

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (New Administrative Regulation)

4 900 KAR 6:125. Certificate of Need annual surveys, and registration requirements
5 for new Magnetic Resonance Imaging units.

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

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

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

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

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

11 This administrative regulation establishes the requirements for registration of Magnetic

12 Resonance Imaging units and the requirements for submission of annual survey data

13 that are used to produce annual reports necessary for the orderly administration of the

14 Certificate of Need Program.

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

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

17 (3) "Entities" means any licensed hospital, licensed home health agency, licensed
18 ambulatory surgery center, licensed hospice agency, licensed long term care facility,
19 facility with megavoltage radiation equipment, facility with positron emission tomography
20 equipment, or person or facility with magnetic resonance imaging equipment.

21 (4) "Exempt Physicians" means a physician that operates a Magnetic Resonance

1 Imaging unit pursuant to the exemption allowed in KRS216B.020(2)(a).

2 (5) "Long term care facility" means any entity with licensed long term care beds
3 which include: nursing facility, nursing home, intermediate care, Alzheimer's,
4 intermediate care facility for the mentally retarded, and personal care.

5 (6) "Office of Inspector General" means the office within the Cabinet for Health and
6 Family Services that is responsible for licensing and regulatory functions of health
7 facilities and services.

8 (7) "Owner" means a person as defined in KRS 216B.015(21) who is applying for the
9 certificate of need and will become the licensee of the proposed health service or
10 facility.

11 (8) "Year" means a calendar year from January 1 through December 31.

12 Section 2. Magnetic Resonance Imaging Equipment registration. (1) A new
13 Magnetic Resonance Imaging unit (MRI) utilized in the Commonwealth shall be
14 disclosed to the Cabinet for Health and Family Services.

15 (2) The following information shall be submitted by telephone contact and followed
16 up in writing with the Office of Health Policy about every MRI unit utilized in the
17 Commonwealth:

18 (a) Name, address, and telephone number of the facility at which each unit is
19 located or to be utilized;

20 (b) Identification of designated contact person or authorized agent of each facility;

21 (c) Make, model, and serial number of each unit;

22 (d) Date the unit became operational at each site; and

23 (e) Whether the unit is free-standing or mobile (if the unit is mobile, then also identify

1 the number of days the unit is operational).

2 (3) The owner or operator of any MRI unit that becomes operational at an
3 unlicensed facility after August 1, 2006, shall have 30 (thirty) days after use of the unit is
4 commenced to provide the information required by subsection (2) of this section.

5 (4) Within 30 (thirty) days of a change in the facility's address or the addition of
6 another MRI unit as well as the discontinuation of any units, the designated contact
7 person or authorized agent shall notify the Office of Health Policy in writing.

8 Section 3. Entities completing surveys. (1) Entities that are required to submit
9 annual surveys are as follows:

- 10 (a) Licensed Ambulatory Surgery Centers;
- 11 (b) Licensed Hospitals performing ambulatory surgery services or performing
12 outpatient surgical services;
- 13 (c) Licensed Home Health Agencies;
- 14 (d) Licensed Hospice Agencies;
- 15 (e) Licensed Hospitals;
- 16 (f) Facilities with licensed long term care beds;
- 17 (g) Entities that hold a certificate of need for MRI equipment;
- 18 (h) Exempt Physicians that have MRI equipment.
- 19 (i) Facilities with Megavoltage Radiation equipment; and
- 20 (j) Facilities with Positron Emission Tomography equipment.

21 (2) Entities that did not perform any services or utilize specified equipment during the
22 reporting year are not required to submit annual surveys.

23 Section 4. Annual survey submission. (1) Annual surveys shall be completed for the

1 previous year and transmitted electronically by accessing the Office of Health Policy's
2 website at <http://chfs.kv.gov/ohp>.

3 Section 5. Surveys shall be submitted annually as follows:

4 (1) Kentucky Annual Ambulatory Surgical Services Survey;

5 (2) Kentucky Annual Home Health Services Survey;

6 (3) Kentucky Annual Hospice Services Survey;

7 (4) Kentucky Annual Hospital Utilization and Services Survey;

8 (5) Kentucky Annual Long Term Care Services Survey;

9 (6) Kentucky Annual Magnetic Resonance Imaging Services Survey;

10 (7) Kentucky Annual Megavoltage Radiation Services Survey; and

11 (8) Kentucky Annual Positron Emission Tomography Survey;

12 Section 6. Annual surveys shall be completed no later than March 15th of each
13 year. If the 15th falls on a weekend or holiday, the submission due date shall be the
14 next working day.

15 Section 7. Extensions for survey submission. (1) A request for an extension for
16 submission of data must be made in writing or via email to the administrator of the
17 specific survey.

18 (2) The request for an extension shall state the facility name, survey log-in
19 identification number, contact person, contact phone number, contact email address,
20 and a detailed reason the requested extension.

21 (3) One extension per survey of up to 10 (ten) days shall be granted.

22 (4) Additional extensions shall only be granted when circumstances beyond the
23 entities control prevents timely completion of surveys.

1 Section 8. Data Corrections. (1) Prior to release of draft survey reports to facilities
2 for their review, the Office of Health Policy shall review data for completeness and
3 accuracy. If an error is identified, the facility shall be contacted by the Office of Health
4 Policy and allowed 14 (fourteen) days to make corrections.

5 (2) Prior to publication of the survey reports, the Office of Health Policy shall publish
6 draft survey reports available only to the entities included in each individual report. The
7 facilities shall be notified of a website with a login and password required to access the
8 draft survey report(s) and shall have 14 (fourteen) days to review their data for errors.
9 Corrections shall be submitted in writing to the Office of Health Policy before the
10 expiration of the 14 (fourteen) day review period.

11 (3) After publication of the survey reports, reports will not be revised as a result of
12 data reported to the Office of Health Policy incorrectly by the facility. Corrections
13 received after the 14 (fourteen) day review period shall not be reflected in the published
14 survey report. Facilities may provide a note in the comments section for the following
15 year's survey report, referencing the mistake from the previous year.

16 Section 9. Annual Reports. (1) Utilizing data submitted in the annual surveys, the
17 Office of Health Policy will publish reports annually as follows:

- 18 (a) Kentucky Annual Ambulatory Surgical Services Report;
- 19 (b) Kentucky Annual Home Health Services Report;
- 20 (c) Kentucky Annual Hospice Services Report;
- 21 (d) Kentucky Annual Hospital Utilization and Services Report;
- 22 (e) Kentucky Annual Long Term Care Services Report;
- 23 (f) Kentucky Annual Magnetic Resonance Imaging Services Report;

1 (g) Kentucky Annual Megavoltage Radiation Services Report; and

2 (h) Kentucky Annual Positron Emission Tomography Report.

3 (2) Electronic copies of annual reports may be obtained at no cost on the Office of
4 Health Policy's website <http://chfs.kv.gov/ohp> . A paper copy can be obtained for a fee
5 of 20 (twenty) dollars at the Cabinet for Health and Family Services, Office of Health
6 Policy, 275 East Main Street 4WE, Frankfort, Kentucky 40621

7 Section 10. Any facility that fails to complete the annual surveys for which they are
8 required will be referred to the Office of Inspector General for further action which may
9 impact the facility's license renewal as provided for in 902 KAR 20:008 Section 2 (6).

10 Section 11. Open Records Requests. (1) Prior to publication of the survey reports,
11 during the data collection and compiling process, the survey and related data is
12 considered preliminary and in use and is not subject to open records requests. No
13 survey and related data shall be released prior to the official publication of each survey
14 report.

15 (2) After official publication of each survey report, the survey and related data may
16 be released upon receipt of an open records request.

900 KAR 6:125

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

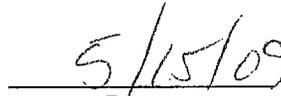


Date

APPROVED:



Janie Miller
Secretary
Cabinet for Health and Family Services



Date

900 KAR 6:125

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 6:125

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 requirements for completion of annual surveys and the requirement to register new Magnetic Resonance Imaging (MRI) units with the Office of Health Policy.

(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.062, 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.062, 216B.990 by establishing the requirements for completion of annual surveys and the requirement to register new Magnetic Resonance Imaging units with the Office of Health Policy for the orderly administration of 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.062, 216B.990 by establishing the requirements for completion of annual surveys and the requirement to register new Magnetic Resonance Imaging units with the Office of Health Policy.

(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 affects an entity required to submit annual surveys and an entity required to register a Magnetic Resonance Imaging unit. Approximately 800 entities complete a survey each year.

(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 annual survey process and MRI registration process identified in the administrative regulation are already established, no 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 annual survey process and the registration of MRI units identified in the administrative regulation are already established, 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 will provide specific instructions for submission of annual surveys and the requirement to register new Magnetic Resonance Imaging units with the Office of Health Policy for the administration of the certificate of need program.

(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 regulation as we already utilize these surveys and MRI registration process as part of our normal operations.

(b) On a continuing basis: No additional costs will be incurred to implement this 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 annual survey process and registration of MRI units identified in the administrative regulation 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 establishes a \$20.00 fee for anyone wishing to purchase a paper copy of annual reports. As the reports are available electronically at no cost, the fee is necessary to recuperate the agency's printing costs incurred in producing paper reports.

(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 6:125

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.062, 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:

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

additional costs will be incurred to implement this amendment 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: