



1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (New administrative regulation)

4 900 KAR 6:120. Certificate of Need pilot projects.

5 RELATES TO: KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1, 216B.330

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

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

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

10 This administrative regulation establishes the provisions for the pilot project for primary
11 angioplasty in hospitals without on-site open heart surgery ("pilot program") established
12 in the 2004-2006 State Health Plan for the certificate of need program necessary for the
13 orderly administration of the Certificate of Need Program.

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

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

16 (3) "Improvement" means change or addition to the premises of an existing facility
17 that enhances its ability to deliver the services that it is authorized to offer under its
18 existing license or an approved certificate of need.

19 Section 2. Pilot Angioplasty Program. The provisions of this section shall apply to
20 the pilot project for primary angioplasty in hospitals without on-site open heart surgery
21 ("pilot program") initially established in the 2004-2006 State Health Plan. (1) Hospitals

1 participating in the pilot program shall, within twenty-four (24) hours of the event or on
2 the first business day following the event, report the following events to the Office of
3 Health Policy by fax at (502) 564-0302 or by emailing the executive director:

4 (a) A death that occurs within twenty-four (24) hours of the cardiac catheterization
5 procedure or hospital discharge. The report shall indicate if the death was a cardiac
6 death or a noncardiac death.

7 1. A death shall be considered a cardiac death if the death was due to any of the
8 following:

9 a. Acute myocardial infarction;

10 b. Cardiac perforation/pericardial tamponade;

11 c. Arrhythmia or conduction abnormality;

12 d. Cerebrovascular accident related to, or suspected of being related to, the cardiac
13 catheterization procedure. An event shall be considered to be a cerebrovascular
14 accident if there were acute neurological deficits recorded by clinical staff that persisted
15 more than twenty-four (24) hours. The report shall note if these events occurred:

16 (i) During the index catheterization; or

17 (ii) During the index hospitalization;

18 e. Death due to complication of the procedure including bleeding, vascular repair,
19 transfusion reaction, or bypass surgery; or

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

21 2. A death shall be considered a noncardiac death if the death was not due to
22 cardiac causes as described in subparagraph 1 of this paragraph;

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

1 hours of the procedure or hospital discharge. An event shall be considered to be an
2 emergency if there is a sudden and often life-threatening mishap that arises in the
3 course of, and as a result of, the performance of a cardiac catheterization or angioplasty
4 procedure. It shall not include patients either transferred directly from the cardiac
5 catheterization procedure room or taken within twenty-four (24) hours to the operating
6 room for surgical correction of emergent/life threatening cardiac disease; or

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

8 (2) Hospitals participating in the pilot program shall report in writing within seven (7)
9 days to the Office of Health Policy any of the following events:

10 (a) Cerebrovascular accident, which are acute neurological deficits recorded by
11 clinical staff that persisted more than twenty-four (24) hours. The report shall note if
12 these events occurred within thirty (30) days after the catheterization but were not
13 clearly related to the procedure;

14 (b) Any intracranial bleed within thirty (30) days of the cardiac catheterization
15 procedure;

16 (c) Recurrent Q wave or Non-Q wave myocardial infarction (MI) during the initial
17 hospitalization; or

18 (d) Vascular complications which occur within twenty-four (24) hours of the cardiac
19 catheterization procedure or hospital discharge. These shall include:

20 1. Hematoma of more than four (4) centimeters;

21 2. Retroperitoneal Bleed;

22 3. False Aneurysm;

23 4. AV fistula;

1 5. Peripheral ischemic/nerve injury; or

2 6. Hemolysis and Hemolytic anemia.

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

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

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

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

7 following disciplines from both the pilot program hospital and the collaborating tertiary

8 hospital:

9 1. Physicians;

10 2. Nurses; and

11 3. Administrators.

12 (b) Convene the Joint PI Committee at least quarterly but sooner if twenty-five (25)

13 patients have been treated to review the care provided to patients under the pilot

14 program. This review process shall focus on patient outcomes and, at a minimum,

15 include:

16 1. An assessment of the appropriateness of the selection of each patient entered

17 into the pilot program;

18 2. All complications, any adverse outcomes, number of the patients requiring, and

19 reason for transfer to a tertiary facility;

20 3. The technical quality of the catheterization and angioplasty procedures

21 performed; and

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

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

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

3 (e) Require the Joint PI Committee to make a quarterly recommendation to the
4 Office of Health Policy whether the pilot program should continue; and

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

9 (4) Performance of primary angioplasty at a hospital as measured by quality
10 indicators including mortality, morbidity, and adverse reactions shall be comparable, on
11 a risk adjusted basis, to the performance of existing angioplasty programs in Kentucky
12 and with similar organizations nationally, according to the National Cardiovascular Data
13 Registry.

14 (a) If the outcomes are worse at a pilot hospital, that facility shall file and implement
15 a plan of correction with the Office of Health Policy.

16 (b) If the facility's results do not improve after one (1) quarter of implementing a plan
17 of correction, the Office of Health Policy may terminate the facility's participation in the
18 pilot program.

19 (5) Hospitals participating in the pilot program shall:

20 (a) Continue to make available the cardiac catheterization service twenty-four (24)
21 hours per day and seven (7) days per week;

22 (b) Develop policies and procedures that will assure that all interventional
23 cardiologists performing primary angioplasty procedures at the pilot program hospital

1 will maintain an appropriate level of proficiency as a member of the team performing
2 primary angioplasty at the pilot program hospital. The policies and procedures shall
3 detail the process the physician director will utilize to assure the establishment,
4 maintenance, and monitoring of the proficiency of each interventional cardiologist;

5 (c) Maintain a collaborative association and a current, valid collaboration agreement
6 with a tertiary hospital including Joint PI and staff education programs; and

7 (d) Perform a minimum of thirty-six (36) primary angioplasty procedures per year. At
8 least thirty (30) of these angioplasty procedures shall be primary angioplasty
9 procedures, excluding patients that have "rescue angioplasty" procedures performed.

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

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

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

23 (9) All physicians performing percutaneous coronary intervention (PCI) at a pilot

1 program hospital shall:

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

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

8 (10)(a) All staff that are hired after the completion of the initial training at the pilot
9 program hospital shall complete a training program that mirrors the initial training
10 program. The relevant collaborating tertiary and pilot program hospitals shall develop
11 this training program.

12 (b) Training of all staff including all interventional cardiologists, nurses, and
13 technicians, shall be performed on the intra-aortic balloon pump annually.

14 (c) All staff involved in providing PCI, including the interventional cardiologists,
15 nurses and technicians, shall have a current Advanced Cardiac Life Support (ACLS)
16 certification.

17 (d) Inservice programs shall be based upon need identified through staff evaluations
18 and quality assurance process.

19 (11) The Office of Health Policy may discontinue the pilot program at a participant
20 hospital at any time after reviewing the following:

21 (a) Quarterly reports made by the American College of Cardiology - National
22 Cardiovascular Data Registry (ACC-NCDR);

23 (b) Records obtained through an audit;

1 (c) Peer review reports; or

2 (d) Reports on serious adverse events.

3 (12) Upon notification to the hospital by the Office of Health Policy, the hospital shall
4 terminate the pilot program and cease to perform primary angioplasty procedures.

5 (13) In order to assist the Office of Health Policy in evaluating the pilot program, the
6 performance of pilot hospitals, and the formulation of recommendations for continuing or
7 modifying the project, the Office of Health Policy may collaborate with university-based
8 researchers to:

9 (a) Evaluate and compare performance data of pilot hospitals with existing Kentucky
10 angioplasty programs; and

11 (b) Conduct an evaluation of the short-and long-term outcomes of patients
12 undergoing primary angioplasty at pilot hospitals with those patients transferred to
13 hospitals with open heart surgical backup.

14 (14) The Office of Health Policy shall review reports from the collaborating university
15 based researchers as well as quarterly reports made by the ACC-NCDR, records
16 obtained through audit, peer review reports, and reports of serious adverse events in
17 order to develop recommendations for continuing, discontinuing, or modifying the pilot
18 program. If the project is continued, these recommendations shall include establishing
19 criteria for determining need to expand angioplasty services to additional hospitals
20 without on-site surgical backup, qualifications of those hospitals, and ongoing
21 requirements for a hospital's continued provision of this service.

22 (15) The Office of Health Policy may convene all hospitals participating in the pilot
23 program on a regular basis for the purpose of discussing and assessing the status of

1 the implementation of the pilot program.

2 (16) Three (3) years from the start date of the pilot program, the Office of Health
3 Policy shall publish a report on the program that shall:

4 (a) Indicate whether it is in the best interest of the Commonwealth to eliminate the
5 requirement for open heart surgery for hospitals to perform therapeutic cardiac
6 catheterization; and

7 (b) Include the requirements for patient selection, procedural volume, and staffing
8 that hospitals shall continue to meet if the Office of Health Policy finds that this service
9 may be provided by hospitals in the absence of on-site open heart surgery.

900 KAR 6:120

This is to certify that the Executive Director of the Office of Health Policy has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 156.070(4)

APPROVED:



Carrie Banahan
Executive Director
Office of Health Policy



Date

APPROVED:



Janie Miller
Secretary
Cabinet for Health and Family Services



Date

900 KAR 6: 120

A public hearing on this administrative regulation shall, if requested, be held on July 21, 2009, at 9:00 a.m. in the Public Health Auditorium located on the First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by July 14, 2009, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business July 31, 2009. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, (502) 564-7905, Fax: (502) 564-7573

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 900 KAR 6:120

Contact Person: Carrie Banahan or Shane O'Donley, 564-9592

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the provisions for the pilot project for primary angioplasty in hospitals without on-site open heart surgery ("pilot program") established in the 2004-2006 State Health Plan for the certificate of need program. Formerly 900 KAR 6:050 established the requirements necessary for the orderly administration of the certificate of need program. Due to the large size of that administrative regulation, LRC staff requested that it be separated into several smaller regulations. Therefore, this new administrative regulation was drafted to establish the provisions for the pilot project for primary angioplasty in hospitals without on-site open heart surgery ("pilot program") established in the 2004-2006 State Health Plan for the certificate of need program. This regulation creates no substantive change to current policies.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990 by establishing the provisions for the pilot program initially established in the 2004-2006 State Health Plan for the certificate of need program.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990 by establishing the provisions for the pilot program initially established in the 2004-2006 State Health Plan for the certificate of need program.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation only affects the entities approved to participate in the pilot program. We

currently have 2 entities participating in the program.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: As the provisions for the pilot program initially established in the 2004-2006 State Health Plan for the certificate of need program set forth in the administrative regulation are currently established and operational, no new action will be required of regulated entities to comply with this regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): As the provisions for the pilot program initially established in the 2004-2006 State Health Plan for the certificate of need program set forth in the administrative regulation are currently established and operational, no cost will be incurred by regulated entities to comply with this regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This administrative regulation will provide potential health care providers with a mechanism to establish health care facilities and services in compliance with KRS 216B.

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

(a) Initially: No additional costs will be incurred to implement this administrative regulation as entities already adhere to the provisions for the pilot program initially established in the 2004-2006 State Health Plan for the certificate of need program.

(b) On a continuing basis: No additional costs will be incurred to implement this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used for the implementation and enforcement of this administrative regulation will be from Office of Health Policy's existing budget. As stated above, the provisions for the pilot program initially established in the 2004-2006 State Health Plan for the certificate of need program are already used as part of our normal operations so no additional funding will be required.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change if it is an amendment: No increase in fees or funding will be necessary to implement this administrative regulation.

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

(9) TIERING: Is tiering applied? (explain why or why not) Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:120

Contact Person: Carrie Banahan or
Shane O'Donley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No _____

If yes, complete questions 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation affects the Office of Health Policy within the Cabinet for Health and Family Services.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate any revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate any revenue.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a continuing basis.

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

Revenues (+/-): Expenditures (+/-): Other Explanation: