

FILED WITH LRC
TIME: 3 pm
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Emily B. Caudill
REGULATIONS COMPILER

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (New administrative regulation)

4 900 KAR 6:070. Certificate of Need considerations for formal review.

5 RELATES TO: KRS 216B.010, 216B.040, 216B.990

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

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

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

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

10 This administrative regulation establishes the requirements necessary for the

11 consideration for formal review of applications for the orderly administration of the

12 Certificate of Need Program.

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

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

15 (3) "Formal review" means the review of applications for certificate of need which are

16 reviewed within ninety (90) days from the commencement of the review as provided by

17 KRS 216B.062(1) and which are reviewed for compliance with the review criteria set

18 forth at KRS 216B.040 and 900 KAR 6:065.

19 (4) "Public information channels" means the Office of Communication and

20 Administrative Review in the Cabinet for Health and Family Services.

21 (5) "Public notice" means notice given through:

- 1 (a) Public information channels; or
- 2 (b) The cabinet's Certificate of Need Newsletter.

3 Section 2. Considerations for Formal Review. In determining whether to approve or
4 deny a certificate of need, the cabinet's review of applications under formal review shall
5 be limited to the following considerations:

6 (1) Consistency with plans.

7 (a) To be approved, a proposal shall be consistent with the State Health Plan
8 established in 900 KAR 5:020.

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

13 (c) An application seeking to re-establish a licensed healthcare facility or service
14 that was provided at the healthcare facility and which was voluntarily discontinued by
15 the applicant, shall be considered consistent with the State Health Plan under the
16 following circumstances:

17 1. The termination or voluntary closure of the former healthcare service or facility:

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

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

22 c. Did occur while the facility was in substantial compliance with applicable
23 administrative regulations and was otherwise eligible for relicensure;

1 d. Was not an express condition of any subsequent Certificate of Need approval;

2 and

3 e. Did not occur less than twenty-four (24) months prior to the submission of the

4 application to re-establish;

5 2. The proposed healthcare service shall be provided within the same geographic

6 service area as the former healthcare service;

7 3. The proposed healthcare facility shall be located within the same county as the

8 former healthcare facility and at a single location; and

9 4. The application shall not seek to re-establish any type of bed utilized in the care

10 and treatment of patients for more than twenty-three (23) consecutive hours.

11 (2) Need. The cabinet shall determine:

12 (a) If the applicant has identified a need for the proposal in the geographic service

13 area defined in the application; and

14 (b) If the applicant has demonstrated that it is able to meet the need identified in the

15 geographic service area defined in the application.

16 (3) Accessibility. The cabinet shall determine if the health facility or health service

17 proposed in the application will be accessible in terms of timeliness, amount, duration,

18 and personnel sufficient to provide the services proposed.

19 (4) Interrelationships and linkages. The cabinet shall determine:

20 (a) If the proposal shall serve to accomplish appropriate and effective linkages with

21 other services, facilities, and elements of the health care system in the region and state;

22 and

23 (b) If the proposal is accompanied by assurance of effort to achieve comprehensive

1 care, proper utilization of services, and efficient functioning of the health care system.

2 (5) Costs, economic feasibility, and resource availability. The cabinet shall
3 determine:

4 (a) If it is economically feasible for the applicant to implement and operate the
5 proposal; and

6 (b) If applicable, if the cost of alternative ways of meeting the need identified in the
7 geographic area defined in the application would be a more effective and economical
8 use of resources.

9 (6) Quality of services. (a) The cabinet shall determine if the applicant:

10 1. Is prepared to, and capable of undertaking and carrying out, the responsibilities
11 involved in the proposal in a manner consistent with appropriate standards and
12 requirements established by the cabinet; and

13 2. Has the ability to comply with applicable licensure requirements.

14 (b) Absence of an applicable licensure category shall not constitute grounds for
15 disapproving an application.

900 KAR 6:070

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

4/25/09
Date

APPROVED:



Janie Miller
Secretary
Cabinet for Health and Family Services

5/15/09
Date

900 KAR 6:070

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 6:070

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 guidelines considerations for formal review of applications 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 include information specific to certificate of need considerations for formal review. 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.040, 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.040, 216B.990 by establishing the considerations for formal review of certificate of need applications.

(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.040, 216B.990 by establishing the considerations for formal review of certificate of need applications.

(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 file a certificate of need application. 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 considerations for formal review of certificate of need applications 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 considerations for formal review of certificate of need applications 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 amendment as entities already adhere to the requirements for considerations for formal review.

(b) On a continuing basis: No additional costs will be incurred to implement 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: 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 considerations for formal review requirements 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 6:070

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.040, 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 amendment.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this amendment 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: