

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Health Policy

3 (Amended After Comments)

4 900 KAR 5:020. 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,
7 216B.015(27), 216B.040(2)(a)2a

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 **2009 Update to the 2007-2009 State Health Plan as amended**
14 **June 2009 [2008 Update to the 2007-2009 State Health Plan as amended December**
15 **31, 2008]** [2007-2009 State Health Plan as amended October 15, 2007] shall be used to

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

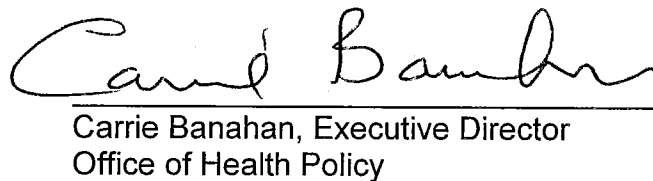
17 (2) Determine whether a substantial change to a health service has occurred pursuant
18 to KRS 216B.015(28)(a) and 216B.061(1)(d).

19 Section 2. Incorporation by Reference. (1) The **2009 Update to the 2007-2009**
20 **State Health Plan as amended June 2009 [2008 Update to the 2007-2009 State**

1 ~~Health Plan as amended December 31, 2008~~ [2007-2009 State Health Plan as
2 amended October 15, 2007] is incorporated by reference.

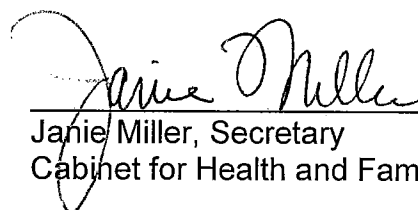
3 (2) This material may be inspected, copied, or obtained, subject to applicable
4 copyright law, at the Division of Certificate of Need, 275 East Main Street, fourth floor,
5 Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (24 Ky.R. 1433;
6 Am. 1714; eff. 4-13-98; 26 Ky.R. 484; 1017; 1161; eff. 10-20-99; 27 Ky.R. 606; 1319;
7 1492; eff. 12-21-2000; 29 Ky.R. 2377; eff. 6-16-03; Recodified from 902 KAR 17:041, 5-
8 26-04. Am. 31 Ky.R. 236; 782; eff. 11-17-04; 32 Ky.R. 1785; 2295; eff. 7-24-06; 34
9 Ky.R. 408; 1004; eff. 12-17-2007.)

900 KAR 5:020
(Amended After Comments)
REVIEWED:


Carrie Banahan, Executive Director
Office of Health Policy

4/10/09
Date

APPROVED:


Janie Miller, Secretary
Cabinet for Health and Family Services

4/14/09
Date

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 5:020

Contact Person: Shane P. O'Donley, Policy Advisor (502) 564-9589 extension 3274

1. Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation incorporates by reference the State Health Plan, which is used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040.
 - (b) The necessity of this administrative regulation: KRS 216B.015(27) requires that the State Health Plan be prepared triennially and updated annually. This administrative regulation incorporates the 2007-2009 State Health Plan by reference.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: The preparation of the State Health Plan is required by KRS 216B.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: The preparation of the State Health Plan is required by KRS 216B.

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 update the 2007-2009 State Health Plan for 2007.
 - (b) The necessity of the amendment to this administrative regulation: KRS 216B.015(27) requires that the State Health Plan be prepared triennially. The last triennial State Health Plan was prepared in 2005, so the next triennial plan is being prepared for 2007-2009.
 - (c) How the amendment conforms to the content of the authorizing statutes: The amendment carries out the requirement of KRS 216B.015(27) that the State Health Plan be updated on an annual basis.
 - (d) How the amendment will assist in the effective administration of the statutes: This amendment will provide an updated State Health Plan for purposes of certificate of need review.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect health care providers governed by the Certificate of Need law, citizens who use health care in Kentucky, health planners in the Certificate

of Need Program, and local communities that plan for, use, or develop community health care facilities.

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: The modifications will only apply to potential Certificate of Need applicants for Psychiatric Hospital Beds, Home Health Services, Magnetic Resonance Imaging Equipment, Megavoltage Radiation Therapy Equipment, Positron Emission Tomography Equipment, Prescribed Pediatric Extended Care Facilities and Private Duty Nursing Services.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): None. The CON application fee is unaffected by this proposed amendment.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Applicants proposing to establish prescribed pediatric extended care facilities will benefit from an expedited review process because those service categories have been removed from the State Health Plan. These changes may increase access to prescribed pediatric extended care facilities for our medically needy children and their working parents.
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. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The "equal protection" and "due process" clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT
AMENDED AFTER COMMENTS

Regulation No. 900 KAR 5:020 Contact Person: Shane O'Donley, Policy Advisor

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 amendment may impact any government owned, controlled or proposed healthcare facilities or services.
3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.015(27) requires that the State Health Plan be prepared triennially and updated annually. This administrative regulation incorporates the 2007-2009 State Health Plan by reference.
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. 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 to 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

STATEMENT OF CONSIDERATION RELATING TO
900 KAR 5:020
Office of Health Policy

Amended After Comments

(1) A public hearing on 900 KAR 5:020 was held on February 23rd at 9:00 a.m., in the Health and Family Services Auditorium located at 275 East Main Street, Frankfort, Kentucky, 40621.

(2) The following people submitted written comments via the public comment process:

<u>NAME</u>	<u>AGENCY/ORGANIZATION/ENTITY/OTHER</u>
Dr. Bobby Baker	CyberKnife Associates of Louisville
Heidi Schissler Lanaham	Protection and Advocacy
Rod Hieneman	Our Lady of Bellefonte Hospital
Margaret Young Levi	Ephraim McDowell Health
Lisa English Hinkle	McBrayer McGinnis, Leslie & Kirkland on behalf of 21st Century Oncology of Kentucky, Richmond Open MRI and Diagnostic Center, Physician Services, P.S.C., Our Lady of Bellefonte Hospital
Marian Hayden	Cull, Hayden & Vance on behalf of Saint Joseph Health System
Brian Lebanion	Professional Home Health Care Agency
Marie Alagia Cull	Cull, Hayden & Vance on behalf of the Kentucky Hospital Association
Andy Sears	Baptist Healthcare System
Bill Kindred	T.J. Samson Community Hospital
Fred Jackson	King's Daughter's Medical Center
Darlene Litteral	Friends and Companions Day Health Care Center
Mary Jo Bean	Norton Healthcare
Susan Swinford	Hospice of the Bluegrass
Pat Hagen	Nurses Registry, Inc.
Nancy Galvagni	Kentucky Hospital Association

(3) The following people from the promulgating administrative body responded to the comments received:

<u>NAME AND TITLE</u>	<u>AGENCY/ORGANIZATION/ENTITY/OTHER</u>
Shane O'Donley Policy Advisor	Office of Health Policy Cabinet for Health and Family Services

SUMMARY OF COMMENTS AND RESPONSES

1. Subject: Technical Notes

- (a) Comment: Lisa English Hinkle, on behalf of Physician Services, P.S.C. and Richmond Open MRI & Diagnostic Center, supports that Cabinet's amendment to technical note (4).
- (b) Response: The Cabinet appreciates the support for the proposed amendment.
- (c) Comment: Andy Sears, on behalf of Baptist Healthcare System, recommends the Cabinet require the medical office's of physicians, dentists and other practitioners of the healing arts which operate a MRI to report their MRI utilization to the Cabinet for inclusion in the annual MRI Utilization Report.
- (d) Response: Pursuant to 900 KAR 6:050 Section 28, all MRI units utilized in the Commonwealth shall be disclosed to the Cabinet for Health and Family Services, Office of Health Policy for publication in the *Kentucky Annual Magnetic Resonance Imaging Services Report*.

2. Subject: Acute Care Beds

- (a) Comment: Rod Hieneman, on behalf of Our Lady of Bellefonte Hospital, recommends preventing additional acute care beds from being approved unless all hospitals in the service area are operating at a 70% - 75 % annual occupancy rate.
- (b) Response: The Cabinet has considered this comment but believes that such modifications are not warranted at this time. The current CON review mechanism allows the hearing officer to consider available beds in the proposed service area before approving the expansion of an existing facility.

3. Subject: Comprehensive Physical Rehabilitation Beds

- (a) Comment: Rod Hieneman, on behalf of Our Lady of Bellefonte Hospital recommends allowing for the conversion of chemical dependency beds to comprehensive physical rehabilitation beds.
- (b) Response: The Cabinet has considered this comment but believes that such modifications are not warranted at this time. There is no relationship between chemical dependency beds and comprehensive physical rehabilitation beds.

4. Subject: Open Heart Surgery

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, recommends requiring applicants for an open heart surgery program to provide interventional cardiac catheterization services.
- (b) Response: The Cabinet has considered this comment but believes that such modifications are not warranted at this time.
- (c) Comment: Rod Hieneman, on behalf of Our Lady of Bellefonte Hospital, recommends reducing the number of open heart procedures to be performed from 400 to 200.
- (d) Response: The Cabinet has considered this comment but believes that such modifications are not warranted at this time.

5. Subject: Home Health Services

- (a) Comment: Brian Lebanion, on behalf of Professional Home Health Care Agency, Inc., recommends the existing home health review criteria remain in the SHP and opposes any amendment which would provide differential treatment for pediatric specific home health agencies.
- (b) Response: The Cabinet has considered this comment and agrees that such modifications are not warranted at this time.
- (c) Comment: Pat Hagen and Lisa English, on behalf of NR Inc., recommends the Cabinet exempt home health agencies that exclusively serve pediatric patients from CON review. They also presented oral comments at the public hearing consistent with their written comments.
- (d) Response: The Cabinet has considered this comment but believes that such modifications are not warranted at this time. The Cabinet is considering making additional changes to the home health criteria in the future at which time input will be solicited from interested parties and your recommendations will be reconsidered.

6. Subject: Adult Day Health Care Programs

- (a) Comment: Darlene Litteral, on behalf of Friends and Companions Day Health Care Center recommends the existing adult day health care program review criteria remain in the SHP.
- (b) Response: The Cabinet has considered this comment and has re-inserted the current review criteria for Adult Day Health Care Programs into the proposed SHP.
- (c) Comment: Heidi Schissler Lanham, on behalf of Protection & Advocacy recommends the existing adult day health care program review criteria remain in the SHP.
- (d) Response: The Cabinet has considered this comment and has re-inserted the current review criteria for Adult Day Health Care Programs into the proposed SHP.

7. Subject: Cardiac Catheterization

- (a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association (KHA), supports the removal of the exception which permitted the approval of a therapeutic cardiac catheterization program because there is not an existing program in the Area Development District (ADD). KHA also recommends a complete revision of the existing review criteria for interventional cardiac catheterization. KHA further recommends the creation of a non-substantive review category which would allow both TJ Samson Community Hospital and Ephraim McDowell Regional Medical Center to perform elective therapeutic cardiac catheterization procedures.
- (b) Response: The Cabinet contracted with the University of Louisville's Department of Bioinformatics and Biostatistics, Cardiovascular Innovation Institute (CII) to perform a statistical analysis that evaluated whether primary PCI should be allowed to be performed at facilities in the Commonwealth of Kentucky that do not have onsite open-heart surgery capabilities. The Cabinet is still in the process of considering KHA's comments and will delay any action until after the CII's presentation of their findings and recommendations to the Interim Joint Committee on Health and Welfare. This delay will allow additional time for other interested parties to react and comment on CII's findings and recommendations.
- (c) Comment: Margaret Young Levi, on behalf of Ephraim McDowell Regional Medical Center (EMRMC), and Bill Kindred on behalf of TJ Samson Community Hospital (TJSCH) recommend amending the SHP or

900 KAR 6:050 to provide for an expedited review process which will allow both hospitals to perform elective interventional cardiac catheterizations.

- (d) Response: The Cabinet contracted with the University of Louisville's Department of Bioinformatics and Biostatistics, Cardiovascular Innovation Institute (CII) to perform a statistical analysis that evaluated whether primary PCI should be allowed to be performed at facilities in the Commonwealth of Kentucky that do not have onsite open-heart surgery capabilities. The Cabinet is still in the process of considering EMRMC and TJSCH's comments and will delay any action until after the CII's presentation of their findings and recommendations to the Interim Joint Committee on Health and Welfare. This delay will allow additional time for other interested parties to react and comment on CII's findings and recommendations.
- (e) Comment: Fred Jackson, on behalf of King's Daughters Medical Center (KDMC), opposes KHA's recommended changes to the cardiac catheterization review criteria.
- (f) Response: The Cabinet contracted with the University of Louisville's Department of Bioinformatics and Biostatistics, Cardiovascular Innovation Institute (CII) to perform a statistical analysis that evaluated whether primary PCI should be allowed to be performed at facilities in the Commonwealth of Kentucky that do not have onsite open-heart surgery capabilities. The Cabinet is still in the process of considering KDMC's comments and will delay any action until after the CII's presentation of their findings and recommendations to the Interim Joint Committee on Health and Welfare. This delay will allow additional time for other interested parties to react and comment on CII's findings and recommendations.
- (g) Comment: Rod Hieneman, on behalf of Our Lady of Bellefonte Hospital (OLBH), recommends permitting providers of diagnostic catheterizations to perform therapeutic catheterizations and that the distinction between diagnostic and therapeutic catheterizations be omitted from the SHP.
- (h) Response: The Cabinet contracted with the University of Louisville's Department of Bioinformatics and Biostatistics, Cardiovascular Innovation Institute (CII) to perform a statistical analysis that evaluated whether primary PCI should be allowed to be performed at facilities in the Commonwealth of Kentucky that do not have onsite open-heart surgery capabilities. The Cabinet is still in the process of considering OLBH's comments and will delay any action until after the CII's presentation of their findings and recommendations to the Interim Joint Committee on Health and Welfare. This delay will allow additional time for other

