FILED WITH LRC
TIME: NOON
SEP 27 2016
Donna Little
REGULATIONS COMPILER

STATEMENT OF EMERGENCY

900 KAR 5:020E

(1) This emergency administrative regulation is being promulgated in accordance with KRS 13A.190 to correct a finding of deficiency issued on September 8, 2015 by the Administrative Regulation Review Subcommittee. This action must be taken on an emergency basis to protect public health and safety. This emergency administrative regulation amends the State Health Plan regarding the need for ambulatory surgical centers in the Commonwealth of Kentucky. Pursuant to KRS 216B.040(2)(a)2.a, the Cabinet for Health and Family Services is charged with responsibility for promulgating regulations to establish criteria for the issuance and denial of certificates of need. The Cabinet must take this action to amend the State Health Plan regarding ambulatory surgical centers to assure that there will not be a proliferation of unnecessary ambulatory surgical centers that have the potential to negatively impact the viability of our full-service safety-net hospitals, thereby protecting human health and safety. This concern was raised by legislators and stakeholders when the current version of the ambulatory surgical center review criteria were unanimously found deficient by the Administrative Regulation Review Subcommittee on September 8, 2015. This immediate amendment would revise the ambulatory surgical center review criteria and allow the administration and General Assembly to further study and consider the impact of potential changes to ambulatory surgical center review criteria without the potential to inflect unnecessary and irreversible damage to the viability of safety-net hospitals.

(2) Failure to enact this administrative regulation on an emergency basis in accordance with KRS 13A.190(1)(a) will compromise the Cabinet's ability to act quickly in its efforts to address the ambulatory surgical center needs of the Commonwealth.

(3) This emergency administrative regulation shall be replaced by an ordinary administrative regulation to be concurrently filed with the Regulations Compiler.

(4) The ordinary administrative regulation is identical to this emergency administrative regulation.

Matthew G. Bevin
Governor

Vickie Yates Brown Glisson
Cabinet for Health and Family Services

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Health Policy

3 (Emergency Amendment)

4 900 KAR 5:020E. State Health Plan for facilities and services.

5 RELATES TO: KRS 216B.010-216B.130

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28),

7 216B.040(2)(a)2.a.

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

9 the cabinet to promulgate an administrative regulation, updated annually, to establish

10 the State Health Plan. The State Health Plan is a critical element of the certificate of

11 need process for which the cabinet is given responsibility in KRS Chapter 216B. This

12 administrative regulation establishes the State Health Plan for facilities and services.

13 Section 1. The 2016 Update to the 2015-2017 State Health Plan shall be used to:

14 (1) Review a certificate of need application pursuant to KRS 216B.040; and

15 (2) Determine whether a substantial change to a health service has occurred

16 pursuant to KRS 216B.015(29)(a) and 216B.061(1)(d).

17 Section 2. Incorporation by Reference. (1) The "2016 Update to the 2015-2017

18 State Health Plan", September 2016 [~~August 2015~~], is incorporated by reference.

19 (2) This material may be inspected, copied, or obtained, subject to applicable

20 copyright law, at the Office of Health Policy, 275 East Main Street, 4WE, Frankfort,

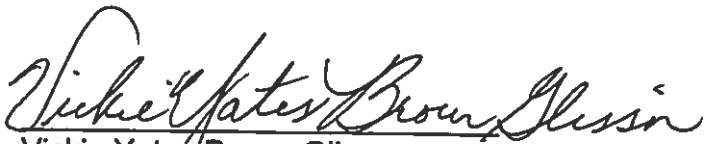
21 Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

1 ~~[Section 3. This administrative regulation was found deficient by the Administrative~~

2 ~~Regulation Review Subcommittee on September 8, 2015.]~~

900 KAR 5:020E

APPROVED:



Vickie Yates Brown Glisson
Secretary
Cabinet for Health and Family Services

9/26/16
Date

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 5:020E
Contact Persons: Diona Mullins, Office of Health Policy, phone (502) 564-9592, email Diona.mullins@ky.gov; Tricia Orme, Office of Legal Services, phone (502) 564-7905, email tricia.orme@ky.gov.

1. Provide a brief summary of:

   (a) What this administrative regulation does: This administrative regulation incorporates by reference the 2016 Update to the 2015-2017 State Health Plan which shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a.
   (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statutes: KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), and 216B.040(2)(a)2.a.
   (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation revises the 2013-2015 State Health Plan to address the ambulatory surgical center review criteria.
   (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: The amendment of the State Health Plan will assist in the effective administration of KRS 216B.040(2)(a)2.a. The plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a.

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: The amendment will revise the ambulatory surgical center review criteria in the State Health Plan.
   (b) The necessity of the amendment to this administrative regulation: The administrative regulation is necessary to comply with the content of the authorizing statutes as the present and future needs of the population are to be addressed in the State Health Plan. The amendment is necessary to assure that there is not a proliferation of unnecessary ambulatory surgical centers.
   (c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by incorporating by reference the revised criteria of the 2016 Update to the 2015-2017State Health Plan.

(d) How the amendment will assist in the effective administration of the statutes: This amendment to the ambulatory surgical center review criteria of the State Health Plan will address the needs of the population and assist in the effective administration of KRS 216B.040(2)(a)2.a.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Annually, approximately five (5) ambulatory surgical center certificate of need applications are filed.

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: Entities which submit certificate of need applications for ambulatory surgical centers will be subject to the revised criteria set forth in the 2016 Update to the 2015-2017 State Health Plan.
   (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to entities to comply with this amendment.
   (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Entities which submit certificate of need applications for ambulatory surgical centers will be subject to the revised criteria set forth in the 2016 Update to the 2015-2017 State Health Plan, which addresses the need for expansion of ambulatory surgical centers in the Commonwealth.

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

   (a) Initially: No cost
   (b) On a continuing basis: No cost

6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No funding is necessary since there is no cost to implementing 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.

8. State whether or not this administrative regulation established any fees or directly

or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.

9. TIERING: Is tiering applied? (Explain why or why not)
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 5:020E
Contact Persons: Diona Mullins, Office of Health Policy, phone (502) 564-9592, email Diona.mullins@ky.gov; Tricia Orme, Office of Legal Services, phone (502) 564-7905, email tricia.orme@ky.gov.

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment may impact any government owned, controlled or proposed ambulatory surgical centers.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. The authorizing statutes are KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), and 216B.040(2)(a)2.a.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None.

   (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? No impact to revenues.

   (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? No revenues will be generated for state or local government.

   (c) How much will it cost to administer this program for the first year? None.

   (d) How much will it cost to administer this program for subsequent years? None.

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

Revenues (+/-): None
Expenditures (+/-): None
Other Explanation: None

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
Office of Health Policy

900 KAR 5:020E. State Health Plan for facilities and services.

Summary of Material Incorporated by Reference

The 2016 Update to the 2015-2017 State Health Plan, revised September 2016, is being incorporated by reference. The 2016 Update to the 2015-2017 State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a. The 2016 Update to the 2015-2017 State Health Plan, September 2016 includes revisions to the following:

a. The cover page was changed to reflect a title change and a September 2016 revision date.

b. Page ii, Table of Contents was revised to change page numbers for Chemical Dependency Treatment Beds and Private Duty Nursing Service.

c. Page 58 was revised to delete criterion 1.

d. Page 58 was revised to add criterion 2 which states:

2. A new ASC shall be located within twenty (20) minutes normal driving time of at least one (1) acute care hospital;

e. Page 58 was revised to add criterion 3 which states:

3. The applicant shall have a transfer agreement for the proposed ASC in place with at least one (1) acute care hospital which is located within twenty (20) minutes normal driving time of the center; and

f. Pages 58-60, criterion 3 was revised to state:

4. Notwithstanding criterion 1, an application to establish an ASC limited to a specific type of procedure shall be consistent with this Plan if the following conditions are met:

a. The applicant documents that patients are not receiving the specific type of surgical procedures (as identified by procedure codes) proposed by the applicant at facilities in the planning area; and

b. The application contains an explanation of why the unmet need for the specific type of surgical procedure has not been reasonably addressed by providers in the planning area.

g. Pages 59-60 were revised to delete criteria 4, 5, 6, 7, and 8.