KENTUCKY BOARD OF EMERGENCY MEDICAL SERVICES

(Amendment)

202 KAR 7:510. Air ambulance services.

RELATES TO: KRS 311A.030, 311A.190, 14 C.F.R. Parts 91, 135

STATUTORY AUTHORITY: KRS 311A.020, 311A.025, 311A.030, 311A.190

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311A.020 requires the board to exercise all administrative functions in the regulation of the emergency medical services system and the practice of emergency medical services, except those functions regulated by the Board of Medical Licensure or the Cabinet for Health and Family Services.[~~air ambulance services the EMS system and the licensing of air ambulance services~~]. KRS 311A.030 requires the board to promulgate administrative regulations for the licensing, inspection, and regulation of air ambulance providers. This administrative regulation establishes minimum licensing requirements for air ambulance providers.

Section 1. Provider Licensing Requirements.

(1) A person or entity shall not provide, advertise, or profess to engage in the provision of air ambulance service originating in Kentucky without having first obtained a license from the board pursuant to this administrative regulation.

(2) A provider shall comply with local ordinances, state and federal statutes and administrative regulations.

(3) A provider shall display its license in a prominent public area at the service base station and all satellite locations. The following information shall be included on the license:

(a) Operating name of the provider;

(b) Physical location of the base station;

(c) The number and physical location of satellite stations, if any, operated by the licensee;

(d) The license classification;

(e) The level of service provided;

(f) The number of rotor and fixed-wing aircraft operated by the provider; and

(g) The specific geographic area to be served by the licensee.

(4) Providers shall provide the KBEMS Office with an accurate map and a written description of its geographic service area within the commonwealth, which shall identify with specificity the complete boundary of the area served by the provider when applying for initial licensure or if the service area has changed since the last map was provided to the KBEMS Office.

(5) A licensed provider may respond to emergency calls outside of its geographic service area only if the provider is providing:

(a) Mutual aid under an existing agreement with another licensed provider whose geographic service area includes the area in which the emergency call is made;

(b) Disaster assistance; or

(c) Nonemergency transfers from damaged or closed health facilities.

Section 2. Licensing, Inspection and Change of Ownership.

(1) To obtain a license, an air ambulance provider shall file an "Kentucky Application for Ambulance Service Licensing", Form EMS-1 (6/96), with the KBEMS Office.

(2) An applicant for a license or a licensee shall, as a condition precedent to licensing or relicensing, be in compliance with all applicable sections of this administrative regulation as determined through means including a physical inspection process, subject to subsection (4)(b)2 of this section.

(3) A license shall expire on December 31 following the original date of issue and shall subsequently expire annually on December 31 of each year.

(4) A license may be renewed upon:

(a) Payment of the prescribed fee; and

(b) Action by the board, based upon recommendation of staff following the physical inspection of the provider.

(5) A license to operate shall be issued only for the person or entity, service area, and premises, including the number of aircraft, named in the application, and shall not be transferable.

(6) A new application shall be filed if a change of ownership of an air ambulance service occurs. A change of ownership for licenses shall be deemed to occur if more than fifty (50) percent of the assets, capital stock, or voting rights of a corporation or provider operating an air ambulance is purchased, transferred, leased, or acquired by comparable arrangement by one (1) person or entity from another.

(7) If a new application for a license is filed due to change of ownership, the new license shall be issued for the remainder of the current licensure period.

(8) There shall be full disclosure to the board of the changes in ownership, such as name and address, of:

(a) Each person having direct or indirect ownership interest of ten (10) percent or more in the service;

(b) Officers and directors of the corporation, if a service is organized as a corporation; or

(c) Partners, if a provider is organized as a partnership.

(9) Representatives of the board shall have access to the service during hours that the service operates.

(10) A regulatory violation identified during an inspection shall be transmitted in writing by the board and given to the provider.

(11) The provider shall submit a written plan for the elimination or correction of a regulatory violation to the KBEMS Office within ten (10) working days after receipt of the statement of violation and shall include the specific date by which the violation may be corrected.

(12) Within ten (10) working days following a review of the plan, the KBEMS Office shall notify the provider in writing whether or not the plan is accepted as providing for the elimination or correction of the violation.

(13) The KBEMS Office may conduct a follow-up visit to verify compliance with the plan.

(14) If a portion or all of the plan is insufficient:

(a) The KBEMS Office shall specify the reasons why the plan cannot be accepted; and

(b) The provider shall modify or amend the plan and resubmit it to the KBEMS Office within ten (10) days after receipt of notice that the plan is insufficient.

(15) Unannounced inspections may be conducted at the discretion of the board or its representative.

(16) Any licensed provider may be recommended for discipline based upon:

(a) Failure to submit, amend, or modify a plan of correction in order to eliminate or correct regulatory violations;

(b) Failure to eliminate or correct regulatory violations;

(c) Falsifying an application for licensing;

(d) Changing a license issued by the board;

(e) Attempting to obtain or obtaining a license by:

1. Fraud;

2. Forgery;

3. Deception;

4. Misrepresentation; or

5. Subterfuge;

(f) Providing false or misleading advertising;

(g) Falsifying, or causing to be falsified a:

1. Patient record;

2. Service run report; or

3. Other reports provided to the KBEMS Office;

(h) Providing an unauthorized level of service;

(i) Demonstrating a history of staff violations that have resulted in disciplinary action;

(j) Failing to provide the board or its representative with information upon request, or obstructing an investigation regarding alleged or confirmed violations of statutes or administrative regulations;

(k) Issuing a check for a license on an invalid account or an account with insufficient funds to pay fees to KBEMS; or

(l) Submitting fraudulent or misleading claims for reimbursement to:

1. An individual;

2. A private insurance company;

3. A governmental agency; or

(m) Any violation of KRS Chapter 311A or 202 KAR Chapter 7.

Section 3. Utilization of Aircraft by Licensed Providers.

(1) At the time of initial inspection, each provider shall inform the KBEMS Office of the make, model, year, serial number, and FAA identification number for each aircraft it uses.

(2) Except as provided by this administrative regulation, an aircraft shall not be placed into operation until after the board has been notified and has verified through a physical inspection that the aircraft meets the requirements of this administrative regulation.

(3) Each provider shall notify the KBEMS Office via U.S. mail, email, or fax, no later than the next board business day, of the permanent removal of any licensed aircraft from service by the license holder.

(4) A licensed provider may use a replacement aircraft on a temporary basis if an approved aircraft is out of service, if:

(a) The KBEMS Office receives notice within twenty-four (24) hours or on the next business day by fax or email of the need for the provider to place an aircraft into service on a temporary basis; and

(b) Within five (5) business days, the provider provides the board written notice identifying:

1. The make, model, year, serial number, and FAA identification number for the aircraft being removed from service and for the aircraft being placed into temporary service; and

2. The temporary replacement aircraft meets the requirements of this administrative regulation.

(5) A temporary replacement aircraft shall not be used for more than sixty (60) days, unless the KBEMS Office has verified through a physical inspection that it meets the requirements of this administrative regulation.

(6) The KBEMS Office shall be notified by email or fax within twenty-four (24) hours or on the next business day when a temporary aircraft is removed from service and the original licensed aircraft is returned to service.

(7) A provider that fails to meet the reporting requirements for use of a temporary aircraft may be required to immediately cease use of the replacement aircraft until the reporting requirements are met.

(8) A provider that fails to remove a temporary aircraft from service upon written order may be fined an amount not to exceed $1,000 per day for each day or partial day the aircraft is in service and the reporting requirements are not met.

(9) This administrative regulation shall not prevent a provider from utilizing other means of transporting patients in:

(a) Disasters;

(b) Mass casualty incidents; or

(c) Extraordinary scene conditions that may impair the safety of the patient or personnel operating at the scene.

Section 4. Provider Management Requirements.

(1) All providers shall:

(a) Maintain an organizational chart that establishes lines of authority, including the designation of:

1. An administrator responsible for assuring compliance with this administrative regulation during the daily operation of the service; and

2. A designee who shall serve in the absence of the administrator;

(b) Maintain records and reports at the ambulance service base station or at a location where the records can be made readily available to KBEMS staff including an original, microfilm, electronic equivalent, or copy of all run reports whether reported on:

1. The EMS-8A and EMS-8B "Kentucky Emergency Medical Ambulance Run Report" (9/98), with all nonshaded portions of the run report completed as appropriate for each patient and each run; or

2. A paper or electronic run form developed by the provider that contains all of the data components of the nonshaded areas of the EMS-8A and EMS-8B (9/98);

(c) Maintain a copy of all completed run report forms, maintained to ensure confidentiality and safekeeping, for a minimum of five (5) years from the date on which the service was rendered, or in the case of a minor, until five (5) years after the minor reaches eighteen (18) years of age. Copies of run reports shall be accessible so as to be immediately available to the board, KBEMS Office or representatives upon request;

(d) Maintain personnel files for each employee or volunteer who staffs an aircraft. Personnel files shall be maintained for a minimum of five (5) years following separation from employment. As a minimum, personnel files shall contain:

1. Current certification or licensure with corresponding numbers and expiration dates for the position that the individual fulfills on the aircraft;

2. Proof that the provider has conducted a pre-employment criminal background check; and

3. Health records, maintained in accordance with state and federal laws and administrative regulations, in a separate secure file, that include:

a. A post-offer of employment health assessment;

b. Annual tuberculin skin testing or other method of evaluation;

c. Hepatitis-B vaccinations and seroconversion testing unless exempted by the employees' physician, or an employee signed waiver; and

d. A record of all work-related illnesses or injuries;

(e) Maintain a plan and records for the provision of continuing education for staff and volunteers including a written plan for the method of assessment of staff continuing education needs and a coordinated plan to meet those needs including:

1. Training or continuing education rosters that include the printed name, signature, and certification or license number of those in attendance;

2. A curriculum vitae for the instructor; and

3. A brief outline of the presentation including the educational objective for the offering and the method of presentation used for the presentation;

(f) Maintain an infection control plan in accordance with KyOSHA guidelines;

(g) Maintain a written plan for training or educating personnel for responding to hazardous materials, criminal, and potential terrorist incidents, including plans for the protection and decontamination of patients, aircraft, equipment, and staff;

(h) Maintain a written plan for the quality assessment of patient care and provider quality improvement including a periodic review of ambulance run report forms, and evaluation of staff performance related to patient care. This plan shall address as a minimum:

1. Aircraft maintenance as it impacts the clinical aspects of patient care delivery, employee health and safety;

2. Compliance with protocols and operating procedures;

3. Transport response and transport limitations;

4. Assessment of dispatch procedures;

5. Aircraft operations and safety;

6. Equipment preventive maintenance programs; and

7. A process for the resolution of customer complaints;

(i) Maintain a written plan for training personnel and responding to mass casualty incidents and disasters, which shall include an internal incident command structure and how it will integrate into a community response plan;

(j) Maintain an orientation program for all personnel related to:

1. Aircraft, scene, ground and base safety;

2. Communication equipment at the base station and on each aircraft;

3. The location and use of fire extinguishers;

4. Transport response and transport limitation standards;

5. Map reading and geographic orientation;

6. Mutual aid agreements;

7. Cleaning of equipment including aircraft;

8. Stretcher operations and use;

9. Completion of run reports; and

10. Other standard operating procedures that have been established by the provider;

(k) Maintain proof of professional liability malpractice insurance; and

(l) Maintain proof of aircraft liability insurance.

(m) Provide a copy of the current FAA Air Carrier Certificate; and

(n) Maintain a written policy regarding patient criteria for interfacility transfers including a written statement of medical necessity signed by a physician for each patient transferred.

(2) Each provider shall, in the county in which their base station or a substation is located;

(a) Document evidence of participation in county emergency management disaster exercises, if conducted;

(b) Coordinate with the county emergency management director plans for the possible utilization of a provider's personnel for use in the emergency operations center in a disaster; and

(c) Maintain a copy of the county and state emergency management agency's emergency operations plan at the ambulance base station.

Section 5. Operating Requirements.

(1) All air ambulance providers shall provide service twenty-four (24) hours a day, seven (7) days a week, subject to safety issues and weather conditions established in Part 135 of the FAR. These provisions may be met through a call system or through mutual aid agreements.

(2) A provider shall have a written plan, developed in consultation with the air ambulance provider's medical director that requires:

(a) Utilization of the air medical intake flow chart;

(b) Dispatch of requests for emergency service within two (2) minutes of the call taker's determination of the correct address or location of the emergency incident site and completion of a weather check;

(c) Disclosure of the accurate availability of provider's aircraft, including the estimated time of arrival to the requesting agency. If the provider's closest aircraft is not available, and so requested by the requesting agency, the provider shall attempt to contact the closest known aircraft to the scene; and

(d) The air ambulance provider to share current aircraft position data, through computer interface with other air ambulance providers, if the air ambulance provider utilizes a satellite tracking position mechanism.

(3) A provider may enter into mutual aid agreements with other Kentucky licensed air ambulance services operating within the same geographic area.

(4) A provider may accept a request to provide service outside of its service area except it shall require documentation from the requesting facility or provider that a good faith effort was made to utilize a provider licensed for the area.

(5) A preventive maintenance program shall be maintained that complies with Part 135 FAR or Part 92 FAR.

(6) Minimally, documentation of annual inspections or annual preventative maintenance records in addition to any records of maintenance performed shall be maintained by the provider to support evidence of periodic inspections or calibrations required for maintenance and operation of medical equipment utilized on the aircraft.

(7) Each aircraft and its equipment shall be checked after each use to ensure that it is in a clean and sanitary condition, unless precluded by emergency conditions. Minimally, documentation shall be maintained by the provider to support the evidence of a daily medical equipment checklist.

(8) A communications system shall be developed, coordinated, and maintained by each ambulance provider. The communication system shall meet the following requirements:

(a) Radio equipment used in emergency medical services aircraft shall be appropriately licensed through the FCC. Copies of the current FCC licenses shall be on file in the provider's office;

(b) Aircraft shall be equipped with two (2) way radio communication equipment capable, under normal conditions, of contacting dispatch centers and hospitals;

(c) Aircraft shall have air-to-air, ground-to-air, and air-to-ground communication capabilities and shall be capable of communicating with ground personnel to properly coordinate the landing and primary medical responders on the ground who may be caring for the patient;

(d) Aircraft shall have a minimum of two (2) portable communication devices capable of operating on the provider frequency that shall be provided for personnel when away from the aircraft; and

(e) All aircraft when approaching and departing a landing zone in uncontrolled airspace shall announce their intentions to other aircraft via 123.025 MHz.

(9) Air ambulance providers shall comply with FAR specifications for flight following and position plotting by a provider based or maintained communication center. The communication center shall be equipped with communications equipment and staffed by a properly trained ACS to receive and coordinate all calls as provided for by FAR. If providing fixed-wing service, this requirement may be met by filing an FAA flight plan.

(10) An ACS shall have documented training appropriate to the transport of the provider that shall as a minimum address the following areas:

(a) FAA and FCC regulations pertinent to air ambulance operations;

(b) Air medical radio communications;

(c) Medical terminology;

(d) Flight coordination and utilization;

(e) Navigation and weather interpretation;

(f) Flight following; and

(g) Emergency procedures.

(11) An air ambulance provider shall provide proof that it:

(a) Complies with FAR pertaining to maintenance inspections, flight, and duty time;

(b) Complies with FAA and FAR required maintenance activities; and

(c) Holds FAR required air ambulance operations specifications.

Section 6. Aircraft Requirements.

(1) Fixed and rotor-wing air ambulance aircraft shall:

(a) Have an entry that allows patient loading and unloading without tilting the patient greater than thirty (30) degrees from the horizontal axis;

(b) Be climate controlled and maintain a temperature of not less than sixty-five (65) degrees nor more than eighty-five (85) degrees Fahrenheit in the patient compartment during patient transport or demonstrate a procedure for maintaining patient temperature sufficient to prevent hypothermia and hyperthermia;

(c) All pharmaceuticals shall be kept within the recommended temperature range as established by the manufacturer or as otherwise established by FDA standards;

(d) Utilize an alternate aircraft or alternate mode of transportation, if the environment within the aircraft is such that it would be detrimental to the staff's physical welfare or the patient's condition, until those conditions are alleviated;

(e) Be configured in such a way that air medical personnel shall have access to the patient in order to begin and maintain both basic and advanced life support;

(f) Have interior lighting adequate to ensure complete observation of the patient;

(g) Have a procedure in place to limit light in the cockpit area during night operation;

(h) Have an electric inverter, with two (2) outlets, to convert direct current (DC) to alternating current (AC) for operation of specialized equipment, such as an isolette or intra-aortic balloon pump;

(i) Have equipment, stretchers, and seating:

1. Arranged so as not to block rapid egress by air ambulance personnel or patients; and

2. Affixed or secured in FAA approved racks, compartments, or strap restraints which meet FAR "G" loading requirements;

(j) Have a patient stretcher or litter which:

1. Has the capability to raise the head of the patient; and

2. Has appropriate devices to secure the patient to the stretcher.

(k) Provide proof of an FAR Part 135 certificate with an FAR required air ambulance specification; and

(l) Not transport more patients, personnel, and other persons than can be safely secured by means of seat safety belts or similar devices in the aircraft during flight.

(2) Fixed-wing aircraft shall be pressurized if patient flights are to exceed 6000 feet mean sea level.

Section 7. Air Ambulance Medical Personnel.

(1) A rotor-wing air ambulance service operating an ALS aircraft shall assure that it is minimally staffed by:

(a) A pilot as required by this administrative regulation; and

(b) Two (2) attendants that meet one (1) of the following staffing configurations:

1. A Kentucky licensed paramedic and RN authorized to practice in the state of Kentucky pursuant to KRS Chapter 314;

2. A RN and RN both of which are authorized to practice in the state of Kentucky pursuant to KRS Chapter 314; or

3. A physician authorized to practice in the state of Kentucky pursuant to KRS Chapter 311 and RN authorized to practice in the state of Kentucky pursuant to KRS Chapter 314.

(2) Each attendant required by subsection (1)(a) of this section shall additionally maintain documentation of current certification or the equivalent thereof as approved by the board of the following:

(a) ACLS;

(b) BLS;

(c) PALS;

(d)

1. PHTLS;

2. ITLS; or

3. TNATC; and

(e) NRP.

(3) BLS fixed-wing patient transports shall be minimally staffed by:

(a) A pilot as required by this administrative regulation; and

(b) Two (2) attendants whom shall be minimally certified as EMT's by the board.

(4) ALS fixed-wing patient transports shall be minimally staffed by:

(a) A pilot as required by this administrative regulation; and

(b) Two (2) attendants of which:

1. The first patient attendant shall be:

a. A flight nurse; or

b. A RN authorized to practice in the state of Kentucky pursuant to KRS Chapter 314, qualified by specific patient population, experience, and current competencies in emergency and critical care; and

2. The second patient attendant shall be:

a. A RN authorized to practice in the state of Kentucky pursuant to KRS Chapter 314, qualified by specific patient population, experience, and current competency in emergency and critical care;

b. A licensed paramedic;

c. A certified or registered respiratory therapist qualified by specific patient population, experience, and current competency in mission-specific patient care; or

d. A physician authorized to practice in the state of Kentucky pursuant to KRS Chapter 311 and qualified by relevant training, experience, and current competency in mission-specific patient care;

(5) A staffing variance on an ALS fixed-wing patient mission necessitated by staffing or patient care requirements shall not be permitted unless prior approval is granted by the medical director or designee.

(6) ALS specialty care transport patient transports by rotor or fixed wing air ambulance shall be minimally staffed by:

(a) A pilot meeting the requirements of this administrative regulation; and

(b) Two (2) attendants with relevant training, experience and current competency in transport-specific patient care as authorized by the medical director or designee of which:

1. The first patient attendant shall be:

a. A RN authorized to practice in the state of Kentucky pursuant to KRS Chapter 314;

b. A nurse practitioner; or

c. A physician authorized to practice in the state of Kentucky pursuant to KRS Chapter 311; and

2. The second patient attendant shall be:

a. A RN authorized to practice in the state of Kentucky pursuant to KRS Chapter 314;

b. A Kentucky licensed paramedic;

c. A certified or registered respiratory therapist;

d. A nurse practitioner; or

e. A physician authorized to practice in the state of Kentucky pursuant to KRS Chapter 311.

(7) All regular and specialty care air ambulance patient attendants shall attend and document flight orientation training Flight orientation training shall include:

(a) Altitude physiology;

(b) Aircraft-specific operations and in-flight safety;

(c) Emergency egress and survival training;

(d) Crew resource management; and

(e) Communication equipment utilization and emergency procedures.

(8) All regular air ambulance patient attendants shall complete and document additional flight orientation training to include:

(a) Scene safety;

(b) Use of extrication equipment;

(c) Scene triage;

(d) Kentucky EMS statutes and administrative regulations;

(e) Advanced airway management;

(f) Anatomy, physiology and assessment of adult, pediatric and neonatal patients as outlined within the program's scope of care;

(g) Cardiac emergencies and advanced critical car;

(h) Burns;

(i) Environmental emergencies;

(j) High risk OB;

(k) Multitrauma emergencies;

(l) Toxicology;

(m) Hazardous materials awareness level training;

(n) Hemodynamic monitoring;

(o) Mechanical ventilation and respiratory physiology; and

(p) Pharmacology;

(9) All regular air ambulance patient attendants shall complete and document annual continuing education which shall include a review of:

(a) Infection control;

(b) Kentucky EMS administrative regulations regarding ground and air transport;

(c) Crew resource management;

(d) Stressors of flight if not included in crew resource management;

(e) Survival training; and

(f) Skill maintenance program or competency program for invasive, high risk, or low volume procedures as outlined in the program's scope of care.

(10) An attendant shall remain with the patient, in the patient compartment, at all times during transport.

(11) [~~All aircraft, providing ALS care, that are licensed and based in Kentucky shall have a Kentucky licensed paramedic on board all aircraft that respond to scene flights. A variance from the paramedic requirement for all other flights that is necessitated by patient care requirements, shall be permitted only if the medical director or designee approves the action.~~] All aircraft responding to flights originating in Kentucky shall be licensed by the board.

(12) Aircraft that are licensed in Kentucky[~~but based in contiguous states~~] may use the staffing requirements of the state in which they are located if they are licensed in that state and the staffing requirements for that state, at a minimum for scene flights shall be:

(a) Paramedic and RN;

(b) RN and RN; or

(c) Physician and RN.

(13) This administrative regulation shall not prevent a provider from utilizing staff other than that required by this administrative regulation in:

(a) Disasters;

(b) Mass casualty incidents; or

(c) Extraordinary scene conditions that may impair the safety of the patient or personnel operating at the scene.

(14)

(a) Staffing configurations as outlined in this administrative regulation may supplement or replace the patient care attendants on a ground ambulance licensed in Kentucky for the purpose of facilitating the care and the transport of a patient if:

1. The aircraft was unable to complete a patient flight due to deteriorating weather conditions or other unplanned events; or

2. For the purpose of providing a continuum of care from the scene to the aircraft or from the aircraft to the patient destination.

(b) Air ambulance personnel shall assure the availability of necessary equipment to care for the patient during transport.

Section 8. Provider Requirements for Air Ambulance Pilots. The air ambulance provider shall assure that prior to performing emergency medical service transports the PIC complies with all requirements as set forth in 14 FAR Part 135.4. All documentation of having met this requirement shall be provided upon request.

Section 9. Basic Life Support Equipment and Supplies.

(1) All rotor air ambulance providers shall carry and maintain, in full operational order, the following minimum BLS equipment and supplies:

(a) Suction equipment, which shall include:

1. Two (2) sources of suction apparatus, one (1) of which shall be fixed, and one (1) of which shall be portable;

2. Rigid catheters;

3. Flexible catheters in adult, pediatric and infant sizes;

4. Bulb syringe or meconium aspiration device for infant and neonate suction;

(b) Oxygen and airway supplies and equipment, including:

1. An installed oxygen system with a capacity of at least 2,000 liters of oxygen for each aircraft;

2. Portable oxygen system supplying at least 300 liters;

3. A backup source of oxygen, which may be the required portable tank if it is carried in the patient care area during flight in the event the main system fails. The backup source shall be delivered via a nongravity dependent delivery device;

4. Pressure gauge and flow rate regulator for fixed and portable units with a range of zero to fifteen (15) liters per minute;

5. Oxygen supply tubing;

6. Transparent nonrebreather oxygen masks for adults and pediatrics;

7. Nasal cannulas for adults and pediatrics;

8. Disposable adult, pediatric, and infant bag-valve-mask ventilation units with oxygen reservoir, oxygen tubing and masks;

9. Nasopharyngeal and oropharyngeal airway kits in sizes for adult and children with water soluble lubricant; and

10. Bite stick;

(c) Trauma equipment and supplies including:

1. Two (2) sterile universal dressings at least 10 in. x 30 in., compactly folded and packaged;

2. Four (4) by four (4) gauze pads;

3. Soft roller self-adhering bandages, various sizes;

4. Four (4) rolls of adhesive tape, minimum of two (2) sizes;

5. Two (2) sterile burn sheets;

6. Two (2) eye protector pads and shields or an approved substitute;

7. Two (2) occlusive dressings;

8. Shears for bandages;

9. Splints, including:

a. Lower extremity mechanical traction splint in adult and pediatric sizes; and

b. Splints for arm, full leg and foot using semi-rigid immobilization devices; and

10. Immobilization devices, including:

a. Lower adult and pediatric long spine boards or other full body immobilization device with straps and cervical immobilization accessories;

b. Five (5) rigid, still cervical collars in four (4) different sizes including pediatric sizes; and

c. Towel rolls or other bulk dressings to be used for cervical immobilization for infants;

(d) Patient assessment and management equipment and supplies, including:

1. Adult, obese adult, pediatric, and infant sphygmomanometer cuffs with stethoscope. A permanently mounted sphygmomanometer shall not satisfy this requirement;

2. One (1) penlight;

3. An AED with a minimum of two (2) complete sets of pads for all non-ALS air ambulances;

4. A device for monitoring pulse oximetry; and

5. Thermometer;

(e) Personal protective equipment, which shall be available to each staff member responding on the aircraft, including:

1. One (1) clean scrub gown or substitute, such as disposable coveralls;

2. Simple disposable face mask;

3. Clear protective goggles or safety glasses;

4. Disposable gloves;

5. One (1) particulate filter mask rated at N95 or better without an exhaust port for patient use;

6. One (1) particulate filter mask rated at N95 or better with or without an exhaust port for protection of crew members; and

7. A means of cleansing the hands, such as disposable towelettes or other solutions;

(f) Patient comfort items including:

1. Two (2) clean blankets and sheets; and

2. An emesis container or similar substitute; and

(g) Miscellaneous supplies, including:

1. Hand held flashlight capable of providing adequate lighting to assess a scene or a patient away from the aircraft;

2. One (1) sterile obstetrical kit;

3. Instant glucose; and One (1) multipurpose fire extinguisher which meets FAA requirements for each specific aircraft and configuration.

(2) All aircraft shall have a stretcher or litter with:

(a) Head-raising capabilities;

(b) An FAA approved aircraft-specific mechanism for securing the stretcher or litter in the aircraft during transit; and

(c) An FAA approved aircraft-specific patient to stretcher securing mechanism.

(3) Cleaning materials shall be available, including:

(a) Hospital type disinfectants;

(b) Glass or multisurface cleaner;

(c) Trash bags for disposal of nonbiohazard waste materials;

(d) Biohazard bags for the disposable of biohazard waste; and

(e) Environment, terrain, and mission-specific rescue and survival supplies; and

(4) Current expiration dates shall be required for any item that carries an expiration date.

Section 10. Advanced Life Support Equipment and Supplies.

(1) All ALS providers shall maintain evidence in the form of a letter that medical protocols have been reviewed and approved by the board.

(2) In addition to the BLS equipment required in Section 9 of this administrative regulation, an ALS provider shall carry on each aircraft and maintain in fully-operational order, supplies and equipment required by the providers protocols, including as a minimum:

(a) Endotracheal intubation equipment consisting of:

1. Laryngoscope handle;

2. Various laryngoscope blades in adult, pediatric, and infant sizes;

3. Extra batteries and bulbs for handles or blades;

4. A minimum of seven (7) different sizes of endotracheal tubes for oral and nasal placement in adult, pediatric, and infant sizes;

5. Equipment necessary to perform emergency cricothyrotomy;

6. Alternative airway device to include at least one (1) of the following:

a. LMA;

b. Combitube;

c. King Airway; or

d. Additional alternative airway device as approved by the service medical director;

7. End tidal carbon dioxide detection devices, including:

a. A Capnography device that provides continuous waveform and digital readout of end tidal CO2; and

b. A disposable colormetric device;

8. Stylettes in adult and pediatric sizes;

9. Magill forceps in adult and pediatric sizes;

10. One-half (1/2) inch wide twill tape or equivalent for securing endotracheal tubes; and

11. Water soluble lubricant for lubrication of endotracheal and nasotracheal tubes;

(b) A portable monitor defibrillator that:

1. Is capable of displaying a visual display of cardiac electrical activity;

2. Is capable of providing a hard copy of cardiac electrical activity measure;

3. Is capable of delivering direct current energy over a variable range, which is suitable for pediatric and adult usage;

4. Is capable of providing external cardiac pacing;

5. Has adult and pediatric external paddle electrodes or pads, capable of utilization for immediate monitoring of heart activity and delivery of counter shock in both the adult and pediatric patient;

6. Is capable of being operated from internal rechargeable batteries;

7. Has synchronized counter-shock capability for cardioversion; and

8. Has a patient monitoring cable with:

a. Electrode paste or gel or equivalent;

b. Electrode pads or equivalent for use with the patient monitoring cable; and

c. One (1) additional roll of paper for hard copy printout;

(c) Pulse oximeter;

(d) Mechanical ventilation device;

(e) Sterile, disposable needles, in types and sizes sufficient for personnel to administer medications and perform procedures allowed by the providers' patient treatment protocols;

(f) Disposable syringes in types and sizes sufficient for personnel to administer medications and perform procedures allowed by the providers' patient treatment protocols;

(g) Restriction band appropriate for use with venipuncture procedure;

(h) Dextrostix or equivalent for the measure of blood glucose levels;

(i) Disposable, individually-packaged antiseptic wipes;

(j) Intravenous fluids as required by the provider's protocol, with macrodrip and microdrip fluid sets, extension sets and accessory items including over-the-needle catheter devices in sizes fourteen (14) to twenty-four (24) gauge;

(k) Intraosseous needles; and

(l) Pediatric drug dosage tape or equivalent that provides easy reference for pediatric and infant treatment and drug dosages.

(3) An ALS provider shall stock and maintain drugs and medications as required by the master drug list contained in protocols established in accordance with this section.

(4) Controlled drugs shall be stored in a locked storage box in a locked compartment on the aircraft. A provider that stores and utilizes controlled substances shall show proof of having submitted the provider's protocols to the Cabinet for Health Services' Drug Control Branch.

(5) A provider may maintain other supplies or equipment that are required to carry out its protocols as approved by the board.

(6) Current expiration dates shall be required for any item that carries an expiration date.

(7) Drugs and fluids maintained on the aircraft shall be stored based on manufacturer's recommendations.

Section 11. Specialty Care Equipment. A provider may maintain other equipment specified by the medical director if needed for the transport of neonates or other special needs patients.

Section 12. Medical Directors.

(1) All providers of air ambulance services shall have a medical director.

(2) Medical directors shall meet the requirements as set forth in 202 KAR 7:801.

Section 13. Request for Waiver.

(1) A provider licensed or contemplating licensure under this administrative regulation may make a written request to the board for certain provisions of this administrative regulation to be waived.

(2) A request shall justify that a proposed waiver, if approved, shall not jeopardize the quality of patient care or public safety.

(3) The board may approve a request based on at least one (1) of the following:

(a) Circumstances where public health and safety is a factor;

(b) Extenuating or mitigating circumstances that warrant consideration to assure the delivery of adequate emergency medical services;

(c) Substitution of equipment authorized by this administrative regulation; or

(d) Testing of new procedures, techniques, or equipment in a pilot study authorized by the board.

(4) The board shall establish time limits and conditions on all waivers.

Section 14. Exemptions from Regulations.

(1) The following situations shall be exempt from the provisions of this administrative regulation:

(a) First aid or transportation provided in accordance with KRS 216B.020(2)(f);

(b) An aircraft serving as an ambulance during a disaster or major catastrophe; or

(c) An aircraft operated by the United States government on property owned by the United States government.

(2) In addition, the following out-of-state providers shall be exempt from the provisions of this administrative regulation:

(a) An aircraft licensed by another state that is transporting a patient from out of state to a Kentucky medical facility or other location in Kentucky;

(b) An aircraft licensed by another state that is transporting a patient from out of state through Kentucky to another location out of state; and

(c) An aircraft licensed in an adjoining state that responds to a mutual aid request from a Kentucky licensed provider for emergency assistance if the out-of-state service is the closest service appropriately capable of responding to the request or if Kentucky licensed providers:

1. Are unavailable;

2. Have already responded; or

3. Are physically unable to reach the incident.

Section 15. Public Notice of Negative Action. The board office shall cause to be published, in the KBEMS News or similar publication of the board, or otherwise disseminate, the name of an ambulance provider that is fined, placed on probationary status, placed on restricted status, suspended, or had a license revoked.

Section 16. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) Form EMS-8A, "Kentucky Emergency Medical Services Ambulance Run Report", 9/98;

(b) Form EMS-8B, "Kentucky Emergency Medical Services Ambulance Run Report", 9/98;

(c) Form EMS-1, "Kentucky Application for Ambulance Service Licensing", 6/96; and

(d) "Air Medical Intake Flow Chart", 10/2008.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of the Kentucky Board of Emergency Medical Services, 500 Mero Street, 5th Floor 5SE32, Frankfort, Kentucky 40601[~~300 N. Main Street, Versailles, Kentucky 40383~~], Monday through Friday, 8 a.m. to 4:30 p.m.

JOHN R. HOLDER, Chair

APPROVED BY AGENCY: April 14, 2023

FILED WITH LRC: May 15, 2023 at 10:30 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on July 26, 2023, at 1:00 PM Eastern Time, at the Kentucky Board of Emergency Medical Services, 500 Mero Street, 5th Floor 5SE32, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five (5) workdays prior to the hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through June 30, 2023. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: John K. Wood, Legal Counsel, Kentucky Board of Emergency Medical Services, 163 E. Main Street, Suite 200, Lexington, Kentucky 40507, Phone: (859) 225-4714, Email: administrativeregulations@wgmfirm.com.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: John K. Wood

(1) Provide a brief summary of:

(a) What this administrative regulation does:

KRS 311A.020 requires the board to exercise all administrative functions in the regulation of the emergency medical services system and the practice of emergency medical services, except those functions regulated by the Board of Medical Licensure or the Cabinet for Health and Family Services. KRS 311A.030 requires the board to promulgate administrative regulations for the licensing, inspection, and regulation of air ambulance providers. This administrative regulation establishes minimum licensing requirements for air ambulance providers.

(b) The necessity of this administrative regulation:

KRS 311A.020 requires the board to exercise all administrative functions in the regulation of the emergency medical services system and the practice of emergency medical services, except those functions regulated by the Board of Medical Licensure or the Cabinet for Health and Family Services. KRS 311A.030 requires the board to promulgate administrative regulations for the licensing, inspection, and regulation of air ambulance providers. This administrative regulation is necessary to establish minimum licensing requirements for air ambulance providers.

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

This administrative regulation conforms to the content of KRS 311A.020 and KRS 311A.030 by establishing minimum licensing requirements for air ambulance providers.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

KRS 311A.020 requires the board to exercise all administrative functions in the regulation of the emergency medical services system and the practice of emergency medical services, except those functions regulated by the Board of Medical Licensure or the Cabinet for Health and Family Services. KRS 311A.030 requires the board to promulgate administrative regulations for the licensing, inspection, and regulation of air ambulance providers. This administrative regulation assists in the effective administration of the foregoing statutes by establishing minimum licensing requirements for air ambulance providers.

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

(a) How the amendment will change this existing administrative regulation:

This amendment removes the requirement that all aircraft licensed and based in Kentucky and providing ALS care have a paramedic on-board the aircraft. Instead, all aircraft licensed in Kentucky will be required to have on-board, at a minimum, either (1) a paramedic and a registered nurse, (2) two registered nurses, or (3) a physician and a registered nurse.

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

There remains a shortage of paramedics throughout the Commonwealth. This amendment is necessary to allow air ambulances to operate without having a paramedic on-board.

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

This administrative regulation conforms to the content of KRS 311A.020 and KRS 311A.030 by establishing minimum licensing requirements for air ambulance providers.

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

KRS 311A.020 requires the board to exercise all administrative functions in the regulation of the emergency medical services system and the practice of emergency medical services, except those functions regulated by the Board of Medical Licensure or the Cabinet for Health and Family Services. KRS 311A.030 requires the board to promulgate administrative regulations for the licensing, inspection, and regulation of air ambulance providers. This amendment will assist in the effective administration of the foregoing statutes by establishing minimum licensing requirements for air ambulance providers.

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

This administrative regulation will affect the Kentucky Board of Emergency Medical Services, air ambulances services, and air ambulance services personnel.

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

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

To comply with this amendment, air ambulance services will have to have, at a minimum, either (1) a paramedic and a registered nurse, (2) two registered nurses, or (3) a physician and a registered nurse on-board each of their aircraft when conducting scene flights.

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

There will be no cost to any entity identified in question (3).

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

This amendment will benefit air ambulance services and their personnel by allowing air ambulances to operate without having a paramedic on-board.

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

(a) Initially:

There will be no cost to the administrative body to implement this administrative regulation.

(b) On a continuing basis:

There will be no cost to the administrative body to implement this administrative regulation.

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

No funding source is necessary to implement and enforce this administrative regulation.

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

No increase in fees or funding will be necessary.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This regulation does not establish any fees.

(9) TIERING: Is tiering applied?

Tiering is not applied to this administrative regulation because this amendment applies equally to all air ambulance services.

FISCAL NOTE

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

This administrative regulation will affect the Kentucky Board of Emergency Medical Services, air ambulance services, and air ambulance services personnel.

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

KRS 311A.020 requires the board to exercise all administrative functions in the regulation of the emergency medical services system and the practice of emergency medical services, except those functions regulated by the Board of Medical Licensure or the Cabinet for Health and Family Services. KRS 311A.030 requires the board to promulgate administrative regulations for the licensing, inspection, and regulation of air ambulance providers. This administrative regulation establishes minimum licensing requirements for air ambulance providers.

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

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

This administrative regulation will generate no revenue for the first year.

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

This administrative regulation will generate no revenue for subsequent years.

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

Administration of this administrative regulation will not require any costs.

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

Administration of this administrative regulation will not require any costs.

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

Revenues (+/-): This administrative regulation will not generate revenue.

Expenditures (+/-): This administrative regulation will not require any additional expenditures.

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

This administrative regulation will not generate any cost savings.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

This administrative regulation will not generate any cost savings.

(c) How much will it cost the regulated entities for the first year?

This administrative regulation will not impose any costs.

(d) How much will it cost the regulated entities for subsequent years?

This administrative regulation will not impose any costs.

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

Cost Savings (+/-): This administrative regulation will not generate any cost savings.

Expenditures (+/-): This administrative regulation will not impose any costs.

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. This administrative regulation will not have a major economic impact.