

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.
- (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.

(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.

(36 Ky.R. 239; Am. 626; 808; eff. 10-28-2009; 38 Ky.R. 339; 1007; 1140; eff. 12-7-2011; 39 Ky.R. 857; 1467; 1695; eff. 3-8-2013; 42 Ky.R. 546; 1781; eff. 12-16-2015; 45 Ky.R. 1427, 2395; eff. 5-31-2019; 46 Ky.R. 2332; eff. 7-29-2020.)