

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Health Policy

3 (Amended After Comments)

4 900 KAR 6:075. Certificate of need nonsubstantive review.

5 RELATES TO: KRS 216B.010, 216B.015, 216B.090[~~216B.095~~], 216B.455, 216B.990

6 STATUTORY AUTHORITY: KRS[~~194A.030, 194A.050,~~] 216B.040(2)(a)1, 216B.095

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 KRS 216B.095 authorizes the review of certificate of need applications that are granted

11 nonsubstantive status. This administrative regulation establishes the requirements nec-

12 essary for consideration for nonsubstantive review of applications for the orderly admin-

13 istration of the Certificate of Need Program.

14 Section 1. Definitions. (1) "Ambulatory surgical center" is defined by KRS

15 216B.015(4).

16 (2) "Cabinet" is defined by KRS 216B.015(6).

17 (3) "Certificate of Need Newsletter" means the monthly newsletter that is published

18 by the cabinet regarding certificate of need matters and is available on the Certificate of

19 Need Web site at <http://chfs.ky.gov/ohp/con>.

20 (4) "Days" means calendar days, unless otherwise specified.

21 (5) "Formal review" means the review of an application for certificate of need which is

1 reviewed within ninety (90) days from the commencement of the review as provided by  
2 KRS 216B.062(1) and which is reviewed for compliance with the review criteria set forth  
3 at KRS 216B.040 and 900 KAR 6:070.

4 (6) "Nonsubstantive review" is defined by KRS 216B.015(18).

5 (7) "Public information channels" means the Office of Communication and Adminis-  
6 trative Review in the Cabinet for Health and Family Services.

7 (8) "Public notice" means notice given through:

8 (a) Public information channels; or

9 (b) The cabinet's Certificate of Need Newsletter. [~~(9) "Therapeutic cardiac catheteriza-  
10 tion outcomes" means in hospital mortality rates, door to balloon time, door to balloon  
11 time less than or equal to ninety (90) minutes, Percutaneous Coronary Intervention  
12 (PCI) related cardiac arrests, and emergency open heart surgeries performed as a re-  
13 sult of the PCI.]~~

14 Section 2. Nonsubstantive Review. (1) The cabinet shall grant nonsubstantive review  
15 status to an application to change the location of a proposed health facility or to relocate  
16 a licensed health facility only if:

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

18 (b)1. The change of location or relocation is within the same county; or

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

21 (2) The cabinet shall grant nonsubstantive review status to an application that pro-  
22 poses to establish an ambulatory surgical center pursuant to the conditions specified in  
23 KRS 216B.095(7).

1 (3) In addition to the projects specified in KRS 216B.095(3)(a) through (e), pursuant  
2 to KRS 216B.095(f), the Office of Health Policy shall grant nonsubstantive review status  
3 to an application for which a certificate of need is required if:

4 (a) The proposal involves the establishment or expansion of a health facility or health  
5 service for which there is not a component in the State Health Plan;

6 ~~(b) [The proposal involves an application from a hospital to reestablish the number of  
7 acute care beds that it converted to nursing facility beds pursuant to KRS 216B.020(4),  
8 if the number of nursing facility beds so converted are delicensed;~~

9 (e) The proposal involves an application to relocate or transfer certificate of need  
10 approved acute care beds or licensed acute care beds, not including neonatal Level  
11 III or Level IV beds, from one (1) existing licensed hospital to another existing licensed  
12 hospital within the same area development district and the requirements established in  
13 this paragraph are met.

14 1.a. There shall not be an increase in the total number of licensed acute care beds in  
15 that area development district; and

16 b. The hospital from which the licensed beds are relocated delicensures those beds.

17 2. If neonatal Level II beds are relocated or transferred pursuant to this paragraph:

18 a. The receiving hospital shall have an existing licensed Level II, ~~or~~ Level III, or Lev-  
19 el IV neonatal unit;

20 b. A minimum of four (4) beds shall be relocated; and

21 c. The relocation shall not leave the transferring hospital with less than four (4) neo-  
22 natal Level II beds unless the relocated beds represent all of its neonatal Level II beds;

23 ~~(c) [(d)]~~ The proposal involves an application by an existing licensed acute care

1 hospital to:

2 1. Convert licensed psychiatric or chemical dependency beds to acute care beds, not  
3 including special purpose acute care beds such as neonatal Level II beds,~~[or neonatal]~~  
4 Level III beds, or Level IV beds;

5 2. Convert and implement the beds on-site at the hospital's existing licensed facility;  
6 and

7 3. Delicense the same number of psychiatric or chemical dependency beds that are  
8 converted;

9 ~~(d)~~~~(e)~~ The proposal involves an application by an existing licensed hospital provid-  
10 ing inpatient psychiatric treatment to:

11 1. Convert psychiatric beds licensed for use with geriatric patients to acute care beds,  
12 not including special purpose acute care beds such as neonatal Level II beds,~~[or neona-~~  
13 ~~tal]~~ Level III beds, or Level IV beds;

14 2. Convert and implement the beds on-site at the existing licensed hospital; and

15 3. Delicense the same number of converted beds;

16 ~~(e)~~~~(f)~~ ~~The proposal involves an application by a psychiatric hospital to convert li-~~  
17 ~~censed geriatric, adult, adolescent, or child psychiatric beds to psychiatric beds and the~~  
18 ~~requirements established in this paragraph are met.~~

19 ~~1. The psychiatric hospital is located within twenty (20) miles of a United States mili-~~  
20 ~~tary base;~~

21 ~~2. The psychiatric hospital provides inpatient behavioral health services to active duty~~  
22 ~~military personnel, families of active duty military personnel, and veterans;~~

23 ~~3. The psychiatric hospital shall convert and implement the beds on-site at the exist-~~

1 ~~ing licensed hospital; and~~

2 ~~4. The psychiatric hospital shall delicense the same number of converted beds.~~

3 ~~(g) The proposal involves an application to transfer or relocate existing certificate of~~  
4 ~~need approved nursing facility beds between certificate of need approved nursing facili-~~  
5 ~~ties or from a certificate of need approved nursing facility to a proposed nursing facility~~  
6 ~~and the requirements established in this paragraph are met.~~

7 ~~1. The selling or transferring facility has a certificate of need nursing facility bed in-~~  
8 ~~ventory of at least 250 beds;~~

9 ~~2. The transfer or relocation takes place within the same Area Development District;~~

10 ~~3. The application includes:~~

11 ~~a. A properly completed OHP Form 9, Notice of Intent to Acquire a Health Facility or~~  
12 ~~Health Service, incorporated by reference in 900 KAR 6:055; and~~

13 ~~b. Evidence of the selling or transferring entity's binding commitment to sell or trans-~~  
14 ~~fer upon approval of the application; and~~

15 ~~4. A certificate of need approved nursing facility shall not sell or transfer more than~~  
16 ~~fifty (50) percent of its certificate of need approved nursing facility beds;~~

17 ~~(h) The proposal involves an application to establish a therapeutic cardiac catheteri-~~  
18 ~~zation program and the requirements established in this paragraph are met.~~

19 ~~1. The applicant is an acute care hospital which was previously granted a certificate~~  
20 ~~of need to participate in a primary angioplasty pilot project and was evaluated after the~~  
21 ~~first two (2) years of operation by an independent consultant who determined the hospi-~~  
22 ~~tal successfully demonstrated good therapeutic cardiac catheterization outcomes.~~

23 ~~2. The applicant shall document that the nursing and technical catheterization labora-~~

- 1 ~~tery staff are experienced and participate in a continuous call schedule.~~
- 2 ~~3. The applicant shall document that the catheterization laboratory shall be equipped~~
- 3 ~~with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump~~
- 4 ~~support.~~
- 5 ~~4. The applicant shall document that the cardiac care unit nurses shall be proficient in~~
- 6 ~~hemodynamic monitoring and intra-aortic balloon pump management.~~
- 7 ~~5. The applicant shall document formalized written protocols in place for immediate~~
- 8 ~~and efficient transfer of patients to an existing licensed cardiac surgical facility.~~
- 9 ~~6. The applicant shall utilize a Digital Imaging and Communications in Medicine (DI-~~
- 10 ~~COM) standard image transfer system between the hospital and the backup surgical fa-~~
- 11 ~~cility.~~
- 12 ~~7. The applicant shall employ an interventional program director who has performed~~
- 13 ~~more than 500 primary PCI procedures and who is board certified by the American~~
- 14 ~~Board of Internal Medicine in interventional cardiology.~~
- 15 ~~8. The applicant shall document that each cardiologist performing the therapeutic~~
- 16 ~~catheterizations shall perform at least seventy-five (75) PCIs per year.~~
- 17 ~~9. The applicant shall document the ability to perform at least 200 interventions per~~
- 18 ~~year, with an ideal minimum of 400 interventions per year by the end of the second year~~
- 19 ~~of operation.~~
- 20 ~~10. The applicant shall participate in the American College of Cardiology National~~
- 21 ~~Cardiovascular Data Registry quality measurement program.~~
- 22 ~~11. The applicant shall report therapeutic cardiac catheterization data annually to the~~
- 23 ~~Cabinet for Health and Family Services.~~

~~12. The application shall document the applicant's ability to produce therapeutic cardiac catheterization outcomes which are within two (2) standard deviations of the national means for the first two (2) consecutive years;~~

~~(i) The proposal involves an application to transfer or relocate existing certificate of need approved nursing facility beds from one (1) long-term care facility to another long-term care facility and the requirements established in this paragraph are met.~~

~~1. The selling or transferring facility fails to meet regulations promulgated by the Centers for Medicare and Medicaid Services at 42 C.F.R. 483.70(a)(8) requiring nursing facilities to install sprinkler systems throughout their buildings;~~

~~2. The selling or transferring facility may sell or transfer portions of its total bed component to one (1) or more existing nursing facility;~~

~~3. The facility acquiring the beds shall be located in a county contiguous to that of the selling or transferring facility;~~

~~4. The selling or transferring facility shall be licensed only for nursing facility beds at the time of transfer or application to transfer and shall not sell or transfer more than thirty (30) of its licensed nursing facility beds to an individual facility; and~~

~~5. The application shall include a properly completed OHP Form 9, Notice of Intent to Acquire a Health Facility or Health Service, incorporated by reference in 900 KAR 6:055;~~

~~(j) The proposal involves an application to re-establish a licensed healthcare facility or service that was provided at a hospital [with fifty (50) or fewer licensed beds] and [which] was voluntarily discontinued by the applicant under the following circumstances:~~

- 1        1. The termination or voluntary closure of the hospital:
- 2        a. Was not the result of an order or directive by the cabinet, governmental agency,
- 3        judicial body, or other regulatory authority;
- 4        b. Did not occur during or after an investigation by the cabinet, governmental agency,
- 5        or other regulatory authority;
- 6        c. Did occur while the facility was in substantial compliance with applicable adminis-
- 7        trative regulations and was otherwise eligible for re-licensure; and
- 8        d. Was not an express condition of any subsequent certificate of need approval;

9        2. The application to re-establish the healthcare facility or service that was voluntarily

10       discontinued is filed no more than one (1) year from the date the hospital last provided

11       the service which the applicant is seeking to re-establish;

12       3. A proposed healthcare facility shall be located within the same county as the for-

13       mer healthcare facility and at a single location; and

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

15       and treatment of patients for more than twenty-three (23) consecutive hours; or

16       ~~(f)~~1. The proposal involves an application to establish an ambulatory surgical

17       center which does not charge its patients and does not seek or accept commercial in-

18       surance, Medicare, Medicaid, or other financial support from the federal government;

19       and

20       2. The proposed ambulatory surgical center shall utilize the surgical facilities of an

21       existing licensed ambulatory surgical center during times the host ambulatory surgical

22       center is not in operation.

23       ~~(4)~~ A certificate of need approved for an application submitted under subsection

1 ~~(3)(f)(2)(f)(4)~~ of this section shall state the limitations specified under subsection  
2 ~~(3)(f)(2)(f)(4)~~ 1. and 2. of this section.

3 ~~(5)(4)~~ If an application is denied nonsubstantive review status by the Office of  
4 Health Policy, the application shall automatically be placed in the formal review process.

5 ~~(6)(5)~~ If an application is granted nonsubstantive review status by the Office of  
6 Health Policy, notice of the decision to grant nonsubstantive review status shall be given  
7 to the applicant and all known affected persons.

8 ~~(7)(6)~~(a) If an application is granted nonsubstantive review status by the Office of  
9 Health Policy, any affected person who believes that the application [~~applicant~~] is not  
10 entitled to nonsubstantive review status or who believes that the application should not  
11 be approved may request a hearing by filing a request for a hearing within ten (10) days  
12 of the notice of the decision to conduct nonsubstantive review.

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

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

17 (2. If [unless] the capital expenditure proposed involves the establishment or ex-  
18 pansion of a health facility or health service for which there is a component in the State  
19 Health Plan, the nonsubstantive review applications shall be comparatively re-  
20 viewed.

21 (d) Nonsubstantive review applications[but] may be consolidated for hearing purpos-  
22 es.

23 ~~(8)(7)~~ If an application for certificate of need is granted nonsubstantive review status

1 by the Office of Health Policy, there shall be a presumption that the facility or service is  
2 needed and a presumption that the facility or service is consistent with the State Health  
3 Plan~~[and an application granted nonsubstantive review status by the Office of Health~~  
4 ~~Policy shall not be reviewed for consistency with the State Health Plan].~~

5 ~~(9)~~**(8)** Unless a hearing is requested pursuant to 900 KAR 6:090, the Office of  
6 Health Policy shall approve each application for a certificate of need that has been  
7 granted nonsubstantive review status~~if:~~

8 ~~(a) The application does not propose a capital expenditure; or~~

9 ~~(b) The application does propose a capital expenditure, and the Office of Health Poli-~~  
10 ~~cy finds the facility or service with respect to which the capital expenditure proposed is~~  
11 ~~needed, unless the cabinet finds that the presumption of need provided for in subsec-~~  
12 ~~tion (7) of this section has been rebutted by clear and convincing evidence by an affect-~~  
13 ~~ed party].~~

14 ~~(10)~~**(9)** The cabinet shall disapprove an application for a certificate of need that has  
15 been granted nonsubstantive review if the cabinet finds that the:

16 (a) **Application [Applicant]** is not entitled to nonsubstantive review status; or

17 (b) Presumption of need or presumption that the facility or service is consistent with  
18 the State Health Plan provided for in subsection ~~(8)~~**(7)** of this section has been rebut-  
19 ted by clear and convincing evidence by an affected party.

20 ~~(11)~~**(10)** In determining whether an application is consistent with the State Health  
21 Plan, the cabinet, in making a final decision on an application, shall apply the latest cri-  
22 teria, inventories, and need analysis figures maintained by the cabinet and the version  
23 of the State Health Plan in effect at the time of the public notice of the application.

1        (12)[(11)] In determining whether an application is consistent with the State Health  
2        Plan following a reconsideration hearing pursuant to KRS 216B.090 or a reconsidera-  
3        tion hearing which is held by virtue of a court ruling, the cabinet shall apply the latest cri-  
4        teria, inventories, and need analysis figures maintained by the cabinet and the version  
5        of the State Health Plan in effect at the time of the reconsideration decision or decision  
6        following a court ruling.

7        (13)[(12)] A decision to approve or disapprove an application which has been grant-  
8        ed nonsubstantive review status shall be rendered within thirty-five (35) days of the date  
9        that nonsubstantive review status has been granted.

10       (14)[(13)][(11)] If a certificate of need is disapproved following nonsubstantive review,  
11       the applicant may:

12       (a) Request that the cabinet reconsider its decision pursuant to KRS 216B.090 and  
13       900 KAR 6:065;

14       (b) Request that the application be placed in the next cycle of the formal review pro-  
15       cess; or

16       (c) Seek judicial review pursuant to KRS 216B.115.

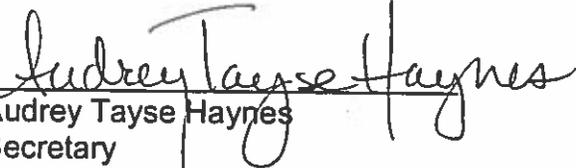
900 KAR 6:075

REVIEWED:

  
\_\_\_\_\_  
Emily Whelan Parento  
Executive Director  
Office of Health Policy

7/31/14  
Date

APPROVED:

  
\_\_\_\_\_  
Audrey Tayse Haynes  
Secretary  
Cabinet for Health and Family Services

8/7/14  
Date

## REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Regulation: 900 KAR 6:075  
Contact Person: Diona Mullins, Policy Advisor  
Office of Health Policy  
502-564-9592

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the guidelines for review of certificate of need applications which are granted nonsubstantive review.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statutes, specifically KRS 216B.040(2)(a)1 and KRS 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 establishing the requirements necessary for consideration of nonsubstantive review of certificate of need applications. w this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 216B.095 allows a certificate of need applicant to waive a formal review process and request nonsubstantive review if specific conditions are met. This regulation establishes the requirements necessary for consideration of nonsubstantive 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: The regulation is being revised to be consistent with KRS 216B.095(4) to require the Cabinet to consider consistency with the State Health Plan when reviewing a nonsubstantive certificate of need application. Also, the amendment will delete select proposal scenarios from the listing of proposals that may be granted nonsubstantive review status.

(b) The necessity of the amendment to this administrative regulation: The amendment is necessary to be consistent with KRS 216B.095(4) which requires the Cabinet to consider consistency with the State Health Plan when reviewing a nonsubstantive certificate of need application.

(c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation establishes requirements necessary for consideration for nonsubstantive review of certificate of need applications.

(d) How the amendment will assist in the effective administration of the statutes: This administrative regulation establishes requirements necessary for consideration for nonsubstantive review of certificate of need applications.

(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 nonsubstantive review certificate of need application. Annually, approximately 150 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: A certificate of need application requesting nonsubstantive review will be required to meet the requirements of this regulation, including the amendment to require a nonsubstantive review application to address consistency with the State Health Plan if the Plan addresses the proposed service.

(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 additional 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): The amendment is necessary to be consistent with KRS 216B.095(4) which requires the Cabinet to consider consistency with the State Health Plan when reviewing a nonsubstantive certificate of need application.

(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: 900 KAR 6:075

Contact Person: Diona Mullins, (502) 564-9592

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? Health care facilities owned by the state, county, or city which submit certificate of need applications requesting nonsubstantive review will be impacted by this regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.040(2)(a)1 and KRS 216B.095.

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.

(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 amendment will not generate additional revenue for state or local government during the first year.

(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 amendment will not generate additional revenue for state or local government during subsequent years.

(c) How much will it cost to administer this program for the first year? No additional costs are necessary to administer this program during the first year.

(d) How much will it cost to administer this program for subsequent years? No additional costs are necessary to administer this program for subsequent years.

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

STATEMENT OF CONSIDERATION RELATING TO  
900 KAR 6:075  
Office of Health Policy

Amended After Comments

(1) The public hearing on 900 KAR 6:075 scheduled for June 23, 2014 at 9:00 a.m. in the Health Services Building was cancelled; however written comments were received during the public comment period.

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

<u>NAME AND TITLE</u>	<u>AGENCY/ORGANIZATION/ENTITY/OTHER</u>
Michael T. Rust President	Kentucky Hospital Association Louisville, KY
Mary Jo Bean VP Planning and Business Analysis	Norton Healthcare, Inc. Louisville, KY
Joseph G. Koch CEO	Bourbon Community Hospital Paris, KY
Erika Skula President/CEO	Manchester Memorial Hospital Manchester, KY
Wade R. Stone Exec. Vice President	The Medical Center Bowling Green, KY
Tim Trottier CEO	Spring View Hospital Lebanon, KY
Robert Parker CEO	Meadowview Regional Medical Center Maysville, KY
Andy Sears Chief Strategy and Marketing Officer	Baptist Health Louisville, KY
Mary C. Akers	The Visitation Birth & Family Wellness Center

CNM, PhD, FACNM Elizabethtown, KY

Emily Whelan Parento Office of Health Policy  
Executive Director Frankfort, KY

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

<u>NAME AND TITLE</u>	<u>AGENCY/ORGANIZATION/ENTITY/OTHER</u>
Emily Whelan Parento Executive Director	Office of Health Policy

Diona Mullins Office of Health Policy  
Policy Advisor

#### SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Transfer or relocation of CON approved beds

(a) Comment: Michael T. Rust, Kentucky Hospital Association; Joseph G. Koch, Bourbon General Hospital; Erika Skula, Manchester Memorial Hospital; Wade R. Stone, The Medical Center; Robert Parker, Meadowview Regional Medical Center; Andy Sears, Baptist Health; and Mary Jo Bean, Norton Healthcare, Inc provided comments expressing concern that the proposed revision would allow an existing provider to demonstrate functional capacity, get approval to add beds and then not establish those beds, but rather transfer or relocate them to another provider within the area development district without that hospital having demonstrated need.

(b) Response: After consideration of the comments received during the public comment period, the Cabinet will revise the administrative regulation to delete the language regarding transfer or relocation of CON approved acute care beds.

(a) Comment: Mary Jo Bean, Norton Healthcare, Inc provided the following comment:

"...Section 2(3)(b)1.a is proposed to be modified by inserting the word "licensed " to read as follows: 'The hospital from which the licensed beds are relocated delicensses those beds.' We support this change but this would limit this section to only 'licensed ' beds, not certificate of need approved beds."

(b) Response: After consideration of the comments received during the public comment period, the Cabinet will revise the administrative regulation to delete the language regarding transfer or relocation of CON approved acute care beds.

(a) Comment: Tim Trottier, Spring View Hospital and Robert Parker, Meadowview

Regional Medical Center provided comments expressing concern that diluting current CON law would result in the growth of unnecessary services while adding financial burdens to already strained providers.

(b) Response: After consideration of the comments received during the public comment period, the Cabinet will revise the administrative regulation to delete the language regarding transfer or relocation of CON approved acute care beds.

(2) Subject: Nonsubstantive Review Process

(a) Comment: Mary C. Akers, The Visitation Birth & Family Wellness Center provided the following comments:

"While *affected persons* as defined in 216B.015 includes any health facilities which provide similar services, allowing all hospital corporations that claim that they provide similar services to a Freestanding Birth Center to testify against having a birth center is contrary to all available professional literature and research at this time.

1. Hospitals provide NO services similar to the home-like environment of a birth center.
2. Many hospitals in Kentucky "restrain the trade" of Certified Nurse Midwives (licensed professionals) by not allowing admitting privileges to their hospital.

If *affected persons* continue to be large corporations, then the ability of small-business health care services to meet the needs of Kentucky families will continue to flounder. Further Kentuckians will continue to pay big-business prices for their non-personalized health care.

Recommendation: Affected persons are limited to those operating the same business. Especially once granted a nonsubstantive review, the ability of corporations to limit access to choices in health care must be denied. (Testimony provided by other Freestanding Birth Centers would make sense.)

My only other comment concerns the impact analysis. ... (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 **additional** cost to entities to comply with this amendment."

Having placed several hundred thousand dollars into providing a freestanding birth center in which to apply my beliefs about women's rights in health care, the costs of these regulations are VERY substantial. Please do not imply that there are no costs associated with this regulation. Adding the word "additional" would help with clarity."

(b) Response: The Cabinet does not have authority to modify the statutory definition of "affected persons" via a regulation. Regarding the Cabinet's response to 4.b of the Regulatory Impact Analysis and Tiering Statement, the intent of the response was to indicate that there would be no additional cost to providers to comply with the proposed

amendment to this regulation. The Cabinet will revise the response to state that there will be no additional cost to providers to comply with the proposed amendment.

(3) Subject: Drafting and Formatting Changes

(a) Comment: Agency staff determined that a number of drafting and formatting changes were needed to comply with KRS Chapter 13A by correcting section numbering, changing plural to singular, and clarifying intent.

(b) Response: Drafting and formatting changes will be made as needed.

**SUMMARY OF STATEMENT OF CONSIDERATION  
AND  
ACTION TAKEN BY PROMULGATING ADMINISTRATIVE BODY**

The Office of Health Policy (OHP) has considered the comments received regarding 900 KAR 6:075 and is amending the administrative regulation as follows:

**Page 1**

**TITLE**

**Line 4**

Lower case "Need".

**Page 2**

**Section 2(1)(b)2.**

**Line 21**

After "change of location", insert "or relocation".

**Page 3**

**Section 2(3)(b)**

**Lines 10 and 11**

After "transfer", delete the following:

certificate of need approved acute care beds or.

**Page 3**

**Section 2(3)(b)**

**Lines 11 and 12**

After "Level III or", insert "Level".

**Page 3**

**Section 2(3)(b)2.a.**

**Line 19**

After "Level III, or", insert "Level".

**Page 4**  
**Section 2(3)(c)**  
**Line 1**

After "licensed", insert "acute care".

**Page 7**  
**Section 2(3)(e)**  
**Line 23**

After "and", delete "which".

**Page 8**  
**Section 2(3)(e)1.d.**  
**Line 9**

Change "Certificate of Need" to lower case.

**Page 9**  
**Section 2(3) – the second one**  
**Line 1**

Before "(3)", insert "(4)".

Delete "(3)".

Change "Certificate of Need" to lower case.

**Lines 1 and 2**

After "submitted under subsection", insert "(3)(f)".

Delete "(2)(f)".

**Line 2**

After "specified under subsection", insert "(3)(f)".

Delete "(2)(f)".

**Page 9**  
**Section 2(4) and (5)**  
**Lines 4 and 6**

Renumber these two subsections by inserting "(5)" and "(6)", respectively, and by deleting "(4)" and "(5)", respectively.

**Page 9**  
**Section 2(6)(a)**  
**Line 9**

Before "(6)(a)", insert "(7)".

Delete "(6)".

**Line 10**

After "that the", insert "application".

Delete "applicant".

**Page 9**  
**Section 2(6)(c)**

**Line 16**

After "(c)", insert

1. Except as provided in subparagraph 2. of this paragraph,

After "reviewed", insert "2. If"

Delete "unless".

**Line 18**

After "Plan", insert

, the nonsubstantive review applications shall be comparatively reviewed.

**Page 9**

**Section 2(7)**

**Line 21**

Before "(7)", insert "(8)".

Delete "(7)".

**Page 10**

**Section 2(8)**

**Line 3**

Before "(8)", insert "(9)".

Delete "(8)".

**Page 10**

**Section 2(9)**

**Line 12**

Before "(9)", insert "(10)".

Delete "(9)".

**Page 10**

**Section 2(9)(a)**

**Line 14**

After "(a)", insert "Application"

Delete "Applicant"

**Page 10**

**Section 2(9)(b)**

**Line 16**

After "subsection", insert "(8)".

Delete "(7)".

**Pages 10 and 11**

**Section 2(10), (11), and (12)**

**Lines 18, 22, and 5**

Re-number these three subsections by inserting "(11)", "(12)", and "(13)", respectively,

and by deleting "(10)", "(11)", and "(12)", respectively.

**Page 11**

**Section 2(13)**

**Line 8**

Before "(13)", insert "(14)".

Delete "(13)".