

Legend: (Proposed Amendment(s))

Single Underline = Proposed new language

**[Bold, Print, and Brackets]** = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

#### §157.13. Fixed-wing Air Ambulance Operations

(a) Fixed wing aircraft operated by a licensed EMS provider shall be at the mobile intensive care level. Persons or entities operating fixed wing air ambulances must direct and control the integrated activities of both the medical and aviation components. Although the aircraft operator is directly responsible to the Federal Aviation Administration (FAA) for the operation of the aircraft, one organization, typically the one in charge of the medical functions, directs the combined efforts of the aviation and medical components during patient transport operations. Licensed fixed wing aircraft must also meet the requirements of §157.11 of this title, relating to requirements for an EMS provider license, as long as the rule does not violate the Federal Aviation Act of 1958, 49 U.S.C. §§ et seq. and Airline Deregulation Act of 1978, 49 U.S.C. § 41713 (b) (1).

(b) When being used as an ambulance, a fixed wing aircraft shall:

(1) be multi-engine or be a single, turbo-prop engine capable of maintaining cabin pressurization;

(2) maintain a cabin altitude consistent with patient diagnosis, condition, and destination;

(3) be equipped and kept current for instrument flight rules (IFR) flight;

(4) have a door large enough to allow a patient on a stretcher with the manufacturer's recommended or FAA approved restraint system in place to be planed without excessive maneuvering or tipping of the patient which compromises the function of monitoring devices, intravenous (IV) lines or ventilation equipment;

(5) be designed or modified to accommodate at least one stretcher patient with the manufacturer's recommended or FAA approved restraint system in place;

(6) have a lighting system which can provide adequate intensity to illuminate the patient care area and an adequate method (curtain, distance) to limit the cabin light from entering the cockpit and impeding cockpit crew vision during night operations;

(7) have a permanently installed climate control equipment to provide an environment appropriate for the medical needs of the patient(s). **[have an environmental system (heating and cooling) capable of maintaining a comfortable temperature at all times];**

(8) have an interior cabin configuration large enough to accommodate the number of air medical personnel needed to provide care to the patient, as well as an adult stretcher in the cabin area with access to the patient. The configuration shall not impede the normal or emergency evacuation routes;

(9) have an electrical system capable of servicing the power needs of electrically powered on-board patient care equipment;

(10) have all installed and carry-on equipment secured using FAA-approved devices and methods;

(11) specialized medical equipment, such as but not limited to, intra-aortic balloon pump, extracorporeal membrane oxygenation, left ventricular assist device, temperature management system, is secured throughout transport with adequately engineered, designated engineering representative approved mount.

(12) [(11)] have sufficient space in the cabin area where the patient stretcher is installed so that equipment can be stored and secured with FAA-approved devices in such a manner that it is accessible to the air medical personnel; and

(13) [(12)] have two FAA approved fire extinguishers approved for aircraft use. Each shall be fully charged with valid inspection certification and capable of extinguishing type A, B, or C fires. One extinguisher shall be accessible to the cockpit crew and one shall be in the cabin area accessible to the medical crew member.

(c) An operator of aircraft in an air ambulance program shall be FAA certified as an air taxi and commercial operator (ACTO) with operation specifications allowing air ambulance operations.

(d) The fixed-wing air ambulance provider shall meet the responsibilities of EMS providers as in §157.11[(I)] of this title (relating to Requirements for an EMS Provider License) and shall also:

(1) submit proof that the fixed-wing aircraft provider carries bodily injury and property damage insurance with a company licensed to do business in Texas, in order to secure payment for any loss or damage resulting from any occurrence arising out of or caused by the operation or use of any of the certificate holder's aircraft. **[Coverage amounts shall insure that:**

**(A) each aircraft shall be insured for the minimum amount of \$1 million for injuries to, or death of, any one person arising out of any one incident or accident;**

**(B) the minimum amount of \$3 million for injuries to, or death of, more than one person in any one accident; and**

**(C) for the minimum amount of \$500,000 for damage to property arising from any one accident;]**

(2) submit proof that the air ambulance provider carries professional liability insurance coverage in the minimum amount of \$500,000 per occurrence, with a company licensed to do business in Texas in order to secure payment for any loss or damage resulting from any occurrence arising out of or caused by the care or lack of care of a patient; and

(3) submit a letter of agreement that all fixed-wing aircraft shall meet the specifications of subsection (b) of this section, if the aircraft is leased from a pool; and

(4) submit a copy of current Federal Aviation Administration Air Taxi and Commercial Operator Certification.

(e) The air ambulance provider shall **[designate or]** employ a medical director who shall meet the following qualifications:

(1) be a physician approved by the Texas Department of Health and in practice;

(2) have knowledge and experience consistent with the transport of patients by air;

(3) be knowledgeable in aeromedical physiology, stresses of flight, aircraft safety, patient care, and resource limitations of the aircraft, medical staff and equipment;

(4) have access to consult with medical specialists for patient(s) whose illness and care needs are outside the medical director's area of practice; and

(5) shall comply with the requirements in [**Chapter 6, Medicine, Article 4495b, Medical Practice Act, §197.3 subparagraphs (a)(2)-(7) and (b).**] the Medical Practice Act, Occupations Code, Chapters 151 – 168, and Title 22 of the Texas Administrative Code, Chapter 197; and

(f) The physician shall fulfill the following responsibilities:

(1) ensure that there is a comprehensive plan/policy to address selection of appropriate aircraft, staffing and equipment;

(2) be involved in the selection, hiring, educating, training and continuing education of all medical personnel;

(3) be responsible for overseeing the development and maintenance of a continuous quality improvement program;

(4) ensure that there is a plan to provide direction of patient care to the air medical personnel during transport. The system shall include on-line (radio/telephone) medical control,

and/or an appropriate system for off-line medical control such as written guidelines, protocols, procedures, patient specific written orders or standing orders;

(5) participate in administrative decision making processes that affect patient care;

(6) ensure that there is an adequate method for on-line medical control, and that there is a **[well]** defined plan or procedure and resources in place to allow off-line medical control; and

(7) oversee the review, revision and validation of written policies and protocols annually for the treatment and transportation of adult, pediatric, and neonatal patients to include a policy defining the specific instances in which a patient could be accompanied by only one attendant; and [.]

(8) attest to the following capabilities:

(A) experience consistent with the transport of patients by air;

(B) knowledge of aeromedical physiology, stresses of flight, aircraft safety, resources limitations of the aircraft;

(C) knowledge on Texas EMS laws and regulations affecting local, regional and state operations;

(D) awareness that the EMS provider has provided safety education for ground emergency services personnel.

(g) There shall be at least one licensed or certified paramedic, registered nurse, or physician on board an air ambulance to perform patient care duties on that air ambulance. The qualifications and numbers of air medical personnel shall be appropriate to patient care needs. Personnel employed by providers who are based in another state, do not need Texas certification/licensure but shall be certified/licensed in their respective state.

(1) Documentation of successful completion of education [training] specific to the fixed-wing transport environment in general and the licensee's operation specifically shall be required. The curriculum shall be consistent with the Department of Transportation (DOT) Air Medical Crew- National EMS Education Standards [Standard Curriculum], or equivalent program.

(2) Each attendant's qualifications shall be documented.

(3) Air medical personnel shall not be assigned or assume the cockpit duties of the flight crew members concurrent with patient care duties and responsibilities.

(4) The aircraft shall be operated by a pilot or pilots certified in accordance with applicable Federal Aviation Regulations.

(h) Medical supplies and equipment shall be consistent with the service's scope of care as defined in the protocols/standing orders for adult, pediatric, and neonatal patients. Medical equipment shall be functional without interfering with the avionics nor should avionics interfere with the function of the medical equipment. Additionally, the following equipment, clean and in working order, must be on the aircraft or immediately available for all providers:

(1) one or more stretchers installed in the aircraft cabin which meet the following criteria:

(A) can accommodate an adult, 6 feet tall, weighing 212 pounds except for a neonatal stretcher, with recommended manufacturer's or FAA approved restraint system in place, which has been fitted with an isolette. There shall be restraining devices or additional appliances available to provide adequate restraint of all patients including those under 60 pounds or 36 inches in height;

(B) the head of each stretcher, with recommended manufacturer's or FAA approved restraint system in place, shall be capable of being elevated up to 45 degrees. The elevating section must hinge at or near the patient's hips and shall not interfere with or require that the patient or stretcher securing straps and hardware be removed or loosened;

(C) each stretcher, with recommended manufacturer's or FAA approved restraint system in place, shall be positioned in the cabin to allow the air medical personnel clear view of the patient and shall ensure that medical personnel always have access to the patient's head and upper body for airway control procedures as well as sufficient space over the area where the patients chest is to adequately perform closed chest compression or abdominal thrusts on the patient;

(D) a pad or mattress impervious to moisture and easily cleaned and disinfected according to Occupation Safety and Health Administration (OSHA) bloodborne pathogen requirements;

(E) a device to make the stretcher surface rigid enough if the surface of the stretcher under the patient's torso is not firm enough to support adequate chest compressions; and

(F) shall have a supply of linen for each patient;

(2) an adequate and manually-controlled supply of gaseous or liquid medical oxygen, attachments for humidification, and a variable flow regulator for each patient;

(A) a humidifier, if used, shall be a sterile, disposable, one-time usage item;

(B) the licensee shall have and demonstrate the method used to calculate the volume of oxygen required to provide sufficient oxygen for the patients needs for the duration of the transport;

(C) the licensee shall have a plan to provide the calculated volume of oxygen plus a reserve equal 1000 liters or the volume required to reach an appropriate airport, whichever is longer;

(D) all necessary regulators, gauges and accessories shall be present and in good working order;

(E) the oxygen system shall be securely fastened to the airframe using FAA-approved restraining devices;

(i) a separate emergency backup supply of oxygen of not less than 57 liters with regulator and flow meter;

(ii) one adult, one child, one pediatric, one neonatal size non-rebreathing mask, one adult size nasal cannula and necessary connective tubing and appliances.

(3) an electrically-powered suction apparatus with wide bore tubing, a large reservoir and various sizes suction catheters. The suction system may be built into the aircraft or provided with a portable unit. Backup suction is required and can be a manually operated device. (Bulb syringe not acceptable);

(4) hand operated bag-valve-mask ventilators of adult, pediatric and infant sizes with clear masks in adult, pediatric, and neonatal patients [**pediatric and infant sizes**]. It shall be capable of use with a supplemental oxygen supply and have an oxygen reservoir;

(5) airway adjuncts as follows:

(A) oropharyngeal airways in at least five assorted sizes, including adult, pediatric, and neonatal patients [**child and infant**]; and

(B) nasopharyngeal airways in at least three sizes with water soluble lubricant;

(6) assessment equipment as follows:

(A) equipment suitable to determine blood pressure of the adult, pediatric, and neonatal patients [**pediatric and infant patient(s)**] during flight;

(B) stethoscope;

(C) penlight/flashlight;

(D) heavy duty bandage scissors; and

(E) pulse oximeter;

(7) bandages and dressings as follows:

(A) sterile dressings such as 4x4s, ABD pads;

(B) bandages such as Kerlix, Kling; and

(C) tape in various sizes.

(8) container(s) and methods to collect, contain, and dispose of body fluids such as emesis, oral secretions, and blood consistent with OSHA bloodborne pathogen requirements;

(9) urinal and bedpan with toilet tissue;

(10) infection control equipment. The licensee shall have a sufficient quantity of the following supplies for all air medical personnel, each flight crew member, and all ground personnel with incidental exposure risks according to OSHA requirements which includes but is not limited to:

(A) protective gloves;

(B) protective gowns;

(C) protective eyewear;

(D) protective face masks, National Institute for Occupational Safety and Health (NIOSH) approved N95 or greater;

(E) an approved bio-hazardous waste plastic bag or impervious container to receive and dispose of used supplies; and

(F) handwashing capabilities or antiviral towelettes.

(11) an adequate trash disposal system exclusive of bio-hazardous waste control provisions;

(12) the following additional equipment in amounts and sizes specified by the medical director is required for an air ambulance provider to function at the advanced level:

(A) advanced airway management equipment appropriate to the patient's needs;

(B) sterile crystalloid solutions in plastic containers, IV catheters, and administration tubing sets;

(C) hanger for IV solutions;

(D) pressure bag;

(E) tourniquets, tape, dressings;

(F) container appropriate to contain used sharp devices, needles, scalpels which meets OSHA requirements;

(G) a list signed by medical director defining quantities and types of drugs to be carried; and

(H) any specialized equipment required in medical treatment protocols/standing orders.

(13) cardiac monitor defibrillator-DC battery powered portable monitor/defibrillator with paper printout, accessories and supplies, with sufficient power supply to meet demands of the mission; and

(14) survival kit which shall include, but not be limited to, the following items which are appropriate to the terrain and environments the provider operates over:

(A) instruction manual;

(B) water;

(C) shelter-space blanket;

(D) knife;

(E) signaling devices;

(F) compass; and

(G) fire starting items.

(i) A system for security of medications, fluids, and controlled substances shall be maintained by each air ambulance licensee in compliance with local, state, and federal drug laws.

(j) The air ambulance provider shall own the following equipment or shall have a written lease agreement explaining the availability of the equipment for use when the patient's condition indicates the need:

(1) external cardiac pacing device;

(2) IV infusion pump capable of strict mechanical control of an IV infusion drip rate. Passive devices such as dial-a-flow are not acceptable; and

(3) a mechanical ventilator that can deliver up to 100 % oxygen concentration at pressures, rates and volumes appropriate for the size of the patient.