

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(Amendment)

902 KAR 20:016. Hospitals; operations and services.

RELATES TO: KRS 198B.260, Chapter 209, 211.842-211.852, Chapter 214, 216.2970, 216B.010, 216B.015, 216B.040, 216B.042, 216B.0425(2), 216B.045, 216B.050, 216B.055, 216B.075, 216B.085, 216B.105-216B.125, 216B.140-216B.175, 216B.185, 216B.190, 216B.230-216B.239, 216B.250, 216B.400-216B.402, 216B.990, ~~[219.011-219.081,]~~ Chapter 310, 311.560, 311.992, Chapter 311B, 314.011(8), 314.042(8), ~~[320.210(2),]~~ 333.030, 446.400, Chapter 620, 29 C.F.R. 1910.1030(d)(2)(vii), 40 C.F.R. Part 403, 42 C.F.R. Part 405, 412.22~~[(c)],~~ 412.92, 413.65, 482.12(c), ~~489.24[489.25],~~ Part 493, 45 C.F.R. Part 160, Part 164, 42 U.S.C. 1320d-2~~==[-]~~1320d-8, 1395u(b)(18)(C), 1395x(r)(2)-(5), 1395dd

STATUTORY AUTHORITY: KRS 216B.042(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes the minimum licensure requirements for the operation of hospitals and the basic services provided by hospitals.

Section 1. Definitions.

- (1) "Accredited record technician" means an individual who:
 - (a) Has graduated from a program for medical record technicians that is accredited by the Council on Medical Education of the American Medical Association and the American Health Information Management Association; and
 - (b) Is certified as an accredited record technician by the American Health Information Management Association.
- (2) "Governing authority" means the individual, agency, partnership, or corporation in which the ultimate responsibility and authority for the conduct of the health facility is vested.
- (3) "Long-term acute inpatient hospital services" means acute inpatient services provided to patients whose average inpatient stay is greater than twenty-five (25) days.
- (4) "Organ procurement agency" means a federally designated organization that coordinates and performs activities to encourage the donation of organs or tissues for transplantation.
- (5) "Protective device" means a device designed to protect a person from falling, and may include:
 - (a) Side rails;
 - (b) A safety vest; or
 - (c) A safety belt.
- (6) "Psychiatric unit" means a department of a general acute care hospital consisting of eight (8) or more psychiatric beds organized for the purpose of providing psychiatric services.
- (7) "Registered health information administrator" means an individual who has obtained professional certification from the American Health Information Management Association.
- (8) "Registered or registry-eligible dietician" means an individual who is licensed as a dietician in accordance with KRS Chapter 310.

(9) "Restraint" means any pharmaceutical agent or physical or mechanical device used to restrict the movement of a patient or the movement of a portion of a patient's body.

Section 2. Requirements to Provide Services. A facility shall not be licensed as or hold itself out to be a hospital unless it provides:

- (1) The full range of services required by Section 4 of this administrative regulation; and
- (2) Treatment for a variety of illnesses.

Section 3. Administration and Operation.

(1) Governing authority licensee.

(a) The hospital shall have a recognized governing authority that has overall responsibility for:

1. The management and operation of the hospital; and
2. Compliance with federal, state, and local law pertaining to its operation.

(b) The governing authority shall:

1. Appoint an administrator whose qualifications, responsibilities, authority, and accountability shall be defined in writing and approved by the governing authority; and
2. Designate a mechanism for the annual performance review of the administrator.

(2) Administrator.

(a) The administrator shall:

1. Act as the chief executive officer;
2. Be responsible for the management of the hospital; and
3. Act as the liaison between the governing authority and the medical staff.

(b) The administrator shall keep the governing authority fully informed of the conduct of the hospital through:

1. Reports; and
2. Attendance at meetings of the governing authority.

(c) The administrator shall:

1. Develop an organizational structure including lines of authority, responsibility, and communication; and
2. Organize the day-to-day functions of the hospital through appropriate departmentalization and delegation of duties.

(d) The administrator shall establish formal means of accountability on the part of each subordinate to whom the administrator has assigned duties.

(e) The administrator shall:

1. Hold interdepartmental and departmental meetings as appropriate;
2. Attend or be represented at the meetings on a regular basis; and
3. Report to each department and to the governing authority the pertinent activities of the hospital.

(3) Administrative records.

(a) The hospital shall establish administrative records that reflect and guide the administrative operations of the hospital, including:

1. Minutes of the governing authority;
2. Financial records;
3. Personnel records; and
4. Employee health records.

(b) A hospital shall have discretion as to the form or content of any administrative record it establishes.

(c) The hospital shall maintain a:

1. Patient admission register;
2. Discharge register;
3. Birth register, if applicable; and

4. Surgical register, if applicable.
- (d) Licensure inspection reports and plans of correction shall be made available to the general public upon request.
- (4) Policies. The hospital shall have written policies and procedures governing all aspects of the operation of the facility and the services provided, including:
- (a) A written description of the organizational structure of the facility that includes the lines of authority, responsibility, and communication, and departmental organization;
 - (b) The admission procedure to assure that a patient is admitted to the hospital in accordance with medical staff policy;
 - (c) Any constraint imposed on admissions by a limitation of:
 - 1. Services;
 - 2. Physical facilities;
 - 3. Staff coverage; or
 - 4. Other relevant factor;
 - (d) Financial requirements for patients on admission;
 - (e) Emergency admissions;
 - (f) Requirements for informed consent by patient, parent, guardian, or legal representative for diagnostic or treatment procedures;
 - (g) Effective procedures for tracking incidents, including transfusion reactions, drug reactions, and medication errors that may occur in the facility. A hospital shall have discretion as to its process, and the procedures shall encourage statistical analysis to inform process improvement activities;
 - (h) Procedures for meeting the requirements of KRS Chapter 214 and 902 KAR 2:020, including the reporting of:
 - 1. Notifiable infectious conditions;
 - 2. Notifiable non-infectious conditions;
 - 3. Multi-drug resistant organisms;
 - 4. Other reportable disease surveillance; and
 - 5. Electronic laboratory reporting;~~;~~
 - (i) Use of restraints and a mechanism for monitoring and controlling the use of restraints;
 - (j) The internal transfer of a patient from one (1) level or type of care to another, if applicable;
 - (k) The discharge and termination of services;
 - (l) An organ procurement for transplant protocol developed by the medical staff in consultation with the organ procurement agency; ~~and~~
 - (m) Policies that assure the reporting of cases of abuse, neglect, or exploitation of adults and children to the cabinet pursuant to KRS Chapters 209 and 620, including evidence that all allegations of abuse, neglect, or exploitation are thoroughly investigated internally to prevent further potential abuse while the investigation is in progress; and
 - (n) Policies that assure the reporting and investigation of quality of care and safety problems in accordance with KRS 216B.165, including assurance that retaliatory action shall not be taken against a staff member who in good faith reports a patient care or safety problem.
- (5) Patient identification. The hospital shall have a system for identifying each patient from the time of admission to discharge. For example, an identification bracelet imprinted with the following:
- (a) Name of patient;
 - (b) Hospital identification number;
 - (c) Date of admission; and
 - (d) Name of attending medical staff member.

- (6) Discharge planning.
- (a) The hospital shall have a discharge planning program to assure continuity of care for a patient who is:
 - 1. Transferred to another health care facility; or
 - 2. Discharged to the home.
 - (b) The professional staff of the facility involved in the patient's care during hospitalization shall participate in discharge planning of the patient whose illness requires a level of care outside the scope of the general hospital.
 - (c) The hospital shall:
 - 1. Coordinate the discharge of the patient with the patient and the person or agency responsible for the postdischarge care of the patient;
 - 2. Provide pertinent information concerning postdischarge needs to the responsible person or agency, including the full range of qualified providers or appropriate support organizations in the community available to provide post-acute care services; and
 - 3. Comply with the requirements established in KRS 216B.230 to 216B.239, which include providing each patient or the patient's legal guardian, if applicable, with at least one (1) opportunity to designate a lay caregiver.
- (7) Transfer procedures and agreements.
- (a) The hospital shall have a written patient transfer procedure and agreement with at least one (1) of each type of other health care facility able to provide a level of inpatient care not provided by the hospital.
 - (b) A hospital that does not have a transfer agreement in effect, but has documented a good faith effort to enter into an agreement, shall be in compliance with paragraph (a) of this subsection.
 - (c) A transfer procedure and agreement shall:
 - 1. Specify the responsibilities each institution assumes in the transfer of a patient; and
 - 2. Establish the hospital's responsibility for:
 - a. Notifying the receiving entity promptly of the impending transfer of a patient; and
 - b. Arranging for appropriate and safe transportation.
 - (d) If a patient is transferred to another health care facility or to the care of a home health agency:
 - 1. A transfer form containing the following information shall accompany the patient or be sent immediately to the other health care facility or home health agency:
 - a. Attending medical staff member's instructions for continuing care;
 - b. Current summary of the patient's medical record;
 - c. Information as to special supplies or equipment needed for patient care; and
 - d. Pertinent social information on the patient and family; and
 - 2. A copy of the patient's signed discharge summary shall be forwarded to the health care facility or home health agency within thirty (30) days of the patient's discharge.
 - (e) If a patient is transferred to another licensed level of care within the same facility:
 - 1. The history and physical examination report shall:
 - a. Be transferred to the other licensed level of care within the same hospital pursuant to KRS 216B.175(3); and
 - b. Serve to meet the history and physical examination requirement for the licensed level of care to which the patient has been transferred; and
 - 2. The complete medical record or a current summary of the record shall be transferred with the patient.
- (8) Medical staff.

- (a) The hospital shall have a medical staff organized under bylaws approved by the governing authority.
- (b) The medical staff shall be responsible:
1. To the governing authority for the quality of medical care provided to the patients; and
 2. For the ethical and professional practice of its members.
- (c) The organized medical staff shall be composed of doctors of medicine or doctors of osteopathy.
- (d) At the discretion of the hospital, the governing body may elect to include the following practitioners as eligible for appointment to the medical staff to provide only those services authorized within the practitioner's respective scope of practice:
1. A licensed practitioner described in 42 U.S.C. 1395x(r)(2) – (5); or
 2. A licensed practitioner described in 42 U.S.C. 1395u(b)(18)(C).
- (e) The governing body of a hospital shall not be required to open eligibility for medical staff appointment to any licensed practitioner in addition to doctors of medicine or doctors of osteopathy.
- (f) The medical staff shall develop and adopt policies or bylaws, subject to the approval of the governing authority that address the following:
1. Qualifications for medical staff membership, including licensure to practice in Kentucky in accordance with authorized scope of practice, except for graduate doctors of medicine or doctors of osteopathy in their first year of hospital training;
 2.
 - a. Responsibilities and duties of each category of medical staff membership the medical staff may choose to create, for example, active, associate, or courtesy;
 - b. Clinical privileges that may be possessed by medical staff members and allied health professionals;
 - c. Procedures for granting and withdrawing medical staff membership and clinical privileges; and
 - d. Procedures for reviewing credentials;
 3. A mechanism for appeal of decisions adversely affecting medical staff membership or clinical privileges;
 4. A method for the selection of officers of the medical staff;
 5. Policy regarding the frequency of and attendance at meetings of the medical staff;
 6. Authority to appoint committees to address areas of operation or clinical focus, which may include the following:
 - a. Executive committee;
 - b. Credentials committee;
 - c. Medical audit committee;
 - d. Medical records committee;
 - e. Infection control committee;
 - f. Tissue committee;
 - g. Pharmacy and therapeutics committee;
 - h. Utilization review committee; or
 - i. Quality assurance committee; and
 7. A policy requiring a member of the medical staff to sign a verbal order for diagnostic testing or treatment:
 - a. As soon as possible after the order was given; or
 - b. If the patient was discharged prior to the order being authenticated, within thirty (30) days of the patient's discharge.
- (g) All licensed practitioners appointed to the medical staff shall:
1. Be privileged in accordance with and function under the policies or bylaws required by paragraph (f) of this subsection; and

2. Comply with the hospital infection control and employee health policies.
- (9) Personnel. The hospital shall:
- (a) Employ a sufficient number of qualified personnel to provide effective patient care and other related services;
 - (b) Have written personnel policies and procedures available to hospital personnel;
 - (c) Have a written job description for each position subject to review and revision as necessary;
 - (d) Have an employee health program for the mutual protection of employees and patients, including provisions for preemployment medical examination and follow-up medical examination no less than every three (3) years thereafter for staff who serve patients;
 - (e) Have a tuberculosis infection control program;
 - (f) Comply with the tuberculosis testing requirements established for health care workers in 902 KAR 20:205; and
 - (g) Maintain the following information in each employee's personnel record:
 1. Name, address, Social Security number;
 2. Health record;
 3. Evidence of current registration, certification, or licensure;
 4. Record of training and experience; and
 5. Record of performance evaluation.
- (10) Physical and sanitary environment.
- (a) The condition of the physical plant and the overall hospital environment shall be maintained in such a manner that the safety and well-being of patients, personnel, and visitors are assured.
 - (b) A person shall be designated responsible for services and for the establishment of practices and procedures in each of the following areas:
 1. Plant maintenance;
 2. Laundry operations; and
 3. Housekeeping.
 - (c) There shall be an infection control program charged with responsibility for investigating, controlling, and preventing infections in the hospital. A multidisciplinary infection control committee shall have oversight of the program. The program shall:
 1. Be directed by:
 - a. A certified infection control preventionist; or
 - b. An infection preventionist that has education or specialized training and experience necessary to be certified within two (2) years of employment;
 2. Have assigned administrative and professional staff to perform:
 - a. Infection control surveillance;
 - b. Investigation of cases and outbreaks;
 - c. Infection control training;
 - d. Reporting of diseases; and
 - e. Infection control collaborations with employee health services;
 3. Receive every report of an infection incident discovered by an employee; and
 4. Develop written infection control policies consistent with the Centers for Disease Control and Prevention guidelines.
 - (d) The infection control policies shall address the:
 1. Prevention of disease transmission to and from patients, visitors, and employees, including:
 - a. Universal blood and body fluid precautions;
 - b. Precautions for infections that can be transmitted by the airborne route;
 - c. Work restrictions, including return to work policies for employees with infectious diseases;

- d. Policies for vaccinating health care personnel or documenting immunity status for:
 - (i) Hepatitis B;
 - (ii) Influenza;
 - (iii) Measles;
 - (iv) Mumps;
 - (v) Rubella;
 - (vi) Pertussis; and
 - (vii) Varicella;
 - e. Policies for vaccinating health care personnel to prevent meningococcal disease, typhoid fever, or polio for personnel who have certain health conditions or are at risk for work-related exposure;
 - f. Handwashing and hand hygiene;
 - g. Antimicrobial stewardship; and
 - h. Reporting, investigating, and controlling outbreaks of healthcare-associated infections;
- 2. Use of environmental cultures. Culture testing results shall be recorded and reported to the Infection Control Committee; and
 - 3. Cleaning, disinfection, and sterilization methods used for equipment and the environment.
- (e) The hospital shall provide in-service education programs on the cause, effect, transmission, prevention, and elimination of infections.
- (f) The hospital buildings, equipment, and surroundings shall be kept in a condition of good repair, neat, clean, and free from accumulations of dirt, rubbish, and foul, stale, or musty odors.
- 1. An adequate number of housekeeping and maintenance personnel shall be provided.
 - 2. A written housekeeping procedure shall be:
 - a. Established for the cleaning of each area; and
 - b. Made available to personnel.
 - 3. Equipment and supplies shall be provided for cleaning of all surfaces. The equipment shall be maintained in a safe, sanitary condition.
 - 4. Hazardous cleaning solutions, compounds, and substances shall be:
 - a. Labeled;
 - b. Stored in closed metal containers; and
 - c. Kept separate from other cleaning materials.
 - 5. The facility shall be kept free from insects, rodents, and their nesting places, and entrances to their nesting places shall be eliminated.
 - 6. Garbage and trash shall be:
 - a. Stored in areas separate from those used for preparation and storage of food; and
 - b. Removed from the premises regularly.
 - 7. Trash containers shall be cleaned on a regular basis.
- (g) Sharp wastes.
- 1. Sharp wastes, including needles, scalpels, razors, or other sharp instruments used for patient care procedures, shall be:
 - a. Segregated from other wastes; and
 - b. Placed in puncture resistant containers immediately after use.
 - 2. A needle or other contaminated sharp shall not be purposely bent, broken, or otherwise manipulated by hand as a means of disposal, except as permitted by Occupational Safety and Health Administration guidelines at 29 C.F.R. 1910.1030(d)(2)(vii).

3. A sharp waste container shall be:
 - a. Incinerated on or off site; or
 - b. Rendered nonhazardous.
 4. Nondisposable sharps, such as large-bore needles or scissors, shall be placed in a puncture resistant container for transport to the Central Medical and Surgical Supply Department, in accordance with 902 KAR 20:009, Section 22.
- (h) Disposable waste.
1. Disposable waste shall be:
 - a. Placed in a suitable bag or closed container to prevent leakage or spillage; and
 - b. Handled, stored, and disposed of to minimize direct exposure of personnel to waste materials.
 2. The hospital shall establish specific written policies regarding handling and disposal of waste material.
 3. The wastes identified in this subparagraph shall receive special handling.
 - a. Microbiology laboratory waste including a viral or bacterial culture, contaminated swab, or a specimen container or test tube used for microbiologic purposes shall be incinerated, autoclaved, or otherwise rendered nonhazardous.
 - b. Pathological waste including a tissue specimen from a surgical or necropsy procedure shall be incinerated.
 4. Blood, blood specimens, used blood tubes, or blood products shall be:
 - a. Disposed of by incineration;
 - b. Autoclaved before disposal; or
 - c. Carefully poured down a drain connected to a sanitary sewer, subject to limitations in subparagraph 5. of this paragraph.
 5. Wastes conveyed to a sanitary sewer shall comply with applicable federal, state, and local pretreatment law, including 40 C.F.R. Part 403 and relevant local ordinances.
 6. An incinerator used for the disposal of waste shall be in compliance with 401 KAR 59:020 and 401 KAR 61:010.
- (i) The hospital shall have available at all times a quantity of linen essential to the proper care and comfort of patients.
1. Linens shall be handled, stored, and processed to control the spread of infection.
 2. Clean linen and clothing shall be stored in a clean, dry, dust-free area designated exclusively for this purpose.
 3. An uncovered mobile cart may be used to distribute a daily supply of linen in patient care areas.
 4. Soiled linen and clothing shall be placed in a suitable bag or closed container to prevent leakage or spillage, and there shall be minimal handling of soiled linen to prevent generating further aerosols.
 5. Soiled linen shall be stored in an area separate from clean linen.
- (11) Medical and other patient records.
- (a) The hospital shall have a medical records service with administrative responsibility for medical records.
 - (b) A medical record shall be maintained in accordance with accepted professional principles for every patient admitted to the hospital or receiving outpatient services.
 1. The medical records service shall:
 - a. Be directed by:
 - (i) A registered health information administrator on a full-time, part-time, or consultative basis; or
 - (ii) An accredited record technician on a full-time or part-time basis; and
 - b. Have available a sufficient number of regularly assigned employees so that medical record services may be provided as needed.

2. Medical records shall be retained for at least:
 - a. Six (6) years from date of discharge; or
 - b. If a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longest.
 3. A provision shall be made for written designation of the specific location for storage of medical records if the hospital ceases to operate because of disaster or for any other reason.
 4. The hospital shall be responsible for safeguarding the record and its informational content against loss, defacement, and tampering.
 5. Particular attention shall be given to protection from damage by fire or water.
- (c) A system of identification and filing to assure the prompt location of a patient's medical record shall be maintained in accordance with the requirements of this paragraph.
1. Index cards, if used, shall bear at least the patient's full name, birth date, and medical record number.
 2. There shall be a system for coordinating the inpatient and outpatient medical records of a patient whose admission is a result of, or related to, outpatient services.
 3. Clinical information pertaining to inpatient and outpatient services shall be centralized in the patient's medical record.
 4. A hospital using automated data processing shall keep patient indices electronically or reproduced on paper and kept in books.
- (d) Ownership.
1. Medical records shall be the property of the hospital.
 2. The original medical record shall not be removed from the facility except by court order or subpoena.
 3. Copies of a medical record or portions of the record may be used and disclosed. Use and disclosure shall be as established by paragraph (e) of this subsection.
- (e) Confidentiality and Security: Use and Disclosure.
1. The hospital shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.
 2. The hospital may use and disclose medical records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.
 3. A hospital may establish higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.
- (f) Medical record contents shall be pertinent, current, and include the following:
1. Identification data and signed consent forms, including name and address of next of kin, and of the person or agency responsible for patient;
 2. Date of admission, name of attending medical staff member, and allied health professional in accordance with subsection (8)(d)2. of this section;
 3. Chief complaint;
 4. Medical history including present illness, travel history, occupational history, past history, family history, and physical examination results;
 5. Report of special examinations or procedures, which may include consultations, clinical laboratory tests, x-ray interpretations, or EKG interpretations;
 6. Provisional diagnosis or reason for admission;
 7. Orders for diet, diagnostic tests, therapeutic procedures, and medications, including patient limitations, signed and dated by the medical staff member or other

ordering personnel acting within the limits of his or her statutory scope of practice;
8. Medical, surgical, or dental treatment notes and reports, signed and dated by a physician, dentist, licensed practitioner, or other ordering personnel acting within the limits of his or her statutory scope of practice if applicable, including records of all medication administered to the patient;

9. Complete surgical record signed by the attending surgeon or oral surgeon, including the:

- a. Anesthesia record signed by the anesthesiologist or an advanced practice registered nurse who is a certified registered nurse anesthetist;
- b. Preoperative physical examination and diagnosis;
- c. Description of operative procedures and findings;
- d. Postoperative diagnosis; and
- e. Tissue diagnosis by qualified pathologist on tissue surgically removed;

10. Patient care plan that addresses the comprehensive care needs of the patient, including the coordination of the facility's service departments that have impact on patient care;

11. Nurses' observations and progress notes of a physician, dentist, licensed practitioner, or other ordering personnel acting within the practitioner's statutory scope of practice;

12. Record of temperature, blood pressure, pulse, and respiration;

13. Final diagnosis using terminology in the current version of the International Classification of Diseases or the American Psychiatric Association's Diagnostic and Statistical Manual, if applicable;

14. Discharge summary, including:

- a. Condition of patient on discharge; and
- b. Date of discharge; and

15. In case of death:

- a. Autopsy findings, if performed; and
- b. An indication that the patient has been evaluated for organ donation in accordance with hospital protocol.

(g) Records shall be indexed according to disease, operation, and attending medical staff member using a recognized indexing system.

1. The disease and operative indices shall:

- a. Use recognized nomenclature;
- b. Include each specific disease diagnosed and each operative procedure performed; and
- c. Include essential data on each patient having that particular condition.

2. The attending medical staff index shall include all patients attended or seen in consultation by each medical staff member.

3. Indexing shall be current, within six (6) months following discharge of the patient.

(12) Organ donation.

(a) The hospital shall establish and maintain a written protocol regarding organ procurement for transplant in consultation with an organ procurement agency.

(b) If a patient has died or death is imminent, the patient's attending physician shall determine, in accordance with the hospital's protocol, whether the patient is a potential organ or tissue donor.

(c) The hospital protocol shall include:

1. Criteria developed in consultation with the organ procurement agency for identifying potential donors;
2. Procedures for obtaining consent for organ donation;

3. Procedures for the hospital administrator or the administrator's designee to notify the organ procurement agency of a potential organ donor; and
4. Procedures by which the patient's attending physician or designee shall document in the patient's medical record:

- a. If the patient is a potential donor, that the organ procurement agency has been notified; or
- b. The contraindications to donation.

(d) A patient with impending or declared brain death or cardiopulmonary death, as determined pursuant to KRS 446.400, shall not be a potential donor if contraindications are identified and documented in the patient's medical record.

Section 4. Provision of Services.

(1) Medical staff services.

(a) Medical care provided in the hospital shall be under the direction of a medical staff member in accordance with staff privileges granted by the governing authority.

(b) An attending medical staff member shall assume responsibility for diagnosis and care of his or her patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization, subject to this paragraph:

1. If a patient is admitted by a practitioner identified in 42 C.F.R. 482.12(c)(4):

- a. The patient shall be under the care of the practitioner for any condition that is specifically within the scope of practice of the practitioner as that scope is defined by the medical staff and permitted by state law; and
- b. A doctor of medicine or doctor of osteopathy shall be responsible for care of the patient for any condition beyond the scope of the admitting practitioner's license.

2.

a. Except as provided by clause b. of this subparagraph, if a patient is admitted by a licensed practitioner identified at 42 U.S.C. 1395u(b)(18)(C), a doctor of medicine or doctor of osteopathy shall be responsible for diagnosis and care of the patient.

b. If a non-Medicare patient is admitted by a certified nurse midwife, the patient shall be under the care of the certified nurse midwife for all services within that professional's scope of practice.

(c) Other qualified personnel may:

1. Complete medical histories;
2. Perform physical examinations; or
3. Record findings and compiler discharge summaries in accordance with the:
 - a. Practitioner's scope of practice; and
 - b. Hospital's protocols and bylaws.

(d) A complete history and physical examination shall be conducted according to the requirements of KRS 216B.175(2).

1. The history and physical examination shall include:

- a. A description of the patient's chief complaint and the major reason for hospitalization;
- b. A history of the patient's:
 - (i) Present illness;
 - (ii) Past illnesses;
 - (iii) Surgeries;
 - (iv) Medications;
 - (v) Allergies;
 - (vi) Social history;
 - (vii) Occupational history;

- (viii) Travel history; and
 - (ix) Immunizations;
 - c. A review of the patient's anatomical systems and level of function at the time of the exam;
 - d. The patient's vital signs; and
 - e. A general observation of the patient's:
 - (i) Alertness;
 - (ii) Debilities; and
 - (iii) Emotional behavior.
- 2. The results of the history and physical examination shall be:
 - a. Recorded;
 - b. Reviewed for accuracy; and
 - c. Signed by the practitioner conducting the examination.
- (e) The attending medical staff member shall:
 - 1. State his or her final diagnosis;
 - 2. Assure that the discharge summary is completed; and
 - 3. Sign the records within thirty (30) calendar days following the patient's discharge.
- (f) Physician services shall be available twenty-four (24) hours a day on at least an on-call basis.
- (g) There shall be sufficient medical staff coverage for all clinical services of the hospital, in keeping with their size and scope of activity.
- (2) Nursing service.
 - (a) The hospital shall have a nursing department organized to meet the nursing care needs of the patients and maintain established standards of nursing practice.
 - (b) A registered nurse with a bachelor of science degree in nursing shall serve as director of the nursing department.
 - (c) There shall be a registered nurse on duty at all times.
 - 1. There shall be registered nurse supervision and staff nursing personnel for each service or nursing unit to insure the immediate availability of a registered nurse for all patients on a twenty-four (24) hour basis.
 - 2. There shall be other nursing personnel in sufficient numbers to provide nursing care not requiring the service of a registered nurse.
 - 3. There shall be additional registered nurses for surgical, obstetrical, emergency, and other services of the hospital, in keeping with their size and scope of activity.
 - 4. Persons not employed by the hospital who render special duty nursing services in the hospital shall be under the supervision of the nursing supervisor of the department or service concerned.
 - (d) The hospital shall have written nursing care procedures and written nursing care plans for patients.
 - (e) Patient care shall be carried out in accordance with:
 - 1. Attending medical staff member's orders;
 - 2. Nursing process; and
 - 3. Nursing care procedures.
 - (f) The nurse shall evaluate the patient using standard nursing procedure.
 - (g) A registered nurse shall assign staff and evaluate the nursing care of each patient in accordance with the patient's need and the nursing staff available.
 - (h) Nursing notes shall be:
 - 1. Written and signed on each shift by nursing staff rendering care to patients;
 - 2. Descriptive of the nursing care given; and
 - 3. Include information and observations of significance that contribute to the continuity of patient care.
 - (i) A medication shall be administered only by a:

1. Registered nurse;
2. Physician;
3. Dentist;
4. Physician's assistant;
5. Advanced practice registered nurse;
6. Licensed practical nurse under the supervision of a registered nurse;
7. Paramedic acting within his or her statutory scope of practice and in accordance with the hospital's operating policies and procedures; or
8. Nurse extern in accordance with 201 KAR 20:400.

(j) Except in a circumstance that requires a verbal order, a medication, diagnostic test, or treatment shall not be given without a written order signed by a physician, dentist, licensed practitioner, or other ordering personnel acting within his or her statutory scope of practice.

(k) A verbal order for a medication shall be:

1. Given only to a licensed practical or registered nurse, paramedic, or pharmacist; and
2. Signed by a member of the medical staff or other ordering practitioner as soon as possible after the order was given, or if the patient was discharged prior to the order being authenticated, within thirty (30) calendar days of the patient's discharge.

(l) A verbal order for a diagnostic test or treatment order may be given to a licensed practitioner acting within his or her statutory scope of practice and the hospital's protocols.

(m) A person receiving a verbal order for medication, a diagnostic test, or treatment shall, at the time the order is received:

1. Immediately transcribe the order;
2. Repeat the order to the person issuing the order; and
3. Annotate the order on the patient's medical record, as repeated and verified.

(n) A patient restraint or protective device, other than bed rails, shall not be used except:

1. In an emergency until the attending medical staff member can be contacted; or
2. Upon a written or telephone order of the attending medical staff member.

(o) If a patient restraint is necessary, the least restrictive form of protective device shall be used that affords the patient the greatest possible degree of mobility and protection.

(p) A locking restraint shall not be used under any circumstances.

(q) Meetings of the nursing staff and other nursing personnel shall be held at least monthly to discuss patient care, nursing service problems, infection control, employee health policies, and administrative policies.

(r) Written minutes of all meetings shall be kept.

(3) Dietary services.

(a) The hospital shall have a dietary department organized, directed, and staffed to provide quality food service and optimal nutritional care.

(b) The dietary department shall be directed on a full-time basis by an individual who by education, or specialized training and experience, shall be knowledgeable in food service management.

(c) The dietary service shall have at least one (1) registered or registry-eligible dietician working full-time, part-time, or on a consultative basis to supervise the nutritional aspects of patient care.

(d) Sufficient additional personnel shall be employed to perform assigned duties to meet the dietary needs of all patients.

(e) The dietary department shall have current written policies and procedures for food storage, handling, and preparation.

(f) Written dietary policy and procedure shall be available to dietary personnel.

- (g) An in-service training program that includes the proper handling of food, safety, and personal grooming shall be given at least quarterly for new dietary employees.
 - (h) Menus shall be planned, written, and rotated to avoid repetition.
 - (i) Nutritional needs shall be met in accordance with:
 - 1. Recommended dietary allowances of the Food and Nutrition Board of the National Research Council of the National Academy of Sciences; and
 - 2. The medical staff member's orders.
 - (j) Each meal shall correspond with the posted menu.
 - (k) If a change is necessary, substitution shall provide equal nutritive value and the change shall be recorded on the menu.
 - (l) Each menu shall be kept on file for thirty (30) calendar days.
 - (m) Every diet, regular or therapeutic, shall be prescribed in writing, dated, and signed by the attending medical staff member or other ordering personnel acting within his or her statutory scope of practice.
 - (n) Information on the diet order shall be specific and complete and include:
 - 1. The title of the diet;
 - 2. Modifications in specific nutrients stating the amount to be allowed in the diet; and
 - 3. Specific problems that may affect the diet or eating habits.
 - (o) Food shall be:
 - 1. Prepared by methods that conserve nutritive value, flavor, and appearance;
 - 2. Served at the proper temperatures; and
 - 3. Prepared in a form such as cut, chopped, or ground to meet individual needs.
 - (p) If a patient refuses foods served, a nutritious substitution shall be offered.
 - (q) At least three (3) meals or their equivalent shall be served daily with not more than a fifteen (15) hour span between a substantial evening meal and a breakfast unless otherwise directed by the attending medical staff member.
 - (r) Meals shall be served at regular times with between-meal or bedtime snacks of nourishing quality offered.
 - (s) There shall be at least a three (3) day supply of food available in the facility at all times to prepare well-balanced palatable meals for all patients.
 - (t) There shall be an identification system for patient trays and methods used to assure that each patient receives the appropriate diet as ordered.
 - (u) The hospital shall comply with all applicable provisions of ~~KRS 219.011 to KRS 219.081~~ and 902 KAR 45:005, the Kentucky food code.
- (4) Laboratory services.
- (a) The hospital shall have a well-organized, adequately supervised laboratory with the necessary space, facilities, and equipment to perform services commensurate with the hospital's needs for its patients.
 - (b) Anatomical pathology services and blood bank services shall be available in the hospital or by arrangement with other facilities.
 - 1. Clinical laboratory. Basic clinical laboratory services necessary for routine examinations shall be available regardless of the size, scope, and nature of the hospital.
 - a. Equipment necessary to perform the basic tests shall be provided by the hospital.
 - b. Equipment shall be in good working order, routinely checked, and precise in terms of calibration.
 - c. Provision shall be made to carry out adequate clinical laboratory examinations including chemistry, microbiology, hematology, immunology, and immunochemistry.

- d. Services may be provided through arrangement with another licensed hospital that has the appropriate laboratory facilities, or with an independent laboratory licensed pursuant to 42 C.F.R. Part 493, KRS 333.030, and relevant administrative regulations.
- e. The original report from a test performed by an outside laboratory shall be contained in the patient's medical record.
- f. Laboratory facilities and services shall be available at all times.
- g. Emergency laboratory services shall be available twenty-four (24) hours a day, seven (7) days a week, including holidays, in the hospital or through arrangement as specified in clause d. of this subparagraph.
- h. The conditions, procedures, and availability of a service performed by an outside laboratory shall be in writing and available in the hospital.
- i. There shall be a clinical laboratory director and a sufficient number of supervisors, technologists, and technicians to perform promptly and proficiently the tests requested of the laboratory.
- j. The laboratory shall not perform a procedure or test outside the scope of training of the laboratory personnel.
- k. Laboratory services shall be under the direction of a:
 - (i) Pathologist;
 - (ii) Doctor of medicine or osteopathy with training and experience in clinical laboratory services; or
 - (iii) Laboratory specialist with a doctoral degree in physical, chemical, or biological sciences, and training and experience in clinical laboratory services.
- l. A report of each laboratory service provided shall be filed with the patient's medical record.
 - (i) A duplicate copy shall be kept in the department.
 - (ii) Each request for a laboratory test shall be ordered and signed by qualified personnel in accordance with his or her scope of practice and the hospital's protocols and bylaws.
2. Anatomical pathology. Anatomical pathology services shall be provided as indicated by the needs of the hospital, either in the hospital or under arrangement as specified in subparagraph 1.d. of this paragraph.
 - a. Anatomical pathology services shall be under the direct supervision of a pathologist full-time, part-time, or on a consultative basis.
 - b. If the supervision is provided on a consultative basis, the hospital shall provide for at least monthly consultative visits by a pathologist.
 - c. The pathologist shall participate in staff, departmental, and clinicopathologic conference.
 - d. The pathologist shall be responsible for establishing the qualifications of staff and in-service training.
 - e. Except for exclusions listed in written policies of the medical staff, tissues removed at surgery shall be examined macroscopically, and if necessary, microscopically by the pathologist.
 - f. A list of tissues that do not routinely require microscopic examination shall be developed in writing by the pathologist or designated physician with the approval of the medical staff.
 - g. A tissue file shall be maintained in the hospital.
 - h. In the absence of a pathologist, there shall be an established plan for sending tissue to a pathologist outside the hospital if examination is required.
 - i. A signed report of a tissue examination shall be filed promptly with the patient's medical record.
 - j. A duplicate copy shall be kept in the department.

- k. Each report of a macroscopic or microscopic examination performed shall be signed by the pathologist.
 - l. Examination results shall be filed promptly in the patient's medical record.
 - m. The medical staff member requesting the examination shall be notified promptly.
 - n. A duplicate copy of each examination report shall be filed in the laboratory in a manner that permits ready identification and accessibility.
3. The laboratory shall meet the proficiency testing and quality control provisions in accordance with the certification requirements of 42 C.F.R. Part 493.
4. Blood bank. Facilities for procurement, safekeeping, and transfusion of blood and blood products shall be provided or shall be readily available.
- a. The hospital shall maintain proper blood storage facilities under adequate control and supervision of the pathologist or other authorized physician.
 - b. For emergency situations, the hospital shall:
 - (i) Maintain at least a minimum blood supply in the hospital at all times; and
 - (ii) Be able to obtain blood quickly from community blood banks or institutions.
 - c. If the hospital provides donor services, the hospital shall have an up-to-date list of donors and equipment necessary to obtain blood.
 - d. If the hospital utilizes outside blood banks, there shall be a written agreement governing the procurement, transfer, and availability of blood products between the hospital and donor center.
 - e. There shall be a provision for:
 - (i) Prompt blood typing and cross-matching; and
 - (ii) Laboratory investigation of transfusion reactions, either through the hospital or by arrangement with others on a continuous basis, under the supervision of a physician.
 - f. Blood storage facilities in the hospital shall have an adequate alarm system, which shall be:
 - (i) Regularly inspected and tested; and
 - (ii) Safe and adequate. Inspections of the alarm system shall be documented.
 - g. Records shall be kept on file indicating the receipt and disposition of blood provided to patients in the hospital.
 - h. A committee of the medical staff, or its equivalent, shall:
 - (i) Review transfusions of blood or blood derivatives; and
 - (ii) Make recommendations concerning policies governing transfusion practices.
 - i. Samples of each unit of blood used at the hospital shall be retained for further testing if there was an adverse reaction.
 - j. Blood not retained that has exceeded its expiration date shall be disposed of promptly.
 - k. The review committee shall:
 - (i) Investigate each transfusion reaction occurring in the hospital; and
 - (ii) Make recommendations to the medical staff regarding improvement in transfusion procedure.
- (5) Pharmaceutical services.
- (a) The hospital shall have adequate provisions for the handling, storing, recording, and distribution of pharmaceuticals in accordance with state and federal law.
 - (b) A hospital that maintains a pharmacy for compounding and dispensing of drugs shall provide pharmaceutical services under the supervision of a registered pharmacist on a full-time or part-time basis, according to the size and demands of the hospital.

- (c) The pharmacist shall be responsible for supervising and coordinating the activities of the pharmacy department.
- (d) Additional personnel competent in their respective duties shall be provided in keeping with the size and activity of the department.
- (e) A hospital that does not maintain a pharmacy shall have a drug room utilized only for the storage and distribution of drugs, drug supplies, and equipment.
1. Prescription medications shall be dispensed by a registered pharmacist elsewhere.
 2. The drug room shall be operated under the supervision of a pharmacist employed at least on a consultative basis.
- (f) The consulting pharmacist shall assist in drawing up correct procedures and directions for the distribution of drugs.
- (g) The consulting pharmacist shall visit the hospital on a regularly scheduled basis in the course of his or her duties.
- (h) The drug room shall be kept locked and the key shall be in the possession of a responsible person on the premises designated by the administrator.
- (i) Records shall be kept of the transactions of the pharmacy or drug room and correlated with other hospital records if indicated.
- (j) The pharmacy shall establish and maintain a system of records and bookkeeping in accordance with accounting procedures and policies of the hospital for:
1. Maintaining adequate control over the requisitioning and dispensing of drugs and drug supplies; and
 2. Charging patients for drugs and pharmaceutical supplies.
- (k) A record of the stock on hand and of the dispensing of every controlled substance shall be maintained to ensure that the disposition of any particular item may be readily traced.
- (l) The medical staff in cooperation with the pharmacist and other disciplines, as necessary, shall develop policies and procedures that govern the safe administration of drugs, including:
1. The administration of medications only upon the order of an individual who has been assigned clinical privileges or who is an authorized member of the house staff;
 2. Review of the original order or a direct copy by the pharmacist dispensing the drugs;
 3. The establishment and enforcement of automatic stop orders;
 4. Proper accounting for, and disposition of, unused medications or special prescriptions returned to the pharmacy if:
 - a. The patient is discharged; or
 - b. The medication or prescription does not meet requirements for sterility or labeling;
 5. Emergency pharmaceutical services; and
 6. Reporting adverse medication reactions to the:
 - a. Appropriate committee of the medical staff; and
 - b. Food and Drug Administration MedWatch Program.
- (m) Therapeutic ingredients of medications dispensed shall be favorably evaluated in the:
1. United States Pharmacopoeia;
 2. National Formulary; or
 3. United States Homeopath-Pharmacopoeia; Other necessary medication shall be approved for use by the appropriate committee of the medical staff.
- (n) A pharmacist shall be responsible for determining specifications and choosing acceptable sources for drugs with approval of the appropriate committee of the medical staff.

- (o) There shall be available a formulary or list of drugs accepted for use in the hospital, developed and amended as necessary by the appropriate committee of the medical staff.
- (6) Radiology services.
- (a) The hospital shall have:
1. Diagnostic radiology facilities currently licensed or registered pursuant to KRS 211.842 to 211.852;
 2. At least one (1) fixed diagnostic x-ray unit capable of general x-ray procedures;
 3. A radiologist on at least a consulting basis to:
 - a. Function as medical director of the department; and
 - b. Interpret films requiring specialized knowledge for accurate reading; and
 4. Personnel adequate to supervise and conduct services, including one (1) certified radiation operator who shall be on duty or on call at all times.
- (b) There shall be written policies and procedures governing radiologic services and administrative routines that support sound radiologic practices.
- (c) Signed reports shall be filed in the patient's record and duplicate copies kept in the department.
- (d) Radiologic services shall be performed only upon the written order of qualified personnel in accordance with the:
1. Professional's scope of practice; and
 2. Hospital's protocols and bylaws.
- (e) The written order shall contain a concise statement of the reason for the service or examination.
- (f) Reports of interpretations shall be written or dictated and signed by the radiologist.
- (g) Only an individual licensed pursuant to 201 KAR Chapter 46 and KRS Chapter 311B, under the direction of medical staff members, if necessary, shall use any x-ray apparatus or material. Uses include application, administration, and removal of:
1. Radioactive elements;
 2. Disintegration products; and
 3. Radioactive isotopes.
- (h) An individual licensed pursuant to 201 KAR Chapter 46 and KRS Chapter 311B, under the direction of a physician, may administer medications allowed within:
1. The professional's scope of practice; and
 2. Context of radiological services and procedures being performed.
- (i) The radiology department shall be free of hazards for patients and personnel.
- (j) Proper safety precautions shall be maintained against:
1. Fire and explosion hazards;
 2. Electrical hazards; and
 3. Radiation hazards.
- (7) Physical restoration or rehabilitation service.
- (a) If the hospital provides rehabilitation, work hardening, physical therapy, occupational therapy, audiology, or speech-language pathology services, the services shall be organized and staffed to insure the health and safety of patients.
- (b) A hospital that provides physical restoration or rehabilitation services shall provide individualized techniques intended to:
1. Achieve maximum physical function normal to the patient; and
 2. Prevent unnecessary debilitation and immobilization.
- (c) The hospital shall develop written policies and procedures for each rehabilitation service provided.
- (d) The hospital shall designate a member of the medical staff to coordinate restorative services provided to patients in accordance with their needs.
- (e) Therapeutic equipment shall be:

1. Adequate to meet the needs of the service; and
 2. In good condition.
- (f) Therapy services shall be provided only upon written orders of qualified personnel in accordance with the practitioner's scope of practice and according to the hospital's protocols and bylaws.
- (g) Therapy services shall be provided by or under the supervision of a licensed therapist, on a full-time, part-time, or consultative basis.
- (h) The hospital shall maintain a complete therapy record for each patient provided physical therapy services.
- (i) The report shall be:
1. Signed by the therapist who prepared the report; and
 2. Maintained in the patient's medical record.
- (8) Emergency services.
- (a) A hospital shall develop written procedures for emergency patient care, including a requirement for:
1. Each patient requesting emergency care to be evaluated by a registered nurse;
 2. At least one (1) registered nurse on duty to perform patient evaluation; and
 3. A physician to be on call.
- (b) A patient who presents at the hospital for emergency services shall be triaged by a registered nurse or paramedic acting:
1. Within his or her scope of practice; and
 2. In accordance with the hospital's formal operating policies and procedures.
- (c) The medical staff of a hospital within an organized emergency department shall establish and maintain a manual of policy and procedures for emergency and nursing care provided in the emergency room.
- (d) The emergency service shall be under the direction of a licensed physician.
- (e) Medical staff members shall be available at all times for the emergency service, either on duty or on call.
- (f) Current schedules and telephone numbers shall be posted in the emergency room.
- (g) Nursing personnel shall be assigned to or designated to cover the emergency service at all times.
- (h) Facilities shall be provided to assure prompt diagnosis and emergency treatment.
- (i) A specific area of the hospital shall be utilized for patients requiring emergency care on arrival.
- (j) The emergency area shall be:
1. Located in close proximity to an exterior entrance of the facility; and
 2. Independent of the operating room suite.
- (k) Diagnostic and treatment equipment, drugs, and supplies shall be:
1. Readily available for the provision of emergency services; and
 2. Adequate in terms of the scope of services provided.
- (l) Adequate medical records shall be:
1. Kept on every patient seen in the emergency room, under the supervision of the Medical Record Service; and
 2. If appropriate, integrated with inpatient and outpatient records.
- (m) Emergency room records shall include at least:
1. A log listing the patient visits to the emergency room in chronological order, including:
 - a. Patient identification;
 - b. Means of arrival;
 - c. Person transporting patient; and
 - d. Time of arrival;
 2. History of present complaint and physical findings;

3. Laboratory and x-ray reports, if applicable;
4. Diagnosis;
5. Treatment ordered and details of treatment provided;
6. Patient disposition;
7. Record of referrals;
8. Instructions to the patient or family for those not admitted to the hospital; and
9. Signatures of attending medical staff member, and nurse if applicable.

(9) Outpatient services.

(a) A hospital with an organized outpatient department shall have written policies and procedures relating to the staff, functions of service, and outpatient medical records.

(b) The outpatient department shall be organized in sections or clinics, the number of which shall depend on the:

1. Size and degree of departmentalization of the medical staff;
2. Available facilities; and
3. Needs of the patients the outpatient department serves.

(c) The outpatient department shall have appropriate cooperative arrangements and communications with community agencies, which may include:

1. Home health agencies;
2. The local health department;
3. Social and welfare agencies; and
4. Other outpatient departments.

(d) Each service offered by the outpatient department shall be under the direction of a:

1. Physician who shall be a member of the medical staff; or
2. Licensed healthcare practitioner qualified by education, experience, and specialized training related to the specific type of service under the practitioner's direction if the hospital has a separate director for each outpatient service.

(e) A registered nurse shall be responsible for the nursing services of the outpatient department.

(f) The number and type of other personnel employed shall be determined by the:

1. Volume and type of services provided; and
2. Type of patient served in the outpatient department.

(g) Necessary laboratory and other diagnostic tests shall be available through:

1. The hospital;
2. A laboratory in another licensed hospital; or
3. A laboratory licensed pursuant to KRS 333.030.

(h) Medical records shall be maintained and if appropriate, coordinated with other hospital medical records.

(i) The outpatient medical record shall be filed in a location that insures ready accessibility to the:

1. Medical staff members;
2. Nurses; and
3. Other personnel of the outpatient department.

(j) Information in the medical record shall be complete and sufficiently detailed relative to the patient's:

1. History;
2. Physical examination;
3. Laboratory and other diagnostic tests;
4. Diagnosis; and
5. Treatment.

(10) Surgery services.

(a) A hospital in which surgery is performed shall have an operating room and a recovery room supervised by a registered nurse qualified by training, experience, and

ability to direct surgical nursing care.

(b) Sufficient surgical equipment, including suction facilities and instruments in good repair, shall be provided to assure safe and aseptic treatment of surgical cases.

(c) If flammable anesthetics are used, precautions shall be taken to eliminate hazards of explosions, including:

1. Use of shoes with conductive soles; and
2. Prohibition of garments or other items of silk, wool, or synthetic fibers that accumulate static electricity.

(d) There shall be effective policies and procedures regarding:

1. Surgical staff privileges;
2. Functions of the service; ~~and~~
3. Evaluation of the surgical patient; and
4. Surgical smoke safety and control. The smoke evacuation policy shall be available to staff in all areas where surgical smoke is generated.

(e)

1. In accordance with KRS 216B.153, a hospital that utilizes an energy-generating device shall make use of a smoke evacuation system:

a. That effectively captures and neutralizes surgical smoke at the site of origin and before the smoke can make ocular contact or contact with the respiratory tract of the occupants of the room; and

b. During any surgical procedure that is likely to produce surgical smoke.

2. The cabinet shall impose fines in accordance with KRS 216B.990(8) for each violation of noncompliance with KRS 216B.153 only if the violation has not been remedied after the hospital has had an opportunity to correct the violation through the filing of a plan of correction in accordance with 902 KAR 20:008, Section 2(13).

(f) Surgical privileges shall be delineated for each member of the medical staff performing surgery in accordance with the competencies of each staff member.

(g) ~~(f)~~ A roster of medical staff specifying the surgical privileges of each shall be maintained.

(h) ~~(g)~~ Except in emergency, a surgical operation or other hazardous procedure shall be performed only on written consent of the patient or the patient's legal representative.

(i) ~~(h)~~ The operating room register shall:

1. Be complete and up to date; and
2. Include the following:
 - a. Patient's name;
 - b. Hospital room number;
 - c. Preoperative and postoperative diagnosis;
 - d. Complications, if any;
 - e. Names of:
 - (i) Surgeon;
 - (ii) First assistant;
 - (iii) Anesthesiologist or an advanced practice registered nurse who is a certified registered nurse anesthetist; and
 - (iv) Scrub and circulating nurse;
 - f. Operation performed; and
 - g. Type of anesthesia.

(j) ~~(i)~~ There shall be a complete history and physical workup in the chart of each patient prior to surgery.

(k) ~~(j)~~ If the history and workup has been transcribed, but not yet recorded in the patient's chart, there shall be a statement to that effect and an admission note by the attending medical staff member in the chart.

(l) ~~(k)~~ The chart shall:

1. Accompany the patient to the operating suite; and
 2. Be returned to the patient's floor or room after the operation.
- (m) ~~[(1)]~~ An operative report describing the techniques and findings shall be:
1. Written or dictated immediately following surgery; and
 2. Signed by the surgeon.
- (n) ~~[(m)]~~ Tissues removed by surgery shall be:
1. Placed in suitable solutions;
 2. Properly labeled; and
 3. Submitted to the pathologist for macroscopic and, if necessary, microscopic examination.
- (o) ~~[(n)]~~ An infection of a clean surgical case shall be recorded and reported to the Infection Control Program. The program shall investigate according to established procedures for investigation and review of surgical site infections.
- (p) ~~[(o)]~~ Rules and policies related to the operating rooms shall be available and posted.
- (11) Anesthesia services.
- (a) A hospital that provides surgical or obstetrical services shall have anesthesia services available.
 - (b) Anesthesia services shall be organized under written policies and procedures regarding:
 1. Staff privileges;
 2. The administration of anesthetics; and
 3. The maintenance of safety controls.
 - (c) A physician member of the medical staff shall be the medical director of anesthesia services.
 - (d) If possible, the director shall be a physician specializing in anesthesiology.
 - (e) If anesthetics are not administered by an anesthesiologist, the medical staff shall designate an advanced practice registered nurse who is a certified registered nurse anesthetist qualified to administer anesthetics.
 - (f) A qualified medical staff member or licensed practitioner functioning within their scope of practice shall perform a preanesthetic physical examination for every patient requiring anesthesia services.
 - (g) The following shall be recorded within forty-eight (48) hours of surgery:
 1. Findings of the preanesthetic physical examination;
 2. An anesthetic record on a special form; and
 3. A postanesthetic follow-up, with findings recorded by the:
 - a. Anesthesiologist; or
 - b. Advanced practice registered nurse who is a certified registered nurse anesthetist.
 - (h) The postanesthetic follow-up note shall:
 1. Be written:
 - a. Upon discharge from the postanesthesia recovery area; or
 - b. Within three (3) to twenty-four (24) hours after the procedure requiring anesthesia; and
 2. Include:
 - a. Blood pressure and pulse measurements;
 - b. Presence or absence of the swallowing reflex and cyanosis;
 - c. Postoperative abnormalities or complications; and
 - d. The patient's general condition.
- (12) Obstetrics service.
- (a) A hospital providing obstetrical care shall have:
 1. Adequate space;

2. Necessary equipment and supplies; and
 3. A sufficient number of nursing personnel to:
 - a. Assure safe and aseptic treatment of mothers and newborns; and
 - b. Provide protection from infection and cross-infection.
 - (b) The obstetrics service shall be under the:
 1. Medical direction of a physician; and
 2. Supervision of a registered nurse qualified by training, experience, and ability to direct effective obstetrical and newborn nursing care.
 - (c) If a hospital has an obstetrical caseload that does not justify a separate nursing staff, the hospital's obstetrical nurses shall be designated and oriented to the specific needs of obstetrical patients.
 - (d) A registered nurse shall be on duty in the labor and delivery unit if a patient is in the unit.
 - (e) Each obstetrics patient shall be kept under close observation by professional personnel during the period of recovery after delivery, whether in the delivery room or in a recovery area, until the patient is transferred to the maternity unit.
 - (f) An on-call schedule or other suitable arrangement shall be provided to ensure that a physician who is experienced in obstetrics is readily available for consultation and for an obstetrical emergency.
 - (g) Patients in labor shall be cared for in adequately equipped labor rooms.
 - (h) An adequate supply of prophylaxis for the prevention of infant blindness shall be kept on hand and administered within thirty (30) minutes after delivery~~[, in accordance with 902 KAR 4:020]~~.
 - (i) The hospital shall comply with the provisions of KRS 214.155 and 902 KAR 4:030 in administering tests for inborn errors of metabolism and other inherited and congenital disorders.
 - (j) The hospital shall have a method and procedure for the positive associative identification of the mother and infant.
 - (k) The identifiers shall be placed on mother and newborn in the delivery room at the time of birth and shall remain in place during the entire period of hospitalization.
 - (l) An up-to-date register book of deliveries shall be maintained containing the following information:
 1. Infant's full name, sex, date, time of birth, and weight;
 2. Mother's full name, including maiden name, address, birthplace, and age at time of this birth;
 3. Father's full name, birthplace, and age at time of this birth; and
 4. Full name of attending physician or nurse midwife.
 - (m) Each hospital providing maternity service shall provide a nursery not used for any other purpose.
 - (n) Specific routines for daily care of infants and their environment shall be prepared in writing and posted in the nursery workroom.
 - (o) A policy shall be established for:
 1. A delivery occurring outside the delivery room; and
 2. A patient with an infectious disease.
 - (p) Written policies and procedures shall be developed to cover alternative use of obstetrical beds.
 - (q) The hospital shall comply with the provisions of KRS 214.175 by participating in surveys conducted by the cabinet for the purpose of determining the prevalence of alcohol or other substance abuse among pregnant women and newborn infants.
 - (r) The hospital shall comply with the provisions of KRS 216.2970 by providing an auditory screening for all newborn infants.
- (13) Pediatric services.

- (a) A hospital providing pediatric care shall have proper facilities for the care of children apart from the newborn and maternity nursing services.
 - (b) If there is not a separate area permanently designated as the pediatric unit, there shall be an area within an adult care unit for pediatric patient care.
 - (c) There shall be available beds and other equipment that are appropriate in size for pediatric patients.
 - (d) There shall be proper facilities and procedures for the isolation of children with infectious, contagious, or communicable conditions.
 - (e) At least one (1) patient room shall be available for isolation use.
 - (f) A physician with pediatric experience shall be on call at all times for the care of pediatric patients.
 - (g) Pediatric nursing care shall be under the supervision of a registered nurse qualified by training, experience, and ability to direct effective pediatric nursing.
 - (h) Nursing personnel assigned to pediatric service shall be oriented to the special care of children.
 - (i) Policies shall be established to cover conditions under which parents may stay with small children or "room-in" with their hospitalized child for moral support and assistance with care.
- (14) Psychiatric services. A hospital with a psychiatric unit shall:
- (a) Designate the location and number of beds to be licensed as psychiatric beds; and
 - (b) Meet the requirements of 902 KAR 20:180.
- (15) Chemical dependency treatment services. A hospital providing chemical dependency treatment services shall:
- (a) Meet the requirements of 902 KAR 20:160, Sections 3 and 4; and
 - (b) Designate the location and number of beds to be used for chemical dependency treatment services.
- (16) Medical library.
- (a) The hospital shall maintain appropriate medical library services according to the professional and technical needs of hospital personnel.
 - (b) The medical library shall be in a location accessible to the professional staff.
 - (c) If printed resources are used, the library collection shall be organized.
 - (d) The library collection may be composed of digital references, which shall be on line or accessible on a computer.

Section 5. Long-term Acute Inpatient Hospital Services.

- (1) A hospital licensed pursuant to this administrative regulation and seeking to qualify for available Title XVIII Medicare reimbursement may provide long-term acute inpatient hospital services pursuant to applicable federal law and in accordance with this section.
- (2) The area of the hospital designated to provide long-term acute inpatient hospital services shall provide services in compliance with:
 - (a) This administrative regulation; and
 - (b) 42 C.F.R. 412.22.
- (3) A hospital wishing to provide long-term acute inpatient hospital services shall request authorization from the Office of Inspector General, Cabinet for Health and Family Services.
- (4) The Office of Inspector General shall conduct a survey to determine if the requirements of this section are met and notify the hospital of the survey results by letter.

Section 6. Optional Designations. A hospital shall be designated as a:

- (1) Primary stroke center if the hospital meets the criteria established in KRS 216B.0425(2); or
- (2) SANE-ready hospital if the hospital meets the criteria established in KRS 216B.401(1).

Section 7. Off-campus, Kentucky Hospital-Owned Freestanding Emergency Department (FSED).

(1) A hospital licensed pursuant to this administrative regulation may provide off-campus emergency services in a hospital-owned FSED. For purposes of this section, "off-campus" shall mean a location:

(a) Off the campus of the parent hospital that owns the FSED; and

(b) At least thirty-five (35) miles from an existing hospital that is:

1. Licensed pursuant to this administrative regulation; and

2. Designated as a sole community hospital pursuant to 42 C.F.R. 412.92.

(2) If a Kentucky-licensed hospital owns and operates an outpatient clinic that provides ambulatory care ~~clinic licensed under 902 KAR 20:073 prior to July 15, 2018, or holds a certificate of need for an ambulatory care clinic that is not licensed by that date, the hospital shall notify the cabinet no later than ninety (90) days from the effective date of this administrative regulation of the clinic's scope of operations. The hospital's notification shall inform the cabinet whether the clinic will:~~

~~[(a)] [Operate as an FSED, in which case the facility shall:]~~

~~[1.] [Provide emergency services in accordance with Section 4(8) of this administrative] [regulation;]~~

~~[2.] [Be designated as provider-based pursuant to 42 C.F.R. 413.65;]~~

~~[3.] [Not be required to obtain a new certificate of need; and]~~

~~[4.] [Obtain a separate license under 902 KAR Chapter 20 for any existing service provided under the ambulatory care clinic license and covered under Section IV of the State Health Plan without being subject to a separate certificate of need; or]~~

~~[(b)] [Provide] services that are limited to treatment for minor injury or illness, [in which case] the clinic shall not hold itself out to the public as an emergency treatment center or use similar terminology that expresses or implies that emergency medical service is offered at the clinic. This subsection[paragraph] shall not prohibit the clinic from holding itself out to the public as an urgent treatment center.~~

(3) A Kentucky-licensed hospital that seeks to establish an FSED ~~[under circumstances not covered under subsection (2)(a) of this section]~~ shall obtain a certificate of need.

(4) An FSED shall:

(a) Be owned by an accredited Kentucky hospital licensed under this administrative regulation;

(b) Be included under the same license and accreditation as the parent hospital;

(c) Meet the requirements of and be certified by the Centers for Medicare and Medicaid Services as a provider-based entity under 42 C.F.R. 413.65;

(d) Pay a fee in the amount of \$1,000 for the FSED location at the time of annual renewal of the hospital's license;

(e) Operate twenty-four (24) hours per day, seven (7) days per week;

(f) Comply with the provisions of Section 4(8) of this administrative regulation governing emergency services;

(g) Be under the direction of a licensed physician who is a member of the parent hospital's organized medical staff;

(h) Ensure that nursing personnel are assigned to or designated to cover the emergency service at all times;

(i) Comply with the Emergency Medical Treatment and Labor Act (42 U.S.C. 1395dd) and 42 C.F.R. 489.24;

(j) Have facilities sufficient to assure prompt diagnosis, treatment, and stabilization of injuries and trauma;

(k) Have a written patient transportation agreement with a local emergency medical services (EMS) provider; and

(l) Maintain compliance with applicable federal, state, and local laws.

- (5) An FSED shall cease to operate under this administrative regulation if the:
- (a) Cabinet finds that there has been substantial failure by the facility to comply with the provisions of KRS Chapter 216B or this administrative regulation; and
 - (b) Facility fails to submit and implement an acceptable plan of correction or amended plan of correction in accordance with 902 KAR 20:008, Section 2(13).
- (6) If an FSED receives notice to cease operations in accordance with subsection (5) of this section, the parent hospital may file a request in writing for a hearing pursuant to KRS 216B.105.

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: November 12, 2021

FILED WITH LRC: December 28, 2021 at 8:30 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on March 21, 2022, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by March 14, 2022, 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. This hearing is open to the public. Any person who attends virtually 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 be heard at the public hearing, you may submit written comments on this proposed administrative regulation until March 31, 2022. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Kara Daniel; Stephanie Brammer-Barnes; Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the minimum licensure requirements for the operation of and services provided by hospitals.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to comply with KRS 216B.042(1), which requires the Cabinet for Health and Family Services to establish licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

This administrative regulation conforms to the content of KRS 216B.042(1) by establishing the minimum licensure requirements for the operation of and services provided by hospitals.

(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 the statutes by establishing the minimum licensure requirements for the operation of and services provided by hospitals.

(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 is required by KRS 216B.153, a new law created by the passage of SB 38 from the 2021 session of the Kentucky General Assembly. KRS 216B.153(2) directs the cabinet to promulgate administrative regulations to require a health facility that utilizes energy generating devices to make use of a smoke evacuation system during any surgical procedure that is likely to produce surgical smoke. In addition, this amendment updates Section 4(1)(b)2. to align with federal guidelines that do not require Medicaid or other non-Medicare patients to be under the care of a doctor of medicine or osteopathy if the patient is admitted by a certified nurse midwife. This amendment also deletes an outdated reporting requirement from Section 7 that required hospitals to notify the cabinet within ninety (90) days from the effective date of this administrative regulation (August 31, 2018) if the hospital owned a previously licensed, off-campus ambulatory care clinic that provided emergency services, in which case the clinic's licensure status was converted to a freestanding emergency department operating under the hospital's license. The outdated reporting requirement also pertained to any hospital that previously held an unimplemented certificate of need for an ambulatory care clinic in which case the hospital was required to report whether it intended to operate the facility as a freestanding emergency department in the future.

(b) The necessity of the amendment to this administrative regulation:

This amendment is required by KRS 216B.153.

(c) How the amendment conforms to the content of the authorizing statutes:

This amendment conforms to the content of KRS 216B.153 by creating a requirement for hospitals to make use of a smoke evacuation system during any surgical procedure that is likely to produce surgical smoke.

(d) How the amendment will assist in the effective administration of the statutes:

This amendment will assist in the effective administration of the statutes by adding a requirement for the use of surgical smoke evacuation systems pursuant to KRS 216B.153 and by making additional housekeeping changes.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

This amendment affects hospitals that provide surgical procedures that are likely to produce surgical smoke. There are currently 69 acute care hospitals licensed in Kentucky.

(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:

Hospitals will be required to make use of a smoke evacuation system during any surgical procedure that is likely to produce surgical smoke.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

If a hospital does not currently have a smoke evacuation system as defined by KRS 216B.153(1)(b), the facility will incur costs associated with the purchase of a system.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Surgical smoke generated by the use of an energy-generating device during a surgical procedure contains toxic and biohazardous substances that present risks to perioperative team members and patients. Therefore, the use of smoke evacuation equipment required by this amendment will protect health care workers and patients from the harmful effects of surgical smoke.

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

(a) Initially:

There are no additional costs to the Office of Inspector General for implementation of this amendment.

(b) On a continuing basis:

There are no additional costs to the Office of Inspector General for implementation of this amendment 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 used for the implementation and enforcement of the licensure function is from federal funds and state matching funds of general and agency appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

No increase in fees or funding is necessary to implement this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees:

This amendment does not establish or increase any fees.

(9) TIERING: Is tiering applied?

Tiering is not applicable as compliance with this administrative regulation applies equally to all hospitals regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

This administrative regulation affects Kentucky-licensed hospitals. This administrative regulation also impacts the Cabinet for Health and Family Services, Office of Inspector General.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 216B.042, 216B.153

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

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

Although KRS 216B.990(8) authorizes the cabinet to impose a fine ranging from \$100 to \$500 for each violation of KRS 216B.153, the cabinet is unable to predict with accuracy how many violations may be cited or otherwise determine the amount of fines that may be collected.

(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?

The cabinet is unable to predict with accuracy how many violations may be cited or otherwise determine the amount of fines that may be collected.

(c) How much will it cost to administer this program for the first year?

This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years?

This amendment imposes no additional costs on the administrative body during subsequent years.

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

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.

29 C.F.R 1910.1030(d)(2)(vii), 40 C.F.R. Part 403, 42 C.F.R. Part 405, 412.22, 412.92, 413.65, 482.12(c), 489.24, Part 493, 45 C.F.R. 160, 164, 42 U.S.C. 1320d-2 - 1320d-8, 1395u(b)(18)(C), 42 U.S.C. 1395x(r)(2) – (5), 1395dd

(2) State compliance standards.

KRS 216B.042

(3) Minimum or uniform standards contained in the federal mandate.

29 C.F.R 1910.1030(d)(2)(vii) establishes the prohibition against contaminated needles and other contaminated sharps from being bent, recapped, or removed except in certain limited situations. Shearing or breaking of contaminated needles is prohibited. 40 C.F.R. Part 403 implements sections of the Federal Water Pollution Control Act, which establishes responsibilities of federal, state, and local government, industry and the public to implement National Pretreatment Standards to control pollutants which pass through or interfere with treatment processes in Publicly Owned Treatment Works (POTWs) or which may contaminate sewage sludge. 42 C.F.R. Part 405 establishes the Medicare program. 42 C.F.R. 412.22 establishes rules for hospitals and hospital units that are excluded from prospective payment systems for inpatient services. 42 C.F.R. 412.92 establishes rules for classification as a sole community hospital. 42 C.F.R. 413.65 establishes rules for determination of provider-based status for payment purposes. 42 C.F.R. 482 establishes the Conditions of Participation that hospitals must meet to participate in the Medicare and Medicaid Programs. 42 C.F.R. 482.12(c)(1) establishes federal requirements for a hospital's governing body. 42 C.F.R. 489.24 requires hospitals with an emergency department to comply with the Emergency Medical Treatment and Labor Act (EMTALA). 42 C.F.R. 493 is the section of the federal regulations titled "Standards and Certification: Laboratory Requirements", issued by the Centers for Medicare and Medicaid Services to enact the Clinical Laboratory Improvement Amendments (CLIA) law that establishes quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid, and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health. 45 C.F.R. 160, 164, and 42 U.S.C. 1320d-2 – 1320d-8 establish the HIPAA privacy rules to protect individuals' medical records and other personal health information. 42 U.S.C. 1395x(r)(2) – (5) and 42 U.S.C. 1395u(b)(18)(C) are federal Medicare laws that describe what types of licensed practitioners may be appointed to the medical staff of a hospital. 42 U.S.C. 1395dd, the Emergency Medical Treatment and Labor Act, ensures public access to emergency services regardless of ability to pay.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

This administrative regulation does not impose requirements that are more strict than federal laws or regulations.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

Not applicable.