

CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Certificate of Need

(Amendment)

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

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 reviewed  
3 within ninety (90) days from the commencement of the review as provided by KRS  
4 216B.062(1) and that is reviewed for compliance with the review criteria set forth at KRS  
5 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 Newsletter.

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

10 Section 2. Nonsubstantive Review.

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

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

14 (b)

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

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

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

20 (3) In addition to the projects specified in KRS 216B.095(3)(a) through (e), pursuant to KRS  
21 216B.095(3)[(f)], the Office of Inspector General shall grant nonsubstantive review status to an  
22 application for which a certificate of need is required if:

23 (a) The proposal involves the establishment or expansion of a health facility or health service  
24 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 receive supplemental university directed payments from Kentucky Medicaid for the state fiscal year preceding the date the application was filed; or

b. If the existing hospital is not a state university teaching hospital, the existing hospital's overall rating by the Centers for Medicare and Medicaid Services Hospital Compare was

three (3) stars or higher on the most recent annual update to the overall star ratings preceding the date the application was filed;

(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;

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

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

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

7 3.

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

9 and

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

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

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

16 (i) The proposal involves an application by a Kentucky-licensed acute care hospital, critical  
17 access hospital, or nursing facility proposing to expand a home health service to provide  
18 services exclusively to patients discharged from its facility who require home health services  
19 at the time of discharge and no existing, licensed home health agency is available and willing  
20 to accept the referral. The hospital or nursing facility shall document its efforts to find a Home  
21 Health Agency. A license issued under this subsection shall contain the limitation set forth  
22 herein<sub>1</sub>~~[.]~~

23 (j) Level II PRTFs shall be subject to the nonsubstantive review process<sub>1</sub>~~[.]~~

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

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

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

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

10        4. The new pediatric teaching hospital may include the same types of pediatric services  
11     and diagnostic equipment as currently provided at the existing pediatric teaching hospital,  
12     including pediatric acute care, Level II, III, and IV special neonatal beds, pediatric open heart  
13     surgery and cardiac catheterization, pediatric organ and tissue transplant program, pediatric  
14     psychiatric beds, and pediatric megavoltage radiation, positron emission tomography, and  
15     magnetic resonance imaging equipment, with no additional certificate of need application  
16     required for establishing any of these specific pediatric services and diagnostic equipment at the  
17     new pediatric teaching hospital;

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

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

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

4 (m) The proposal involves an application to establish a comprehensive (diagnostic and  
5 therapeutic) cardiac catheterization service, and the applicant is under common ownership with  
6 an existing provider of comprehensive (diagnostic and therapeutic) cardiac catheterization within  
7 the same county.

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

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

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

15 (7)

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

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

23 (c)



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

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

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

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

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

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

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

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

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

12 (12) In determining whether an application is consistent with the State Health Plan, the cabinet,  
13 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).

1 (3)

2 (a) If a hospital-owned ambulance service has certificate of need approval prior to the most  
3 recent effective date of this administrative regulation to provide transport services from  
4 another health facility to its hospital, the service shall not be required to obtain authorization  
5 in accordance with paragraph (b) of this subsection.

6 (b) A hospital-owned ambulance service that is exempt from certificate of need under KRS  
7 216B.020(7) may provide transport services from another health facility to its hospital if  
8 authorized as established~~[set out]~~ in KRS 311A.025(4).

9 (c)

10 1. As used in paragraph (b) of this subsection, a hospital is authorized to provide inter-facility  
11 transport of a patient if:

12 a. The hospital contacts by phone at least one (1) ground ambulance provider with  
13 jurisdiction in the territory in which the other health facility is located, using contact  
14 information from the most recent edition of the agency directory maintained by the  
15 Kentucky Board of Emergency Medical Services at the following link  
16 ([https://kbems.ky.gov/Legal/Pages/EMS-](https://kbems.ky.gov/Legal/Pages/EMS-Directory.aspx)  
17 [Directory.aspx](https://kbems.ky.gov/Legal/Pages/EMS-Directory.aspx))~~[(<https://kbems.ky.gov/Legal/Pages/EMS-Directory.aspx>)]~~ and

18 b. The ground ambulance provider:

19 (i) Declines the hospital's request for patient transport; or

20 (ii) Is not able to initiate the patient's transport within four (4) hours of receiving the  
21 hospital's request.

22 2. For purposes of this paragraph, a provider initiates transport when it arrives at the hospital  
23 to transport the patient.

1        3. The hospital shall document the ambulance service contacted and the reason for  
2        authorization to provide transport from another health facility to its hospital.

3        (4)

4        (a) In accordance with KRS 216B.020(12)(a), the provisions of this section and Section 2(3)(e)  
5        of this administrative regulation shall expire on July 1, 2026.

6        (b) In accordance with KRS 216B.020(12)(b), a certificate of need exemption granted to an  
7        ambulance service under this section of this administrative regulation shall remain in effect  
8        on and after July 1, 2026.

900 KAR 6:075

REVIEWED:

6/9/2025

Date

Signed by:  
*Tricia Steward*  
33D33857C4674D0  
Tricia Steward, Acting Inspector General  
Office of Inspector General

APPROVED:

6/9/2025

Date

DocuSigned by:  
*Eric Friedlander*  
DAEA1D6C15D6431  
Eric C. Friedlander, Secretary  
Cabinet for Health and Family Services

## PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on August 25, 2025, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by August 18, 2025, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation through August 31, 2025. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621; Phone: 502-564-7476; Fax: 502-564-7091; CHFSregs@ky.gov.

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 900 KAR 6:075

Agency Contact: Valerie Moore

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Contact Person: Krista Quarles

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(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.

(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) 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 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 (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 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.

(5) 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.

(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 establishes any fees or directly or



indirectly increases 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 two (2) new categories.

## FISCAL IMPACT STATEMENT

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

Contact Person: Valerie Moore

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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.