CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Certificate of Need

(Emergency Amended After Comments)

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

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

(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;

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(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
(d) The proposal involves an application to establish an industrial ambulance service;

(e) The proposal involves an application by a licensed health facility to establish a Class I ground ambulance service operating at the Advanced Life Support (ALS) or Basic Life Support (BLS) level to provide [nonemergency] transport of individuals if the applicant agrees to the following restrictions to be placed on its proposed certificate of need and ground ambulance license:

1. The applicant shall only transport individuals who are patients of the licensed health facility or a health facility under common ownership; and

2. The applicant shall only transport individuals to or from its health facility or a health facility under common ownership and another licensed health facility, the individual's place of residence, or other community-based setting; [or]

(f)[(e)] 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.i. 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

ii. 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 two (2) most recent updates to the overall star ratings [for three (3) out of the last four (4) reported quarters] 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 an approved agreement with the Centers for Medicare and Medicaid Services (CMS) and the Department for Medicaid Services (DMS); and

b. Ensures that 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. Coordinates health services only and does not provide health services to its members or others; or

b. Provides only services for which it has already obtained CON approval
under KRS Chapter 216B within the approved CON service area [and 3. No more
than fifty (50) percent of the existing hospital's acute care beds shall be
transferred to the new 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)(e) or (g)(d) 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.
900 KAR 6:075E, Amended After Comments

REVIEWED:

4/6/2022

Date

Adam Mather, Inspector General
Office of Inspector General

APPROVED:

4/14/2022

Date

Eric C. Friedlander, Secretary
Cabinet for Health and Family Services
REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation: 900 KAR 6:075E, Amended After Comments
Agency Contact: Kara Daniel; Stephanie Brammer-Barnes
Phone Number: (502) 564 – 2888
Email: karal.daniel@ky.gov; sbrammerbarnes@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-6746
Email: CHFSregs@ky.gov

(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: In accordance with with KRS 216B.095(3)(e), this emergency amended after comments regulation adds industrial ambulance services to the list of categories subject to nonsubstantive review under Section 2(3). This emergency amended after comments regulation also clarifies that proposals from licensed entities under Section 2(3)(e) shall not be limited to nonemergency transportation services only.

Additionally, this emergency amended after comments regulation updates the language of Section 2(3)(e) [renumbered as (f)] as it relates to using the most recent quality indicators on CMS Hospital Compare as one of the criteria for granting nonsubstantive review status to certificate of need applications for acute care hospitals.
that wish to transfer existing acute care beds to a new facility under common ownership located in the same county. Also, in lieu of meeting the overall star ratings in the case of state university teaching hospitals, the cabinet clarified that such hospitals shall exceed 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.

This emergency amended after comments regulation will permit a Program of All-Inclusive Care for the Elderly (PACE) applicant that has not already obtained certificate of need (CON) approval to provide services such as home health, adult day care, or another service subject to CON to seek approval under nonsubstantive review in Section 2(3)(g).

(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.

(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 emergency amended after comments regulation will permit nonsubstantive review of certificate of need applications for health facility-based Class I ground ambulance service operating at the ALS or BLS level to provide transport in accordance with the circumstances prescribed by Section 2(3)(e) of this administrative regulation. This amendment will also permit nonsubstantive review of certificate of need applications for acute care hospitals that wish to transfer existing acute care beds to a new facility under common ownership located in the same county and in accordance with additional criteria proposed in Section 2(3)(f) of this administrative regulation. Additionally, the emergency amended after comments regulation will permit PACE programs that have not already obtained approval to provide services such as home health, adult day care,
or another service subject to CON to seek approval under nonsubstantive review in Section 2(3)(g).

(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 services without a duplication of acute care beds as well as enhance patient care in an effort to address ongoing delays in nonemergency ambulance transportation. The emergency amended after comments regulation will help enable older adults to live in the community as long as medically and socially feasible by adding a new category to allow PACE programs that have not already obtained approval to provide services such as home health, adult day care, or another service subject to CON to seek approval under nonsubstantive review.

(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 established any fees or directly or indirectly increased any fees: This amendment does not establish or increase any fees.

(9) TIERING: Is tiering applied? (Explain why or why not) 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 three (3) new categories.
FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation: 900 KAR 6:075E, Amended After Comments
Agency Contact: Kara Daniel; Stephanie Brammer-Barnes
Phone Number: (502) 564 – 2888
Email: karal.daniel@ky.gov; sbrammerbarnes@ky.gov
Contact Person: Krista Quarles
Phone Number: (502) 564-6746
Email: CHFSregs@ky.gov

(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.040(2)(a)1., 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:
STATEMENT OF CONSIDERATION
Relating to 900 KAR 6:075E

Cabinet for Health and Family Services, Office of Inspector General,
Division of Certificate of Need
(Emergency Amended After Comments)

I. The public hearing on 900 KAR 6:075E was held on March 21, 2022, at 9:00 a.m. in
a Zoom meeting format by the CHFS Office of Legislative and Regulatory Affairs. In
addition, written comments were received during the public comment period.

II. The following people submitted comments:

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<thead>
<tr>
<th>Name and Title</th>
<th>Agency/Organization/Entity/Other</th>
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<tbody>
<tr>
<td>Sherri Craig, Market Vice President, Public Policy</td>
<td>CHI Saint Joseph Health</td>
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<tr>
<td>Joseph G. Koch, Market President, CEO</td>
<td>Meadowview Regional Medical Center, Fleming County Hospital</td>
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<tr>
<td>Mark Leach, Counsel for Emergent</td>
<td>Emergent Care EMS</td>
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<tr>
<td>Jody Prather, Chief Strategy and Marketing Officer</td>
<td>Baptist Health</td>
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<tr>
<td>Russ Ranallo, Vice President of Finance</td>
<td>Owensboro Health</td>
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<tr>
<td>Wade R. Stone, Executive Vice President</td>
<td>Med Center Health</td>
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<tr>
<td>Kara Daniel, Deputy Inspector General</td>
<td>Cabinet for Health &amp; Family Services</td>
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III. The following people from the promulgating administrative body responded to the
written comments:

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<thead>
<tr>
<th>Name and Title</th>
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<tr>
<td>Adam Mather, Inspector General</td>
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<tr>
<td>Kara L. Daniel, Deputy Inspector General</td>
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<tr>
<td>Stephanie Brammer-Barnes, Contractor</td>
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IV. Summary of Comments and Responses

(1) Subject: Nonsubstantive Review for Ambulance Services

Please note that, due to renumbering, all references to Section 2(3)(d) are referring to the paragraph currently numbered as Section 2(3)(e).

(a) Comment: Wade R. Stone, Med Center Health, provided the following comments: "On behalf of Med Center Health, I am writing in support of Section 2(3)(d) of 900 KAR 6:075E and 900 KAR 6:075. Med Center Health operates Medical Center EMS, which is a non-profit Class I ground ambulance service that provides 911 response in Warren County, Kentucky. Med Center EMS has a history of providing superior services and is one of only three agencies in Kentucky accredited by the Commission on Accreditation of Ambulance Services, which is considered the gold standard for EMS.

As you know, the new Section 2(3)(d) grants nonsubstantive review to a CON application by a licensed health facility to establish a ground ambulance service when the applicant agrees to certain restrictions on its license, primarily that it provides nonemergency transports of patients to or from its health facility or a health facility under common ownership only. Med Center Health believes that Section 2(3)(d) adequately addresses the capacity and transport issues that some hospitals may be experiencing without unnecessarily endangering the financial stability of many 911-response EMS agencies currently serving Kentucky communities.

Many ground ambulance services in Kentucky that respond to 911 calls are operated by non-profit or governmental agencies. Many of these agencies depend on revenue from nonemergency runs to offset some of the losses they experience from providing 911 transports. Med Center Health believes that Section 2(3)(d) appropriately grants nonsubstantive review to CON applications by hospitals that are seeking to address their own capacity and transport issues without duplicating existing ground ambulance services already adequately available. We believe that any expansion of Section 2(3)(d) to include CON applications to establish ground ambulance services that provide 911 response and transports for non-affiliated facilities could result in harm to the financial feasibility of existing providers and could be detrimental to 911 response in parts of the state. Therefore, while we support Section 2(3)(d) as it is currently written, we are opposed to any expansion of it for the reasons stated above."

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General appreciates the comments of support for 900 KAR 6:075E and 900 KAR 6:075.

(a) Comment: Jody Prather, M.D., Baptist Health, provided the following comments: "Baptist Health would like to comment on Section 2(3)(d) of 900 KAR 6:075, which grants nonsubstantive review to CON applications under the following circumstances:
The proposal involves an application by a licensed health facility to establish a Class I ground ambulance service operating at the Advanced Life Support (ALS) or Basic Life Support (BLS) level to provide nonemergency transport of individuals if the applicant agrees to the following restrictions to be placed on its proposed certificate of need and ground ambulance license:

1. The applicant shall only transport individuals who are patients of the licensed health facility or a health facility under common ownership; and
2. The applicant shall only transport individuals to or from its health facility or a health facility under common ownership and another licensed health facility, the individual's place of residence, or other community-based setting.

In its Statement of Emergency, the Cabinet states that the purpose of this new language is to address the delays that some hospitals are experiencing in transporting patients to their homes or other levels of care. Baptist Health has experienced delays in transporting patients in recent years and believes that the Cabinet's language strikes the appropriate balance in allowing hospitals to more quickly address a need to transport some patients without negatively affecting existing ambulance agencies that provide valuable 911-response services. However, Baptist Health would like the Cabinet to consider making one change that Baptist Health believes would be consistent with the intent of the existing language. The language is currently limited to CON applications for 'nonemergency' transports only. It appears from the Cabinet's Statement of Emergency that it intended 'nonemergency' to mean 'non-911.' However, some non-911 transports that hospitals need to perform may be considered 'emergency,' such as a transport from a hospital emergency room to a trauma center at a different hospital.

Therefore, Baptist Health proposes to delete 'nonemergency' from Section 2(3)(d) of 900 KAR 6:075E and 900 KAR 6:075 as follows:

The proposal involves an application by a licensed health facility to establish a Class I ground ambulance service operating at the Advanced Life Support (ALS) or Basic Life Support (BLS) level to provide nonemergency transport of individuals if the applicant agrees to the following restrictions to be placed on its proposed certificate of need and ground ambulance license...

Baptist Health believes that this change will allow hospitals to perform all necessary runs without altering the intent or purpose of the existing language."

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General agrees with the comments and will make the requested change to 900 KAR 6:075E. It should also be noted that the passage of HB 777, anticipated to take effect in July 2022, will grant a certificate of need exemption until July 1, 2026, to all hospital-owned ambulances that provide nonemergency and emergency transport services originating from the hospital, and city or county-owned emergency ambulances that provide transport services within their jurisdictional boundaries and comply with the
other requirements of Section 9(8) of the Act. In addition, HB 777 will grant nonsubstantive review until July 1, 2026 to hospital-owned ambulances and city or county-owned ambulances seeking to provide services that do not qualify for the certificate of need exemption of Section 9(7) or (8) of the Act.

After the public comment period for the ordinary version of 900 KAR 6:075 ends on April 30, 2022, the cabinet will amend the language of Section 2(3) in the separate “ordinary” version of the Statement of Consideration (SOC) and Amended After Comments (AAC) regulation to align with the passage of HB 777. The ordinary SOC and AAC regulation will be filed with the Legislative Research Commission no later than June 15, 2022.

(a) Comment: Kara Daniel, Deputy Inspector General, Cabinet for Health & Family Services, provided the following comments:

Currently, KRS 216B.095(3)(e) allows the cabinet to grant nonsubstantive review status to any proposal that involves an application for a certificate of need to establish an industrial ambulance service. However, a drafting error within HB 777 removed industrial ambulance services from KRS 216B.095. Therefore, to retain its long-standing status under nonsubstantive review, the cabinet will add industrial ambulance services to 900 KAR 6:075, Section 2(3).

(b) Response: The Office of Inspector General will amend 900 KAR 6:075E, Section 2(3) via agency comment by adding industrial ambulance services to the list of categories subject to nonsubstantive review.

(a) Comment: Mark Leach, Emergent Care EMS, requested that the comments he made during the public hearing on 900 KAR 5:020E also apply to 900 KAR 6:075E as follows: “I am commenting on the regulation change to create a new type of classification for a Class I and lower the review standard for the health facility-based ALS or BLS ambulance service to nonsub review.

It appears that this is a solution looking for a problem, and I say that because I am not aware of what evidence the cabinet is relying on to support this rule change. When you review the certificate of need search tool for applications for ground ambulance, there are very few that have actually been submitted by hospitals in the most recent years. So, it has not been demonstrated that the current system needs to be changed in order to address what they feel is a need for a new type of ambulance service. And I shouldn’t just limit that to hospitals, but health facilities.

So, I say again, I’m not sure what evidence the Cabinet is relying on, and lacking any evidence, particularly substantial evidence, this would be a capricious rule change. Moreover, it would jeopardize the provision of emergency services statewide. This was an issue that was addressed several years ago when the State Health Plan sought to be amended to remove ambulance services from formal review, making it such that all ground ambulance applications would be
nonsubstantive review.

And at the same time, there was a great number of comments from county providers that noted that if you take away the more reliably paid nonemergency runs from the services’ inventory such that they are doing a higher percentage of the less likely to be paid emergency runs, they would not be fiscally feasible. They would be operating in the red all the time because they balance out the less likely paid emergency runs by doing the more likely paid nonemergency transports.

What this regulation change would do would be to provide to health facilities that are already at least financially feasible because they are operating and then giving them another review line that is needed for the area emergency ambulance providers. Moreover, because the rule change allows for ALS services, that means that you are taking paramedics which are a very rare resource in our state right now – any ambulance service would attest to this – and you’re offering them the opportunity to take the less risky, more likely to be paid, less stressful nonemergency runs instead of being able to respond to the emergency runs in the counties in which they are situated.

I would ask the cabinet to go back and look at those comments from when they sought to remove the ambulance service from the State Health Plan because the same points there are effectively made here. Overall, this will weaken ambulance response, not strengthen it, and I would ask that the Cabinet not move forward with this change. Thank you.”

In addition to his verbal testimony at the public hearing, Mr. Leach provided the following written comments: “I write on behalf of Emergent Care EMS LLC (‘Emergent’) in opposition to 900 KAR 5:020E and 900 KAR 6:075E (collectively referred to herein as the ‘emergency regulations’), specifically the removal of health facility-based ground ambulance providers limited to non-emergency scheduled transports from formal review. This proposed change runs exactly counter to the purposes of Kentucky’s certificate of need (CON) law. Emergent made verbal comments at the March 21, 2022 hearing on the emergency regulations; these comments are made in addition to those made at the hearing.

Ambulance economics

Most people think of ambulances responding to 9-1-1 calls, with sirens screaming as they run down the road to save a life. Emergency runs are the most costly runs to an ambulance service for several reasons:

1. They require 24 hour operations with higher level personnel, a paramedic and an EMT;
2. They involve using more supplies and equipment; and, critically,
3. They are the most likely not to be reimbursed.
How full-service ambulance companies cover those costs is through providing non-emergency transports. These runs are more cost-effective for the opposite reasons:
1. They can be responded to by a first responder and an EMT;
2. They typically use few supplies and equipment; and,
3. They are the most likely to be reimbursed.

Non-emergency runs are what allow ambulance companies to be there when citizens most need them: in an emergency. The emergency regulations put this balance in jeopardy.

Ramifications if proposed changes are accepted

If permitted to take effect, the emergency regulations would put CON applications for health facility based ground ambulance services limited to non-emergency scheduled transports through the much more deferential non-substantive review process. Instead of being evaluated on whether the applicant operates in a cost-effective manner, offering a more cost-efficient alternative to existing services, and provides quality service, the application will be reviewed solely on whether there is a need for the new service, and need is presumed. See KRS 216B.095(4), 900 KAR 6:075(7).

Beyond risking bringing in providers that fail to provide quality services, this new system will result in services only doing the most cost-effective runs, the non-emergency runs. This will result in a domino effect endangering citizens’ health and resulting in higher taxes.

As new providers siphon off the non-emergency runs, the percentage that non-paying emergency runs make up of existing full service providers' transports will increase. No company can continue operating at loss, which will put the local governing body and its citizens in a tough position for the publicly operated services: either the emergency responders will close operations or they will have to be subsidized through a local tax. Given this option—and no way to compel the new companies to provide emergency services—responsible public officials will have no choice but to impose a new tax, or raise an existing tax levy, for ambulance services. For private providers, charges will have to increase to cover the shortfall from not having reliably paid nonemergency transports. As a result, the emergency regulations will make emergency ambulance services more expensive, either through higher taxes or higher charges for service.

This effect runs entirely counter to the entire purpose of the certificate of need law, namely to provide safe, adequate, and efficient health care services. The proposed change to the SHP will result in the exact opposite: citizens will be endangered due to inadequate service and will result in greater public spending to ensure emergency response.

Existing system for ambulance service should remain unchanged
The emergency regulations are a baseless solution looking for a problem.

Under the existing regulations and State Health Plan ("SHP"), applicants who wish to just cherry-pick the nonemergency runs must prove that the existing providers are not serving those runs. Similarly, where two applicants are considered, the one offering the higher level of service, i.e. performing both emergency and non-emergency runs, is favored by the SHP. The SHP further requires applicants to notify all licensed ambulance services operating in the proposed service area of the applicant's intent to apply to provide service. This would no longer be required if ground ambulance is removed from the SHP, and, given the very short turnaround time required by statute for non-substantive review, existing providers would not have the notice or time to prepare if they wished to oppose an unnecessary, or worse, poor-quality provider from moving into their county and sweeping up the non-emergency runs.

The SHP currently addresses these concerns and should remain unchanged. As mentioned in the verbal comments at the March 21 hearing, there is no established basis for the proposed change. Emergent was the only party to offer comments, despite close to twenty other attendees, several of whom represent hospitals seeking the change to the SHP. So, the only evidence in the record regarding this regulatory change is Emergent's opposition.

Further, the Cabinet has institutional knowledge based on its responsibility of operating the Office of CON, which collects all CON applications. It would be one thing if there were a number of applications by health facilities seeking to establish an ambulance service that had been improperly denied or that had been granted because there was such clear need demonstrated in the hearings. But, the fact is, there is not. There are no applications in recent years where an applicant proved at a hearing that the existing ambulance providers cannot meet the need for scheduled non-emergency transports. Similarly, there are no applications by health facilities that were denied but shown in an appeal to Franklin Circuit Court to have been improperly denied. As such, there is zero evidence, much less the required substantial evidence, to support this regulatory change. Without substantial evidence, allowing the emergency regulations to take effect would be the definition of arbitrary and capricious action.

Aggravating an existing crisis of personnel shortage

The emergency regulations will further threaten the provision of quality emergency and non-emergency ambulance service by aggravating an existing crisis: the shortage of qualified, trained emergency medical technicians (EMTs) and paramedics.

Ask any ambulance service in the state and they will tell you one of the biggest challenges they have is staffing their service with qualified, trained EMTs and
paramedics. There is a scarcity of personnel in this career field. In order to staff a BLS service, it requires at least an EMT and to staff an ALS service it requires at least a paramedic, each trained staff member riding in the back of the ambulance rendering care to the patient. EMTs and paramedics are leaving the field of ambulance services to seek better pay, more reliable hours, and less traumatic scenes by being hired on by health facilities, particularly hospitals. As a result, existing services struggle to fully staff their services. The emergency regulations will greatly exacerbate this problem.

With the proposed change carving out Class I ALS/BLS services that are health facility based to do only non-emergency transports, it creates the attractive service that will siphon off personnel from full service ambulance providers. These health facility based services will offer exactly what is causing EMTs and paramedics to leave full service providers: better pay, more reliable hours (since transports rarely occur during nighttime), and fewer trauma scenes. The proposed change will wreck staffing for full service ambulance providers endangering every citizen that needs timely emergency response.

Conclusion

There has not been given a reason to justify the emergency regulations. Rather, in the public comments made at the March 21, 2022 hearing and in the filing of written comments, including this one, abundant reasons have been given as to why the emergency regulations would be counter to the purposes of the CON program.

Duplicative services would enter existing providers’ service areas, syphoning off the nonemergency transports and trained personnel, leaving emergency services understaffed and needing public subsidization through taxes or higher charges for private providers. Quality would suffer as emergency services become less cost feasible endangering all citizens in need of emergency response.

The current system permits private providers, like Emergent, to be good community partners as well as sound businesses, by providing the proper mix of emergency and non-emergency runs to make a full service emergency responder cost feasible and fully staffed. The emergency regulations will endanger our citizens, increase taxes, increase ambulance charges, and lower quality services. There has not been demonstrated by substantial evidence a need for the emergency regulations. The emergency regulations should not go into effect."

(b) Response: The Cabinet for Health and Family Services amended 900 KAR 6:075E and 900 KAR 6:075, Section 2(3)(d) to address widespread complaints from hospitals, long-term care facilities, and others about ongoing delays with nonemergency ambulance transportation.

It should also be noted that the passage of HB 777, anticipated to take effect in July 2022, will grant a certificate of need exemption until July 1, 2026, to all hospital-
owned ambulances that provide nonemergency and emergency transport services originating from the hospital, and city or county-owned emergency ambulances that provide transport services within their jurisdictional boundaries and comply with the other requirements of Section 9(8) of the Act. In addition, HB 777 will grant nonsubstantive review until July 1, 2026 to hospital-owned ambulances and city or county-owned ambulances seeking to provide services that do not qualify for the certificate of need exemption of Section 9(7) or (8) of the Act.

After the public comment period for the ordinary version of 900 KAR 6:075 ends on April 30, 2022, the cabinet will amend the language of Section 2(3) in the separate “ordinary” version of the Statement of Consideration (SOC) and Amended After Comments (AAC) regulation to align with the passage of HB 777. The ordinary SOC and AAC regulation will be filed with the Legislative Research Commission no later than June 15, 2022.

(2) Subject: Program of All-Inclusive Care for the Elderly (PACE)

(a) Comment: Kara Daniel, Deputy Inspector General, Cabinet for Health & Family Services, provided the following comments:

For services provided on or after June 1, 2022, the Department for Medicaid Services will begin reimbursing approved PACE programs that coordinate the delivery of comprehensive health care services to eligible participants. The overall goal of PACE programs is to enable older adults to live in the community as long as medically and socially feasible.

For PACE programs that intend to provide health services that require certificate of need (CON) approval, the cabinet proposes an agency amendment so that PACE programs that have not already obtained approval to provide services such as home health, adult day care, or another service subject to CON will be subject to nonsubstantive review status.

(b) Response: The Office of Inspector General will amend 900 KAR 6:075E, Section 2(3) via agency comment by adding the following language:

(g)1. The proposal involves an application from a Program of All-Inclusive Care for the Elderly (PACE) program that:
   a. Has an approved agreement with the Centers for Medicare and Medicaid Services (CMS) and the Department for Medicaid Services (DMS); and
   b. Ensures that 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. Coordinates health services only and does not provide health services to its members or others; or
   b. Provides only services for which it has already obtained CON approval under KRS Chapter 216B within the approved CON service area

(3) Subject: Acute Care Beds

(a) Comment: Sherri Craig, CHI Saint Joseph Health, provided the following comments: “CHI Saint Joseph Health is a community partner driven to ensure that Kentuckians receive the best healthcare available throughout the Commonwealth. The purpose of the Certificate of Need process is to safeguard the utilization of efficient and effective healthcare services that are representative to the demographic of the Commonwealth. CHI Saint Joseph Health, therefore respectfully requests that if any healthcare entity seeks to establish a new acute care hospital in the same county, under common ownership, through the transfer of licensed acute care beds, such request be subject to the formal substantive Certificate of Need process. The establishment of any new acute care hospital will create substantial financial and operational burdens on the entity constructing and operating the new facility, but also on the Commonwealth of Kentucky – when such need for a new acute care hospital may not be required based on the demographic need of Kentuckians.”

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General appreciates the comments regarding 900 KAR 6:075E and 900 KAR 6:075, Section 2(3)(e). However, with the exception of the addition of clarifying language described in the agency comment on page 25, the cabinet will retain the language of Section 2(3)(e) as written in an effort to enhance access to hospital services without unnecessary duplication of acute care beds as the proposals would involve the transfer of existing beds.

(a) Comment: Russ Ranallo, Owensboro Health, provided the following comments: “We have several concerns and observations on the acute care bed change:

1. To our knowledge, neither the Cabinet nor any of its predecessors has ever allowed under non-substantive review the establishment of an additional licensed hospital in a county that already has one or multiple hospitals.
2. Even if the project involves licensed beds, there are many hospitals that do not operate all of their beds, thus this would likely increase the actual number of beds across the state. According to the 2020 Annual Kentucky Hospital Utilization and Service Report, only 13,320 hospital beds of the 16,289 licensed beds were operational. Almost 20% of the licensed beds were not operational and, under this change, could be used to create new hospitals throughout the state.
3. Even if the total number of beds did not increase, it is substantially more costly
to operate the same number of beds in two separate locations than to operate at a single site. Duplicating overhead alone in two separate locations would increase costs significantly.
4. The e-reg is would allow for the establishment of one or more additional licensed hospitals in every county that already has one or more hospitals. This is not based upon any identified need for a new hospital at any particular location.
5. The Cabinet has never conducted a study to show where or if an additional hospital is needed in any particular location or in any particular county.
6. There is absolutely no basis for creating a ‘presumption of need’ for an additional hospital in any particular location or in any particular county.
7. There is absolutely no basis for determining that there is a need for an emergency regulation to allow the establishment of an additional hospital in any particular location or in any particular county.
8. While the e-reg call for the new hospital to be under common ownership with the original hospital, there is no prohibition to selling that hospital as soon as it is completed.
9. Before processing or acting on any application to establish a new hospital under nonsubstantive review, the Cabinet should fully consider and address all comments through the normal regulation review process.

We ask that any health care entity seeking to establish an acute care hospital be subject to the formal substantive review process of CON and that the language for establishing a new acute care hospital through the transfer of licensed beds be removed from the State Health Plan.”

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General appreciates the comments regarding 900 KAR 6:075E and 900 KAR 6:075, Section 2(3)(e). However, with the exception of the addition of clarifying language described in the agency comment on page 25, the cabinet will retain the language of Section 2(3)(e) as written in an effort to enhance access to hospital services without unnecessary duplication of acute care beds as the proposals would involve the transfer of existing beds.

(a) Comment: Joseph Koch, Meadowview Regional Medical Center and Fleming County Hospital provided similar comments as follows: “On behalf of LifePoint Health in Kentucky and our 9 hospitals and health systems, please find below our comments on Emergency Administrative Regulation 900 KAR 6:075E, Section 2, subsection 3(e) regarding granting nonsubstantive review status to an application to transfer acute care beds from one or more existing Kentucky-licensed hospitals to establish a new hospital under certain circumstances (the “Emergency Regulation”).

It is important to note that neither the Cabinet nor any of its predecessors has ever allowed under nonsubstantive review the establishment of an additional licensed hospital in a county that already has one or more hospitals. The Emergency Regulation would allow for the establishment of one or more additional licensed hospitals in every county that already has one or more hospitals. This is not based
upon an identified need for a new hospital at any particular location.

The Cabinet has never conducted a study to show where or if an additional hospital is needed in any particular location or in any particular county. Therefore, there is absolutely no basis for creating a "presumption of need" for an additional hospital in any particular location or in any particular county. Additionally, there is no basis for determining that there is a need for an emergency regulation to allow for the establishment of an additional hospital in any particular location or in any particular county.

Lastly, even if the project involves licensed beds, there are many hospitals that do not operate all of their beds, thus the Emergency Regulation would likely result in an increase in the actual number of beds. Furthermore, even if the total number of beds does not increase, it is substantially more costly to operate the same number of beds in two separate locations than to operate at a single site.

Before processing or acting on an application to establish a new hospital under nonsubstantive review, the Cabinet should fully consider and address all comments through the normal regulation review process."

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General appreciates the comments regarding 900 KAR 6:075E and 900 KAR 6:075, Section 2(3)(e). However, with the exception of the addition of clarifying language described in the agency comment below, the cabinet will retain the language of Section 2(3)(e) as written in an effort to enhance access to hospital services without unnecessary duplication of acute care beds as the proposals would involve the transfer of existing beds.

(a) Comment: Kara Daniel, Deputy Inspector General, Cabinet for Health & Family Services, provided the following comments:

The Overall Hospital Quality Star Ratings summarize hospital quality data on the Hospital Compare website. CMS updates the overall star ratings on a bi-annual schedule during the Hospital Compare releases but the months in which they are released may vary. Therefore, the cabinet will replace the phrase "for three (3) out of the last four (4) reported quarters" in Section 2(3)(e) with "on the two (2) most recent updates to the overall star ratings".

Additionally, in lieu of meeting the overall star ratings if the hospital is a state university teaching hospital, the cabinet will clarify that such hospitals shall exceed 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.

(b) Response: The cabinet will amend Section 2(3)(e) [renumbered as (f)] as stated above.
Summary of Statement of Consideration and Action Taken by Promulgating Administrative Body

The public hearing on this emergency administrative regulation was held on March 21, 2022. In addition to testimony provided during the hearing, written comments were received during the public comment period. The Cabinet for Health and Family Services, Office of Inspector General responded to the comments and amends the emergency administrative regulation as follows:

Page 4
Section 2(3)(d)
Line 2
After “application”, insert the following:

   to establish an industrial ambulance service;

(e) The proposal involves an application

Renumber remaining paragraphs.

Section 2(3)(d)
Line 4
After “provide”, delete “nonemergency”.

Section 2(3)(d).2.
Line 11
After “,”, delete “or”.

Section 2(3)(e).2.
Line 17
After “2,”, insert the following:

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

   i. 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

   ii. If the existing hospital is not a state university teaching hospital.

Line 18
After “higher”, insert the following:

   on the two (2) most recent updates to the overall star ratings

Delete the following:
   for three (3) out of the last four (4) reported quarters

Line 19
After “filed;”, insert the following:
or (g)1. The proposal involves an application from a Program of All-Inclusive Care for the Elderly (PACE) program that:
a. Has an approved agreement with the Centers for Medicare and Medicaid Services (CMS) and the Department for Medicaid Services (DMS); and
b. Ensures that 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. Coordinates health services only and does not provide health services to its members or others; or
b. Provides only services for which it has already obtained CON approval under KRS Chapter 216B within the approved CON service area.

Delete the following:
and 3. No more than fifty (50) percent of the existing hospital’s acute care beds shall be transferred to the new facility