

CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Certificate of Need

(Amended at ARRS Committee)

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.

(8) "Psychiatric residential treatment facility" or "PRTF" is defined in KRS 216B.450(5) as a Level I facility or a Level II facility.

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 (20) percent of the facility's ~~twenty-five (25)~~ acute care beds up to a maximum of twenty-five (25) 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;~~

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~~† (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 *provide services exclusively to patients discharged from its facility who require home health services at the time of discharge and no existing, licensed home health agency is available and willing to accept the referral. The hospital or nursing facility shall document its efforts to find a Home Health Agency. A license issued under this subsection shall contain the limitation set forth herein.* ~~serve~~~~

~~*exclusively patients who require home health services at the time of discharge } { discharged } { from its facility.}*~~

(j) Level II PRTFs shall be subject to the nonsubstantive review process.

(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.

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