

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (New administrative regulation)

4 900 KAR 6:100. Certificate of Need standards for implementation and biennial
5 review.

6 RELATES TO: KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990

7 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1, 216B.330

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the

9 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need

10 Program and to promulgate administrative regulations as necessary for the program.

11 This administrative regulation establishes the required timetables and standards for

12 implementation as well as requirements for biennial reviews for the orderly

13 administration of the Certificate of Need Program.

14 Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(5).

15 (2) "Days" means calendar days, unless otherwise specified.

16 (3) "Long-term care beds" means nursing home beds, intermediate care beds,

17 skilled nursing beds, nursing facility beds, and Alzheimer nursing home beds.

18 (4) "Office of Inspector General" means the office within the Cabinet for Health and

19 Family Services that is responsible for licensing and regulatory functions of health

20 facilities and services.

21 (5) "Show cause hearing" means a hearing during which it is determined whether a

1 person or entity has violated provisions of KRS Chapter 216B.

2 Section 2. Standards for Implementation. (1) As a condition for the issuance of a
3 certificate of need, a holder of a certificate of need shall submit progress reports on the
4 OHP - Form 8, Certificate of Need Six (6) Month Progress Report, as incorporated by
5 reference in 900 KAR 6:055, at the six (6) month intervals specified in this section.

6 (2) A notice specifying the date each progress report is due shall be sent to every
7 holder of a certificate of need whose project is not fully implemented.

8 (3) The cabinet or its designee shall review a progress report and shall determine:

9 (a) If the required elements have been completed; and

10 (b) If the required elements have not been completed, if sufficient reasons for failure
11 to complete have been provided.

12 (4) A certificate of need shall be deemed complete when:

13 (a) The project has been approved for licensure or occupancy by the Office of
14 Inspector General; and

15 (b) A final cost breakdown has been submitted.

16 (5) Until a project is deemed complete by the cabinet, the cabinet may require:

17 (a) The submission of additional reports as specified in subsections (16) through
18 (18) of this section; or

19 (b) Progress reports in addition to those required at six (6) month intervals under the
20 provisions of this section.

21 (6) Except for long-term care bed proposals, a certificate of need shall not be
22 revoked for failure to complete the items required during a six (6) month period if the
23 holder of the certificate of need establishes that the failure was due to circumstances

1 that:

2 (a) Could not reasonably be anticipated and avoided by the holder; or

3 (b) Were not the result of action or inaction of the holder.

4 (7) If the cabinet determines that required elements have not been completed for
5 reasons other than those set forth in subsection (6) of this section, it shall notify the
6 holder of the certificate of need, in writing, that it has determined to revoke the
7 certificate of need.

8 (8) The revocation shall become final thirty (30) days from the date of notice of
9 revocation unless the holder requests a hearing pursuant to KRS 216B.086.

10 (9) The first progress report for all projects other than long-term care beds shall
11 include:

12 (a) For projects for the addition of new services or expansion of existing services
13 that do not involve construction, renovation or the installation of equipment: plans for
14 implementation of the project;

15 (b) For projects for the purchase of equipment only, a copy of the purchase order;

16 (c) For projects involving the acquisition of real property, evidence of an option to
17 acquire the site; or

18 (d) For construction or renovation project, evidence that schematic plans have been
19 submitted to the Public Protection Cabinet, Department of Housing, Buildings, and
20 Construction, and the Office of Inspector General.

21 (10) For projects other than long-term care beds not deemed complete, a second
22 progress report shall include:

23 (a) For projects converting beds, documentation that all beds are licensed;

1 (b) For projects for addition of new services or expansion of existing services that do
2 not involve construction, renovation, or the installation of equipment, documentation of
3 approval for licensure and occupancy by the Office of Inspector General or the
4 Kentucky Board of Emergency Medical Services; or

5 (c) For construction or renovation projects, the schedule for project completion,
6 evidence of preliminary negotiation with a financial agency, and evidence of preliminary
7 negotiation with contractors.

8 (11) For projects other than long-term care beds not deemed complete, a third
9 progress report shall include:

10 (a) For construction or renovation projects:

11 1. A copy of the deed or lease of land;

12 2. Documentation of final enforceable financing agreement, if applicable;

13 3. Documentation that final plans have been submitted to the Public Protection
14 Cabinet, Department of Housing, Buildings, and Construction, and the Office of
15 Inspector General; and

16 4. An enforceable contract with a construction contractor; or

17 (b) For projects for purchase of equipment only, evidence of approval for licensure
18 and occupancy by the Office of Inspector General.

19 (12) For projects other than long-term care beds not deemed complete, a fourth
20 progress report shall include documentation of final plan approval by the Public
21 Protection Cabinet, Department of Housing, Buildings, and Construction, and the Office
22 of Inspector General and evidence that construction has begun.

23 (13) For projects other than long-term care beds not deemed complete, a fifth

1 progress report shall include documentation that construction or renovation is
2 progressing according to schedule.

3 (14) For projects other than long-term care beds not deemed complete, a sixth
4 progress report shall include documentation that the project has been approved for
5 licensure or occupancy by the Office of Inspector General and, if required, that the
6 appropriate license has been approved for the health care service or facility.

7 (15) For projects other than long-term care beds not deemed complete after the
8 sixth progress report, the certificate holder shall, upon request, provide the cabinet or its
9 designee with a written statement showing cause why the certificate should not be
10 revoked. The cabinet may defer revocation action upon a showing by the certificate
11 holder that the project shall be completed on a revised schedule. The cabinet or its
12 designee may require additional progress reports.

13 (16) For projects involving long-term care beds:

14 (a) The first progress report shall include:

15 1. A copy of the deed or lease of land for projects requiring acquisition of real
16 property; and

17 2. Evidence that final plans have been submitted to the Public Protection Cabinet,
18 Department of Housing, Buildings, and Construction, and the Office of Inspector
19 General.

20 (b) For projects involving long-term care beds not deemed complete, a second
21 progress report shall include:

22 1. For conversion of bed projects, documentation that the beds in the project are
23 licensed; or

1 2. For construction projects:

2 a. A schedule for project completion with projected dates;

3 b. Documentation of final financing;

4 c. Documentation of final plan approval by the Public Protection Cabinet,
5 Department of Housing, Buildings, and Construction, and the Office of Inspector
6 General; and

7 d. An enforceable construction contract.

8 (17) For projects involving long-term care beds not deemed complete, a third
9 progress report shall include documentation that construction or renovation is
10 progressing according to the schedule for project completion.

11 (18) For projects involving long-term care beds not deemed complete, a fourth
12 progress report shall include documentation that the project has been appropriately
13 licensed and approved for occupancy by the Office of Inspector General.

14 (19) The cabinet or its designee may grant no more than three (3) additional
15 extensions of six (6) months for good cause shown if the certificate holder of long-term
16 care beds has failed to comply with the relevant progress report requirements
17 established in this section.

18 (20) If the project involves a capital expenditure, a final cost breakdown shall be
19 included in the final progress report.

20 (21) If the Office of Inspector General discovers a violation of terms and conditions
21 listed on a certificate of need and license while it is conducting its annual licensure
22 inspection, it shall refer this violation for a show cause hearing in accordance with 900
23 KAR 6:090, Section 4.

1 Section 3. Biennial Review. (1) Certificate of need holders may be subject to
2 biennial review to determine if they are in compliance with the terms as listed on their
3 certificate of need.

4 (2) Biennial review may be conducted within sixty (60) days of the second
5 anniversary of the final progress report and at twenty-four (24) month intervals
6 thereafter.

7 (3) The cabinet or its designee shall provide sixty (60) days' advance written
8 notification to the subject of any biennial review, including the following:

9 (a) When the biennial review shall be initiated;

10 (b) Request for information necessary for the review to which the cabinet does not
11 have ready access; and

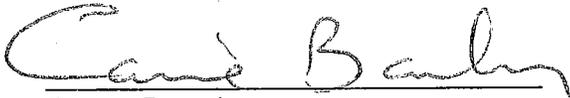
12 (c) A deadline for response to the request for information.

13 (4) If the cabinet finds that any of the terms and conditions of a certificate of need
14 approval and license have been violated, the review of, and any sanctions for, this
15 violation shall be conducted in accordance with 900 KAR 6:090, Section 4.

900 KAR 6:100

This is to certify that the Executive Director of the Office of Health Policy has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 156.070(4)

APPROVED:

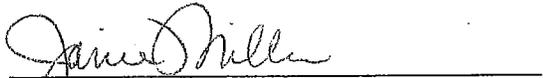


Carrie Banahan
Executive Director
Office of Health Policy

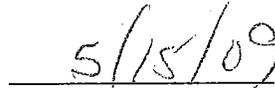


Date

APPROVED:



Janie Miller
Secretary
Cabinet for Health and Family Services



Date

900 KAR 6:100

A public hearing on this administrative regulation shall, if requested, be held on July 21, 2009, at 9:00 a.m. in the Public Health Auditorium located on the First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by July 14, 2009, 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. The hearing is open to the public. Any person who attends 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 attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business July 31, 2009. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, (502) 564-7905, Fax: (502) 564-7573

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 900 KAR 6:100

Contact Person: Carrie Banahan or Shane O'Donley, 564-9592

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the required standards for implementation as well as requirements for biennial reviews for the certificate of need program. Formerly 900 KAR 6:050 established the requirements necessary for the orderly administration of the certificate of need program. Due to the large size of that administrative regulation, LRC staff requested that it be separated into several smaller regulations. Therefore, this new administrative regulation was drafted to establish the required standards for implementation as well as requirements for biennial reviews for the certificate of need program. This regulation creates no substantive change to current policies.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990 by establishing the required standards for implementation as well as requirements for biennial reviews for the certificate of need program.

(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 KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990 by establishing the required standards for implementation as well as requirements for biennial reviews for the certificate of need program.

(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 is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity wishing to acquire or maintain a certificate of need. Approximately 100 entities file a certificate of need application each year.

(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: As the required standards for implementation as well as requirements for biennial reviews for the certificate of need program set forth in the administrative regulation are currently established and operational, no new action will be required of regulated entities to comply with this regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): As the required standards for implementation as well as requirements for biennial reviews for the certificate of need program set forth in the administrative regulation are currently established and operational, no cost will be incurred by regulated entities to comply with this regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This administrative regulation will provide potential health care providers with a mechanism to establish health care facilities and services in compliance with KRS 216B.

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

(a) Initially: No additional costs will be incurred to implement this administrative regulation as entities already adhere to the required standards for implementation as well as requirements for biennial reviews for the certificate of need program.

(b) On a continuing basis: No additional costs will be incurred to implement this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used for the implementation and enforcement of this administrative regulation will be from Office of Health Policy's existing budget. As stated above, the required standards for implementation as well as requirements for biennial reviews for the certificate of need program are already used as part of our normal operations so no additional funding will be required.

(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 will be necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? (explain why or why not) Tiering is not applicable as compliance with this administrative regulation applies equally to all

individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:100

Contact Person: Carrie Banahan or
Shane O'Donley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No _____

If yes, complete questions 2-4.

2. 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 the Office of Health Policy within the Cabinet for Health and Family Services.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990.

4. 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 administrative regulation will not generate any revenue.

(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 administrative regulation will not generate any revenue.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a continuing basis.

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: