

## **902 KAR 20:101. Facility specifications; ambulatory surgical center.**

RELATES TO: KRS 216B.010-216B.130, 216B.990(1), (2)

STATUTORY AUTHORITY: KRS 216B.042, 216B.105

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 and 216B.105 mandate that the Kentucky Cabinet for Human Resources regulate health facilities and health services. This administrative regulation provides licensure requirements for facility specifications for construction, alteration and maintenance of ambulatory surgical centers.

Section 1. Definitions. (1) "Board" means the Commission for Health Economics Control in Kentucky.

(2) "License" means an authorization issued by the Board for the purpose of operating an ambulatory surgical center and offering ambulatory surgical services.

(3) "Licensure agency" means the Division for Licensing and Regulation in the Office of the Inspector General, Cabinet for Human Resources.

Section 2. Preparation and Approval of Plans and Specifications. After receiving a certificate of need from the board, the following procedures shall be followed:

(1) Before construction is begun for the erection of new buildings or alterations to existing buildings or any change in facilities, the licensee or applicant shall submit plans in the detail specified in Section 3 to the licensure agency for approval.

(2) All architectural, mechanical and electrical drawings shall bear either the seal of an architect registered in the Commonwealth of Kentucky or the seal of a professional engineer registered in the Commonwealth of Kentucky, or both.

(3) Drawings shall not exceed thirty-six (36) inches by forty-six (46) inches when trimmed.

(4) All such plans and specifications shall be approved by the licensure agency prior to commencement of construction of new buildings or alterations of existing buildings.

(5) Plans and specifications in specific detail as required by the Kentucky Building Code shall be submitted together with architectural and/or engineering stamps as required by KRS Chapters 322 and 323, to the Department of Housing, Buildings and Construction for determining compliance with the Kentucky Building Code. All such plans and specifications shall be approved by the Department of Housing, Buildings and Construction, and appropriate local building permits shall be obtained prior to commencement of construction.

Section 3. Submission of Plans and Specifications. (1) First stage; schematic plans. Single line drawings of each floor shall show the relationship of the various departments or services to each other and the room arrangement in each department. The name of each room shall be noted. Drawings shall include the typical patient room layouts (scaled one-fourth (1/4) inch equals one (1) foot) with dimensions noted. The proposed roads and walks, service and entrance courts, parking and orientation shall be shown in a plot plan.

(2) Second stage; preliminary plans.

(a) Architectural: plans of basement and floors.

(b) Outline specifications.

1. General description of the construction, including interior finishes, types and locations of acoustical material, and special floor covering;

2. Description of the air-conditioning, heating, and ventilation systems and their controls, duct and piping systems; and dietary, laundry, sterilizing and other special equipment;

3. General description of electrical service including voltage, number of feeders, and whether feeders are overhead or underground.

(3) Third stage; contract documents.

(a) Working drawings. Working drawings shall be complete and adequate for bid, contract, and construction purposes. Drawings shall be prepared for each of the following branches of the work: architectural, structural, mechanical, and electrical. They shall include the following:

1. Architectural drawings.

- a. Approach plan showing all new topography, newly established levels and grades, existing structures on the site (if any), new building structures, roadways, walks, and parking areas;
- b. Plan of each basement, floor and roof;
- c. Elevations of each facade;
- d. Sections through building;
- e. Required scale and full-size details;
- f. Schedule of doors, windows, and room finishes;
- g. Equipment; location of all fixed equipment. Layout of typical and special rooms indicating all fixed equipment and major items of movable equipment. Equipment not included in contract shall be so indicated;
- h. Conveying systems; details of construction, machine and control spaces necessary, size and type of equipment, and utility requirements, for the following: dumbwaiters: electric, hand, hydraulic; elevators: freight, passenger, patient; loading dock devices; pneumatic tube systems.

2. Structural drawings.

- a. Plans for foundations, floors, roofs, and all intermediate levels with sizes, sections, and the relative location of the various structural members;
- b. Dimensions of special openings;
- c. Details of all special connections, assemblies, and expansion joints.

3. Mechanical drawings.

- a. Heating, steam piping, and air-conditioning systems; radiators and steam heated equipment, such as sterilizers, warmers, and steam tables; heating and steam mains and branches with pipe sizes; diagram of heating and steam risers with pipe sizes; sizes, types, and capacities of boilers, furnaces, hot water heaters with stokers, oil burners, or gas burners; pumps, tanks, boiler breeching, and piping and boiler room accessories; air-conditioning systems with required equipment, water and refrigerant piping, and ducts; supply and exhaust ventilation systems with heating/cooling connections and piping; air quantities for all room supply and exhaust ventilating duct openings.
- b. Plumbing, drainage, and standpipe systems; size and elevation of: street sewer, house sewer, house drains, street water main, and water service into the building; location and size of soil, waste, and water service with connections to house drains, clean-outs, fixtures, and equipment; size and location of hot, cold and circulating branches, and risers from the service entrance, and tanks; riser diagram of all plumbing stacks with vents, water risers, and fixture connections; gas, oxygen, and vacuum systems; standpipe and sprinkler systems where required; all fixtures and equipment that require water and drain connections.

4. Electrical drawings.

- a. Electric service entrance with switches and feeders to the public service feeders, characteristics of the light and power current, transformers and their connections if located in the building;
- b. Location of main switchboard, power panels, light panels, and equipment. Diagram of feeder and conduits with schedule of feeder breakers or switches;
- c. Light outlets, receptacles, switches, power outlets, and circuits;
- d. Telephone layout showing service entrance, telephone switchboard, strip boxes, telephone outlets, and branch conduits;
- e. Nurses' call systems with outlets for beds, duty stations, door signal light, annunciators, and wiring diagrams;
- f. Fire alarm system with stations, signal devices, control board, and wiring diagrams;

g. Emergency electrical system with outlets, transfer switch, sources of supply, feeders, and circuits;

h. All other electrically operated systems and equipment.

(b) Specifications. Specifications shall supplement the drawings to fully describe types, sizes, capacities, workmanship, finishes and other characteristics of all materials and equipment and shall include:

1. Cover or title sheet;

2. Index;

3. Sections describing materials and workmanship in detail for each class of work.

(c) Access to the work. Representatives of the appropriate state agencies shall have access at all reasonable times to the work wherever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

Section 4. Compliance with Building Codes, Ordinances and Regulations. (1) This section may be administered independently from other sections of this administrative regulation.

(2) General. Nothing stated herein shall relieve the sponsor from compliance with building codes, ordinances, and regulations which are enforced by city, county, or state jurisdictions.

(3) The following requirements shall apply where applicable and as adopted by the respective agency authority:

(a) Requirements for safety pursuant to 815 KAR 10:020, as amended.

(b) Requirements for plumbing pursuant to 815 KAR 20:010 through 190, as amended.

(c) Requirements for air contaminants for incinerators pursuant to 401 KAR 59:020 and 401 KAR 61:010.

(d) Requirements for elevators pursuant to 803 KAR 4:010.

(e) Requirements for making buildings and facilities accessible to and usable by the physically handicapped, pursuant to KRS 198B.260 and administrative regulations promulgated thereunder.

(f) Requirements for radiation protection in x-ray and gamma ray installations pursuant to 902 KAR Chapter 100.

(4) Prior to occupancy, the facility shall have final approval from appropriate agencies.

(5) All facilities shall be currently approved by the Fire Marshal's Office in accordance with the Life Safety Code, before relicensure is granted by the licensure agency.

Section 5. General Facility Requirements and Special Conditions. (1) All ambulatory surgical center facilities shall contain at least all the elements described herein, or the narrative program shall indicate the manner in which the needed services are to be provided and identify appropriate modifications or deletions in space and equipment requirements. Each element provided in the ambulatory surgical center facility must meet the construction requirements outlined herein as a minimum, with the understanding that in many instances the elements will need to be expanded to fulfill the program requirements.

(2) A narrative program for each project shall be provided by the sponsor which describes the functional space requirements, staffing patterns, departmental relationships, and other basic information relating to the fulfillment of the objectives of the facility.

(3) The extent (number and types of rooms) of the diagnostic, clinical, and administrative facilities to be provided shall be determined by the services contemplated and the estimated patient load as described in the narrative program.

(4) The planning of ambulatory surgical center facilities shall provide for the privacy and dignity of the patient during interview, examination, and treatment.

(5) Facilities shall be available and accessible to the public, staff, and patients who may be physically handicapped. Special attention shall be given to ramps, drinking fountain height, mirrors, and

other items deemed necessary for the physically handicapped.

(6) The facility shall have adequate administrative, public, and staff facilities (e.g., offices, lobby, toilet facilities) to accommodate the needs of the public, patients, and staff without interfering with the provision of medical care services.

Section 6. Clinical Facilities. (1) General purpose examination room(s) to be used for medical examinations shall have a minimum clear floor area of eighty (80) square feet, excluding such other spaces as vestibule, toilet, closet, and work counter (whether fixed or movable). Arrangement shall permit at least thirty (30) inches of clear space at each side and at foot of examination table. Provide lavatory or sink with handwashing facility and counter or shelf space for writing.

(2) Facilities for charting and for clinical records (nurses' station(s)). Provide counter space, temporary storage, and communication device; these may be located in each examination room and each treatment room.

(3) Drug distribution station. If the facility is to maintain a medication preparation room for the proper storage of drugs and biologicals, it shall be so located as to be under the nursing staff's visual control. It shall contain a work counter, refrigerator, and locked storage for drugs and biologicals.

Section 7. Medical Records Unit. This unit shall include:

- (1) Active record storage area;
- (2) Record review and dictating room;
- (3) Work area for sorting, recording, or microfilming;
- (4) Inactive record storage area. (May be omitted if microfilming is used.)

Section 8. Diagnostic Facilities. (1) Radiology suite. If the facility provides radiology directly it shall provide equipment for diagnostic purposes but may also include therapeutic equipment. The suite shall contain:

- (a) Radiographic room(s);
- (b) Film processing facilities;
- (c) Viewing and administration area(s);
- (d) Film storage facilities;
- (e) Toilet room which is directly accessible from each fluoroscopy room without entering the general corridor area;
- (f) Dressing area(s) with convenient access to public toilets.

(2) Laboratory facilities. Facilities shall be provided directly within the ambulatory surgical center or through a contract arrangement with a nearby hospital or laboratory service for hematology, clinical chemistry, urinalysis, cytology, and bacteriology. If these facilities are provided through such a contract, then at least the following shall be provided:

- (a) Laboratory work counter(s) with sink, gas and electric service;
- (b) Lavatory(ies) with handwashing facility;
- (c) Storage cabinet(s) or closet(s);
- (d) Specimen collection facilities. Urine collection rooms shall be equipped with a water closet and lavatory. Blood collection facilities shall have space for a chair and work counter.

Section 9. Janitor's Closet(s). This room shall contain a sink and storage for housekeeping supplies and equipment. Provide at least one (1) janitor's closet per floor.

Section 10. Surgical Suite. (1) General. The suite shall be located to prevent through-traffic.

(2) Operating rooms. Each room shall have a minimum clear floor area of 240 square feet, with a minimum dimension of fifteen (15) feet.

(3) Recovery facilities. A separate room with charting space, medication storage and preparation space, and clinical sink is required.

(4) Service areas in each surgical suite. The size of each service area will depend on the surgical workload and shall include:

- (a) Surgical supervisor station;
- (b) Sterilizing facilities; near operating room with high-speed autoclave;
- (c) Facilities for storage and preparation of medication;
- (d) Scrub-up facilities; adjacent to operating rooms;
- (e) Soiled workroom. Shall contain counter, clinical sink, waste receptacles, and soiled linen receptacles;
- (f) Storage for sterile and unsterile supplies (may be in clean workroom);
- (g) Anesthesia workroom for cleaning and storage of equipment;
- (h) Storage room for anesthetic agents;
- (i) Nitrous oxide and oxygen facilities (provide storage room if these services are not piped in);
- (j) Clean workroom for storage and assembly of supplies; shall contain counter and sink;
- (k) Equipment storage room for surgical and monitoring equipment;
- (l) Janitor's closet. Floor receptor or service sink and storage for housekeeping supplies and equipment;
- (m) Clothing change areas, lockers, and toilet rooms for doctors, nurses, orderlies, and other personnel;
- (n) Holding area (for patients) in facilities with two (2) or more operating rooms;
- (o) Stretcher alcove.

Section 11. Central Medical and Surgical Supply Department. The following areas shall be separated from each other:

(1) Receiving and cleanup room. Space for cleaning equipment and disposing or processing of unclean articles shall be provided.

(2) Clean workroom. This room shall be divided into work space, clean storage area, sterilizing facilities, and storage area for sterile supplies.

(3) Unsterile supply storage area. May be located in an area other than this department.

Section 12. Engineering Service and Equipment Areas. The following shall be provided:

(1) Room(s) for boilers, mechanical equipment, and electrical equipment.

(2) Refuse storage room. This shall be located convenient to service entrance.

(3) Waste processing services:

(a) Provide space and facilities for the sanitary storage and disposal of waste by incineration, mechanical destruction, compaction, containerization, or removal, or by a combination of these techniques.

(b) If provided, the incinerator shall be in a separate room, in a designated area within the boiler room, or placed outdoors.

Section 13. Details and Finishes. All details and finishes shall meet the following requirements:

(1) Details.

(a) Corridors inside surgical suite shall be eight (8) feet minimum width.

(b) All doors to toilets which may be used by patients shall be equipped with hardware which will permit access in any emergency.

(c) The minimum width of doors for patient access to examination rooms shall be three (3) feet. Minimum width of doors to all rooms needing access for beds or stretchers shall be three (3) feet and eight (8) inches.

(d) Thresholds and expansion joint covers shall be made flush with the floor surface to facilitate use of wheelchairs and carts.

(e) The location and arrangement of handwashing facilities shall permit their proper use and operation. Particular care shall be given to the clearances required for blade-type operating handles.

(f) Paper towel dispensers and waste receptacles shall be provided at all lavatories and sinks used for hand washing.

(g) Ceiling heights:

1. Boiler rooms: Not less than two (2) feet and six (6) inches above the main boiler header and connecting piping.

2. Radiographic and other rooms containing ceiling mounted equipment and including those having ceiling mounted surgical light fixtures shall have a height of not less than nine (9) feet.

3. All other rooms shall have ceilings not less than eight (8) feet high except that ceilings in corridors, storage rooms, toilet rooms, and other minor rooms may be not less than seven (7) feet and eight (8) inches. Tracks, rails, pipes, etc., located in the path of normal traffic, shall be not less than six (6) feet and eight (8) inches above the floor.

(h) Rooms containing heat producing equipment (such as boiler or heater rooms) shall be insulated and ventilated to prevent any floor surface above from exceeding a temperature ten (10) degrees Fahrenheit above the ambient room temperature.

(2) Finishes.

(a) Floor materials shall be easily cleanable and have wear resistance appropriate for the location involved. In all areas subject to frequent wet cleaning, floor materials shall not be physically affected by germicidal and cleaning solutions. Floors that are subject to traffic while wet, as shower and bath areas and certain work areas, shall have a nonslip surface.

(b) Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth, moisture resistant, and easily cleaned.

(c) Wall bases in areas used for surgical procedures, and other areas subject to frequent wet cleaning shall be made integral and coved with the floor, tightly sealed within the wall, and constructed without voids that can harbor insects.

(d) Floor and wall penetrations by pipes, ducts, conduits, etc., shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(e) Acoustical ceilings shall be provided in corridors, multipurpose rooms, and waiting areas.

(f) Ceilings in operating suites shall be washable.

Section 14. Construction. Foundations shall rest on natural solid bearing if a satisfactory soil is available at reasonable depths. Proper soil-bearing values shall be established in accordance with recognized standards. If solid bearing is not encountered at practical depths, the structure shall be supported on driven piles or drilled piers designed to support the intended load without detrimental settlement, except that one (1) story buildings may rest on a fill designed by a soils engineer. When engineered fill is used, site preparation and placement of fill shall be done under the direct full-time supervision of the soils engineer. The soils engineer shall issue a final report on the grading operation and a certification of compliance with the job specifications. All footings shall extend to a depth not less than one (1) foot below the estimated maximum frost line.

Section 15. Elevators. (1) General. Elevators shall be required where examination or treatment rooms or diagnostic services are located on other than the main entrance floor.

(2) Cars and platforms. Cars shall have a minimum inside floor dimension of not less than five (5) feet. The car door shall have a clear opening of not less than three (3) feet.

(3) Leveling. Elevators shall have automatic leveling of the two (2) way automatic maintaining type with accuracy within plus or minus one-half (1/2) inch.

Section 16. Mechanical Requirements. (1) General. Prior to completion of the contract and final acceptance of the facility, the architect and/or engineer shall obtain from the contractor certification that all mechanical systems have been tested and that the installation and performance of these systems conform to the requirements of the plans and specifications.

(2) Steam and hot water systems.

(a) Boiler accessories. Boiler feed pumps, condensate return pumps, fuel oil pumps, and circulating pumps shall be connected and installed to provide standby service when any pump breaks down.

(b) Valves. Supply and return mains and risers of space heating and process steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return end.

(3) Air-conditioning, heating and ventilating systems.

(a) Temperatures and humidities:

1. The systems shall be designed to provide the temperatures and humidities shown below:

Area Designation	Temp. F.	RH
Operating	70-76*	30-60**
Recovery	75	30-60

\*Variable range required

\*\*If combustible anesthetics are used the range for humidity shall be 50-60.

2. For all other occupied areas, a minimum temperature of seventy-five (75) degrees Fahrenheit shall be provided at winter design conditions.

(b) Ventilation system details. All air-supply and air-exhaust systems shall be mechanically operated. All fans serving exhaust systems shall be located at the discharge end of the system. The ventilation rates shown in Table 1, Section 18 of this administrative regulation, shall be considered as minimum acceptable rates and shall not be construed as precluding the use of higher ventilation rates if they are required to meet design conditions.

1. Outdoor ventilation air intakes, other than for individual room units, shall be located as far away as practicable but not less than twenty-five (25) feet from the exhaust from any ventilating system or combustion equipment. The bottom of outdoor intakes serving central air systems shall be located as high as possible but not less than eight (8) feet above the ground level or, if installed through the roof, three (3) feet above roof level.

2. The ventilation systems shall be designed and balanced to provide the general pressure relationship to adjacent areas as shown in Table 1, Section 18 of this administrative regulation.

3. All air supplied to sensitive areas such as operating rooms shall be delivered at or near the ceiling of the area served, and all air exhausted from the area shall be removed near floor level. At least two (2) exhaust outlets shall be used in all operating rooms. Exhaust outlets shall be located not less than three (3) inches above the floor.

4. Room supply air inlets, recirculation, and exhaust air outlets installed in nonsensitive areas shall be located not less than three (3) inches above the floor.

5. Filters.

a. The ventilation systems serving sensitive areas such as operating rooms, recovery rooms, and laboratory sterile rooms, shall be equipped with a minimum of two (2) filter beds. Filter bed No. 1 shall be located upstream of the conditioning equipment and shall have a minimum efficiency of thirty (30) percent. Filter bed No. 2 shall be located downstream of the conditioning equipment and shall have a minimum efficiency of ninety (90) percent.

b. Central systems serving other than sensitive areas shall be provided with a filter or filters rated at a minimum of twenty-five (25) percent efficiency.

c. The above filter efficiencies shall be warranted by the manufacturer and shall be based on the National Bureau of Standards Dust Spot Test Method with Atmospheric Dust.

6. Acoustical lining materials shall not be used in the interior of duct systems serving sensitive areas such as operating rooms and recovery rooms.

7. Cold-air ducts shall be insulated wherever necessary to maintain the efficiency of the system or to minimize condensation problems.

8. The ventilation system for anesthesia storage rooms shall conform to the requirements of NFPA Standard No. 56A as adopted by the State Fire Marshal's Office for ambulatory surgical center facilities.

9. Boiler rooms shall be provided with sufficient outdoor air to maintain combustion rates of equipment and reasonable temperatures in the rooms and in adjoining areas.

(4) Plumbing fixtures.

(a) The material used for plumbing fixtures shall be of nonabsorptive acid-resistant material.

(b) Lavatories and sinks required in patient care areas shall have the water supply spout mounted so that its discharge point is a minimum distance of five (5) inches above the rim of the fixture. All fixtures used by medical and nursing staff shall be trimmed with valves which can be operated without the use of hands. Where blade handles are used for this purpose they shall not exceed four and one-half (4 1/2) inches in length, except that handles on scrub sinks and clinical sinks shall be not less than six (6) inches long.

(c) Hot, cold, and chilled water piping, and waste piping on which condensation may occur shall be insulated. Insulation of cold and chilled water lines shall include an exterior vapor barrier.

(d) Hot water distribution systems shall be arranged to provide hot water at each fixture at all times.

(5) Hot water heaters and tanks.

(a) The hot water heating equipment shall have a sufficient capacity to supply water at the temperature and amounts indicated below:

	UseClinical
Gal/hr/bed	6 1/2
Temp. F.	125

(b) Storage tank(s) shall be provided and shall be fabricated of noncorrosive metal or lined with noncorrosive material.

(6) Drainage systems.

(a) Drain lines from sinks in which acid wastes may be poured shall be fabricated from an acid-resistant material.

(b) Piping over operating and other critical areas shall be kept to a minimum and shall not be exposed. Special precautions shall be taken to protect these areas from possible leakage of necessary overhead piping systems.

(c) Floor drains shall not be installed in operating rooms.

(d) Building sewers shall discharge into a community sewage system. Where such a system is not available, a facility providing sewage treatment which conforms to applicable local and state regulations is required.

(7) Nonflammable medical gas systems. Nonflammable medical gas system installations shall be in accordance with the requirements of NFPA Standard No. 56F as adopted by the State Fire Marshal's Office for ambulatory surgical center facilities.

Section 17. Electrical Requirements. (1) General. All material including equipment, conductors, controls, and signaling devices shall be installed to provide a complete electrical system with the necessary characteristics and capacity to supply the electrical facilities shown in the specifications or

indicated on the plans. All materials shall be listed as complying with applicable standards of Underwriters' Laboratories, Inc., or other similarly established standards. The essential electrical systems shall be designed in accordance with NFPA Publication Nos. 70 and 76-A as they relate to hospital facilities.

(2) Switchboard and power panels. All breakers and switches shall be indexed.

(3) Lighting.

(a) All spaces occupied by people, machinery, and equipment within buildings, and the approaches thereto, and parking lots shall have electric lighting.

(b) Operating rooms shall have general lighting for the room in addition to local lighting provided by special lighting units at the surgical tables. Each special lighting unit for local lighting at tables shall be connected to an independent circuit.

(4) Receptacles (convenience outlets). Anesthetizing locations: Each operating room shall have at least three (3) receptacles of the interchangeable type as defined in NFPA Standard No. 56A as adopted by the State Fire Marshal's Office for ambulatory surgical center facilities. In locations where mobile x-ray is used, an additional receptacle, distinctively marked for x-ray use, shall be fed by an independent ungrounded circuit.

(5) Equipment installation in special areas.

(a) Installation in hazardous areas. In areas where flammable anesthetic agents are used, such as operating and anesthesia induction rooms, and rooms for storage of flammable gases, all electrical equipment and devices including receptacles, wiring and conductive flooring installations shall comply with NFPA Standard No. 56A as adopted by the State Fire Marshal's Office for ambulatory surgical center facilities.

(b) X-ray film illuminator. Viewing panels shall be installed in each operating room and in the x-ray viewing room.

(6) Nurses' calling system. An emergency nurses' calling station shall be provided for nurses' use in each operating room and recovery room.

(7) Emergency electric service.

(a) General. To provide electricity during an interruption of the normal electric supply that could affect the medical care, treatment, or safety of the occupants, an emergency source of electricity shall be provided and connected to certain circuits for lighting and power.

(b) Sources. The source of this emergency electric service shall be as follows:

1. An emergency generating set, when the normal service is supplied by one (1) or more central station transmission lines.

2. An emergency generating set or a central station transmission line, when the normal electric supply is generated on the premises.

(c) Emergency generating set. The required emergency generating set, including the prime mover and generator, shall be located on the premises and shall be reserved exclusively for supplying the emergency electrical system. Exception: A system of prime movers which are ordinarily used to operate the emergency generator(s) will be permitted provided that the number and arrangement of the prime movers is such that when one (1) of them is out of service (due to breakdown or for routine maintenance), the remaining prime mover(s) can operate the required emergency generator(s) and provided that the connection time requirements described in paragraph (e) of this subsection are met. The emergency generator set shall be of sufficient kilowatt capacity to supply all lighting and power load demands of the emergency system. The power factor rating of the generator shall be not less than eighty (80) percent.

(d) Emergency electrical connections. Emergency electrical service shall be provided to circuits as follows:

1. Lighting.

a. Exitways and all necessary ways of approach thereto including exit signs and exit direction

signs, exterior of exits, exit doorways, stairways, and corridors.

b. Surgical room operating lights.

c. Laboratory, recovery room, nursing station and medication preparation areas.

d. Generator set location, switch-gear location, and boiler room.

2. Equipment essential to life safety and for protection of important equipment or vital materials.

a. Nurses' calling system;

b. Alarm system including fire alarm actuated at manual stations, water flow alarm devices of sprinkler system if electrically operated, fire detection systems, paging or speaker systems if intended for issuing instructions during emergency conditions, and alarms required for nonflammable medical gas systems, if installed;

c. Fire pump, if installed;

d. Pump for central suction system;

e. Sewage or sump lift pump, if installed;

f. Receptacles for blood bank refrigerator;

g. Receptacles in operating and recovery rooms except those for x-ray;

h. One (1) elevator, where elevators are used to transport patients to operating rooms;

i. Equipment such as burners and pumps necessary for operation of one (1) or more boilers and their necessary auxiliaries and controls, required for heating of operating rooms, recovery rooms and sterilization;

j. Ventilation of operating and recovery rooms;

k. Equipment necessary for maintaining telephone service.

3. Heating. Where electricity is the only source of power normally used for space heating, the emergency service shall provide for heating of operating and recovery room.

(e) Details. The emergency electrical system shall be so controlled that after interruption of the normal electric power supply, the generator is brought to full voltage and frequency and connected within ten (10) seconds through one (1) or more primary automatic transfer switches to all emergency lighting, all alarms, blood banks, nurses' call, equipment necessary for maintaining telephone service, pump for central suction system, and receptacles in operating and recovery rooms. All other lighting and equipment required to be connected to the emergency system shall either be connected through the above described primary automatic transfer switching or shall be subsequently connected through other automatic or manual transfer switching. Where fuel is normally stored on the site, the storage capacity shall be sufficient for twenty-four (24) hour operation. Where fuel is normally piped underground to the site from a utility distribution system, storage facilities on the site will not be required.

Section 18. Tables. Table 1 - Pressure Relationships and Ventilation of Certain Areas. Table 2 - Lighting Levels for Certain Areas.

TABLE 1. PRESSURE RELATIONSHIPS AND VENTILATION OF CERTAIN AREAS

Area Designation	Pressure Relationship to Adjacent Areas	All Supply Air From Outdoors	Minimum Air Changes of Outdoor Air per Hour	Minimum Total Air Changes Per Hour	All Air Exhausted Directly To Outdoors
Operating Room	P	--	5	12	--
Recovery	O	--	2	6	yes
Treatment Room	O	--	2	6	--
X-ray, Fluoroscopy Room	N	--	2	6	yes
X-ray, Treatment Room	O	--	2	6	--
Soiled Workroom	N	--	2	4	--
Clean workroom	P	--	2	4	--
Janitor's closet	N	--	--	10	yes
Sterilizer Equipment Room	N	--	--	10	yes
Laboratory, General	N	--	2	6	--
Anesthesia Storage	O	--	--	8	yes
Central Medical & Surgical Supply: Soiled or Decontamination Room	N	--	2	4	--
Clean Workroom	P	--	2	4	--
Unsterile Supply Storage	O	--	2	2	--

P = Positive N = Negative O = Equal -- = Optional

TABLE 2. LIGHTING LEVELS FOR CERTAIN AREAS	
Area	Foot-candles*
Administration and lobby areas, day	50
Corridors and interior ramps	20
Doorways	10
Examination and treatment room general	50
Examining table	100
Exit stairways and landings	5
Janitor's closet	15
Nurses' station, general	50
Nurses' desk, for charts and records	70
Nurses' medicine cabinet	100
Stairways other than exits	30
Utility room, general	20
Utility room, work counter	50

\*Minimum on task at anytime.

(8 Ky.R. 245; eff. 11-5-82; Am. 1174; eff. 6-2-82; 16 Ky.R. 1003; eff. 1-12-90.)

## 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), 489.25, 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.

(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 au-

thorized 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. 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.

(c) Other qualified personnel may:

1. Complete medical histories;

2. Perform physical examinations; or

3. Record findings and compile 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 possi-

ble 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.

1. 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.

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

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

(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.

(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.
    - (i) There shall be a complete history and physical workup in the chart of each patient prior to surgery.
    - (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.
    - (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.
    - (l) An operative report describing the techniques and findings shall be:
      1. Written or dictated immediately following surgery; and
      2. Signed by the surgeon.
    - (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.
    - (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.
    - (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 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 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 regula-

tion;

- (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. (8 Ky.R. 596; eff. 2-1-1982; 9 Ky.R. 1327; eff. 7-6-1983; 11 Ky.R. 467; eff. 10-9-1984; 1173; 1311; eff. 6-4-1985; 13 Ky.R. 331; 645; eff. 10-2-1986; 1282; eff. 2-10-1987; 15 Ky.R. 1157; 1583; eff. 1-18-1989; 18 Ky.R. 2027; 2565; eff. 3-7-1992; 19 Ky.R. 2506; 20 Ky.R. 121; eff. 8-6-1993; 21 Ky.R. 599; 1335; eff. 10-19-1994; 23 Ky.R. 2296; 3040; eff. 4-16-1997; 24 Ky.R. 969; 1268; eff. 11-19-1997; 25 Ky.R. 1714; 2380; eff. 4-21-1999; 27 Ky.R. 1920; 2820; eff. 4-9-2001; 29 Ky.R. 188; 716; eff. 8-21-2002; TAm eff. 3-11-2011; 44 Ky.R.1415, 2054; 45 Ky.R.355; eff. 8-31-2018.)

## **902 KAR 20:073. Clinics: ambulatory care.**

RELATES TO: KRS 216B.010-216B.131, 216B.990(1), (2)

STATUTORY AUTHORITY: KRS 216B.042, 216B.105

NECESSITY, FUNCTION, AND CONFORMITY: The administrative regulation establishing standards for ambulatory care clinics, 902 KAR 20:072, was found deficient by the Interim Joint Committee on Health and Welfare at its November 25, 1991, meeting. The finding of deficiency resulted from the removal of the requirement for an R.N. to be on site during the hours of the ambulatory care clinic's operation as found in Section 3(3)(a) ("Personnel"). Legislation to establish the deletion of the R.N. requirement in KRS Chapter 216B was not enacted during the 1992 regular session of the General Assembly. Therefore, pursuant to KRS 13A.333(1), 902 KAR 20:072 expired. KRS 216B.042 requires the cabinet to establish standards for health facilities and health services, and authorizes it to promulgate administrative regulations. Without an administrative regulation establishing standards for ambulatory care clinics, the cabinet would be in violation of the legislative mandate expressed in KRS 216B.042. KRS 13A.333(6) prohibits an administrative body from promulgating an administrative regulation that is identical to or substantially the same as an administrative regulation that has expired. This administrative regulation is not identical to or substantially the same as 902 KAR 20:072, because: (1) Only the section relating to R.N. staffing was found deficient; (2) this administrative regulation requires R.N. staffing; and (3) it is required, by legislative mandate, by KRS 216B.042.

Section 1. Definitions. "Clinic" means ambulatory care clinic.

Section 2. Scope of Operations and Services. An ambulatory care clinic is an establishment with organized medical staffs, permanent facilities and medical services to provide diagnosis and treatment for patients who have a variety of medical conditions and do not currently require inpatient care.

Section 3. Administration and Operation. (1) Licensee.

(a) The licensee shall be legally responsible for the clinic and for compliance with federal, state and local laws and regulations pertaining to the operation of the clinic.

(b) The licensee shall establish written policies for the administration and operation of the clinic.

(c) The licensee shall establish lines of authority and designate the person who will be principally responsible for the daily operation of the clinics.

(2) Policies.

(a) Administrative policies. The clinic shall have written administrative policies covering all aspects of the clinic's operation, including:

1. A description of organizational structure, staffing and allocation of responsibility and accountability;

2. A description of referral linkages with inpatient facilities and other providers;

3. Policies and procedures for the guidance and control of personnel performances;

4. A description of services included in the clinic's program;

5. A description of the administrative and patient care records and reports;

6. Procedures to be followed in the storage, handling and administration of drugs and biologicals; and

7. A policy to specify the provision of emergency medical services.

(b) Patient rights policies. The clinic shall adopt written policies regarding the rights and responsibilities of patients. These patients' rights policies shall assure that each patient:

1. Is informed of these rights and of all rules and regulations governing patient conduct and re-

sponsibilities, including a procedure for handling patient grievances.

2. Is informed of services available at the clinic and of related charges including any charges not covered under Medicare, Medicaid, or other third-party payor arrangements.

3. Is informed of his medical condition, unless medically contraindicated (as documented in his medical record), and is afforded the opportunity to participate in the planning of his medical treatment and to refuse to participate in experimental research.

4. Is encouraged and assisted to understand and exercise his patient rights; to this end he may voice grievances and recommend changes in policies and services. Upon the patient's request the grievances and recommendations will be conveyed within a reasonable time to an appropriate decision making level within the organization which has authority to take corrective action.

5. Is assured confidential treatment of his records and is afforded the opportunity to approve or refuse their release to any individual not involved in his care except as required by Kentucky law or third-party payment contract.

6. Is treated with consideration, respect, and full recognition of his dignity and individuality, including privacy in treatment and in the care of his personal health needs.

(3) Personnel.

(a) The clinic shall have at least one (1) licensed physician and at least one (1) registered nurse present during operating hours. A licensed physician shall be designated as medical director.

1. Physician. The physician shall be in active practice, and shall be responsible for all medical aspects of the center, and shall provide direct medical services in accordance with the Medical Practice Act, KRS Chapter 311. Physicians employed by or having an agreement with the clinic to perform direct medical services shall be qualified to practice general medicine (e.g., general practitioners, family practitioners, obstetrician/gynecologists, pediatricians, and internists). Physicians employed by or having an agreement with the clinic to perform direct medical services should be members of the medical staff, or hold at least courtesy staff privileges, at one (1) or more hospitals with which the clinic has a formal linkage agreement.

2. Nurse. The registered nurse(s) shall provide services within their respective scope of practice pursuant to KRS Chapter 314.

(b) In-service training. All clinic personnel shall participate in ongoing in-service training programs relating to their respective job activities. These programs shall include thorough job orientation for new personnel, regular in-service training programs, emphasizing professional competence, and the human relationship necessary for effective health care.

(c) At least one (1) person, in addition to the physician, shall be on duty who has current certification in cardiopulmonary resuscitation.

(4) Medical records.

(a) The clinic shall maintain medical records to contain at least the following:

1. Medical and social history, including data obtainable from other providers;

2. Description of each medical visit or contact, to include condition or reason necessitating visit or contact, assessment, diagnosis, services provided, medications and treatments prescribed, and disposition made;

3. Reports of all physical examinations, laboratory, x-ray, and other test findings; and

4. Documentation of all referrals made, to include reason for referral, to whom patient was referred, and any information obtained from referral source.

(b) Confidentiality of all patient records shall be maintained at all times.

(c) Transfer of records. The clinic shall establish systematic procedures to assist in continuity of care where the patient moves to another source of care, and the clinic shall, upon proper release, transfer medical records or an abstract thereof when requested.

(d) Retention of records. After patient's death or discharge the completed medical record shall be placed in an inactive file and retained for five (5) years or, in case of a minor, three (3) years after

the patient reaches the age of majority under state law, whichever is the longest.

(5) Linkage agreements.

(a) The clinic shall have linkages through written agreements with providers of other levels of care which may be medically indicated to supplement the services available in the clinic. These linkages shall include:

1. Hospitals; and
2. Emergency medical transportation services in the service area.

(b) Linkage agreements with inpatient care facilities shall incorporate provisions for appropriate referral and acceptance of patients from the clinic, provisions for appropriate coordination of discharge planning with clinic staff, and provisions for the clinic to receive a copy of the discharge summary for each patient referred to the clinic.

(6) Utilization review and medical audit. In order to determine the appropriateness of the services delivered there shall be a written plan for utilization review developed by the clinic which specifies the frequency of reviews and composition of the body conducting the review.

(7) Quality assurance program. The clinic shall have a written quality assurance program designed to ensure that there is an ongoing quality assurance program that includes effective mechanisms for reviewing and evaluating patient care, and that provides for appropriate response to findings. The written quality assurance plan shall be approved by the licensee and shall:

- (a) Assign responsibility for the monitoring and evaluation activities;
- (b) Delineate scope of care provided by the clinic;
- (c) Identify the aspects of care that the clinic provides;
- (d) Identify indicators, and appropriate clinical criteria that can be used to monitor these aspects of care;
- (e) Collect and organize data for each indicator;
- (f) Evaluate the care in order to identify problems or opportunities to improve care;
- (g) Take actions to correct identified problems or to improve care;
- (h) Assess the effectiveness of the actions taken and document the improvement in care; and
- (i) Communicate relevant information to other individuals, departments, or services as to the quality assurance program.

Section 4. Provision of Services. (1) Hours of operation and coverage. Scheduled hours of the clinic's operation shall reasonably accommodate the various segments of the population served. Provisions shall be made for scheduled evening hours and/or weekend hours.

(2) Basic services. The clinic shall provide directly (except as noted) at least the following services:

(a) Medical diagnostic and treatment services of sufficiently broad scope to accommodate the basic health needs (including prenatal and postnatal care) of all age groups;

(b) Emergency services.

1. The clinic shall provide emergency medical services during the regularly scheduled hours for treatment of injuries and minor trauma.

2. The clinic shall post in a conspicuous area at the entrance, visible from the outside of the clinic, the hours that emergency medical services will be available in the clinic and where emergency medical services not provided by the clinic can be obtained during and after the clinic's regular scheduled hours of operation.

(c) Preventive health services of sufficiently broad scope to provide for the usual and expected health needs of persons in all age groups;

(d) Education in the appropriate use of health services and in the contribution each individual can make to the maintenance of his own health;

(e) Chronic illness management; and

(f) Laboratory, x-ray and treatment services provided directly or arranged through other providers.

(3) Telephone screening and referral. The clinic shall provide telephone screening and referral services for prospective patients after regularly scheduled hours of operation.

(4)(a) Sharp wastes, including needles, scalpels, razors, or other sharp instruments used for patient care procedures, shall be segregated from other wastes and placed in puncture resistant containers immediately after use.

1. Needles shall not be recapped, purposely bent or broken, or otherwise manipulated by hand, except as permitted by Centers for Disease Control and the Occupational Safety and Health Administration guidelines.

2. The containers of sharp wastes shall either be incinerated on or off site, or be rendered non-hazardous by a technology of equal or superior efficacy, which is approved by the Cabinet for Human Resources and the Natural Resources and Environmental Protection Cabinet.

3. All disposable waste shall be placed in suitable bags or closed containers so as to prevent leakage or spillage, and shall be handled, stored, and disposed of in such a way as to minimize direct exposure of personnel to waste materials.

(b) The ambulatory clinic shall establish specific written policies regarding handling and disposal of all wastes.

1. The following wastes shall be disposed of by incineration, or be autoclaved before disposal, or be carefully poured down a drain connected to a sanitary sewer: blood, blood specimens, used blood tubes, or blood products.

2. Any wastes conveyed to a sanitary sewer shall comply with applicable federal, state, and local pretreatment regulations pursuant to 40 CFR 403 and 401 KAR 5:055, Section 9.

3. Any incinerator used for the disposal of wastes shall be in compliance with 401 KAR 59:020 and 401 KAR 61:010. (19 Ky.R. 2196; eff. 6-16-93.)

**902 KAR 20:410. Specialty intermediate care clinics.**

RELATES TO: KRS 198B.260, 209, 216B.010-216B.131, 216B.990, 218A, 311, 314, 507.020, 507.030, 507.040, 508.010-508.032, 509-511, 513, 514.030, 530, 531, 45 C.F.R. 160, 164

STATUTORY AUTHORITY: 216B.042

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 provides minimum licensure requirements for the operation of specialty intermediate care clinics.

Section 1. Definitions. (1) "Clinic" or "specialty intermediate care (IC) clinic" means a clinic located on the grounds of a state-owned facility licensed pursuant to 902 KAR 20:086 as an intermediate-care facility for the intellectually and developmentally disabled.

(2) "Developmental disability" is defined by 42 U.S.C. 15002(8)(A) as a severe, chronic disability of an individual that:

(a) Is attributable to a mental or physical impairment or combination of mental and physical impairments;

(b) Is manifested before the individual attains age twenty-two (22);

(c) Is likely to continue indefinitely;

(d) Results in substantial functional limitations in three (3) or more areas of major life activity, including:

1. Self-care;

2. Receptive and expressive language;

3. Learning;

4. Mobility;

5. Self direction;

6. Capacity for independent living; or

7. Economic self-sufficiency; and

(e) Reflects the individual's need for a combination and sequence of special, interdisciplinary, or generic services, individualized supports, or other forms of assistance that are of life-long or extended duration and are individually planned and coordinated.

(3) "Intellectual disability" means an individual has:

(a) Significantly sub-average intellectual functioning;

(b) An intelligence quotient of seventy (70) or below;

(c) Concurrent deficits or impairments in present adaptive functioning in at least two (2) of the following areas:

1. Communication;

2. Self-care;

3. Home living;

4. Social or interpersonal skills;

5. Use of community resources;

6. Self-direction;

7. Functional academic skills;

8. Work;

9. Leisure; or

10. Health and safety; and

(d) Had an onset prior to eighteen (18) years of age.

(4) "Patient" means an individual who receives services provided by a specialty IC clinic and who:

(a) Is not a resident of, but qualifies for admission to an intermediate-care facility for the intellectually and developmentally disabled by meeting the patient status criteria established in 907 KAR 1:022, Section 4; or

(b) Is a resident of an intermediate-care facility for the intellectually and developmentally disabled which contracts with, or makes arrangements with the specialty IC clinic for outpatient services.

Section 2. Licensure Application and Fee. (1) An applicant for licensure as a specialty IC clinic shall complete and submit to the Office of the Inspector General an Application for License to Operate a Health Facility or Service, pursuant to 902 KAR 20:008, Section 2(2)(f).

(2) The initial and annual fee for licensure as a specialty clinic shall be \$500.

Section 3. Scope of Operations and Services. (1) Services provided by a specialty IC clinic shall be individualized to meet the treatment needs of each of the specialty IC clinic's patients. Patients may receive one (1) or more of the following services from the clinic:

- (a) Dental services;
  - (b) Psychiatric services;
  - (c) Psychological services;
  - (d) Psychotropic medication management;
  - (e) Neurology;
  - (f) Epileptology;
  - (g) Preventive health care;
  - (h) Medical assessment and treatment;
  - (i) Occupational therapy;
  - (j) Physical therapy;
  - (k) Speech therapy;
  - (l) Nutritional or dietary consultation;
  - (m) Mobility evaluation or treatment;
  - (n) Behavioral support services;
  - (o) Audiology;
  - (p) Ophthalmology;
  - (q) Pharmacy;
  - (r) Medication consultation;
  - (s) Medication management;
  - (t) Seizure management;
  - (u) Behavioral support services;
  - (v) Diagnostic services;
  - (w) Clinical laboratory services;
  - (x) Physician services; or
  - (y) Laboratory services.
- (2) Off-site services.

(a) Specialty IC clinic personnel as identified in Section 5(4) of this administrative regulation may provide services off-site at a local health department or in a health facility licensed under 902 KAR Chapter 20 if the specialty IC clinic has an agreement to provide the off-site services at the health department or licensed health facility's location for the purpose of improving patient accessibility or accommodating the patient's individualized healthcare needs.

(b) A psychologist, psychiatrist, behavior specialist, or board certified behavior analyst directly employed by, or under contract with a specialty IC clinic, may provide behavioral assessments or consultation off-site:

1. In a patient's home; or
2. At a day service or other service site where the patient receives services.

Section 4. Administration and Policies. (1) The licensee shall have legal responsibility for the specialty IC clinic, including responsibility for ensuring compliance with federal, state, and local laws and regulations pertaining to the operation of the clinic.

(2) The licensee shall establish lines of authority and designate an administrator who shall be principally responsible for the daily operation of the specialty IC clinic.

(3) A specialty IC clinic shall establish and follow written administrative policies covering all aspects of operation, including:

(a) A description of organizational structure, staffing, and allocation of responsibility and accountability;

(b) Policies and procedures for the guidance and control of personnel performances;

(c) A written program narrative describing in detail the:

1. Services offered;
2. Methods and protocols for service delivery;
3. Qualifications of personnel involved in the delivery of the services; and
4. Goals of the service;

(d) A description of how administrative and patient care records and reports are maintained; and

(e) Procedures to be followed if the clinic performs any functions related to the storage, handling, and administration of drugs and biologicals.

(4) Patient Care Policies. A specialty IC clinic shall develop patient care policies which address:

(a) A description of the services the clinic provides directly and those provided through agreement;

(b) Guidelines for the medical management of health problems which include the conditions requiring medical consultation or patient referral; and

(c) Procedures for the annual review and evaluation of the services provided by the clinic.

Section 5. Personnel. (1)(a) A specialty IC clinic shall have a medical director who is a licensed physician.

(b) The specialty IC clinic's medical director shall:

1. Be responsible for all medical aspects of the clinic and provide direct medical services in accordance with the Medical Practice Act, KRS Chapter 311;

2. Provide medical direction, supervision, and consultation to the staff;

3. In conjunction with the registered nurse described in subsection (2) of this section, participate in the development, execution, and periodic review of the clinic's written policies and services;

4. Periodically review the clinic's patient records, provide medical orders, and provide medical care services to patients of the clinic;

5. Be present for weekly consultation, or delegate responsibility for weekly consultation to another physician employed by, or under contract with the specialty IC clinic if a temporary absence is necessary; and

6. Be available within one (1) hour through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. If a temporary absence is necessary, the

medical director shall designate another physician who is employed by, or under contract with the specialty IC clinic to be available within one (1) hour through direct telecommunication for consultation, assistance with medical emergencies, or patient referral.

(2) A specialty IC clinic shall have at least one (1) registered nurse who shall:

(a) Have at least one (1) year experience in treating or working with individuals with an intellectual disability and a developmental disability;

(b) Participate in the development, execution, and periodic review of the written policies governing the services the clinic provides;

(c) Participate with the medical director in periodic review of patient health records;

(d) Provide services in accordance with clinic policies, established protocols, the Nurse Practice Act (KRS Chapter 314), and with administrative regulations promulgated thereunder;

(e) Arrange for or refer patients to needed services that cannot be provided at the clinic; and

(f) Assure that adequate patient health records are maintained and transferred when patients are referred.

(3) A specialty IC clinic shall maintain, through direct employment or contract, a sufficient number of qualified personnel to provide effective patient care and all other related services.

(4) Qualified personnel directly employed by, or under contract with a specialty IC clinic shall include:

(a) Physicians;

(b) Dentists;

(c) Dental hygienists;

(d) Physician assistants;

(e) Nurse practitioners;

(f) Registered nurses;

(g) Psychologists;

(h) Psychiatrists;

(i) Pharmacists;

(j) Audiologists;

(k) Optometrists;

(l) Dieticians;

(m) Behavior specialists;

(n) Board certified behavior analysts;

(o) Ophthalmologists;

(p) Physical therapists;

(q) Speech therapists;

(r) Occupational therapists;

(s) Physical therapist assistants; and

(t) Occupational therapist assistants.

(5)(a) Prior to providing any service described in Section 3(1) of this administrative regulation, all qualified personnel as identified in subsection (4) of this section shall submit to an in-state criminal background information check conducted by the Justice and Public Safety Cabinet or Administrative Office of the Courts.

(b) An out-of-state criminal background information check shall be obtained for any qualified personnel who have resided or been employed outside Kentucky.

(c) A clinic shall not knowingly employ any person who has been convicted of a felony offense under:

1. KRS Chapter 209;

2. KRS Chapter 218A;

3. KRS 507.020, 507.030, and 507.040;

4. KRS Chapter 509;
  5. KRS Chapter 510;
  6. KRS Chapter 511;
  7. KRS Chapter 513;
  8. KRS 514.030;
  9. KRS Chapter 530;
  10. KRS Chapter 531;
  11. KRS 508.010, 508.020, 508.030, and 508.032;
  12. A criminal statute of the United States or another state similar to subparagraphs 1 to 11 of this paragraph; or
  13. A violation of the uniform code of military justice or military regulation similar to subparagraphs 1 to 11 of this paragraph which has caused the person to be discharged from the Armed Forces of the United States.
- (d) A person who has received a pardon for an offense specified in paragraph (c) or has had the record of the offense expunged may be employed.
- (6) A specialty IC clinic shall maintain written personnel policies which shall be available to all employees.
- (7) A specialty IC clinic shall maintain a written job description for each position which shall be reviewed and revised as necessary.
- (8) A specialty IC clinic shall maintain current personnel records for each employee. An employee's personnel record shall include the following:
- (a) Employee's name and address;
  - (b) Evidence that the health care professional has a valid license or other valid credential required for the professional to be able to practice;
  - (c) Record of training and experience; and
  - (d) Record of performance evaluations.
- (9)(a) Specialty IC clinic personnel shall attend in-service training programs relating to their respective job duties. These training programs shall include:
1. Thorough job orientation for new personnel;
  2. Regular in-service training programs;
  3. Behavior management procedures and techniques;
  4. Training in the detection and reporting of suspected abuse or neglect of a child or adult;
  5. Training in the field of intellectual and developmental disabilities; and
  6. Emergency and safety procedures.
- (b) A written document describing the training programs completed by all clinic employees shall be maintained on the premises of the clinic.

Section 6. Medical Records. (1) A specialty IC clinic shall maintain medical records which contain the following:

- (a) Name of the patient;
- (b) Description of each medical visit or contact, including:
  1. Date of the visit;
  2. Condition or reason for the visit;
  3. Name of health care practitioner providing the service;
  4. Description of the services provided; and
  5. Any medications or treatments prescribed;
- (c) Medical or social history relevant to the services provided, including data obtained from other providers;
- (d) Names of referring physicians, if any, and physicians orders for special diagnostic ser-

vices; and

(e) Documentation of all referrals made, including the reason for the referral and to whom the patient was referred.

(2) A specialty IC clinic shall maintain confidentiality of patient records at all times pursuant to and in accordance with federal, state and local laws and administrative regulations, including the privacy standard promulgated pursuant to Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. 160 and 164.

(3) A specialty IC clinic shall:

(a) Establish systematic procedures to assist in continuity of care if the patient moves to another source of care;

(b) Transfer medical records or an abstract upon request, subject to required releases and authorizations; and

(c) Have a specific location designated for the storage and maintenance of the clinic's medical records, maintain scanned copies of the original medical records in an electronic format, or maintain electronic health records, available for copying to a disk or printing at the clinic.

(4)(a) Medical records shall be maintained by the clinic for a period of six (6) years following the last treatment, assessment, or visit made by the patient, or three (3) years after the patient reaches age eighteen (18), whichever is longer.

(b) A provision shall be made for written designation of a specific location for the storage of medical records if the specialty IC clinic ceases to operate because of disaster, or for any other reason.

(5) A specialty IC clinic shall safeguard each clinic's medical records and content against loss, defacement, and tampering.

Section 7. Provision of Services. (1) Equipment. Equipment used for direct patient care shall comply with the following:

(a) The licensee shall establish and follow a written preventive maintenance program to ensure that equipment shall be operative, properly calibrated, and cleaned regularly;

(b) All personnel engaged in the operation of diagnostic equipment shall have adequate training and be currently licensed, registered or certified in accordance with applicable state statutes and administrative regulations; and

(c) A written plan shall be developed and maintained to provide for training of personnel in the safe and proper usage of the equipment.

(2) Diagnostic services. Diagnostic services shall be performed in accordance with the specialty IC clinic's protocol.

(a) Protocols for diagnostic examinations shall be developed by the medical director.

(b) Diagnostic services shall be provided under the supervision of a physician who is qualified by advanced training and experience in the use of the specific technique utilized for diagnostic purposes.

(c) Physical examination services shall be nonabusive and provided in a manner which ensures the greatest amount of safety and security for the patient.

1. Personnel performing physical examinations shall have adequate training and be currently licensed, registered, or certified in accordance with applicable Kentucky statutes and administrative regulations.

2. Personnel performing physical examinations shall be limited by the relevant scope of practice of state licensure.

(3) Referrals. A specialty IC clinic shall refer a patient for services that cannot be provided at the clinic.

(4) Restraints

(a) A specialty IC clinic shall promote a restraint free environment and ensure that restraints are used only for medical emergencies or if the resident poses an immediate risk to self or others.

(b) Use of any type of restraint as a health-related protection shall be prescribed by a physician if necessary during the conduct of specific medical procedure.

(c) The specialty IC clinic shall have a system to monitor and decrease the use of physical restraint and pre-sedation.

Section 8. Physical Environment. (1) Accessibility. A specialty IC clinic shall meet requirements for making buildings and facilities accessible to and usable by individuals with physical disabilities pursuant to KRS 198B.260 and administrative regulations promulgated thereunder.

(2) Fire safety. A specialty IC clinic shall be approved by the State Fire Marshal's office prior to initial licensure.

(3) Housekeeping and maintenance services.

(a) Housekeeping. A specialty IC clinic shall maintain a clean and safe facility free of unpleasant odors. Odors shall be eliminated at their source by prompt and thorough cleaning of commodes, urinals, bedpans and other sources.

(b) Maintenance. The premises shall be well kept and in good repair as follows:

1. The clinic shall insure that the grounds are well kept and the exterior of the building, including the sidewalks, steps, porches, ramps, and fences are in good repair;

2. The interior of the building including walls, ceilings, floors, windows, window coverings, doors, plumbing and electrical fixtures shall be in good repair. Windows and doors which can be opened for ventilation shall be screened;

3. Garbage and trash shall be stored in areas separate from those used for the preparation and storage of food and shall be removed from the premises regularly. Containers shall be cleaned regularly;

4. A pest control program shall be in operation in the clinic. Pest control services shall be provided by maintenance personnel of the facility or by contract with a pest control company. The compounds shall be stored under lock;

5. Sharp wastes, such as broken glass, scalpel blades, and hypodermic needles shall be segregated from other wastes and aggregated in rigid disposable containers immediately after use. Needles and syringes shall not be cut, dismantled, or destroyed after use but shall be placed intact directly into a rigid container. The rigid containers of sharp wastes shall either be incinerated, on site or off site, or disposed of in a sanitary landfill approved pursuant to 401 KAR 47:080; and

6. The clinic shall establish a written policy for the handling and disposal of all infectious, pathological, and contaminated waste if the clinic generates them. Any incinerator used for the disposal of waste shall be in compliance with 401 KAR 59:020 or 61:010.

a.(i) Infectious waste shall be placed in double impervious plastic bags and each bag shall be two (2) mils in thickness.

(ii) A bag, if full, shall not exceed twenty five (25) pounds.

(iii) All bags shall be securely closed and a tag, which reads "INFECTIOUS WASTE" and identifies the clinic from which the waste is being removed and shall be attached to the bag in a conspicuous manner.

b. All unpreserved tissue specimens procedures shall be incinerated on or off site.

c. The following wastes shall be sterilized before disposal or be disposed of by incineration if they are combustible:

(i) Dressings and materials from open or contaminated wounds;

(ii) Waste materials and disposable linens from isolation rooms;

- (iii) Culture plates;
- (iv) Test tubes;
- (v) Sputum cups; and
- (vi) Contaminated sponges and swabs. (37 Ky.R. 1142; 1731; 2019; eff. 3-4-2011; TAm eff. 12-10-2012; Crt eff. 1-11-2019.)