hearing within ten (10)
11 days of the notice of the decision to conduct nonsubstantive review.

12 (b) The provisions of 900 KAR 6:090 shall govern the conduct of all nonsubstantive
13 review hearings.

14 (c)1. Except as provided in subparagraph 2_ of this paragraph, nonsubstantive review
15 applications shall not be comparatively reviewed.

16 2. If the capital expenditure proposed involves the establishment or expansion of a
17 health facility or health service for which there is a component in the State Health Plan,
18 the nonsubstantive review applications shall be comparatively reviewed.

19 (d) Nonsubstantive review applications may be consolidated for hearing purposes.

20 (8) If an application for certificate of need is granted nonsubstantive review status by
21 the Office of Inspector General~~[Health Policy]~~, there shall be a presumption that the facility
22 or service is needed and a presumption that the facility or service is consistent with the
23 State Health Plan.

1 (9) If each applicable review criterion in the State Health Plan has been met, there
2 shall be a presumption that the facility or service is needed unless the presumption of
3 need has been rebutted by clear and convincing evidence by an affected party.

4 (10) Unless a hearing is requested pursuant to 900 KAR 6:090, the Office of Inspector
5 General~~[Health Policy]~~ shall approve each application for a certificate of need that has
6 been granted nonsubstantive review status if the exception established in subsection
7 (11)(a) of this section does not apply.

8 (11) The cabinet shall disapprove an application for a certificate of need that has been
9 granted nonsubstantive review if the cabinet finds that the:

10 (a) Application is not entitled to nonsubstantive review status; or

11 (b) Presumption of need or presumption that the facility or service is consistent with
12 the State Health Plan provided for in subsection (8) of this section has been rebutted by
13 clear and convincing evidence by an affected party.

14 (12) In determining whether an application is consistent with the State Health Plan,
15 the cabinet, in making a final decision on an application, shall apply the latest criteria,
16 inventories, and need analysis figures maintained by the cabinet and the version of the
17 State Health Plan in effect at the time of the public notice of the application.

18 (13) In determining whether an application is consistent with the State Health Plan
19 following a reconsideration hearing pursuant to KRS 216B.090 or a reconsideration
20 hearing that~~[which]~~ is held by virtue of a court ruling, the cabinet shall apply the latest
21 criteria, inventories, and need analysis figures maintained by the cabinet and the version
22 of the State Health Plan in effect at the time of the reconsideration decision or decision
23 following a court ruling.

1 (14) A decision to approve or disapprove an application that~~[which]~~ has been granted
2 nonsubstantive review status shall be rendered within thirty-five (35) days of the date that
3 nonsubstantive review status has been granted.

4 (15) If a certificate of need is disapproved following nonsubstantive review, the
5 applicant may:


6 (a) Request that the cabinet reconsider its decision pursuant to KRS 216B.090 and
7 900 KAR 6:065;

8 (b) Request that the application be placed in the next cycle of the formal review
9 process; or

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

900 KAR 6:075

REVIEWED:

 9-24-18
Steve Davis Date
Inspector General
Office of Inspector General

APPROVED:

 9-25-18
Adam M. Meier, Secretary Date
Cabinet for Health and Family Services

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall, if requested, be held on November 26, 2018, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky, 40621. Individuals interested in attending this hearing shall notify this agency in writing by November 15, 2018, 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 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 November 30, 2018. 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: Laura Begin, Legislative and Regulatory Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621, Phone: 502-564-6746, Fax: 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 900 KAR 6:075

Contact Persons: Molly Lewis, Deputy Inspector General, Office of Inspector General, molly.lewis@ky.gov, phone 502-564-9592; and Laura Begin, Office of Legislative and Regulatory Affairs, CHFSregs@ky.gov, 502-564-6746

(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 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.

(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 and/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 will change the existing administrative regulation by revising the identity of the regulating agency to reflect the dissolution of the Office of Health Policy and the Office of Inspector General's adoption of the certificate of need program and by adding a type of ambulance application to the list of type of applications qualified for nonsubstantive review status. Additionally, three (3) categories of nonsubstantive review have been deleted in accordance with 2018 Ky. Acts ch. 143 (House Bill 444), which amended KRS 216B.020 to exempt those categories from certificate of need requirements.

(b) The necessity of the amendment to this administrative regulation: The amendment is necessary to address a public health emergency created by lack of access of Class I ambulances in Kentucky's larger counties. According to a recent (July 2018) report published by the Pegasus Institute, "Certificate of Need: Kentucky's CON Regulations and Their Impact on Ambulance Care," counties above 50,000 residents have 25.65% fewer ambulance providers (all classes) compared to six (6) other states

that either border the Commonwealth or are in the same region. Further, the largest discrepancies between Kentucky and the sample were in high population counties. Two (2) Kentucky counties were notable outliers compared to others in the same sample population. Jefferson County has only thirteen (13) providers (all classes) as compared to 26.76 providers from similar sized counties in the sample; and Warren County has only one (1) provider compared to the sample size average of 6.93 licenses in similar sized counties. Relatedly, in Louisville, ambulance response times (10 minutes, 19 seconds) are significantly above national average (8 minutes), and well above Nashville (7 minutes, 12 seconds) and Indianapolis (5 minutes, 44 seconds); and in Bowling Green, Medicare data demonstrates that for emergency services at The Medical Center in Bowling Green (the owner, operator of the sole provider for the county), wait times for emergency services are 55 minutes versus TriStar Greenview (8 minutes) (the county's other hospital). At the Medical Center in Bowling Green, wait times are even longer for STEMI (ST-Elevation Myocardial Infarction, a very serious type of heart attack) patients and pain related to broken bones and patients are six (6) times more likely to leave The Medical Center without seeing a healthcare professional than at TriStar Greenview. As a result of these findings, the Pegasus Institute's top recommendation to the Commonwealth, which is one (1) of only four (4) states with certificate of need requirements for ambulance providers, is that Kentucky immediately suspend its CON requirements for ground ambulances in counties above 50,000 residents and begin phasing out CON laws in rural counties. This administrative regulation is a more conservative response than the recommendation, as it preserves the certificate of need requirement but provides for nonsubstantive review, which is an expedited review process that gives the applicant proposing the service the presumption that the service is needed and transfers the burden of proof to the affected party opposing the application's proposal. The additional changes to delete the three (3) categories of nonsubstantive review are necessary to comply with 2018 Ky. Acts ch. 143 (House Bill 444), which amended KRS 216B.020 to exempt those categories from certificate of need requirements.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment conforms to the content of the authorizing statutes by promulgating an administrative regulation conveying nonsubstantive review status to a specific type of certificate of need application that is necessary to improve access to quality health care in Kentucky and by deleting three (3) categories that are now exempt from certificate of need requirements.

(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 revising the identity of the regulating agency to reflect the dissolution of the Office of Health Policy and the Office of Inspector General's adoption of the certificate of need program and by adding a type of ambulance application to the list of type of applications qualified for nonsubstantive review status. The additional changes to delete the three (3) categories of nonsubstantive review are necessary to comply with 2018 Ky. Acts ch. 143 (House Bill 444), which amended KRS 216B.020 to exempt those categories from certificate of need requirements.

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

regulation affects certificate of need applicants proposing Class I ambulance services and affected parties. In 2018 to date, seven (7) applications proposing Class I ambulance services have been filed. Nineteen (19) of Kentucky's 120 counties have more than 50,000 residents. Of these counties, eleven (11) counties have only one (1) Class I ambulance and six (6) counties (Bullitt, Jessamine, Laurel, McCracken, Pike, and Warren) only have one (1) Class I ambulance that is not owned or operated by a public organization.

(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: Certificate of need applications proposing to establish a Class I ambulance provider serving a county with at least 50,000 residents and only one (1) existing ambulance provider that is not owned or operated by a public organization may be submitted during any batching cycle and request nonsubstantive review status.

(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): If an applicant proposes to establish a Class I ambulance service in a county with a population of at least 50,000 and only one (1) other Class I ambulance provider that is not owned or operated by a public organization, then that applicant will benefit from nonsubstantive review, be relieved of the formal application batching cycle, have the presumption of need, and have an expedited review process.

(5) Provide an estimate of how much it will cost the administrative body 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: No new funding will be needed to implement the provision of the amended 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 fee or funding increase is necessary to implement this administrative regulation.

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

or indirectly increased any fees: The administrative regulation does not establish or increase fees.

(9) TIERING: Is tiering applied? Tiering is used as the CON review criteria for applications proposing a Class I ground ambulance service in a county with a population of at least 50,000 and only one (1) existing ambulance provider that is not owned or operated by a public organization will be expedited and less rigorous than the review criteria for applications proposing other ambulance services.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation: 900 KAR 6:075

Contact Persons: Molly Lewis, molly.lewis@ky.gov, phone 502-564-9592; and Laura Begin, CHFSregs@ky.gov, 502-564-6746

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 Office of Inspector General and may impact any government owned or operated ambulance providers if the public organization is in a county with a population of at least 50,000 and only one (1) other Class I ambulance provider, which is not owned or operated by a public organization.

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(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 will generate revenue for local government only if the government applies to establish a Class I ambulance for a county with a population over 50,000 and with only one (1) Class I provider that is not owned or operated by a public organization. The revenue could be generated from fees for ambulance runs as well as a public necessity tax on residents.

(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? If a local government in a county with a population over 50,000 and with only one (1) Class I provider that is not owned or operated by a public organization applies for certificate of need authority to establish its own Class I ambulance service and the application is approved, that government owned service may generate revenue from fees for ambulance runs as well as a public necessity tax on residents. The amount of revenue will depend on volume, rate of reimbursement, operational costs, and tax if imposed.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a continuing basis.

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: