

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.020, 216B.040, 216B.062, 216B.090, 216B.095, 216B.115, 216B.450(5), 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 Need Web site at <https://chfs.ky.gov/agencies/os/oig/dcn/Pages/cn.aspx>.

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

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

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

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

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

11 Section 2. Nonsubstantive Review.

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

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

15 (b)

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

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

19 (2) The cabinet shall grant nonsubstantive review status to an application that proposes  
20 to establish an ambulatory surgical center pursuant to the conditions specified in KRS  
21 216B.095(7).

(3) In addition to the projects specified in KRS 216B.095(3)(a) through (e), pursuant to KRS 216B.095(3)(f), the Office of Inspector General shall grant nonsubstantive review status to an application for which a certificate of need is required if:

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

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

1. The termination or voluntary closure of the hospital:

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

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

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

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

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

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

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

(c)

1. The proposal involves an application to establish an ambulatory surgical center that does not charge its patients and does not seek or accept commercial insurance, Medicare, Medicaid, or other financial support from the federal government; and
2. The proposed ambulatory surgical center shall utilize the surgical facilities of an existing licensed ambulatory surgical center during times the host ambulatory surgical center is not in operation;

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

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

1. An ambulance service that is owned by a city or county government seeking to provide ambulance transport services pursuant to KRS 216B.020(9)(a)1. or 2.; or
2. A licensed hospital seeking to provide transport from a location that is not a healthcare~~health care~~ facility pursuant to KRS 216B.020(9)(a)3. and (b);

(f) The proposal involves an application to transfer acute care beds from one (1) or more existing Kentucky-licensed hospitals to establish a new hospital under the following circumstances:

1. The existing hospital and new facility shall be under common ownership and located in the same county;
2. No more than fifty (50) percent of the existing hospital's acute care beds shall be transferred to the new facility; and
3.
  - a. If the existing hospital is a state university teaching hospital, the existing hospital exceeded, by at least one (1), the minimum number of quality measures required to

1 receive supplemental university directed payments from Kentucky Medicaid for the  
2 state fiscal year preceding the date the application was filed; or

3 b. If the existing hospital is not a state university teaching hospital, the existing  
4 hospital's overall rating by the Centers for Medicare and Medicaid Services Hospital  
5 Compare was three (3) stars or higher on the most recent annual update to the  
6 overall star ratings preceding the date the application was filed;

7 (g)

8 1. The proposal involves an application from a Program of All-Inclusive Care for the  
9 Elderly (PACE) program that:

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

13 b. Seeks to provide, directly to its members, a health service that is not exempt from  
14 certificate of need (CON) under KRS 216B.020(1); and

15 c. Ensures that all services authorized under the PACE agreement are provided  
16 exclusively to its members who reside within the service area. The service area shall  
17 be:

18 (i) Located within the Commonwealth of Kentucky; and

19 (ii) Approved by both CMS and DMS.

20 2. Only an approved PACE program operating within the applicant's service area shall  
21 qualify as an affected person for the purpose of opposing a PACE program  
22 application.

1 3. A PACE program shall not be required to obtain certificate of need (CON) approval  
2 if the program:

3 a. Provides direct patient health services that are exempt from CON under KRS  
4 216B.020(1) and provides other services subject to CON approval through contracts  
5 with licensed providers; or

6 b. Has already obtained CON approval within the approved PACE service area to  
7 provide a health service that is not exempt from CON;

8 (h) The proposal involves an application to establish an inpatient psychiatric unit in an  
9 existing licensed acute care hospital under the following conditions:

10 1. The hospital is located in a county that has no existing, freestanding psychiatric  
11 hospital;

12 2. The occupancy of acute care beds in the applicant's facility is less than seventy  
13 (70) percent according to the most recent edition of the Kentucky Annual Hospital  
14 Utilization and Services Report;

15 3.

16 a. All of the proposed psychiatric beds are being converted from licensed acute care  
17 beds; and

18 b. No more than twenty (20) percent of the facility's acute care beds up to a  
19 maximum of twenty-five (25) beds will be converted to psychiatric beds;

20 4. All of the psychiatric beds will be implemented onsite~~[on-site]~~ at the applicant's  
21 existing licensed facility; and

22 5. All of the psychiatric beds shall be dedicated exclusively to the treatment of adult  
23 patients, aged eighteen (18) to sixty-four (64);

(i) The proposal involves an application by a Kentucky-licensed acute care hospital, critical access hospital, or nursing facility proposing to expand a home health service to provide services exclusively to patients discharged from its facility who require home health services at the time of discharge and no existing, licensed home health agency is available and willing to accept the referral. The hospital or nursing facility shall document its efforts to find a Home Health Agency. A license issued under this subsection shall contain the limitation set forth herein;[-]

(j) Level II PRTFs shall be subject to the nonsubstantive review process;[-]

(k) The proposal involves an application to establish a new pediatric teaching hospital under the following circumstances:

1. No less than one hundred fifty (150) pediatric acute care beds of the new pediatric teaching hospital are transferred from an existing pediatric teaching hospital that is a Kentucky-licensed hospital;

2. The existing pediatric teaching hospital is under common ownership with the new pediatric teaching hospital;

3. The existing pediatric teaching hospital is located within the same county as the new pediatric teaching hospital;

4. The new pediatric teaching hospital may include the same types of pediatric services and diagnostic equipment as currently provided at the existing pediatric teaching hospital, including pediatric acute care, Level II, III, and IV special neonatal beds, pediatric open heart surgery and cardiac catheterization, pediatric organ and tissue transplant program, pediatric psychiatric beds, and pediatric megavoltage radiation, positron emission tomography, and magnetic resonance

imaging equipment, with no additional certificate of need application required for establishing any of these specific pediatric services and diagnostic equipment at the new pediatric teaching hospital;

5. The total number of pediatric acute care beds at the new pediatric teaching hospital shall not exceed 140% of the total number of pediatric beds at the existing pediatric teaching hospital at the time of application, and the pediatric acute care beds remaining at the existing pediatric teaching hospital shall not be designated as adult beds; and

6. The applicant certifies that the new pediatric teaching hospital will continuously operate as a pediatric teaching hospital, as that term is currently defined; or

~~(I) The proposal involves an application by an existing provider of a Level II service within the same area development district to establish a Level II program with four (4) Level II Special Care Neonatal beds consistent with this plan if the applicant is under common ownership.]~~

**(I) The proposal involves an application to establish a Level II program with four (4) Level II Special Care Neonatal beds and the applicant is under common ownership with an existing provider of Level II services within the same area development district.**

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

(5) If an application is denied nonsubstantive review status by the Office of Inspector General, the application shall automatically be placed in the formal review process.



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

(7)

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

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

(c)

1. Except as provided in subparagraph 2. of this paragraph, nonsubstantive review applications shall not be comparatively reviewed.

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

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

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

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

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

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

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

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

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

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

(14) A decision to approve or disapprove an application that has been granted nonsubstantive review status shall be rendered within thirty-five (35) days of the date that nonsubstantive review status has been granted, as required by KRS 216B.095(1). A hearing officer shall prioritize rendering decisions regarding applications granted nonsubstantive review status pursuant to Section 2(3)(g) of this administrative regulation.

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

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

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

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

### Section 3. Exemption from Certificate of Need.

(1) A city or county government-owned ambulance service that meets the criteria established by KRS 216B.020(8) shall not be required to obtain a certificate of need to provide emergency ambulance transport services.

(2) A hospital-owned ambulance service shall not be required to obtain a certificate of need to provide non-emergency or emergency transport that originates from its hospital pursuant to KRS 216B.020(7).

(3)

(a) If a hospital-owned ambulance service has certificate of need approval prior to the most recent effective date of this administrative regulation to provide transport services

from another health facility to its hospital, the service shall not be required to obtain authorization in accordance with paragraph (b) of this subsection.

(b) A hospital-owned ambulance service that is exempt from certificate of need under KRS 216B.020(7) may provide transport services from another health facility to its hospital if authorized as established~~[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.ky.gov/Legal/Pages/EMS-Directory.aspx>)~~[(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)

- 1 (a) In accordance with KRS 216B.020(12)(a), the provisions of this section and Section
- 2 2(3)(e) of this administrative regulation shall expire on July 1, 2026.
- 3 (b) In accordance with KRS 216B.020(12)(b), a certificate of need exemption granted
- 4 to an ambulance service under this section of this administrative regulation shall
- 5 remain in effect on and after July 1, 2026.


900 KAR 6:075E

REVIEWED:

8/11/2025

Date

Signed by:

  
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Tricia Steward, Inspector General  
Office of Inspector General

APPROVED:

8/11/2025

Date

Signed by:

  
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Steven J. Stack, MD, MBA, Secretary  
Cabinet for Health and Family Services

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 900 KAR 6:075E  
Agency Contact: Valerie Moore  
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Contact Person: Krista Quarles  
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Email: CHFSregs@ky.gov

Subject Headings: Certificate of Need

(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: This amendment maintains consistency with the most recent update to the State Health Plan to increase access to pediatric acute care beds, Level II Special Care Neonatal beds, and to grant nonsubstantive review status to certificate of need applications submitted by licensed health facilities. The Amended After Comments version rewords language in Section 2(3)(l) to allow consistency with the State Health Plan in 900 KAR 5:020.

(b) The necessity of the amendment to this administrative regulation: This amendment is being proposed pursuant to KRS 216B.095(3), 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. These changes were requested by providers to allow them to add needed healthcare services more quickly and

efficiently in response to their patient's changing needs. This amendment is needed to expand access to health services throughout the state, including in rural areas, to enhance immediate access to resources.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to KRS 216B.095(3), 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) Does this administrative regulation or amendment implement legislation from the previous five years? No

(4) 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.

(5) Provide an analysis of how the entities identified in question (4) 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 (4) will have to take to comply with this administrative regulation or amendment: This amendment will require eligible providers that choose to do so to take steps to invest resources to establish a NICU unit in areas of the state that do not have convenient access to one, therefore reducing travel time for expectant and postpartum mothers.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4): 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 (4): The proposed amendment will help improve access to healthcare services by making it easier to obtain a certificate of need to provide these services. This will increase access to services that are closer to home for many patients, particularly in rural areas of the state.

(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no initial costs for implementation of this amendment.

(b) On a continuing basis: There are no continuing costs for implementation of this amendment on a continuing basis.

(7) 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.



(8) 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.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This amendment does not establish or increase any fees.

(10) 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 two (2) new categories.

## FISCAL IMPACT STATEMENT

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

Contact Person: Valerie Moore

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Phone Number: (502) 564-7476

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(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the 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.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions: The promulgating agency is the Office of Inspector General within the Cabinet for Health and Family Services. This administrative regulation affects entities that submit certificate of need applications subject to the nonsubstantive review process.

(a) Estimate the following for the first year:

Expenditures: There are no additional costs for implementation of this amendment.

Revenues: Revenue increases would be dependent on how many facilities applied for nonsubstantive review and is not able to be predicted.

Cost Savings: There are no anticipated cost savings as a result of this amendment.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? There is no anticipated expenditure, revenue, or cost savings difference from subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): This amendment should have no additional effect on local entities.

(a) Estimate the following for the first year:

Expenditures: There are no additional expenditures anticipated from this administrative regulation.

Revenues: No additional revenue is anticipated from this amendment.

Cost Savings: No cost savings are anticipated from this amendment.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? No changes are anticipated as a result of this amendment.

(4) Identify additional regulated entities not listed in questions (2) or (3): 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.

(a) Estimate the following for the first year:

Expenditures: 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.

Revenues: No additional revenue is anticipated from this amendment.

Cost Savings: No cost savings are anticipated from this amendment.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? No changes are anticipated as a result of this amendment.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation: 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.

(b) Methodology and resources used to determine the fiscal impact: The fees for licensure are established in 900 KAR 6:020 fees for licensure.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate) There is not an anticipated negative or adverse economic impact to entities discussed above.

(b) The methodology and resources used to reach this conclusion: The fees are the same whether a facility applies for substantive or nonsubstantive review.

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, scheduled for July 21, 2025, at 9:00 a.m. in Zoom meeting format by the CHFS Office of Legislative and Regulatory Affairs was canceled due to no requests to be heard. However, written comments were received during the public comment period.

- II. The following people submitted comments:

<u>Name and Title</u>	<u>Agency/Organization/Entity/Other</u>
Wesley Duke, General Counsel	Cabinet for Health and Family Services
Steven T. Hester, MD, MBA Sr Vice President, Chief Clinical and Strategy Officer	Norton Healthcare
Donovan Blackburn, Chairman, President and CEO	Pikeville Medical Center

- III. The following people from the promulgating administrative body responded to the comments:

<u>Name and Title</u>	<u>Agency/Organization/Entity/Other</u>
Tricia Steward, Inspector General	Cabinet for Health and Family Services
Valerie Moore, Policy Specialist	Cabinet for Health and Family Services, Office of Inspector General

IV. Summary of Comments and Responses

(1) Subject: Neonatal Beds

- (a) Comment: Wesley Duke, General Counsel, Cabinet for Health and Family Services, pointed out an error in this administrative regulation that needed to be corrected in Section 2(3)(l) to be as follows.

~~[(l) The proposal involves an application to establish a Level II service within the same area development district to establish a Level II program with four (4) Level II Special Care Neonatal beds consistent with this plan if the applicant is under common ownership.]~~

(l) The proposal involves an application to establish a Level II program with four (4) Level II Special Care Neonatal beds and the applicant is under common ownership with an existing provider of Level II services within the same area development district.

- (b) Response: The cabinet appreciates the comments from Mr. Duke. This administrative regulation will be amended as a result of the comment. This change will also be made to the ordinary administrative regulation for consistency.
- (a) Comment: Steven Hester, MD, MBA, Senior Vice President, Chief Clinical and Strategy Officer, Norton Healthcare, submitted a statement of support regarding the creation of Level II Special Care Neonatal beds in teaching hospitals.
- (b) Response: The cabinet appreciates the input and support from Norton Healthcare regarding the issue of addressing the emergent need for the creation of Level II Special Care Neonatal beds in teaching hospitals. The administrative regulation will not be amended as a result of this comment.
- (a) Comment: Donovan Blackburn, President and CEO, Pikeville Medical Center, submitted a statement opposing Section 2(3)(l). Mr. Blackburn pointed out that 900 KAR 6:075E would allow certain hospitals to avoid criteria established for obtaining Certificate of Need (CON) in the State Health Plan (SHP), including utilization review criteria. "Expanding Level II Neonatal services for Qualifying Hospitals without regard to the utilization formula in the Plan goes against the purpose for which Certificate of Need (CON) was established – avoiding unnecessary health care services that result in costly duplication and underuse. If the existing Level II neonatal beds in the Area Development District (ADD) are not being sufficiently utilized already, then adding more Level II neonatal beds in the same ADD for Qualifying Hospitals simply creates duplication and further underutilization. More importantly, removing the Plan's review criteria for Qualifying Hospitals puts all other hospitals with an existing Level II NICU program with no other hospital in the same ADD under common ownership ("Excluded Hospitals") at a terrible competitive disadvantage." Mr. Blackburn further noted that not only would rural hospitals have to "show need to expand their existing Level II NICU, they will be required to wait till the next batching cycle to apply for an expansion of their Level II neonatal bed program while Qualifying Hospitals will be allowed to proceed immediately through nonsubstantive review since the Regulatory Changes were filed on an emergency basis and become effective upon filing." According to OIG's June 2025 hospital inventory filings, this administrative regulation change would potentially negatively affect eighteen (18) other hospitals with existing Level II neonatal programs by excluding them through this regulatory change.
- (b) Response: The cabinet thanks Mr. Blackburn for his comment. CHFS is pursuing this administrative regulation change to increase the neonatal network of care across the Commonwealth. The administrative regulation will not be amended as a result of this comment.

Summary of Statement of Consideration and  
Action Taken by Promulgating Administrative Body

The public hearing on this administrative regulation scheduled for July 21, 2025, was canceled due to no requests to be heard. However, written comments were received during the public comment period. The Cabinet for Health and Family Services, Office of Inspector General, responded to comments and amends the administrative regulation as follows:

Page 8  
Section 2(3)(k)6.  
Line 10

After “currently defined; or” insert the following:

(l) The proposal involves an application to establish a Level II program with four (4) Level II Special Care Neonatal beds and the applicant is under common ownership with an existing provider of Level II services within the same area development district.

Delete the existing (l) in its entirety.