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Emily C Caudill
REGULATIONS COMPILER

Statement of Emergency
900 KAR 6:050E

WHEREAS, it is the policy of the Commonwealth of Kentucky to ensure that its citizens have access to safe, adequate and efficient medical care; and,

WHEREAS, certain areas of the Commonwealth have experienced rapid growth, outpacing the construction of sufficient health care facilities to serve these relatively heavily populated areas. Bullitt County is one such area which, as a consequence of rapid and accelerating population growth, is not adequately served by an in-county acute care hospital; and,

WHEREAS, Bullitt County is the largest county in the Commonwealth without an acute care hospital and is the only Kentucky county with a population exceeding sixty thousand which is not served by such a hospital;

WHEREAS, Bullitt County has previously been designated as a Health Professional Shortage Area for primary care and a Medically Underserved Area by the Health Resources and Services Administration; and

WHEREAS, the population of Bullitt County grew by more than twenty percent between the years 2000 and 2007, a trend expected to continue or accelerate for the foreseeable future; and,

WHEREAS, the United States Department of Defense Base Relocation and Closure Committee intends to substantially increase operations at the Fort Knox military installation by consolidating human resources functions from other bases at that facility. Increased operations at Fort Knox are expected to result in population growth of at least twenty thousand in the area immediately surrounding the base by the year 2011. The Commonwealth has a vital interest in ensuring sufficient infrastructure exists to serve increased operations at Fort Knox and this interest extends to the rapidly growing population of civilian employees associated with the base; and,

WHEREAS, these circumstances create an emergent need to protect the health and safety of residents of heavily populated and rapidly growing counties not currently served by an acute care hospital by providing access to necessary care; and,

WHEREAS, the Governor of the Commonwealth has directed the Secretary of the Cabinet for Health and Family Services to take appropriate and immediate steps to mitigate the emergency circumstances described herein;

NOW, THEREFORE, it is necessary to promulgate this emergency administrative regulation to provide for nonsubstantive review of applications to convert existing licensed outpatient healthcare centers to acute care hospitals of no more than sixty (60) beds in counties with a current population of least 60,000 residents where certain conditions are met; and,

This emergency regulation shall be replaced by an ordinary administrative regulation filed with the regulation complier. The ordinary regulation is identical to the emergency administrative regulation.

Steven L Beshear
Governor

Janie Miller, Secretary
Cabinet for Health and Family Services

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Health Policy

3 Division of Certificate of Need

4 (Emergency Amendment)

5 900 KAR 6:050. Certificate of need administrative regulation.

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

7 216B.990

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

9 216B.330

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

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

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

13 This administrative regulation establishes the requirements necessary for the orderly

14 administration of the Certificate of Need Program.

15 Section 1. Definitions. (1) "Administrative escalation" means an approval from the

16 cabinet to increase the capital expenditure authorized on a previously issued certificate

17 of need.

18 (2) "Cabinet" means the Cabinet for Health and Family Services.

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

20 published by the cabinet regarding certificate of need matters and is available on the

21 Certificate of Need Web site at http://chfs.ky.gov/ohp/con.

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

2 (5) "Emergency circumstances" means situations that pose an imminent threat to
3 the life, health, or safety of a citizen of the Commonwealth.

4 (6) "Formal review" means the review of applications for certificate of need which
5 are reviewed within ninety (90) days from the commencement of the review as provided
6 by KRS 216B.062(1) and which are reviewed for compliance with the review criteria set
7 forth at KRS 216B.040 and Section 6 of this administrative regulation.

8 (7) "Improvement" means change or addition to the premises of an existing
9 facility that enhances its ability to deliver the services that it is authorized to offer under
10 its existing license or an approved certificate of need.

11 (8) "Industrial ambulance service" means a Class I specialized provider licensed
12 by the cabinet to serve the employees, customers, or patrons of a business, race track,
13 recreational facility or similar organization excluding a health care facility.

14 (9) "Long-term care beds" means nursing home beds, intermediate care beds,
15 skilled nursing beds, nursing facility beds, and Alzheimer nursing home beds.

16 (10) "Nonsubstantive review" is defined by KRS 216B.015(17).

17 (11) "Office of Inspector General" means the office within the Cabinet for Health
18 and Family Services that is responsible for licensing and regulatory functions of health
19 facilities and services.

20 (12) "Office or clinic" means the physical location at which health care services
21 are provided.

22 (13) "Outpatient Health Care Center" means a licensed health care facility which
23 is certified by the Centers for Medicare and Medicaid Services under 42 C.F.R. 413.65

1 as a provider-based institution, with permanent facilities on a single campus that is
2 operated under the supervision of an organized medical staff and is comprised of
3 service components for the provision of primary care, ambulatory surgery, twenty-four
4 (24) hour emergency care, and radiological and magnetic resonance imaging.
5 (14) "Owner" means a person as defined in KRS 216B.015(21) who is applying
6 for the certificate of need and will become the licensee of the proposed health service or
7 facility.
8 (15) [~~(14)~~] "Practice" means the individual, entity, or group that proposes to
9 provide health care services and shall include the owners and operators of an office or
10 clinic.
11 (16) [~~(15)~~] "Primarily" means a simple majority or something that occurs at least
12 fifty-one (51) percent of the time.
13 (17) [~~(16)~~] "Proposed service area" means the geographic area the applicant
14 proposes to serve.
15 (18) [~~(17)~~] "Public information channels" means the Division of Communications
16 in the Cabinet for Health and Family Services.
17 (19) [~~(18)~~] "Public notice" means notice given through:
18 (a) Public information channels; or
19 (b) The cabinet's Certificate of Need Newsletter.
20 (20) [~~(19)~~] "Qualified academic medical center" means:
21 (a) An institution of higher education which operates an accredited medical
22 school within the Commonwealth of Kentucky;
23 (b) An institution, organization, or other entity which directly or indirectly owns or

is under common control or ownership with an accredited medical school operated within the Commonwealth of Kentucky; or

(c) An individual, organization, entity, or other person which is qualified under Section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) as a result of supporting or operating in support of an institution, organization, entity, or other person of a type or types referenced in paragraphs (a) or (b) of this subsection.

(21) [~~(20)~~] "Secretary" means the Secretary of the Cabinet for Health and Family Services.

(22) [~~(21)~~] "Show cause hearing" means a hearing during which it is determined whether a person or entity has violated provisions of KRS Chapter 216B.

Section 2. Letter of Intent. (1) The Certificate of Need Letter of Intent (Form #1) shall be filed with the cabinet by all applicants for a certificate of need. This shall:

(a) Include those applicants requesting nonsubstantive review under the provisions of Section 8 of this administrative regulation; and

(b) Not include those applicants requesting nonsubstantive review under the provisions of KRS 216B.095(3)(a) through (e).

(2) Upon receipt of a letter of intent, the cabinet shall provide the sender with written acknowledgment of receipt of the letter and shall publish notice of the receipt in the next published certificate of need newsletter.

(3) An application for a certificate of need shall not be processed until the letter of intent has been on file with the cabinet for thirty (30) days.

Section 3. Certificate of Need Application. (1) An applicant for a certificate of need shall file an application with the cabinet on the appropriate Certificate of Need

1 Application (forms 2A, 2B or 2C).

2 (2) When filing an application for certificate of need, the applicant shall file an
3 original and one (1) copy of the appropriate certificate of need application, together with
4 the prescribed fee set forth in 900 KAR 6:020 with the cabinet on or before the
5 deadlines established by Section 4 of this administrative regulation.

6 (3) Formal or nonsubstantive review of an application for a certificate of need
7 shall not begin until the application has been deemed complete by the cabinet.

8 (4) The cabinet shall not deem an application complete unless:

9 (a) The applicant has provided the cabinet with all of the information necessary to
10 complete the application; or

11 (b) The applicant has declined to submit the requested information and has
12 requested that its application be reviewed as submitted.

13 (5) Once an application has been declared complete, the applicant shall not
14 submit additional information regarding the application unless the information is
15 introduced at a public hearing.

16 (6) Once an application has been declared complete, it shall not be amended to:

17 (a) Increase the scope of the project;

18 (b) Increase the amount of the capital expenditure;

19 (c) Expand the size of the proposed service area;

20 (d) Change the location of the health facility or health service; or

21 (e) Change the owner, unless the application involves a licensed health facility
22 and a change of ownership with appropriate notice has occurred after the application
23 was submitted.

(7) An application that has been declared complete may be amended at a public hearing to:

(a) Decrease the scope of the project;

(b) Decrease the amount of the capital expenditure; or

(c) Decrease the proposed service area.

(8) Applicants who have had proposals for certificates of need approved under the nonsubstantive review provisions of Section 8 of this administrative regulation may request the cabinet to change the specific location to be designated on the certificate of need if:

(a) The facility has not yet been licensed;

(b) The location is within the county listed on the certificate of need application; and

(c) The applicant files a written request with the cabinet within 180 days of the date of issuance of the certificate of need. A request shall include the reason why the change is necessary.

(9) If an application is not filed with the cabinet within one (1) year of the date of the filing of a letter of intent, the letter of intent shall expire, and the applicant shall file a new letter of intent at least thirty (30) days prior to submitting an application.

(10) If an application is withdrawn, the applicant shall file a new letter of intent at least thirty (30) days prior to resubmitting an application.

(11) An application that is not declared complete within one (1) year from the date that it is filed shall expire and shall not be placed on public notice or reviewed for approval.

Section 4. Timetable for Submission of Applications. (1) The cabinet's timetable for giving public notice for applications deemed complete for formal review and for applications granted nonsubstantive review status pursuant to KRS 216B.095(3)(f) and Section 8 of this administrative regulation shall be as follows:

(a) Public notice for organ transplantation, magnetic resonance imaging, megavoltage radiation equipment, cardiac catheterization, open heart surgery, positron emission tomography equipment and new technological developments shall be given on the third Thursday of the following months:

1. January; and

2. July.

(b) Public notice for residential hospice facilities, hospice agencies, [~~and~~] home health agencies and applications granted nonsubstantive review status pursuant to Section 8(2)(g) of this administrative regulation shall be given on the third Thursday of the following months:

1. February; and

2. August.

(c) Public notice for ground ambulance providers, private duty nursing services, mobile services and rehabilitation agencies shall be given on the third Thursday of the following months:

1. March; and

2. September.

(d) Public notice for day health care programs, prescribed pediatric extended care facilities and personal care beds shall be given on the third Thursday of the

1 following months:

2 1. April; and

3 2. October.

4 (e) Public notice for long term care beds, acute care hospitals including all other
5 State Health Plan covered services to be provided within the proposed acute care
6 hospital, acute care hospital beds, psychiatric hospital beds, special care neonatal
7 beds, comprehensive physical rehabilitation beds, chemical dependency beds,
8 ambulatory care centers, freestanding ambulatory surgical centers, outpatient health
9 care centers, and birthing centers shall be given on the third Thursday of the following
10 months:

11 1. May; and

12 2. November.

13 (f) Public notice for intermediate care beds for mental retardation and
14 developmentally disabled facilities and psychiatric residential treatment facilities (PRTF)
15 shall be given on the third Thursday of the following months:

16 1. June; and

17 2. December.

18 (g) A proposal not included in paragraphs (a) through (f) of this subsection shall
19 be placed in the cycle that the cabinet determines to be most appropriate.

20 (2) In order to have an application deemed complete and placed on public notice,
21 an application shall be filed with the cabinet at least fifty (50) days prior to the date of
22 the desired public notice.

23 Section 5. Certificate of Need Review. (1) Prior to being reviewed for the

1 approval or denial of a certificate of need, all applications for certificate of need shall be
2 reviewed for completeness pursuant to Section 6 of this administrative regulation.
3 (2) Unless granted nonsubstantive review status, an application for a certificate
4 of need shall be reviewed for approval or denial of the certificate of need according to
5 the formal review criteria set forth at Section 7 of this administrative regulation.
6 (3) If granted nonsubstantive review status under Section 8 of this administrative
7 regulation, an application for a certificate of need shall be reviewed for approval or
8 denial of the certificate of need according to the nonsubstantive review criteria set forth
9 at Section 8 of this administrative regulation.
10 Section 6. Completeness Review. (1) Fifteen (15) days after the deadline for
11 filing an application in the next appropriate batching cycle, the cabinet shall conduct an
12 initial completeness review to determine whether the application is complete for
13 applications for both formal review and nonsubstantive review requested pursuant to
14 Section 8 of this administrative regulation. Applications for which nonsubstantive review
15 status has been requested pursuant to KRS 216B.095(3)(a) through (e) shall be
16 reviewed within fifteen (15) days of receipt.
17 (2) If the cabinet finds that the application for formal review is complete, the
18 cabinet shall:
19 (a) Notify the applicant in writing that the application has been deemed complete
20 and that review of the application for the approval or denial of a certificate of need shall
21 begin upon public notice being given; and
22 (b) Give public notice in the next appropriate certificate of need newsletter that
23 review of the application for approval or denial of a certificate of need has begun.

(3) If the cabinet finds that the application for nonsubstantive review is complete, the cabinet shall notify the applicant in writing that the application has been deemed complete and that review of the application for the approval or denial of a certificate of need shall begin upon public notice being given.

(4) A decision to grant or deny nonsubstantive review status shall be made within ten (10) days of the date the applicant is notified that the application has been deemed complete.

(5) The cabinet shall give public notice for applications granted nonsubstantive review status under Section 8 of this administrative regulation in the next appropriate certificate of need newsletter that status has been granted and that review of the application for approval or denial of a certificate of need has begun. Public notice for applications granted nonsubstantive review status according to KRS 216B.095(3)(a) through (e) shall be mailed to affected persons.

(6) A determination that an application is complete shall:

(a) Indicate that the applicant has minimally responded to the necessary items on the application;

(b) Not be determinative of the accuracy of, or weight to be given to, the information contained in the application; and

(c) Not imply that the application has met the review criteria for approval of a certificate of need.

(7) If the cabinet finds that the application is incomplete, the cabinet shall:

(a) Provide the applicant with written notice of the information necessary to complete the application; and

1 (b) Notify the applicant that the cabinet shall not deem the application complete
2 unless within fifteen (15) days of the date of the cabinet's request for additional
3 information:
4 1. The applicant submits the information necessary to complete the application
5 by the date specified in the request; or
6 2. The applicant requests in writing that the cabinet review its application as
7 submitted.
8 (8) If, upon the receipt of the additional information requested, the cabinet finds
9 that the application for formal review is complete, the cabinet shall:
10 (a) Notify the applicant in writing that:
11 1. The application for formal review has been deemed complete; and
12 2. Review of the application for the approval or denial of a certificate of need
13 shall begin upon public notice being given; and
14 (b) Give public notice in the next appropriate certificate of need newsletter that
15 review of the application for approval or denial of a certificate of need has begun.
16 (9) If, upon the receipt of the additional information requested, the cabinet finds
17 that an application for nonsubstantive review is complete, the cabinet shall:
18 (a) Notify the applicant in writing that:
19 1. The application has been deemed complete;
20 2. Review of the application for the approval or denial of a certificate of need
21 shall begin upon public notice being given; and
22 3. A decision to grant or deny nonsubstantive review status shall be made within
23 ten (10) days of the date that the application was deemed complete; and

(b) Give public notice in the next appropriate certificate of need newsletter for applications granted nonsubstantive review status under Section 8 of this administrative regulation, that status has been granted and that review of the application for approval or denial of a certificate of need has begun. Public notice for applications granted nonsubstantive review status according to KRS 216B.095(3)(a) through (e) shall be mailed to affected persons.

(10) If the application is incomplete, or if the information submitted is insufficient to complete the application, the cabinet shall:

(a) Request the information necessary to complete the application; and

(b) Inform the applicant that the application shall not be deemed complete and shall not be placed on public notice until:

1. The applicant submits the information necessary to complete the application; or

2. The applicant requests in writing that its application be reviewed as submitted.

(11) Once an application has been deemed complete, an applicant shall not submit additional information to be made part of the public record unless:

(a) The information is introduced at a hearing; or

(b) In the case of a deferred application, the additional information is submitted at least twenty (20) days prior to the date that the deferred application is placed on public notice.

(12) A determination that an application is complete shall:

(a) Indicate that the application is sufficiently complete to be reviewed for approval or disapproval;

1 (b) Not be determinative of the accuracy of, or weight to be given to, the
2 information contained in the application; and
3 (c) Not imply that the application has met the review criteria for approval.
4 Section 7. Considerations for Formal Review. In determining whether to approve
5 or deny a certificate of need, the cabinet's review of applications under formal review
6 shall be limited to the following considerations:
7 (1) Consistency with plans.
8 (a) To be approved, a proposal shall be consistent with the State Health Plan
9 established in 900 KAR 5:020.
10 (b) In determining whether an application is consistent with the State Health Plan,
11 the cabinet shall apply the latest inventories and need analysis figures maintained by
12 the cabinet and the version of the State Health Plan in effect at the time of the cabinet's
13 decision.
14 (c) An application seeking to reestablish a licensed healthcare, facility, or service,
15 which was provided at the healthcare facility and which was voluntarily discontinued by
16 the applicant, shall be considered consistent with the State Health Plan under the
17 following circumstances:
18 1. The termination or voluntary closure of the former healthcare service or facility:
19 a. Was not the result of an order or directive by the cabinet, governmental
20 agency, judicial body, or other regulatory authority;
21 b. Did not occur during or after an investigation by the cabinet, governmental
22 agency, or other regulatory authority;
23 c. Did occur while the facility was in substantial compliance with applicable

1 administrative regulations and was otherwise eligible for relicensure;

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

3 and

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

5 application to reestablish;

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

7 area as the former healthcare service;

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

9 former healthcare facility and at a single location; and

10 4. The application shall not seek to reestablish any type of bed utilized in the care

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

12 (2) Need. The cabinet shall determine:

13 (a) If the applicant has identified a need for the proposal in the geographic area

14 defined in the application; and

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

16 the geographic area defined in the application.

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

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

19 and personnel sufficient to provide the services proposed.

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

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

22 with other services, facilities, and elements of the health care system in the region and

23 state; and

1 (b) If the proposal is accompanied by assurance of effort to achieve
2 comprehensive care, proper utilization of services, and efficient functioning of the health
3 care system.
4 (5) Costs, economic feasibility, and resource availability. The cabinet shall
5 determine:
6 (a) If it is economically feasible for the applicant to implement and operate the
7 proposal; and
8 (b) If applicable, if the cost of alternative ways of meeting the need identified in
9 the geographic area defined in the application would be a more effective and
10 economical use of resources.
11 (6) Quality of services. The cabinet shall determine:
12 (a) If the applicant is prepared to and capable of undertaking and carrying out the
13 responsibilities involved in the proposal in a manner consistent with appropriate
14 standards and requirements established by the cabinet; and
15 (b) Whether the applicant has the ability to comply with applicable licensure
16 requirements. The fact that there is not an applicable licensure category shall not
17 constitute grounds for disapproving an application.
18 Section 8. Nonsubstantive Review. (1) The cabinet may grant nonsubstantive
19 review status to applications to change the location of a proposed health facility or to
20 relocate a licensed health facility only if:
21 (a)1. There is no substantial change in health services or bed capacity; and
22 2. The change of location or relocation is within the same county; or
23 (b) The change of location for a psychiatric residential treatment facility is within

1 the same district as defined in KRS 216B.455 and is to the same campus as a licensed
2 psychiatric residential treatment facility.
3 (2) In addition to the projects specified in KRS 216B.095(3)(a) through (e)
4 pursuant to KRS 216B.095(f), the Division of Certificate of Need may grant
5 nonsubstantive review status to an application for which a certificate of need is required
6 if:
7 (a) The proposal involves the establishment or expansion of a health facility or
8 health service for which there is not a component in the State Health Plan;
9 (b) The proposal involves an application from a hospital to reestablish the
10 number of acute care beds that it converted to nursing facility beds pursuant to KRS
11 216B.020(4), if the number of nursing facility beds so converted are delicensed;
12 (c) The proposal involves an application to relocate nursing facility beds from one
13 long term care facility to another long term care facility and the requirements
14 established in this paragraph are met.
15 1. If the relocation takes place within the same county, the following restrictions
16 shall apply:
17 a. The application shall be filed on or before October 1, 2008; and
18 b. The application shall be accompanied by a properly completed notice of intent
19 to acquire (form #9), and by evidence of the selling or transferring facility's binding
20 commitment to sell or transfer upon approval of the application.
21 2. If the relocation is to be from one county to another county, the following
22 restrictions shall apply:
23 a. The letter of intent shall be filed no later than September 1, 2008 and the

1 application shall be filed no later than October 1, 2008;

2 b. The application shall be accompanied by a properly completed notice of intent
3 to acquire (form #9), and by evidence of the selling or transferring facility's binding
4 commitment to sell or transfer upon approval of the application;

5 c. The selling or transferring facility shall be located in a county that had a
6 nursing facility bed occupancy rate of less than ninety-five (95) percent (rounded up to
7 the next whole number if ninety-four and five-tenths (94.5) percent or greater and
8 rounded down to the next whole number if less than ninety-four and five-tenths (94.5)
9 percent) according to the latest published version of the Kentucky Annual Long Term
10 Care Services Report;

11 d. The acquired beds shall only be relocated to a county whose nursing facility
12 bed occupancy was ninety-five (95) percent or greater (rounded up to the next whole
13 number if ninety-four and five-tenths (94.5) percent or greater and rounded down to the
14 next whole number if less than ninety-four and five-tenths (94.5) percent) according to
15 the latest published version of the Kentucky Annual Long Term Care Services Report;

16 e. A long term care facility shall not sell, transfer, or acquire more than fifteen
17 (15) of its licensed nursing facility beds; and

18 f. Notwithstanding the occupancy rates provided in clauses c and d in this
19 subparagraph, the cabinet may grant nonsubstantive review status to an application to
20 transfer licensed nursing facility beds between facilities that have common ownership or
21 management.

22 (d) .

23 1. The proposal involves an application to relocate or transfer licensed acute care

1 beds, not including neonatal Level III beds, from one (1) existing licensed hospital to
2 another existing licensed hospital within the same area development district; and
3 a. There is no increase in the total number of licensed acute care beds in that
4 area development district; and
5 b. The hospital from which the beds are relocated delicenses those beds; and
6 2. If neonatal Level II beds are relocated or transferred pursuant to this
7 subsection:
8 a. The receiving hospital shall have an existing licensed Level II or Level III
9 neonatal unit;
10 b. A minimum of four (4) beds shall be relocated; and
11 c. The relocation shall not leave the transferring hospital with less than four (4)
12 neonatal Level II beds unless the relocated beds represent all of its neonatal Level II
13 beds;
14 (e) The proposal involves an application by an existing licensed hospital to:
15 1. Convert licensed psychiatric or chemical dependency beds to acute care beds,
16 not including special purpose acute care beds such as neonatal Level II beds or
17 neonatal Level III beds;
18 2. Convert and implement the beds on-site at the hospital's existing licensed
19 facility; and
20 3. Delicense the same number of psychiatric or chemical dependency beds that
21 are converted; or
22 (f) The proposal involves an application by an existing licensed hospital providing
23 inpatient psychiatric treatment to:

1. Convert psychiatric beds licensed for use with geriatric patients to acute care beds, not including special purpose acute care beds such as neonatal Level II beds or neonatal Level III beds;

2. Implement the beds on-site at the existing licensed hospital; and

3. Delicense the same number of converted beds.

(g) The proposal involves an application to convert an existing licensed outpatient health care center to an acute care hospital with no more than sixty (60) acute care beds and the requirements established in this paragraph are met.

1. The letter of intent is filed no later than June 2, 2008 and the application is filed no later than July 2, 2008;

2. The proposed acute care hospital shall be located in a county with a current population of at least sixty thousand (60,000) residents;

3. The proposed acute care hospital shall be located in a county which does not contain a licensed acute care hospital or licensed critical access hospital; and

4. An existing licensed acute care hospital located in a county contiguous to the proposed location provides evidence of their binding commitment to transfer up to sixty (60) acute care beds to the proposed acute care hospital upon approval of the application.

(3) If an application is denied nonsubstantive review status by the Division of Certificate of Need, the application shall automatically be placed in the formal review process.

(4) If an application is granted nonsubstantive review status by the Division of Certificate of Need, notice of the decision to grant nonsubstantive review status shall be

given to the applicant and all known affected persons.

(5) If an application is granted nonsubstantive review status by the Division of Certificate of Need, any affected person who believes that the applicant is not entitled to nonsubstantive review status or who believes that the application should not be approved may request a hearing by filing a request for a hearing within ten (10) days of the notice of the decision to conduct nonsubstantive review. The provisions of Section 16 of this administrative regulation shall govern the conduct of all nonsubstantive review hearings. Nonsubstantive review applications shall not be comparatively reviewed but may be consolidated for hearing purposes.

(6) If an application for certificate of need is granted nonsubstantive review status by the Division of Certificate of Need, there shall be a presumption that the facility or service is needed and applications granted nonsubstantive review status by the Division of Certificate of Need shall not be reviewed for consistency with the State Health Plan.

(7) The cabinet shall approve applications for certificates of need that have been granted nonsubstantive review status by the Division of Certificate of Need if:

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

(b) The application does propose a capital expenditure and the cabinet finds that the facility or service with respect to which the capital expenditure is proposed to be made is required. The cabinet shall find that the facility or service with respect to which the capital expenditure is proposed to be made is required, unless the cabinet finds that the presumption of need provided for in subsection (6) of this section has been rebutted by clear and convincing evidence by an affected party.

(8) The cabinet shall disapprove applications for certificates of need that have

1 been granted nonsubstantive review if:

2 (a) The cabinet finds that the applicant is not entitled to nonsubstantive review

3 status; or

4 (b) The cabinet finds that the presumption of need provided for in subsection (6)

5 of this section has been rebutted by clear and convincing evidence by an affected party.

6 (9) The cabinet shall approve or disapprove an application which has been

7 granted nonsubstantive review status by the Division of Certificate of Need within thirty-

8 five (35) days of the date that public notice is given that nonsubstantive review status

9 has been granted.

10 (10) If a certificate of need is denied following nonsubstantive review, the

11 applicant may:

12 (a) Request that the cabinet reconsider its decision pursuant to KRS 216B.090

13 and Section 17 of this administrative regulation;

14 (b) Request that the application be placed in the next cycle of the formal review

15 process; or

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

17 Section 9. Notice of Decision. (1) The cabinet shall notify the applicant and any

18 party to the proceeding of the final action on a certificate of need application.

19 (2) Notification of approval shall be in writing and shall include:

20 (a) Verification that the review criteria for approval have been met;

21 (b) Specification of any terms or conditions limiting a certificate of need approval,

22 including limitations regarding certain services or patients. This specification shall be

23 listed on the facility or service's certificate of need and license;

1 (c) Notice of appeal rights; and

2 (d) The amount of capital expenditure authorized, if applicable.

3 (3) Written notification of disapproval shall include:

4 (a) The reason for the disapproval; and

5 (b) Notice of appeal rights.

6 (4) An application for certificate of need that is disapproved shall not be refiled for
7 a period of twelve (12) months from the original date of filing, absent a showing of a
8 significant change in circumstances.

9 Section 10. Deferral of an Application. (1) An applicant may defer review of an
10 application by notifying the cabinet in writing of its intent to defer review.

11 (a) If the application has been granted nonsubstantive review status, the notice to
12 defer shall be filed no later than five (5) days prior to the date that the decision is due on
13 the application unless a hearing has been scheduled. If a hearing has been scheduled,
14 the notice to defer shall be filed no later than six (6) days prior to the date of the
15 hearing.

16 (b) If the application is being reviewed under formal review, the notice to defer
17 shall be filed no later than ten (10) days prior to the date that the decision is due on the
18 application unless a hearing has been scheduled. If a hearing has been scheduled, the
19 notice to defer shall be filed eight (8) days prior to the date of the hearing.

20 (c) If a hearing has been scheduled, the applicant shall also notify all parties to
21 the proceedings in writing of the applicant's intent to defer the application.

22 (2) If deferral is requested, the application shall be deferred to the next regular
23 batching cycle and shall be placed on public notice pursuant to the timetables set forth

1 at Section 4 of this administrative regulation.

2 (3) If an application is deferred, an applicant may update its application by
3 providing additional information to the cabinet at least twenty (20) days prior to the date
4 that the deferred application is placed on public notice.

5 (4) In order for a hearing to be held on a deferred application, a hearing shall be
6 requested by either the applicant or an affected person within:

7 (a) Ten (10) days of the deferred application being placed on public notice if the
8 application has been granted nonsubstantive review status; or

9 (b) Fifteen (15) days of the deferred application being placed on public notice if
10 the application is being reviewed under the provision of formal review.

11 Section 11. Withdrawal of an Application. (1) An applicant may withdraw an
12 application for certificate of need prior to the entry of a decision to deny or approve the
13 application by notifying the cabinet in writing of the decision to withdraw the application.

14 (2) If a hearing has been scheduled or held on the application, the applicant shall
15 also notify all parties to the proceedings in writing of the applicant's decision to withdraw
16 the application.

17 Section 12. Emergency Circumstances. (1) If an emergency circumstance arises,
18 a person may proceed to alleviate the emergency without first obtaining a certificate of
19 need if:

20 (a)1. The person is not a hospital, and the person is licensed by the appropriate
21 Kentucky licensing authority to provide the service necessary to alleviate the
22 emergency; or

23 2. The person is a hospital, and the hospital has an already- issued certificate of

1 need to provide the service necessary to alleviate the emergency;

2 (b) The Division of Certificate of Need is notified in writing within five (5) days of

3 the commencement of the provision of the service required to alleviate the emergency;

4 and

5 (c) The Division of Certificate of Need acknowledges in writing that it recognizes

6 that an emergency does exist.

7 (2) The notice to the Division of Certificate of Need shall be accompanied by an

8 affidavit and other documentation from the person proposing to provide emergency

9 services, which shall contain the following information:

10 (a) A detailed description of the emergency which shall include at least the

11 following information:

12 1. A description of health care services that will be provided to the person or

13 persons to whom the services will be provided, including proof of eligibility for the

14 service;

15 2. A list of the providers in the county licensed to provide the services that will be

16 provided during the emergency; and

17 3. Proof that:

18 a. Other providers licensed in the service area to provide the service are aware

19 of the need for the service to be provided to the person and have refused or are unable

20 to provide the service; or

21 b. Circumstances exist under which the transfer of a patient to another provider

22 licensed in the service area to provide the service would present an unacceptable risk to

23 a patient's life, health, or safety;

1 (b) The steps taken to alleviate the emergency;

2 (c) The location or geographic area where the emergency service is being

3 provided; and

4 (d) The expected duration of the emergency.

5 (3) The Division of Certificate of Need may request additional information

6 necessary to make its determination from the person proposing to provide emergency

7 services before it acknowledges that an emergency does exist.

8 (4) If the provision of service to meet the emergency circumstance is required to

9 continue beyond thirty (30) days from the date that the notice is filed with the cabinet,

10 the person providing the emergency service shall file an application for a certificate of

11 need for the next appropriate public notice pursuant to Section 4 of this administrative

12 regulation.

13 (5) The person providing the emergency service may continue to alleviate the

14 emergency circumstances without a certificate of need until:

15 (a) The emergency ceases to exist; or

16 (b) The cabinet issues a final decision to approve or disapprove the application

17 for certificate of need.

18 Section 13. Transfers of Certificates of Need. (1) Certificates of need issued to

19 an existing facility for purposes other than replacement of the facility may be transferred

20 to the new owner of the facility if the change of ownership occurs prior to

21 implementation of the project for which the certificate of need was issued.

22 (2) The purchase of all capital stock or a controlling interest of capital stock of a

23 person who is the holder of an approved certificate of need for the establishment of a

1 new health facility shall not constitute the sale, trade or transfer of a certificate of need
2 to another person for purposes of KRS 216B.061(1)(h) and 216B.0615.
3 Section 14. Location of New and Replacement Facilities. A certificate of need
4 approved for the establishment of a new facility or the replacement of an existing facility
5 shall be valid only for the location stated on the certificate.
6 Section 15. Filings. (1) The filing of all documents required by this administrative
7 regulation shall be made by filing the documents with the Division of Certificate of Need,
8 HS1E-D, 1st Floor, Health Services Building, 275 East Main Street, Frankfort, Kentucky
9 40621 on or before 4:30 p.m. eastern time on the due date.
10 (2) Filings of documents, other than certificate of need applications and proposed
11 hearing reports, may be made by facsimile transmission if:
12 (a) The documents are received by the cabinet by facsimile transmission on or
13 before 4:30 p.m. eastern time on the date due; and
14 (b) An original document is filed with the cabinet on or before 4:30 p.m. eastern
15 time on the next business day after the due date.
16 (3) Failure to file documents in accordance with the schedule and manner
17 provided in subsections (1) and (2) of this section shall result in the materials being
18 returned to the sender and the cabinet shall not take additional action until the material
19 is properly resubmitted.
20 (4) The Division of Certificate of Need shall endorse by file stamp the date that
21 each filing is received and the endorsement shall constitute the filing of the document.
22 (5) In computing any period of time prescribed by this administrative regulation,
23 the date of notice, decision or order shall not be included.

1 (6) The last day of the period so computed shall be included, unless it is a
2 Saturday, a Sunday or legal state holiday, in which event the period shall run until 4:30
3 p.m. eastern time of the first business day following the Saturday, Sunday, or legal state
4 holiday.
5 Section 16. Hearings. (1) Hearings on certificate of need matters shall be held by
6 hearing officers from the Cabinet for Health and Family Services, Health Services
7 Administrative Hearings Branch. A hearing officer shall not act on any matter in which
8 the hearing officer has a conflict of interest as defined in KRS 45A.340. Any party may
9 file with the cabinet a petition for removal based upon a conflict of interest supported by
10 affidavit.
11 (2) The hearing officer shall preside over the conduct of each hearing and shall
12 regulate the course of the proceedings in a manner which shall promote the orderly and
13 prompt conduct of the hearing.
14 (3) Notice of the time, date, place and subject matter of each hearing shall be:
15 (a) Mailed to the applicant and all known affected persons providing the same or
16 similar service in the proposed service area not less than ten (10) days prior to the date
17 of the hearing;
18 (b) Published in the CON newsletter if applicable; and
19 (c) Provided to members of the general public through public information
20 channels.
21 (4) A public hearing shall be canceled if the person or persons who requested the
22 hearing withdraws the request by giving written notification to the Office of Certificate of
23 Need that the hearing is no longer required. The consent of affected persons who have

1 not requested a hearing shall not be required in order for a hearing to be canceled.

2 (5) Any dispositive motion made by a party to the proceedings shall be filed with

3 the hearing officer at least three (3) working days prior to the scheduled date of the

4 hearing.

5 (6) The hearing officer may convene a preliminary conference.

6 (a) The purposes of the conference shall be to:

7 1. Formulate and simplify the issues;

8 2. Identify additional information and evidence needed for the hearing; and

9 3. Dispose of pending motions.

10 (b) A written summary of the preliminary conference and the orders thereby

11 issued shall be made a part of the record.

12 (c) The hearing officer shall:

13 1. Tape record the conference; or

14 2. If requested by a party to the proceedings, arrange for a stenographer to be

15 present at the expense of the requesting party.

16 (d) During the preliminary conference, the hearing officer may:

17 1. Instruct the parties to:

18 a. Formulate and submit a list of genuine contested issues to be decided at the

19 hearing;

20 b. Raise and address issues that can be decided before the hearing; or

21 c. Formulate and submit stipulations to facts, laws, and other matters;

22 2. Prescribe the manner and extent of the participation of the parties or persons

23 who will participate;

1 3. Rule on any pending motions for discovery or subpoenas; or

2 4. Schedule dates for the submission of prefiled testimony, further preliminary

3 conferences, and submission of briefs and documents.

4 (7) At least five (5) days prior to the scheduled date of any nonsubstantive review

5 hearings and at least seven (7) days prior to the scheduled date of all other hearings, all

6 persons wishing to participate as a party to the proceedings shall file an original and

7 one (1) copy of the following for each affected application with the cabinet and serve

8 copies on all other known parties to the proceedings:

9 (a) Notice of Appearance, Form #3;

10 (b) Witness List, Form #4; and

11 (c) Exhibit List, Form #5 and attached exhibits.

12 (8)(a) If a hearing is requested on an application which has been deferred from a

13 previous cycle and for which a hearing had previously been scheduled, parties shall:

14 1. File a new Notice of Appearance, Form #3; and

15 2. Either:

16 a. Incorporate previously-filed witness lists (Form #4) and exhibit lists (Form #5);

17 or

18 b. File amended Forms #4 and #5.

19 (b) A new party to the hearings shall file original Forms #3, #4 and #5.

20 (c) Forms shall be filed in accordance with subsection (7) of this section.

21 (9) The hearing officer shall convene the hearing and shall state the purpose and

22 scope of the hearing or the issues upon which evidence shall be heard. All parties

23 appearing at the hearing shall enter an appearance by stating their names and

1 addresses.

2 (10) Each party shall have the opportunity to:

3 (a) Present its case;

4 (b) Make opening statements;

5 (c) Call and examine witnesses;

6 (d) Offer documentary evidence into the record;

7 (e) Make closing statements; and

8 (f) Cross-examine opposing witnesses on:

9 1. Matters covered in direct examination; and

10 2. At the discretion of the hearing officer, other matters relevant to the issues.

11 (11) A party that is a corporation shall be represented by an attorney licensed to

12 practice in the Commonwealth of Kentucky.

13 (12) The hearing officer may:

14 (a) Allow testimony or other evidence on issues not previously identified in the

15 preliminary order which may arise during the course of the hearing, including any

16 additional petitions for intervention which may be filed;

17 (b) Act to exclude irrelevant, immaterial or unduly repetitious evidence; and

18 (c) Question any party or witness.

19 (13) The hearing officer shall not be bound by the Kentucky Rules of Evidence.

20 Relevant hearsay evidence may be allowed at the discretion of the hearing officer.

21 (14) The hearing officer shall have discretion to designate the order of

22 presentation of evidence and the burden of proof as to persuasion.

23 (15) Witnesses shall be examined under oath or affirmation.

(16) Witnesses may, at the discretion of the hearing officer:

(a) Appear through deposition or in person; and

(b) Provide written testimony in accordance with the following:

1. The written testimony of a witness shall be in the form of questions and answers or a narrative statement;

2. The witness shall authenticate the document under oath; and

3. The witness shall be subject to cross-examination.

(17) The hearing officer may accept documentary evidence in the form of copies of excerpts if:

(a) The original is not readily available;

(b) Upon request, parties are given an opportunity to compare the copy with the original; and

(c) The documents to be considered for acceptance are listed on and attached to the party's Exhibit List (Form #5) and filed with the hearing officer and other parties at least:

1. Seven (7) working days before the hearing for formal review applications; or

2. Five (5) working days for nonsubstantive review applications.

(18) A document shall not be incorporated into the record by reference without the permission of the hearing officer. Any referenced document shall be precisely identified.

(19) The hearing officer may take official notice of facts which are not in dispute, or of generally-recognized technical or scientific facts within the agency's special knowledge.

1 (20) The hearing officer may permit a party to offer, or request a party to
2 produce, additional evidence or briefs of issues as part of the record within a designated
3 time after the conclusion of the hearing. During this period, the hearing record shall
4 remain open. The conclusion of the hearing shall occur when the additional information
5 is timely filed or at the end of the designated time period, whichever occurs first.
6 (21) In a hearing on an application for a certificate of need, the hearing officer
7 shall, upon the agreement of the applicant, continue a hearing beyond the review
8 deadlines established by KRS 216B.062(1) and 216B.095(1).
9 (22) The cabinet shall forward a copy of the hearing officer's final decision by
10 U.S. mail to each party to the proceedings. The original hearing decision shall be filed in
11 the administrative record maintained by the cabinet.
12 Section 17. Requests for Reconsideration. (1) In order to be considered,
13 requests for reconsideration shall be filed within fifteen (15) days of the date of the
14 notice of the cabinet's final decision relating to:
15 (a) Approval or disapproval of an application for a certificate of need;
16 (b) An advisory opinion entered after a public hearing;
17 (c) Revocation of a certificate of need; or
18 (d) A show cause hearing conducted in accordance with Section 18 of this
19 administrative regulation.
20 (2) A copy of the request for reconsideration shall be served by the requester on
21 all parties to the proceedings.
22 (3) A party to the proceedings shall have seven (7) days from the date of service
23 of the request for reconsideration to file a response to the request with the cabinet.

1 (4) If a hearing was held pursuant to subsection (1)(a), (b), or (c) of this section,
2 the hearing officer that presided over the hearing shall enter a decision to grant or deny
3 a request for reconsideration within thirty (30) days of the request being filed.
4 (5) If a hearing was held pursuant to subsection (1)(d) of this section, the
5 secretary shall enter a decision to grant or deny a request for reconsideration within
6 thirty (30) days of the request being filed.
7 (6) If reconsideration is granted a hearing shall be held by the cabinet in
8 accordance with the applicable provisions of Section 16 or 18 of this administrative
9 regulation within thirty (30) days of the date of the decision to grant reconsideration and
10 a final decision shall be entered by the cabinet no later than thirty (30) days following
11 the conclusion of the hearing.
12 (7) If reconsideration is granted on the grounds that a public hearing was not held
13 pursuant to KRS 216B.085, the applicant shall have the right to waive the
14 reconsideration hearing if the deficiencies in the application can be adequately
15 corrected by submission of written documentation to be made a part of the record
16 without a hearing.
17 Section 18. Show Cause Hearings. (1) The cabinet may conduct a show cause
18 hearing on its own initiative or at the request of an affected person, to include hearings
19 requested pursuant to Humana of Kentucky v. NKC Hospitals, Ky., 751 S.W.2d 369
20 (1988), in order to determine if a person has established or is operating a health facility
21 or health service in violation of the provisions of KRS Chapter 216B or this
22 administrative regulation or is subject to the penalties provided by KRS 216B.990 for
23 specific violations of the provisions of KRS Chapter 216B.

(2) Unless initiated by the cabinet, in order for a show cause hearing to be held, a request for a show cause hearing submitted by an affected person shall be accompanied and corroborated by credible, relevant, and substantial evidence, including an affidavit or other documentation which demonstrates that there is probable cause to believe that a person:

(a) Has established, or is operating, a health facility or health service in violation of the provisions of KRS Chapter 216B or this administrative regulation; or

(b) Is subject to the penalties provided by KRS 216B.990 for specific violations of the provisions of KRS Chapter 216B.

(3) Based upon the materials accompanying the request for a show cause hearing, the cabinet shall determine if sufficient cause exists to conduct a hearing.

(4) The cabinet shall conduct a show cause hearing based on its own investigation pursuant to an annual licensure inspection or otherwise which reveals a possible violation of the terms or conditions which are a part of a certificate of need approval and license.

(5) The cabinet shall also conduct a show cause hearing regarding terms and conditions which are a part of a certificate of need approval and license at the request of any person.

(6) The show cause hearing regarding the terms and conditions shall determine whether a person is operating a health facility or health service in violation of any terms or conditions which are a part of that certificate of need approval and license.

(7) Show cause hearings shall be conducted in accordance with the provisions of Section 16 of this administrative regulation.

1 (8) If a show cause hearing is held, the individual or entity alleged to be in
2 violation of KRS Chapter 216B shall have the burden of showing that the individual or
3 entity:
4 (a) Has not established or is not operating a health facility or health service in
5 violation of the provisions of KRS Chapter 216B or this administrative regulation; or
6 (b) Is not subject to the penalties provided by KRS 216B.990 for specific
7 violations of the provisions of KRS Chapter 216B.
8 (9)(a) Except as provided by paragraph (b) or (c) of this subsection, if it is alleged
9 that an office or clinic offering services or equipment covered by the State Health Plan
10 was established or is operating in violation of KRS 216B.020(2)(a), the hearing officer
11 shall base his or her findings of fact and proposed decision on whether the evidence
12 has established the following:
13 1. The practice claiming the exemption is 100 percent owned in any
14 organizational form recognized by the Commonwealth by the individual physician,
15 dentist, or other practitioner of the healing arts or group of physicians, dentists, or other
16 practitioners of the healing arts (hereinafter collectively referred to as "physician")
17 claiming the exemption;
18 2. The practice claiming the exemption primarily provides physician services
19 (e.g., evaluation and management codes) rather than services or equipment covered by
20 the State Health Plan;
21 3. Services or equipment covered by the State Health Plan which are offered or
22 provided at the office or clinic shall be primarily provided to patients whose medical
23 conditions are being treated or managed by the practice;

1 4. A physician or physicians licensed to practice and practicing in Kentucky within
2 the practice claiming the exemption are responsible for all decisions regarding the care
3 and treatment provided to patients;
4 5. Patients are treated on an outpatient basis and are not maintained overnight
5 on the premises of the office or clinic;
6 6. Services or equipment covered by the State Health Plan which are offered or
7 provided at the office or clinic are related to the professional services offered to patients
8 of the practice claiming the exemption;
9 7. Major medical equipment in excess of the limits set forth in 900 KAR 6:030 is
10 not being utilized without a Certificate of Need or other statutory or regulatory
11 exemption; and
12 8. Nothing in this section shall limit or prohibit the continued operation of an office
13 or clinic which was established and in operation prior to January 31, 2006, and
14 operating pursuant to and in accordance with the following:
15 a. Provisions of a Certificate of Need advisory opinion issued specifically with
16 respect to that office or clinic;
17 b. Provisions of an Attorney General opinion issued specifically with respect to
18 that office or clinic; or
19 c. An order issued with respect to that office or clinic by a court of competent
20 jurisdiction in the Commonwealth of Kentucky.
21 (b) A practice owned entirely by a radiologist or group of radiologists shall
22 demonstrate the following:
23 1. Compliance with paragraph (a)1, 4, 5, and 6 of this subsection;

1 2. The radiologists shall regularly perform physician services (e.g., test
2 interpretations) at the location where the diagnostic tests are performed, including
3 interpretations by or through teleradiology; and
4 3. The billing patterns of the practice indicate that the practice is not primarily a
5 testing facility and that it was organized to provide the professional services of
6 radiology.
7 (c) An office or clinic owned and operated by a Qualified Ac ademic Medical
8 Center shall demonstrate the following:
9 1. The physician or physicians providing care and treatment to the patients of the
10 office or clinic shall be licensed to practice in Kentucky and shall be employed by the
11 Qualified Academic Medical Center; and
12 2.a. The office was established and in operation prior to January 31, 2006;
13 b. The office does not provide any services or equipment covered by the State
14 Health Plan; or
15 c. At the time the office began providing care and treatment to patients, it was not
16 located in a county designated as a Metropolitan Statistical Area as defined by the U.S.
17 Office of Management and Budget, and there is a documented agreement of support or
18 collaboration between the Qualified Academic Medical Center and each existing
19 hospital in the county in which the office is located.
20 (10) Prior to convening a show cause hearing, the cabinet shall give the person
21 suspected or alleged to be in violation not less than twenty (20) days' notice of its intent
22 to conduct a hearing.
23 (11) The notice shall advise the person of:

1 (a) The allegations against him;

2 (b) Any facts determined to exist which support the existence of the allegation;

3 and

4 (c) The statute or administrative regulation alleged to have been violated.

5 (12) Notice of the time, date, place, and subject matter of each hearing shall be:

6 (a) Mailed to all known affected persons or entities not less than ten (10)

7 business days prior to the date of the hearing; and

8 (b) Published in the Certificate of Need newsletter if applicable.

9 (13) At least seven (7) business days prior to all hearings required or requested

10 pursuant to KRS Chapter 216B, with the exception of hearings involving applications for

11 or revocation of a certificate of need, all persons or entities wishing to participate as a

12 party to the proceedings shall file an original and one (1) copy of the following with the

13 cabinet and serve copies on all other known parties to the proceedings:

14 (a) Notice of Appearance, (Form #3);

15 (b) Witness List, (Form #4); and

16 (c) Exhibit List, (Form #5) and attached exhibits.

17 (14) Within thirty (30) days of the conclusion of the hearing, the hearing officer

18 shall tender findings of fact and a proposed decision to the secretary.

19 (15) Within thirty (30) days of the receipt of the findings of fact and proposed

20 decision from the hearing officer, the secretary shall issue a final decision on the matter.

21 (16) A copy of the final decision shall be mailed to the person or his legal

22 representative with the original hearing decision filed in the administrative record

23 maintained by the cabinet.

1 (17) If a violation is found to have occurred as a result of a show cause hearing
2 conducted pursuant to subsection (1) of this section, the cabinet shall take action as
3 provided by KRS Chapter 216B.
4 (18) If the person is found to have violated any of the terms or conditions of any
5 certificate of need approval and license as a result of a show cause hearing conducted
6 pursuant to subsection (4) of this section, the cabinet shall take the following action:
7 (a) If the person had not previously been found to be in violation of the terms and
8 conditions which were made a part of the person's certificate of need approval and
9 license, the person shall be given a reasonable period of time, not to exceed sixty (60)
10 days after issuance of the cabinet's decision, in which to demonstrate that the violation
11 has been corrected. At the conclusion of this period, the cabinet shall verify that the
12 facility or service is operating in compliance with the terms or conditions of the
13 certificate of need and license at issue.
14 (b) If the cabinet is unable to verify that the facility or service has corrected the
15 violation in accordance with paragraph (a) of this subsection, or if a person who had
16 previously been found to be in violation of the terms and conditions which were a part of
17 the person's certificate of need approval and license is found in a subsequent show
18 cause hearing conducted pursuant to this section to be in violation of the terms and
19 conditions again, the matter shall be referred to the Office of Inspector General for
20 appropriate action.
21 (19) The deadlines established with respect to hearings shall be modified, if
22 agreed to by all parties and the hearing officer.
23 Section 19. Administrative Escalations. (1) A person shall not obligate a capital

1 expenditure in excess of the amount authorized by an existing certificate of need unless
2 the person has received an administrative escalation or an additional certificate of need
3 from the cabinet.
4 (2) Requests for administrative escalations shall be submitted to the cabinet on
5 the Cost Escalation Form, Form #6.
6 (3) The cabinet shall authorize administrative escalations for funds which have
7 not been obligated and which do not exceed the following limits if there is not a
8 substantial change in the project:
9 (a) Twenty (20) percent of the capital expenditure authorized on the original
10 certificate of need or $100,000, whichever is greater, if the capital expenditure
11 authorized on the certificate of need is less than $500,000;
12 (b) Twenty (20) percent of the capital expenditure if the capital expenditure
13 authorized on the certificate of need is $500,0000 to $4,999,999;
14 (c) Ten (10) percent of the amount in excess of $5,000,000, plus $1,000,000, for
15 projects if the capital expenditure authorized on the certificate of need is $5,000,000 to
16 $24,999,999;
17 (d) Five (5) percent of the amount in excess of $25,000,000, plus $3,000,000, if
18 the capital expenditure authorized on the certificate of need is $25,000,000 to
19 $49,999,999; and
20 (e) Two (2) percent of the amount in excess of $50,000,000, plus $4,250,000, if
21 the capital expenditure authorized on the certificate of need is $50,000,000 or more.
22 (4) If an administrative escalation is authorized, the certificate of need holder
23 shall submit any additional certificate of need application fee required by the increased

1 capital expenditure.

2 (5) The escalation of a capital expenditure in excess of the limits set forth in

3 subsection (3) of this section shall:

4 (a) Constitute a substantial change in a project; and

5 (b) Require a certificate of need pursuant to KRS 216B.061(1)(e).

6 (6) The unauthorized obligation of a capital expenditure in excess of the amount

7 authorized on a certificate of need shall be:

8 (a) Presumed to be a willful violation of KRS Chapter 216B; and

9 (b) Subject to the penalties set forth at KRS 216B.990(2).Section 20. Timetables

10 and Standards for Implementation. (1) As a condition for the issuance of a certificate of

11 need, a holder of a certificate of need shall submit progress reports on the Certificate of

12 Need Six (6) Month Progress Report, Form #8, at the six (6) month intervals specified in

13 this section.

14 (2) A notice specifying the date each progress report is due shall be sent to every

15 holder of a certificate of need whose project is not fully implemented.

16 (3) The cabinet or its designee shall review a progress report and shall

17 determine:

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

19 (b) If the required elements have not been completed, if sufficient reasons for

20 failure to complete have been provided.

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

22 (a) The project has been approved for licensure or occupancy by the Office of

23 Inspector General; and

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

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

3 (a) The submission of additional reports as specified in subsections (16) through

4 (18) of this section; or

5 (b) Progress reports in addition to those required at six (6) month intervals under

6 the provisions of this section.

7 (6) Except for long-term care bed proposals, a certificate of need shall not be

8 revoked for failure to complete the items required during a six (6) month period, if the

9 holder of the certificate of need establishes that:

10 (a) The failure was due to emergency circumstances or other causes that could

11 not reasonably be anticipated and avoided by the holder; or

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

13 (7) If the cabinet determines that required elements have not been completed for

14 reasons other than those set forth in subsection (6) of this section, it shall notify the

15 holder of the certificate of need, in writing, that it has determined to revoke the

16 certificate of need.

17 (8) The revocation shall become final thirty (30) days from the date of notice of

18 revocation, unless the holder requests a hearing pursuant to KRS 216B.086.

19 (9) The first progress report for all projects other than long-term care beds shall

20 include:

21 (a) For projects for the addition of new services or expansion of existing services

22 that do not involve construction, renovation or the installation of equipment: plans for

23 implementation of the project;

1 (b) For projects for the purchase of equipment only: a copy of the purchase
2 order;
3 (c) For projects involving the acquisition of real property: evidence of an option to
4 acquire the site; or
5 (d) For construction or renovation projects: evidence that schematic plans have
6 been submitted to the Environmental and Public Protection Cabinet, Department of
7 Public Protection, Office of Housing, Buildings and Construction, and the Office of
8 Inspector General.
9 (10) For projects other than long-term care beds not deemed complete, a second
10 progress report shall include:
11 (a) For projects converting beds: documentation that all beds are licensed;
12 (b) For projects for addition of new services or expansion of existing services that
13 do not involve construction, renovation, or the installation of equipment: documentation
14 of approval for licensure and occupancy by the Office of Inspector General or the
15 Kentucky Board of Emergency Medical Services; or
16 (c) For construction or renovation projects: the schedule for project completion,
17 evidence of preliminary negotiation with a financial agency, and evidence of preliminary
18 negotiation with contractors.
19 (11) For projects other than long-term care beds not deemed complete, a third
20 progress report shall include:
21 (a) For construction or renovation projects:
22 1. Copy of deed or lease of land;
23 2. Documentation of final enforceable financing agreement, if applicable;

1 3. Documentation that final plans have been submitted to the Environmental and
2 Public Protection Cabinet, Department of Public Protection, Office of Housing, Buildings
3 and Construction, and the Office of Inspector General; and
4 4. Enforceable contract with a construction contractor; or
5 (b) For projects for purchase of equipment only: evidence of approval for
6 licensure and occupancy by the Office of Inspector General.
7 (12) For projects other than long-term care beds not deemed complete, a fourth
8 progress report shall include documentation of final plan approval by the Environmental
9 and Public Protection Cabinet, Department of Public Protection, Office of Housing,
10 Buildings and Construction, and the Office of Inspector General and evidence that
11 construction has begun.
12 (13) For projects other than long-term care beds not deemed complete, a fifth
13 progress report shall include documentation that construction or renovation is
14 progressing according to schedule.
15 (14) For projects other than long-term care beds not deemed complete, a sixth
16 progress report shall include documentation that the project has been approved for
17 licensure or occupancy by the Office of Inspector General and, if required, that the
18 appropriate license has been approved for the health care service or facility.
19 (15) For projects other than long-term care beds not deemed complete after the
20 sixth progress report, the certificate holder shall, upon request, provide the cabinet or its
21 designee with a written statement showing cause why the certificate should not be
22 revoked. The cabinet may defer revocation action upon a showing by the certificate
23 holder that the project shall be completed on a revised schedule. The cabinet or its

1 designee may require additional progress reports.

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

3 (a) The first progress report shall include:

4 1. A copy of the deed or lease of land for projects requiring acquisition of real

5 property; and

6 2. Evidence that final plans have been submitted to the Environmental and Public

7 Protection Cabinet, Department of Public Protection, Office of Housing, Buildings and

8 Construction, and the Office of Inspector General.

9 (b) For projects involving long-term care beds not deemed complete, a second

10 progress report shall include:

11 1. For conversion of bed projects, documentation that the beds in the project are

12 licensed; or

13 2. For construction projects:

14 a. Schedule for project completion with projected dates;

15 b. Documentation of final financing;

16 c. Documentation of final plan approval by the Environmental and Public

17 Protection Cabinet, Department of Public Protection, Office of Housing, Buildings and

18 Construction, and the Office of Inspector General; and

19 d. Enforceable construction contract.

20 (17) For projects involving long-term care beds not deemed complete, a third

21 progress report shall include documentation that construction or renovation is

22 progressing according to the schedule for project completion.

23 (18) For projects involving long-term care beds not deemed complete, a fourth

1 progress report shall include documentation that the project has been appropriately
2 licensed and approved for occupancy by the Office of Inspector General.
3 (19) The cabinet or its designee may grant no more than three (3) additional
4 extensions of six (6) months for good cause shown if the certificate holder of long-term
5 care beds has failed to comply with the relevant progress report requirements
6 established in this section.
7 (20) If the project involves a capital expenditure, a final cost breakdown shall be
8 included in the final progress report.
9 (21) If the Office of Inspector General discovers a violation of terms and
10 conditions listed on a certificate of need and license while it is conducting its annual
11 licensure inspection, it shall refer this violation for a show cause hearing in accordance
12 with Section 18 of this administrative regulation.
13 Section 21. Biennial Review. (1) Certificate of need holders may be subject to
14 biennial review to determine if they are in compliance with the terms as listed on their
15 certificate of need.
16 (2) Biennial review may be conducted within sixty (60) days of the second
17 anniversary of the final progress report and at twenty-four (24) month intervals
18 thereafter.
19 (3) The cabinet or its designee shall provide sixty (60) days' advance written
20 notification to the subject of any biennial review, including the following:
21 (a) When the biennial review shall be initiated;
22 (b) Request for information necessary for the review to which the cabinet does
23 not have ready access; and

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

2 (4) If the cabinet finds that any of the terms and conditions of a certificate of need
3 approval and license have been violated, the review of, and any sanctions for, this
4 violation shall be conducted in accordance with Section 18(4) of this administrative
5 regulation.

6 Section 22. Advisory Opinions. (1) The cabinet shall issue advisory opinions
7 regarding matters related to certificate of need on its own initiative or upon request from
8 any person.

9 (2) Requests for advisory opinions shall be filed with the cabinet and shall be
10 accompanied by the Request for Advisory Opinion, Form #7.

11 (3) In rendering an advisory opinion, a proposal shall be considered to constitute
12 an improvement within the definition of a nonclinically related expenditure exempt from
13 review if the proposed expenditure meets the definition of an improvement contained in
14 Section 1 of this administrative regulation.

15 (4) The cabinet may require verification of information and request additional
16 documentation at its discretion prior to issuing an advisory opinion.

17 (5) The cabinet shall issue a written advisory opinion within thirty (30) days of
18 receipt of a completed request for an advisory opinion or of receipt of additional
19 information.

20 (6) Public notice of the advisory opinion shall be published in the monthly
21 certificate of need newsletter.

22 (7) An affected person may request a public hearing regarding an advisory
23 opinion in writing within thirty (30) days of the public notice of the advisory opinion.

1 (8) The public hearing shall be held within forty-five (45) days of the date of the
2 filing of the request and shall be conducted in accordance with the provisions of Section
3 16 of this administrative regulation.
4 (9) The cabinet shall enter a final decision regarding the advisory opinion, within
5 forty-five (45) days of the completion of the public hearing.
6 (10) If a public hearing is not requested, the advisory opinion shall be the final
7 action of the cabinet.
8 Section 23. Notification of the Addition or Establishment of a Health Service.
9 (1) Health facilities that make additions to an existing health service for which there are
10 review criteria in the State Health Plan but for which a certificate of need is not required
11 to include ICF/MR respite beds, or add equipment for which there are review criteria in
12 the State Health Plan but for which a certificate of need is not required, shall notify the
13 cabinet that a service or equipment has been added within ten (10) days of addition.
14 (2) Notice of Addition of a Health Service or Equipment (Form #10) shall be used
15 in making the notification.
16 Section 24. Certification of Continuing Care Retirement Communities. (1) In order
17 to be certified as a continuing care retirement community, a certificate of compliance
18 shall be obtained from the Division of Certificate of Need.
19 (2) In order to obtain a certificate of compliance, a continuing care retirement
20 community shall complete and file Form #11 thereby certifying that:
21 (a) All residents shall have a written agreement with the continuing care
22 retirement community;
23 (b) The continuing care retirement community shall offer a continuum of

1 residential living options and support services to its residents age sixty (60) and older
2 and may offer these living options and services to persons below age sixty (60) on an
3 as needed basis;
4 (c) None of the health facilities or health services established by the continuing
5 care retirement community under this section shall apply for or become certified for
6 participation in the Medicaid Program, and that this restriction shall be disclosed in
7 writing to each of its residents;
8 (d) A claim for Medicaid reimbursement shall not be submitted for a person for a
9 health service established by the continuing care retirement community under this
10 section, and that this restriction shall be disclosed in writing to its residents;
11 (e) All residents in nursing home beds shall be assessed using the Health Care
12 Financing Administration approved long-term care resident assessment instrument. The
13 assessment shall be transmitted to the state data bank if the nursing home bed is
14 certified for Medicare participation;
15 (f) Admissions to continuing care retirement community nursing home beds shall
16 be exclusively limited to on-campus residents;
17 (g) A resident shall not be admitted to a continuing care retirement community
18 nursing home bed prior to ninety (90) days of residency in the continuing care
19 retirement community unless the resident experiences a significant change in health
20 status documented by a physician;
21 (h) A resident shall not be involuntarily transferred or discharged without thirty
22 (30) days prior written notice to the resident or the resident's guardian;
23 (i) The continuing care retirement community shall assist a resident upon move-

1 out notice to find appropriate living arrangements;

2 (j) The continuing care retirement community shall share information on

3 alternative living arrangements provided by the Division of Aging Services at the time a

4 move-out notice is given to a resident; and

5 (k) Written agreements executed by the resident and the continuing care

6 retirement community shall contain provisions for assisting any resident who has

7 received a move-out notice to find appropriate living arrangements.

8 (3) The Division of Certificate of Need shall issue a certificate of compliance

9 within thirty (30) days of receipt of a completed Form #11 if all conditions are met. If all

10 conditions are not met, the cabinet shall advise the applicant of any deficiencies. Upon

11 correction of the deficiencies, the cabinet shall issue the certificate of compliance within

12 thirty (30) days of correction.

13 (4) A continuing care retirement community's nursing home beds shall be

14 considered to have been established for purposes of KRS Chapter 216B upon the

15 issuance of an authority to occupy by the cabinet.

16 (5) If, after having obtained an initial certificate of compliance, a continuing care

17 retirement community wishes to establish additional nursing home beds, an additional

18 certificate of compliance shall be obtained from the cabinet.

19 (6) Upon request, the continuing care retirement community shall provide the

20 Division of Certificate of Need the payor source for each of its nursing home beds.

21 (7) Upon request, the continuing care retirement community shall provide the

22 Division of Certificate of Need the number of each type of bed or living unit within the

23 continuing care retirement community.

1 Section 25. Critical Access Hospitals. A certificate of need shall not be required
2 for a critical access hospital to reestablish the number of acute care beds that the
3 hospital operated prior to becoming a critical access hospital if the hospital decides to
4 discontinue operating as a critical access hospital.
5 Section 26. Swing Beds. (1) An acute care hospital or a critical access hospital
6 that has been designated as a swing bed hospital by the Office of Inspector General,
7 having met the requirements of 42 C.F.R. 482.66 or 485.645, shall not be required to
8 obtain a certificate of need to utilize its licensed acute or critical access hospital beds as
9 swing beds.
10 (2) For a designated swing bed hospital to add new acute or critical access
11 hospital beds which may be utilized as swing beds, the hospital's proposal shall be
12 consistent with the State Health Plan's review criteria for hospital acute care beds and
13 certificate of need approval shall be required.
14 Section 27. Pilot Angioplasty Program. The provisions of this section shall apply
15 to the pilot project for primary angioplasty in hospitals without on-site open heart surgery
16 ("pilot program") established in the 2004-2006 State Health Plan. (1) Hospitals
17 participating in the pilot program shall immediately (within twenty-four (24) hours of the
18 event or on the first business day following the event) report the following events to the
19 Division of Certificate of Need by fax at (502) 564-0302 or e-mail (joni.cracraft@ky.gov):
20 (a) Death within twenty-four (24) hours of the cardiac catheterization procedure
21 or hospital discharge. The report shall indicate if the death was a "cardiac death" or a
22 "noncardiac death".
23 1. A death shall be considered a "cardiac death" if the death was due to any of

1 the following:

2 a. Acute myocardial infarction;

3 b. Cardiac perforation/pericardial tamponade;

4 c. Arrhythmia or conduction abnormality;

5 d. Cerebrovascular accident related to, or suspected of being related to, the

6 cardiac catheterization procedure. An event shall be considered to be a

7 "cerebrovascular accident" if there were acute neurological deficits recorded by clinical

8 staff that persisted more than twenty-four (24) hours. The report shall note if these

9 events occurred:

10 (i) During the index catheterization; or

11 (ii) During the index hospitalization;

12 e. Death due to complication of the procedure including bleeding, vascular repair,

13 transfusion reaction, or bypass surgery; or

14 f. Any death in which a cardiac cause could not be excluded.

15 2. A death shall be considered a "noncardiac death" if the death was not due to

16 cardiac causes as described in subparagraph 1 of this paragraph;

17 (b) Emergency coronary artery bypass surgery (CABG) within twenty-four (24)

18 hours of the procedure or hospital discharge. An event shall be considered to be an

19 "emergency" if there is a sudden and often life-threatening mishap that arises in the

20 course of, and as a result of, the performance of a cardiac catheterization or angioplasty

21 procedure. It shall not include patients either transferred directly from the cardiac

22 catheterization procedure room or taken within twenty-four (24) hours to the operating

23 room for surgical correction of emergent/life threatening cardiac disease; or

1 (c) Shock within twenty-four (24) hours of the procedure or hospital discharge.

2 (2) Hospitals participating in the pilot program shall report to the Division of

3 Certificate of Need in writing within seven (7) days, any of the following events:

4 (a) Cerebrovascular accident, which are acute neurological deficits recorded by

5 clinical staff that persisted more than twenty-four (24) hours. The report shall note if

6 these events occurred within thirty (30) days after the catheterization but were not

7 clearly related to the procedure;

8 (b) Any intracranial bleed within thirty (30) days of the cardiac catheterization

9 procedure;

10 (c) Recurrent Q wave or Non-Q wave Myocardial infarction (MI) during the initial

11 hospitalization; or

12 (d) Vascular complications which occur within twenty-four (24) hours of the

13 cardiac catheterization procedure or hospital discharge. These shall include:

14 1. Hematoma more than four (4) centimeters;

15 2. Retroperitoneal Bleed;

16 3. False Aneurysm;

17 4. AV fistula;

18 5. Peripheral ischemic/nerve injury; or

19 6. Hemolysis and Hemolytic anemia.

20 (3) Hospitals participating in the pilot program shall:

21 (a) Establish a Joint Performance Improvement Committee (Joint PI Committee)

22 with its collaborating tertiary hospital or with practicing interventional cardiologists. The

23 membership of the Joint PI Committee shall, at a minimum, include each of the

following disciplines: physicians, nurses and administrators from both the pilot program hospital and the collaborating tertiary hospital;

(b) Convene the Joint PI Committee at least quarterly but sooner if twenty-five (25) patients have been treated to review the care provided to patients under the pilot program. This review process shall focus on patient outcomes and, at a minimum, include:

1. An assessment of the appropriateness of the selection of each patient entered into the pilot program;

2. All complications, any adverse outcomes, number of the patients requiring and reason for transfer to a tertiary facility;

3. The technical quality of the catheterization and angioplasty procedures performed; and

4. The "door to cath lab time" and "door to treatment time";

(c) Develop and implement a plan of correction for any problems identified;

(d) Develop a process for including the findings of the Joint PI Committee's review in the pilot program hospital's performance improvement program;

(e) Require the Joint PI Committee to make a quarterly recommendation to the Division of Certificate of Need whether the pilot program should continue; and

(f) Require all staff (including, at a minimum, interventional cardiologists, nurses and technicians) as well as representatives of the Emergency Department and Critical Care Unit staffs participating in the pilot program PI process, to attend a minimum of one (1) meeting of the Joint PI Committee per year.

(4) Performance of primary angioplasty (as measured by quality indicators

1 including mortality, morbidity, and adverse reactions) at a pilot hospital shall be
2 comparable, on a risk adjusted basis, to the performance of existing angioplasty
3 programs in Kentucky and with similar organizations nationally, according to the
4 National Cardiovascular Data Registry.
5 (a) If the outcomes are worse at a pilot hospital, that facility shall file and
6 implement a plan of correction with the Division of Certificate of Need.
7 (b) If the facility's results do not improve after one (1) quarter of implementing a
8 plan of correction, the Division of Certificate of Need may terminate the facility's
9 participation in the pilot program.
10 (5) Hospitals participating in the pilot program shall:
11 (a) Continue to make available the cardiac catheterization service twenty-four
12 (24) hours per day and seven (7) days per week;
13 (b) Develop policies and procedures that will assure that all interventional
14 cardiologists performing primary angioplasty procedures at the pilot program hospital
15 will maintain an appropriate level of proficiency as a member of the team performing
16 primary angioplasty at the pilot program hospital. The policies and procedures shall
17 detail the process the physician director will utilize to assure the establishment,
18 maintenance and monitoring of the proficiency of each interventional cardiologist;
19 (c) Maintain a collaborative association and a current, valid collaboration
20 agreement with a tertiary hospital including Joint PI and staff education programs; and
21 (d) Perform a minimum of thirty-six (36) primary angioplasty procedures per year.
22 At least thirty (30) of these angioplasty procedures shall be primary angioplasty
23 procedures, excluding patients that have "rescue angioplasty" procedures performed.

(6) The time frame for measuring compliance with procedural utilization requirements shall begin six (6) months after the date of the physician director's notification to the Division of Certificate of Need that all training requirements have been fulfilled. Within twelve (12) months from the "start date," the hospital shall have performed eighteen (18) primary angioplasty procedures or shall receive a warning that approval to participate in the pilot program may be withdrawn.

(7) Within the following six (6) months, a total of eighteen (18) months from the date of the department's letter of approval, the hospital shall have performed at least another eighteen (18) procedures (a total of thirty-six (36) primary angioplasty procedures) or the program may be discontinued at that site.

(8) Each site shall continue to perform eighteen (18) primary angioplasty procedures per six (6) months and a total of thirty-six (36) primary angioplasty procedures per year, or the program may be discontinued at that site.

(9) All physicians performing percutaneous coronary intervention (PCI) at a pilot program hospital shall:

(a) Continue to perform no fewer than 100 cardiac catheterization procedures per year (total diagnostic and therapeutic). At least seventy-five (75) procedures shall be angioplasty procedures unless the procedures are being performed at a facility at which more than 400 angioplasty procedures are being performed per year; and

(b) Maintain credentials at a hospital at which that operator performs elective angioplasty procedures.

(10)(a) All staff that are hired after the completion of the initial training at the pilot program hospital shall complete a training program that mirrors the initial training

1 program. The relevant collaborating tertiary and pilot program hospitals shall develop
2 this training program.
3 (b) Training of all staff including, at a minimum, all interventional cardiologists,
4 nurses and technicians, shall be performed on the intra-aortic balloon pump annually.
5 (c) All staff involved in providing PCI, including the interventional cardiologists,
6 nurses and technicians, shall have a current Advanced Cardiac Life Support (ACLS)
7 certification.
8 (d) Inservice programs shall, at a minimum, be based upon need identified
9 through staff evaluations and quality assurance process.
10 (11) The Division of Certificate of Need may discontinue the pilot program at a
11 participant hospital at any time after reviewing the following:
12 (a) Quarterly reports made by the American College of Cardiology - National
13 Cardiovascular Data Registry (ACC-NCDR);
14 (b) Records obtained through an audit;
15 (c) Peer review reports; or
16 (d) Reports on serious adverse events.
17 (12) Upon notification to the hospital by the Division of Certificate of Need, the
18 hospital shall terminate the pilot program and cease to perform primary angioplasty
19 procedures.
20 (13) In order to assist the Division of Certificate of Need in evaluating the pilot
21 program, the performance of pilot hospitals, and the formulation of recommendations for
22 continuing or modifying the project, the Division of Certificate of Need may collaborate
23 with university based researchers to:

1 (a) Evaluate and compare performance data of pilot hospitals with existing
2 Kentucky angioplasty programs; and
3 (b) Conduct an evaluation of the short-and long-term outcomes of patients
4 undergoing primary angioplasty at pilot hospitals with those patients transferred to
5 hospitals with open heart surgical backup.
6 (14) The Division of Certificate of Need shall review reports from the
7 collaborating university based researchers as well as quarterly reports made by the
8 ACC-NCDR, records obtained through audit, peer review reports and reports of serious
9 adverse events in order to develop recommendations for continuing, discontinuing, or
10 modifying the pilot program. If the project is continued, these recommendations shall
11 include establishing criteria for determining need to expand angioplasty services to
12 additional hospitals without on-site surgical backup, qualifications of those hospitals,
13 and ongoing requirements for a hospital's continued provision of this service.
14 (15) The Division of Certificate of Need may convene all hospitals participating in
15 the pilot program on a regular basis for the purpose of discussing and assessing the
16 status of the implementation of the pilot program.
17 (16) Three (3) years from the start date of the pilot program, the Division of
18 Certificate of Need shall publish a report on the program. The report shall;
19 (a) Indicate whether it is in the best interest of the Commonwealth to eliminate
20 the requirement for open heart surgery for hospitals to perform therapeutic cardiac
21 catheterization; and
22 (b) Include the requirements for patient selection, procedural volume, and staffing
23 that hospitals shall continue to meet to provide this service if the Division of Certificate

1 of Need finds that this service may be provided by hospitals in the absence of on-site
2 open heart surgery.
3 Section 28. Magnetic Resonance Imaging Report. (1) A Magnetic Resonance
4 Imaging unit (MRI) utilized in the Commonwealth shall be disclosed to the Cabinet for
5 Health and Family Services, Office of Health Policy for publication in the Kentucky
6 Annual Magnetic Resonance Imaging Services Report.
7 (2) The following information shall be submitted about every MRI unit utilized in
8 the Commonwealth:
9 (a) Name, address, and telephone number of the facility at which each unit is
10 located or to be utilized;
11 (b) Identification of designated contact person or authorized agent of each
12 facility;
13 (c) Make, model, and serial number of each unit;
14 (d) Date the unit became operational at each site;
15 (e) Whether the unit is free-standing or mobile (if the unit is mobile, then also
16 identify the number of days the unit is operational); and
17 (f) Number of scans performed during the previous calendar year.
18 (3) The owner or operator of any MRI unit that becomes operational at an
19 unlicensed facility after August 1, 2006, shall have thirty (30) days after use of the unit is
20 commenced to provide the information required by subsection (2) of this section.
21 (4) The information shall be provided by completion of "The Annual Survey of
22 Magnetic Resonance Imaging Services". A copy of that survey may be obtained,
23 completed, and transmitted electronically by accessing the Office of Health Policy's

1 Web site at http://chfs.ky.gov/ohp/con. A copy can also be obtained at the Cabinet for
2 Health and Family Services, Office of Health Policy, 275 East Main Street 3CB,
3 Frankfort, Kentucky 40621.
4 (5) Within thirty (30) days of an event, the designated contact person or
5 authorized agent shall notify the Office of Health Policy about any change in the facility's
6 address or the addition of another MRI unit as well as the discontinuation of any units.
7 Section 29. Incorporation by Reference. (1) The following material is incorporated
8 by reference:
9 (a) "Letter of Intent", (Form #1) (10/12/99);
10 (b) "Certificate of Need Application", (Form #2A) (3/6/03);
11 (c) "Certificate of Need Application for Ground Ambulance Providers", (Form
12 #2B) (6/15/99);
13 (d) "Certificate of Need Application for Change of Location, Replacement, or Cost
14 Escalation", (Form #2C) (3/6/03);
15 (e) "Notice of Appearance", (Form #3) (3/6/03);
16 (f) "Witness List", (Form #4) (3/6/03);
17 (g) "Exhibit List", (Form #5) (3/6/03);
18 (h) "Cost Escalation Form", (Form #6) (6/15/99);
19 (i) "Request for Advisory Opinion", (Form #7) (3/6/03);
20 (j) "Six (6) Month Progress Report", (Form #8) (6/15/99);
21 (k) "Acquisition of a Health Facility, Notice of Intent to Acquire (Form #9)",
22 (3/6/03);
23 (l) "Notice of Addition of a Health Service or Equipment", (Form #10) (6/15/99);

1 (m) "Application for Certificate of Compliance for a Continuing Care Retirement
2 Community (CCRC)", (Form #11) (11/29/00); and
3 (n) "Annual Survey of Magnetic Resonance Imaging Services", (5/12/06).
4 (2) This material may be inspected, copied, or obtained, subject to applicable
5 copyright law, at the Cabinet for Health and Family Services, Division of Certificate of
6 Need, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m.
7 to 4:30 p.m.

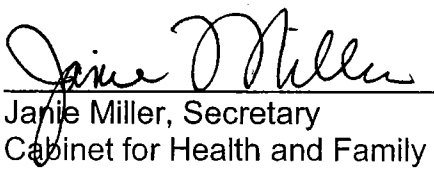
900 KAR 6:050E

Reviewed:

4-29-08

Shane O'Donley, Director — Date
Division of Certificate of Need

APPROVED:



4-29-08

Janie Miller, Secretary — Date
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation #: 900 KAR 6:050E
Contact person: Shane O'Donley 502-564-9589 ext. 3274

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation sets forth the process by which the Certificate of Need program shall be implemented.

(b) The necessity of this administrative regulation: Pursuant to KRS 216B.040, the cabinet may promulgate administrative regulations to establish the certificate of need review procedures.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms with KRS 216B.040 which requires the cabinet implement a Certificate of Need program.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: It will update the administrative regulation to protect the health and safety of residents of heavily populated and rapidly growing counties currently not served by an acute care hospital by providing access to necessary care.

(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 amendment will provide for the following changes:

1. Define the term "outpatient health care center";
2. Update the application batching cycles; and
3. Add a non-substantive review category for the conversion of an existing outpatient health care center to an acute care hospital.

(b) The necessity of the amendment to this administrative regulation: To improve the efficiency and effectiveness of the current certificate of need process.

(c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation conforms with KRS 216B.040 which requires the cabinet promulgate administrative regulations to

establish the certificate of need review procedures.

(d) How the amendment will assist in the effective administration of the statutes: It will improve the efficiency and effectiveness of the current certificate of need process and improve access to affordable quality healthcare for the citizens of the Commonwealth.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: All persons applying for a certificate of need to convert a licensed outpatient health care center to an acute care hospital.

(4) Provide an assessment 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: No actions are necessary unless they choose to apply to convert a licensed outpatient health care center to an acute care hospital. In that case, they would be required to submit a certificate of need letter of intent, application and application fee.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): This amendment will not modify the certificate of need application fee and will therefore have no effect on the cost to persons applying for a certificate of need to convert a licensed outpatient health care center to an acute care hospital.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Persons applying for a certificate of need will encounter a simplified hearing process as well as an opportunity to qualify for non-substantive review.

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

(a) Initially: None

(b) On a continuing basis: None

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Certificate of Need application fees.

(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: The modifications to this administrative regulation will not necessitate additional fees or funding.

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

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used)

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

Regulation Number: 900 KAR6:050E
Contact Person: Shane O'Donley, Division Director

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? Any publicly owned health care facility that receives patients from, or is located in, a county with more than 60,000 residents and no existing licensed acute care hospital.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030, 194A.050, 216B.040(2)(a)1, and 216B.330.

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? If an entity chooses to apply to convert a licensed outpatient health care center to an acute care hospital, they would be required to submit a certificate of need application fee based on the expected capital expenditure of the project. The minimum certificate of need application fee is $1,000 while the maximum application fee is $25,000.

   (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? If an entity chooses to apply to convert a licensed outpatient health care center to an acute care hospital, they would be required to submit a certificate of need application fee based on the expected capital expenditure of the project. The minimum certificate of need application fee is $1,000 while the maximum application fee

is $25,000.

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

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

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

Revenues (+/-): $25,000 per application
Expenditures (+/-): None
Other Explanation: None