

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

§157.12 Rotor-wing Air Ambulance Operations.

(a) Rotary wing aircraft (helicopters) operated by a licensed emergency medical services (EMS) provider shall be at the mobile intensive care level. Persons or entities operating rotary 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, typically the organization in charge of the medical functions directs the combined efforts of the aviation and medical components during patient transport operations. Licensed rotary 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, the helicopter shall:

(1) be configured so that the medical personnel have adequate access to the patient in order to begin and maintain basic and advanced life support treatment;

(2) have an entry that allows loading and unloading of a patient without excessive maneuvering (no more than 45 degrees about the lateral axis and 30 degrees about the longitudinal axis); and does not compromise functioning of monitoring systems, intravenous (IV) lines, or manual or mechanical ventilation;

(3) have a supplemental lighting system in the event standard lighting is insufficient for patient care that includes:

(A) a self-contained lighting system powered by a battery pack or a portable light with a battery source; and

(B) a means to protect the pilot's night adaptation vision. (Use of red lighting or low intensity lighting in the patient care area is acceptable if not able to isolate the patient care area);

(4) have an electric power outlet with an inverter or appropriate power source of sufficient output to meet the requirements of the complete specialized equipment package without compromising the operation of any electrical aircraft equipment;

(5) have protection of the pilot's flight controls, throttles and radios from any intended or accidental interference by the patient, air medical personnel or equipment and supplies; and

(6) have an internal medical configuration located so that air medical personnel can provide patient care consistent with the scope of care of the air medical service, to include:

(A) the space necessary to ensure the patient's airway is maintained and to provide adequate ventilatory support from the secured, seat-belted position of the air medical personnel;

(B) those aircraft with gaseous oxygen systems have equipment installed so that medical personnel can determine if oxygen is on by in-line pressure gauges mounted in the patient care area. Aircraft using liquid or gaseous oxygen should have equipment installed:

(i) with each gas outlet clearly marked for identification;

(ii) with oxygen flow capable of being stopped at the oxygen source from inside the aircraft; and

(iii) so that the measurement of the liter flow and quantity of oxygen remaining is accessible to air medical personnel while in flight. All flow meters and outlets must be padded, flush mounted, or so located as to prevent injury to air medical personnel; or there shall be an operational policy stating that attendants wear helmets;

(C) hangers/hooks available to secure (IV) solutions in place or a mechanism to provide high flow fluids if needed:

(i) all IV hooks shall be padded, flush mounted, or so located as to prevent head trauma to the air medical personnel in the event of a hard landing or emergency with the aircraft; or an operational policy stating that attendants wear helmets; and

(ii) glass containers shall not be used unless required by medication specifications and properly vented;

(D) provision for medication which allows for protection from extreme temperatures if it becomes environmentally necessary; and

(E) secure positioning of cardiac monitors, defibrillators, and external pacers so that displays are visible to medical personnel.

(F) 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.

(c) An air ambulance provider shall meet the responsibilities of EMS providers as in §157.11[(1)] of this title (relating to Requirements for an EMS Provider License) and in addition shall:

(1) submit proof that the rotor-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) 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;

(3) submit a list of all aircraft with the registration number or "N" number for the helicopters in the possession of the provider.

(4) submit a letter of agreement that all helicopters shall meet the specifications of subsection (b) of this section, if the aircraft is leased from a pool;

(5) allow visual and physical inspection of each aircraft and of the equipment to be used on each vehicle for the purpose of determining compliance with the vehicle and equipment specifications within this section; and

(6) submit a copy of current Federal Aviation Administration (FAA) carrier, operational, and airworthiness certification, as per U.S. Code of Federal Regulations, title 14, Subchapter G, Part 135).

(d) 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,] the Medical Practice Act, Occupations Code, Chapters 151 – 168, and Title 22 of the Texas Administrative Code, Chapter 197 [§197.3(a)(2-7) and (b)] ; and [.]

(6) have knowledge on Texas EMS laws and regulations affecting local, regional and state operations.

(e) 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 any 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 medical policies and protocols annually for the treatment and transportation of adult, pediatric, and neonatal patients; 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.

(f) There shall be two Texas licensed/certified personnel on board the helicopter when in service. A waiver to the Texas license/certification may be granted for personnel employed by providers in New Mexico, Oklahoma, Arkansas, Kansas, Colorado and Louisiana who respond in Texas and are licensed in their respective state. Staffing of vehicles shall be as follows:

(1) when responding to an emergency scene, at least one of the personnel shall be a paramedic;

(2) when responding for an inter-facility transfer, at least one of the personnel performing patient care duties shall be a certified or licensed paramedic, registered nurse or physician. The qualifications and numbers of air medical personnel shall be appropriate to patient care needs;

(3) when responding as in paragraphs (1) and (2) of this subsection, the second person may be a certified or licensed paramedic, registered nurse, or a physician; and

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

(g) Documentation of successful completion of education [training] specific to the helicopter 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 and each attendant's qualifications shall be documented.

(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 capable of being secured in the aircraft which meet the following criteria:

(A) can accommodate an adult, 6 feet tall, weighing 212 pounds. 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) shall have the head of the primary stretcher, with recommended manufacturer's or FAA approved restraint system in place, capable of being elevated up to 30 degrees. The elevating section shall not interfere with or require that the patient or stretcher securing straps and hardware be removed or loosened;

(C) shall be sturdy and rigid enough that it can support cardiopulmonary resuscitation. If a backboard or equivalent device is required to achieve this, such device will be readily available;

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

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

(2) adequate amounts of oxygen and masks (for anticipated liter flow and length of flight with an emergency reserve) available for every mission;

(3) one portable oxygen tank;

(4) a back-up source of oxygen (of sufficient quantity to get safely to a facility for replacements). Back-up source may be the required portable tank if the tank is accessible in the patient care area during flight;

(5) airway adjuncts as follows:

(A) oropharyngeal airways in at least five assorted sizes, including for adult, pediatric, and neonatal patients; and

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

(6) at least one suction unit which is portable (bulb syringes or foot pump not acceptable);

(7) the following items in amounts and sizes as specified on a list signed by the medical director:

(A) IV solutions;

(B) IV catheters;

(C) endotracheal tubes;

(D) medications;

(E) any specialized equipment required in medical treatment protocols/standing orders;

(F) pressure bag;

(G) tourniquets, tape, dressings; and

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

(8) assessment equipment as follows:

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

(B) stethoscope;

(C) penlight/flashlight;

(D) heavy duty bandage scissors;

(E) pulse oximeter;

(F) external cardiac pacing device; and

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

(9) bandages and dressings as follows:

(A) sterile dressings such as 4x4s, abdominal (ABD) [**ABD**] pads;

(B) bandages such as Kerlix, Kling; and

(C) tape in various sizes;

(10) 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;

(11) infection control equipment. The licensee shall have a sufficient quantity of the following supplies for all air medical personnel, and 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;

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

(13) security of medications, fluids, and controlled substances shall be maintained by each air ambulance licensee in compliance with local, state, and federal drug laws;

(14) 12-lead 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]

(15) quantity and type of drugs and specialized equipment as specified on the medical director's list; and [.]

(16) permanently installed climate control equipment to provide an environment appropriate for the medical needs of patients.

(17) 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.