CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Certificate of Need

(Amended After Comments)


RELATES TO: KRS 216B.010, 216B.015, 216B.020, 216B.040, 216B.062,
216B.090, 216B.095, 216B.115, 216B.455, 216B.990, 311A.025(4)

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;
(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;

(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 [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 from a location that is not a health care facility pursuant to KRS 216B.020(9)(a)3. and (b);

(f) [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

(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 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 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)(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
(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.
900 KAR 6:075, Amended After Comments

REVIEWED:

6/9/2022

Date

Adam Mather, Inspector General
Office of Inspector General

APPROVED:

6/10/2022

Date

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

Administrative Regulation: 900 KAR 6:075, 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.020(9), 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 KRS 216B.095(3)(e), this amended after comments regulation adds industrial ambulance services to the list of categories subject to nonsubstantive review. This amended after comments regulation aligns the language of Section 2(3)(d) [renumbered as (e)] with the language of HB 777, Section 9(9) [KRS 216B.020(9)].

Additionally, this 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. 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 amended after comments regulation also permits 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 via nonsubstantive review in Section 2(3)(g).

This amended after comments regulation adds a new Section 3 entitled, "Exemption from certificate of need", to make conforming changes that align this regulation with KRS 216B.020(7), (8), (12) and KRS 311A.025(4). Section 3 also clarifies that authorization will not be required for any hospital-owned ambulance service that has certificate of need approval prior to the most recent effective date of the administrative regulation to provide transport services from another health facility to its hospital. However, for any hospital-owned ambulance service that is exempt from certificate of need under KRS 216B.020(7), the hospital will be authorized to provide inter-facility transport of a patient if the hospital contacts at least one (1) ground ambulance provider with jurisdiction in the territory in which the other health facility is located, and the local ground ambulance provider declines the hospital’s request for patient transport or is not able to initiate the patient’s transport within four (4) hours of receiving the hospital’s request.

(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. This amended after comments regulation is being proposed to align 900 KAR 6:075, Section 2(3) with the recent passage of HB 777, and permit a 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 via nonsubstantive review in Section 2(3)(g).

(c) How the amendment conforms to the content of the authorizing statutes: This amended after comments regulation 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 amended after comments regulation 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 amended after comments regulation will permit nonsubstantive review of certificate of need applications for ground ambulance services pursuant to KRS 216B.020(9). This amendment will 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. This 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 via nonsubstantive review in Section 2(3)(g). This amended after comments regulation clarifies the process for obtaining “authorization” in accordance with KRS 311A.025(4).

(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 and enhance patient care in an effort to address ongoing delays in nonemergency ambulance transportation. The 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 6:075, 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.020(9), 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:
(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? This amendment will not generate cost savings for regulated entities during the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? This amendment will not generate cost savings for regulated entities during subsequent years.

(c) How much will it cost the regulated entities for the first year? 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.

(d) How much will it cost the regulated entities for subsequent years? Same response as provided in (4)(c) above.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings(+/-):
Expenditures (+/-):
Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. "Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]

This amendment will not have a major economic impact on regulated entities.
STATEMENT OF CONSIDERATION
Relating to 900 KAR 6:075

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

I. The public hearing on 900 KAR 6:075 was held on April 28, 2022, at 9:00 a.m. in a
Zoom meeting format by the CHFS Office of Legislative and Regulatory Affairs.
Although no one provided comments during the hearing, 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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<tr>
<td>Mary Jo Bean</td>
<td>Norton Healthcare, Inc.</td>
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<tr>
<td>Senior Vice President, Planning and Business Analysis</td>
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<td>Sherri Craig</td>
<td>CHI Saint Joseph Health</td>
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<td>Market Vice President, Public Policy</td>
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<td>Elizabeth D. Fowler</td>
<td>Bluegrass Care Navigators</td>
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<td>President/CEO</td>
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<td>Joseph G. Koch</td>
<td>Meadowview Regional Medical Center</td>
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<td>Market President, CEO</td>
<td>Fleming County Hospital</td>
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<td>Donna Little</td>
<td>Kentucky Hospital Association</td>
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<tr>
<td>Director, Health Policy and Regulatory Affairs</td>
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<td>Jody Prather</td>
<td>Baptist Health</td>
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<td>Chief Strategy and Marketing Officer</td>
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<td>Russ Ranallo</td>
<td>Owensboro Health</td>
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<td>Vice President of Finance</td>
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<td>Wade R. Stone</td>
<td>Med Center Health</td>
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<tr>
<td>Executive Vice President</td>
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<tr>
<td>Kelly Upchurch</td>
<td>Horizon-PACE, LLC</td>
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<td>President and CEO</td>
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<tr>
<td>Kara Daniel</td>
<td>Cabinet for Health &amp; Family Services</td>
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<tr>
<td>Deputy Inspector General</td>
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III. The following people from the promulgating administrative body responded to the written comments:

Name and Title

Adam Mather, Inspector General

Kara L. Daniel, Deputy Inspector General

Stephanie Brammer-Barnes, Contractor

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. It should be noted that since the date of these comments, the General Assembly passed HB 777, which will take effect on July 14, 2022. The Act grants a certificate of need exemption until July 1, 2026, to all hospital-owned ambulance services that provide nonemergency and emergency transport originating from the hospital (or another health facility with authorization), and to city or county government-owned emergency ambulances that provide transport services within their jurisdictional boundaries and comply with the other requirements of Section 9(8) of the Act.

HB 777 also grants nonsubstantive review status until July 1, 2026 to applications from hospital-owned ambulances seeking to provide transport from a location other than another health facility, and city or county-owned ambulances that seek to provide certain transport services. The Office of Inspector General will therefore amend 900 KAR 6:075, Section 2(3) to conform with the language of HB 777.

(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: As stated above, the Office of Inspector General will amend 900 KAR 6:075, Section 2(3) to conform with the language of HB 777.

(a) Comment: Donna Little, Kentucky Hospital Association, provided the following comments: "Thank you for the changes the Office of Inspector General (OIG) included in the emergency and ordinary versions of these administrative regulations regarding ambulance transportation. We appreciate the recognition of the emergency situation for patients across the Commonwealth. These administrative regulations, as the Statement of Emergency, stated, 'help prevent ongoing delays in nonemergency ambulance transportation, promote greater access to care across Kentucky, and help provide relief to the Commonwealth's overburdened healthcare systems.' KHA encourages the OIG to further amend these administrative regulations to align with 2022 KY Acts ch. 126 (House Bill 777), which permits nonsubstantive review for an application by a hospital to establish a ground ambulance service if the application is not otherwise exempt from certificate of need. We note that the Statements of Consideration for the emergency administrative regulations indicated that the cabinet intends to align them with HB 777."

(b) Response: The Office of Inspector General will amend 900 KAR 6:075, Section 2(3) to conform with the language of HB 777.

(a) Comment: Mary Jo Bean, Norton Healthcare, Inc., provided the following comments: "We appreciate the Cabinet's consideration of the following comments regarding its upcoming review of ordinary regulations 900 KAR 5:020 and 900 KAR 6:075 and the State Health Plan Update pertaining to ambulance services. We have reviewed the Cabinet's Statement of Consideration and Emergency Amended After Comments filed April 15, 2022, and write in anticipation of the Cabinet's upcoming review of the ordinary regulations. Recognizing that HB 777, an Act relating to
emergency medical services (hereafter the ‘Act’) enables the Cabinet to promulgate any administrative regulations needed to implement the Act (see Section 22 of the Act), Norton seeks consideration and amendment of the ambulance services regulations as follows:

1. Section 3 of the Act provides that KRS 311A.025 is amended to add subpart (4), providing that an exempt hospital-owned ambulance service ‘may provide transport services from another health facility to its hospital if authorized by the ambulance service provider with jurisdiction in the territory in which the other health facility is located.’ (Emphasis added.) Norton requests that the Cabinet clarify this authorization process so that patient care is not jeopardized.

For example, Norton receives requests from other Kentucky hospitals to transport a patient who is to receive a higher level of care at a Norton facility. Is Norton now prevented from performing that service for vulnerable patients without authorization from ‘the ambulance service provider with jurisdiction in the territory?’ If so, we ask the Cabinet to identify the relevant ambulance service provider within each county and to define the authorization process so that Norton may with all reasonable speed and efficiency attend to a patient’s medical needs. How will Norton satisfy the required authorization? Is there to be deemed only one, e.g., ‘the service provider,’ per jurisdiction, or will authorization from at least one local provider suffice? Is there a period of time in which that local provider must respond to Norton’s request for authorization? In what form must the request be made and the authorization received? Time for transport is always considered for Norton’s pediatric heart patients, stroke patients, potential transplant patients, and even more so with emergencies.

Can language be added to the regulation making clear that a local provider’s failure to respond within six (6) hours by email to an emailed request for authorization deems that request to have been authorized? Can the regulation also make clear that the KBEMS directory is to be updated with accurate email information and is to be used as the official contact address for seeking authorization?

Defining the authorization process for these hospital transports would greatly assist providers and patients needing transport to higher level tertiary services.

2. If no authorization is provided under Section 3 of the Act, and a CON is required for a hospital owned transport service to transfer patients directly from another facility to its hospital for care, we understand that the CON, if granted, would not be restricted. Thus, Norton’s efforts to obtain CON approval and licensure for limited tertiary care transports could skew inventory analysis and create confusion for concluding resource availability and planning.

Can the Cabinet create a category or class of hospital owned provider who only seeks authority to pick up a patient for transfer to its tertiary care facilities, without requiring that hospital owned provider to obtain a CON allowing for broader services
as currently defined? If we seek CON, we do not want to create any community confusion or undertake a broader 24/7 transport obligation for that community. We agree that these broad ambulance service needs are best met by local providers.”

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General appreciates the request for clarification and will add a new Section 3 to this administrative regulation entitled “Exemption from certificate of need” to address the commenter’s questions.

In addition to conforming changes that will align 900 KAR 6:075 with KRS 216B.020(7), (8), (12) and KRS 311A.025(4), Section 3 will clarify that “authorization” will not be required for any hospital-owned ambulance service that has certificate of need approval prior to the most recent effective date of the administrative regulation to provide transport services from another health facility to its hospital. However, for any hospital-owned ambulance service that will be exempt from certificate of need under KRS 216B.020(7), “authorization” to provide transport from another health facility to its hospital shall mean that the hospital uses information from the most recent KBEMS agency directory to contact by phone at least one (1) ground ambulance provider with jurisdiction in the territory in which the other health facility is located. If the ground ambulance provider declines the hospital’s request for inter-facility transport or is not able to initiate the patient’s transport within four (4) hours of receiving the hospital’s request, the hospital-owned ambulance service shall be authorized to provide transport of the patient from the other health facility to the hospital.

In response to the commenter’s questions under “2.”, if a hospital is not authorized to provide inter-facility transport in accordance with KRS 311A.025, it would only be because the local ambulance provider with jurisdiction in the area where the other health facility is located agrees to the hospital’s request for patient transport on a case-by-case basis. Under KRS 311A.025, a new category or class of hospital-owned ambulance provider would not be necessary because the hospital-based provider is CON-exempt under KRS 216B.020(7).

(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 nontestamental 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 nontestamental 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 6:075, Section 2(3) via agency comment by adding industrial ambulance services to the list of categories subject to nontestamental review.
(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:

Upon full implementation of PACE, the Department for Medicaid Services will begin reimbursing approved PACE programs that provide and 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 provide direct-patient 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 6:075, 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 met the requirements of the State Readiness Review (SRR) according to a report submitted by the Department for Medicaid Services to the Centers for Medicare and Medicaid Services;
   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 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.

(a) Comment: Elizabeth Fowler, Bluegrass Care Navigators, provided the following comments: "Please accept these comments from Bluegrass Care Navigators (BCN)"
in response to the proposed regulations regarding the Program of All-Inclusive Care of the Elderly (PACE) and certificate of need (CON). BCN is a nationally recognized leader in the delivery of hospice care and innovator of programs and services that improve the experience of the seriously ill. Building off the specialized workforce and around the clock infrastructure honed from forty years of providing hospice care, BCN has developed several non-hospice services lines that support community needs. Because of a long-standing commitment to innovation and commitment to improving health care for frail older adults, BCN is excited about the prospect of providing superior PACE services in Kentucky.

BCN commends the commitment and tenacity of the Cabinet for Health and Family Services and Department for Medicaid Services for authorizing PACE services in Kentucky. PACE is an innovative model ‘that provides a range of integrated preventative, acute care, and long-term care services to manage the often complex medical, functional, and social needs of the frail elderly.’ PACE was created as a way to provide clients, family, caregivers and professional health care providers the flexibility to meet a person’s health care needs while continuing to live safely in the community. The purpose of a PACE program is to provide pre-paid, capitated, comprehensive health care services that are designed to:

- Enhance the quality of life and autonomy for frail, older adults
- Maximize dignity of and respect for older adults
- Enable frail, older adults to live in their homes and in the community as long as medically and socially feasible
- Preserve and support the older adult’s family unit.

BCN appreciates the careful consideration given to the interplay between the clinical and financial model of PACE and CON in Kentucky. Please accept the comments below in the spirit of collaboration as PACE is new to Kentucky and we work toward a streamlined process that ensures frail older adults receive timely access to high quality health care.

Specific Suggested Changes

After careful study of the changes to 900 KAR 6:075, BCN proposes the following changes to better align the Kentucky CON requirements with federal certification requirements as well as technical changes that will enable a PACE Organization to invest the necessary funding to establish the program in a compliant manner.

1. Require all PACE Organizations to obtain a CON through non-substantive review that allows it to establish a PACE Center and to provide all PACE services to participants regardless of location of the service.

To the best of our knowledge, no other state directly addresses a PACE program as part of its CON processes and consequently there is not a precedent for understanding how PACE fits into the current CON laws. Kentucky, however, has a unique CON statute and program. Because a PACE organization takes on not just
financial responsibility for its participants but also takes on responsibility for providing all covered services including direct patient care to participants, Kentucky's CON requirements are triggered in several aspects for PACE organizations. First, the important requirement that a PACE organization establish a PACE Center where direct patient care is provided and coordinated with other services triggers CON requirements as a PACE Center meets the statutory definition of a Health Facility pursuant to KRS 216B.015(13). Federal participation requirements at 42 CFR 460 require a PACE program to establish a PACE Center where, at a minimum, the following services must be provided:

- Primary care services including physician and nursing services;
- Social work services;
- Restorative therapies, including physical therapy, occupational therapy;
- Personal care and supportive services;
- Nutritional counseling;
- Recreational therapy;
- Meals.

These services are similar to adult day health program services, but also include primary care and nursing services thus integrating certain aspects of long-term care with primary care. Even if the PACE organization contracts with another entity to outsource the PACE Center that entity would require a CON to operate a PACE Center because of the nature of the services. Thus, a PACE Center, just like an adult day health program, is a health facility that must have CON authorization.

Other required services that a PACE program must provide also involve direct care and are not restricted to the PACE Center services or the location of the PACE Center. PACE programs often provide direct patient care including nursing care and rehabilitative therapies in patients' homes. Thus, the provision of these services in patients' homes or other locations constitutes the establishment of a health service that requires CON under Kentucky law. Thus, a CON that authorizes the PACE Organization to provide all PACE services will allow the provision of direct health care services to PACE participants regardless of location of the service.

While a PACE program may contract with institutions like nursing facilities and hospitals to accept PACE program participants, the institutions are required to be certified to participate in Medicare and Medicaid programs and have the necessary state licenses and CON authority to provide services in the first place. Thus, BCN is supportive of the changes that require a PACE organization to obtain a certificate of need to provide PACE services and operate a PACE Center for PACE participants. We believe that the CON should authorize the PACE Organization to provide direct patient care services as well as operate a PACE Center.

2. Eliminate the exemption of PACE programs that coordinate health services only and do not provide health services from CON requirements.

BCN believes, however, that the exemption from CON requirements for providers
that 'coordinate health services only and do[es] not provide health services to its members or others' is not consistent with federal certification requirements for PACE organizations, which are required to operate a PACE Center and provide certain health care services to its members. All PACE programs are required to operate a PACE Center and provide certain direct patient health care services including the integration of care through an interdisciplinary team of licensed providers. Federal law does not permit a PACE program to function as a financial service only program in the role as a payor/insurer for health services for the frail elderly. In short, a PACE organization cannot support enrolled participants with only care coordination or support enrolled participants exclusively through contractual relationships with other providers. A PACE program must provide health care services and operate a PACE Center. When it contracts with other providers for services, those providers must be licensed and certified to participate in the Medicare and Medicaid programs.

3. Allow PACE Organizations to apply for a CON before actual provider agreements are finalized through the certification process.

Applying to be a PACE organization is an intensive and exhaustive process that ensures the applicant is well suited to provide high quality health care services to PACE enrollees. Likewise, certification requirements mandate the establishment of the PACE Center prior to certification. In other words, a physical location for the Center has to be established prior to final certification and execution of the agreement.

While BCN is supportive of the CON requirement, the process should commence before the final agreements are approved by CMS and DMS. As the regulation is currently written, a CON application cannot be approved until a final agreement has been approved, which is the very last step in the process. Because a substantial financial investment is necessary to establish a PACE Program and PACE Center as a step in the approval process, BCN thinks that the CON approval process should commence well before a final agreement is secured from CMS and DMS. One suggestion is to allow an applicant to proceed with an application at the time DMS supports a PACE organization’s initial application with CMS with attestations. Thus, the Cabinet would have input into which organizations are selected to establish PACE programs and the selected provider would be able to receive a CON without making a significant financial investment before the approval is awarded. In addition, the risk of disapproval would be lessened.

In closing, BCN is appreciative of the Cabinet’s hard work to assure that Kentucky residents can benefit from a PACE program. As referenced earlier, a PACE program is a unique financing and delivery model of care guided by federal regulations. PACE organizations are provider-led organizations that assume full financial risk to cover all Medicare and Medicaid benefits for an enrolled participant and need flexibility in how services are provided to PACE participants to ensure quality care and the overall success of the PACE organization.
(b) Response: The Cabinet for Health and Family Services, Office of Inspector General appreciates the comments regarding the addition of PACE programs to the amended after comments version of 900 KAR 6:075E.

As indicated in the agency comment above, the cabinet's proposed amendment is intended to grant nonsubstantive review status to PACE programs that provide direct-patient health services that require certificate of need (CON) approval such as home health services or adult day health care.

However, in response to the comments, the cabinet will modify the language of the CON exemption to clarify that PACE programs shall not be required to obtain CON approval if the program: (1) provides direct patient health services that are exempt from CON and provides other services subject to CON approval through contracts with licensed providers, or (2) has already obtained CON approval within the approved PACE service area to provide a health service that is not exempt from CON.

CON approval shall not be required for the PACE center itself because the services provided at the center (primary care, social services, physical therapy, occupational therapy, personal care and supportive services, nutritional counseling, recreational therapy, and meals) would not require CON approval if provided in another setting.

In response to comments regarding the timing for submission of a CON application, the cabinet will modify the proposed language so that PACE programs may submit their CON application after the program has met the requirements of the State Readiness Review according to a report submitted by the Department for Medicaid Services to the Centers for Medicare and Medicaid Services. Please refer to the agency comment above regarding the revised language.

(a) Comment: Kelly Upchurch, Horizon-PACE, LLC, provided the following comments: "Please accept these comments from Horizon-PACE, LLC in preparation for the Statement of Consideration (SOC) in response to all comments received on the ‘ordinary’ version of 900 KAR 6:075. The emergency regulation was amended after comments and filed with the LRC on April 15, 2022. Horizon's comments are regarding 900 KAR 6:075E(g) concerning the Certificate of Need (CON) process for Programs of All-Inclusive Care of the Elderly.

Horizon commends the Cabinet for Health and Family Services and the Department of Medicaid Services for his ongoing efforts to establish a PACE program in Kentucky. Horizon has been following developments with PACE for nearly 20 years and is beyond excited to have been approved by DMS to establish a PACE program. Horizon has been providing services for more than 20 years in 94 of 120 (74.2%) mostly rural Kentucky counties. Services include skilled health care, adult day health care, case management (3,000+ clients), transportation, meal service, and personal care services (1,000+ clients), all of which are critical to successful PACE organizations. Horizon has an exceptional service platform and is committed
to reaching, in partnership with the state, those PACE-eligible rural Kentuckians in Horizon’s service area.

PACE, or Program of All-Inclusive Care for the Elderly, is an innovative model that provides a range of integrated preventative, acute care, and long-term care services to manage the often complex medical, functional, and social needs of the frail elderly. PACE was created as a way to provide clients, family, caregivers and professional healthcare providers the flexibility to meet a person’s health care needs while continuing to live safely in the community.

PACE services are designed to:
- Enhance the quality of life and autonomy for frail, older adults;
- Maximize dignity of and respect for older adults;
- Enable frail, older adults to live in their homes and in the community as long as medically and socially feasible; and
- Preserve and support the older adult’s family unit.

PACE provides participants all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team (IDT), as well as additional medically necessary care and services not covered by Medicare and Medicaid. There are no limitations or conditions as to the amount, duration or scope of services and there are no deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. The IDT assesses each participant’s needs and develops a comprehensive care plan that meets the needs of its participants across all care settings on a 24 hour basis, each day of the year. Social and medical services are provided primarily in an adult day health care center, but are supplemented by in-home and referral services as needed.

Federal participation requirements at 42 CFR 460.98 require a PACE program to establish a PACE Center where, at a minimum, the following services must be provided:
(1) Primary care, including services furnished by a primary care provider and nursing services.
(2) Social services.
(3) Restorative therapies, including physical therapy and occupational therapy.
(4) Personal care and supportive services.
(5) Nutritional counseling.
(6) Recreational therapy.
(7) Meals.

Given the unique and all-encompassing services required of PACE organizations and the fact that other states have not incorporated PACE services into the CON regulatory scheme, Horizon thought that the Cabinet might exempt PACE from the CON requirement. However, Horizon understands the Cabinet’s position and offers these comments in the spirit of collaboration and to obtain greater clarification regarding 907 KAR 6:075E.
Timing of CON application

The current regulation provides that an applicant desiring to establish a Program of All-Inclusive Care for the Elderly (PACE) program may submit a proposal for nonsubstantive review if the applicant:

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.

Horizon suggests that this provision be clarified to allow applicants to request CON approval prior obtaining an approved three-way agreement between the PACE organization, DMS, and CMS. The process to secure DMS and CMS approval is an intense and exhaustive process that requires the development of numerous policies and procedures, the execution of provider agreements, and a very intensive site review. Accordingly, it does not appear to be practical to require PACE applicants to invest significant time and money to develop a PACE program without the assurance that it will be able to operate in a given service area.

Exemption for PACE programs that only coordinate services

As noted above, the federal PACE participation requirements dictate that ‘a PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.’ 42 CFR 460.98(d). ‘The PACE center provides the bulk of the day to day PACE services for its participants and, at a minimum, must provide: Primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals.’ 42 CFR 460.98(c). Accordingly, Horizon seeks clarification regarding 907 KAR 6:75E(g)(3) which provides that ‘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;’ because this appears to be contrary to federal law which requires a PACE organization to operate a PACE center and provide the minimum direct participant health services noted above. Federal law does not allow PACE organization to function merely as a managed care organization.

Again, Horizon commends the Cabinet for its efforts to develop the PACE model of care for Kentucky residents and looks forward to partnering with the DMS to provide this innovative care. Studies and experiences in other states have proven that PACE services both improve participants’ quality of life and decrease costs for the state. Horizon looks forward to its relationship with the state and pledges its
commitment to the PACE program. Please do not hesitate to contact me if additional information would be helpful."

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General appreciates the comments regarding the addition of PACE programs to the amended after comments version of 900 KAR 6:075E.

As indicated in the above response, the cabinet’s proposed amendment is intended to grant nonsubstantive review status to PACE programs that provide direct patient health services that require certificate of need (CON) approval such as home health services or adult day health care.

In response to comments regarding the timing for submission of a CON application, the cabinet will modify the proposed language so that PACE programs may submit their CON application after the program has met the requirements of the State Readiness Review according to a report submitted by the Department for Medicaid Services to the Centers for Medicare and Medicaid Services.

The cabinet will modify the language of the CON exemption to clarify that PACE programs shall not be required to obtain CON approval if the program: (1) provides direct patient health services that are exempt from CON and provides other services subject to CON approval through contracts with licensed providers, or (2) has already obtained CON approval within the approved PACE service area to provide a health service that is not exempt from CON.

(3) Subject: Acute Care Beds

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

(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 clarifying language described in the agency comment on pages 34 - 35, the cabinet will retain the language of Section 2(3)(e) [renumbered as (f)] 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 nonsubstantive 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-regps 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-regps 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 clarifying language described in the agency comment on pages 34 - 35, the cabinet will retain the language of Section 2(3)(e) [renumbered as (f)] 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 comments as follows: “On behalf of LifePoint Health in Kentucky and our 9 hospitals and health systems, please find below our comments on Proposed Administrative Regulation 900 KAR 6:075, 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 “Proposed 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 multiple hospitals. The Proposed 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 a 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 Proposed 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 6:075, Section 2(3)(e). However, with the exception of clarifying language described in the agency comment on pages 34 - 35, the cabinet will retain the language of Section 2(3)(e) [renumbered as (f)] 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: Donna Little, Kentucky Hospital Association, provided the following comments: "KHA understands the need for the change made in the Emergency Amended After Comments administrative regulations regarding page 3 of the State Health Plan to acknowledge that the months in which the Hospital Compare ratings are released varies from year to year. However, we do not recommend using the CMS star ratings as an indication of the quality of care within a hospital. There are multiple reasons for this opposition, including:

- The CMS star ratings are based on relatively old data. Please see this link, https://qualitynet.cms.gov/inpatient/public-reporting/overall-ratings/data-collection, which shows that many of the measures are based on reporting data collected two (2) or more years prior to the release of the reports;
- The ratings are based on the premise that all improvement is relative to others' improvements, which is why the data is comparative in nature. Thus it is hard to predict and to plan what quality improvement activities will be the most beneficial; and
- The methodology is called the latent variable model and gives more emphasis to certain measures over others based on a number of aspects including variation in performance among hospitals or how much measures correlate to each other. This makes it very difficult for hospitals to predict what improvement measures will effect a change in the rating.

These two (2) articles provide additional information about issues with the star ratings, including how hospitals with sicker patients fare worse due to the severity of illness:

- https://www.fiercehealthcare.com/healthcare/hospital-groups-cms-hasn-t-addressed-star-ratings-concerns and

In the Emergency Amended After Comments versions, changes were made to establish different criteria for proposals based on whether the existing hospital is or is not a state university teaching hospital. The same criteria should be used for all hospitals."

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General appreciates the comments regarding 900 KAR 6:075, Section 2(3)(e). However, with the exception of clarifying language described in the agency comment on pages 34 - 35, the cabinet will retain the language of Section 2(3)(e) [renumbered as (f)] as written. Hospitals that do not meet the proposed quality measures will remain subject to formal review if they seek to transfer acute care beds from one or more existing Kentucky-licensed hospitals to establish a new hospital in accordance with the criteria of Section 2(3)(e).

(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 administrative regulation was held on April 28, 2022. Although no one provided comments 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 administrative regulation as follows:

Page 1
Relates To Section
Line 6
After “216B.015”, insert **216B.020.**

Line 7
After “216B.990”, insert **, 311A.025(4).**

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

*to establish an industrial ambulance service;*

(e) Prior to July 1, 2026, the proposal involves an application

After “by”, insert the following:

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.

After “licensed”, insert “hospital seeking”.

Delete the following:

*health facility to establish a Class I ground ambulance service operating at the Advanced Life Support (ALS) or Basic Life Support (BLS) level*
Line 4
After “provide”, delete “nonemergency”.
After “transport”, insert the following:

from a location that is not a health care facility pursuant to KRS 216B.020(9)(a)3. and (b);

(f)

After “transport”, delete the following:
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
(e)

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
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;

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 met the requirements of the State Readiness Review (SRR) according to a report submitted by the Department for Medicaid Services to the Centers for Medicare and Medicaid Services;
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 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.

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.

Page 7
Section 2(14)
Line 5
After “Section 2(3)”, insert “(g)”. Delete “(d)”.

Section 2(15)
Line 12
After “KRS 216B.115”, insert the following:
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 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.