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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission:	Department of Health
Division:	Emergency Medical Services
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-12-01	General Rules
Rule Number	Rule Title
1200-12-01-.05	Air Ambulance Standards

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

Amendments

Chapter 1200-12-01

Rules for the Division of Emergency Medical Services

Rule 1200-12-01-.05 Air Ambulance Standards is amended by deleting the rule in its entirety and substituting instead the following new language so that 1200-12-01-.05, as amended, shall read:

1200-12-01-.05 Air Ambulance Standards - All air ambulance service providers and crew members operating in Tennessee must comply with Chapter 140 of Title 68 of the Tennessee Code Annotated and this Rule. Failure to comply shall subject the service provider and/or its personnel to disciplinary action pursuant to T.C.A. 68-140-511.

- (1) Definitions - As used in this Rule, the following terms shall have the following meanings:
 - (a) "Air Medical Communications Specialist" means any person employed by an air ambulance service coordinating acknowledgement of medical requests, medical destination, and medical communications during an air medical response and patient transfer.
 - (b) "Medical Crew Member" means any person employed by an air ambulance service for the purpose of providing care to patients transported by and receiving medical care from an air ambulance service.
 - (c) "Special Medical Equipment" means any device which shall be approved by the air ambulance service medical director for the medical care of an individual patient on an air ambulance.
 - (d) "Specialty Crew Member" means any person the air ambulance service medical director assigns for a regular medical crew member for a specialty mission.
 - (e) "Specialty Mission" means an air ambulance service assignment necessitating the medical director to substitute special medical care providers and/or equipment to meet the specified needs of an individual patient.
 - (f) "Utilization Review" means the critical evaluation of health care processes and services delivered to patients to ensure appropriate medical outcome, safety and cost effectiveness.
- (2) Medical Equipment and Supplies. The medical director for the emergency medical service shall ensure that the following medical equipment and supplies are provided on each fixed-wing or helicopter flight mission:
 - (a) Litter or stretcher with at least three sets of restraining straps;
 - (b) An installed and a portable suction apparatus, each of which has the capacity to deliver adequate suction, including sterile suction catheters and a rigid suction tip for both adult and pediatric patients;
 - (c) Bag/valve/mask resuscitator(s) with clear masks and an oxygen reservoir with connections capable of achieving 95% fraction inspired oxygen to provide resuscitation for both adult and pediatric patients;
 - (d) Airway devices for adult and pediatric patients including the following:

1. Oropharyngeal airways;
 2. Endotracheal tubes;
 3. Laryngoscope with assorted blades and accessory items for intubation; and,
 4. Alternative advanced airway devices as approved by the service medical director;
- (e) Resuscitation board suitable for cardiac compression, unless a rigid stretcher or spine board is employed for patient transfer;
- (f) Medical oxygen equipment on board capable of adjustable flow from 2 to 15 liters per minute including the following:
1. Masks and supply tubing capable of administering variable oxygen concentrations from 24% to 95% fraction inspired oxygen for both adult and pediatric patients;
 2. Medical oxygen to allow for treatment during 150% of estimated transport time; and,
- (g) Sanitary supplies including the following:
1. Bedpan (fixed-wing flight mission only);
 2. Urinal (fixed-wing flight mission only);
 3. Towelettes (fixed-wing flight mission only);
 4. Tissues (fixed-wing flight mission only);
 5. Emesis bags;
 6. Plastic trash disposable bags; and,
 7. Non-latex gloves;
- (h) Sheets and blankets for each patient transported;
- (i) Patient assessment devices for adult and pediatric patients, including:
1. Flashlight and/or penlight;
 2. Stethoscope and Doppler stethoscope;
 3. Sphygmomanometer and blood pressure cuffs;
 4. Electro-cardiographic monitor/recorder and defibrillator, with transcutaneous pacemaker, having a back-up power source;
 5. Pulse oximetry;
 6. Capnography, both continuous and portable;

7. Transport ventilator; and
 8. Clinical thermometer or temperature strips;
- (j) Trauma supplies, including:
1. Sterile dressings;
 2. Roller bandages;
 3. Device for chest decompression;
 4. Surgical airway device as approved by medical direction; and
 5. Semi-rigid immobilization devices;
- (k) Intravenous fluids and administration devices;
- (l) Appropriate medications including the advanced life support medications described in Rule 1200-12-01-.03; and
- (m) Neonatal transport equipment that shall conform to the standards adopted in the Tennessee Perinatal Care System Guidelines for Transportation, Tennessee Department of Health, Women's Health and Genetics Section, Fifth Edition, 2006 or successor publication.
1. Isolette shall be capable of being opened from its secured position within the aircraft.
- (3) In addition to the medical equipment and supplies required on either a fixed wing or helicopter flight mission as described in paragraph (2) above, the medical director for the emergency medical service shall ensure that the following medical equipment and supplies are provided on each helicopter flight mission:
- (a) Medical oxygen equipment capable of adjustable flow from 2 to 15 liters per minute which shall include:
1. Portable medical oxygen system with a usable supply of at least 300 liters of oxygen; and
 2. A backup source of oxygen that shall be delivered via a non-gravity dependent delivery source which may be the required portable tank if it is carried in the patient care area during flight;
- (b) Trauma supplies, including:
1. Lower extremity traction device; and
 2. Semi-rigid cervical collars.
- (4) Each air ambulance service shall offer its instruction materials to other EMS providers within its response area to familiarize them with its requirements for control of helicopter access and ground to air communications on the scene.

(5) Air Ambulance Personnel Qualifications and Duties

(a) Medical Director Qualifications and Duties

1. Each helicopter air ambulance service shall employ a Medical Director who is responsible for providing medical direction for the helicopter air ambulance service.
2. The Medical Director for a helicopter air ambulance service must be a physician having the following qualifications:
 - (i) Currently licensed in the State of Tennessee;
 - (ii) Board certified or eligible for Board certification by a professional association or society in General or Trauma Surgery, Family Practice, Internal Medicine, Pediatrics, Emergency Medicine, or Aerospace Medicine;
 - (iii) Certification in Advanced Cardiac Life Support (unless Board certified or eligible for Board certification in Emergency Medicine);
 - (iv) Certification in Advanced Trauma Life Support; and
 - (v) Certification in Pediatric Advanced Life Support or equivalent (unless Board certified or eligible for Board certification in Emergency Medicine), including the following:
 - (I) Certification in a Neonatal Resuscitation Program; and
 - (II) Possess adequate knowledge regarding altitude physiology/stressors of flight.
3. Duties of the Medical Director for a helicopter air ambulance service shall include the following:
 - (i) Active involvement in the Quality Improvement process;
 - (ii) Active involvement in the hiring, training and continuing education of all medical personnel for the service; and
 - (iii) Responsibility for on-line medical control or involved in orienting and collaborating with physicians providing on-line medical direction according to the policies, procedures and patient care protocols of the medical transport service.
4. The service Medical Director shall establish mission specific and clinical procedures. He shall require each medical crew member to complete and maintain documentation of initial and annual training in such procedures, which shall at least include didactic and hands-on components for the following clinical procedures:
 - (i) Pharmacological Assisted Intubation – Adult and Pediatric;
 - (ii) Emergency cricothyrotomy;

- (iii) Alternative airway management – Adult and Pediatric;
- (iv) Chest decompression; and
- (v) Intraosseous Access – Adult and Pediatric.

(b) The medical crew shall include:

1. Each patient transported by a fixed-wing ambulance shall be accompanied by either a physician, a registered nurse, or an EMT-P licensed in the State of Tennessee.
2. Each transport of patients by a helicopter air ambulance shall require staffing by a regular medical crew which as a minimum standard shall consist of one Registered Nurse licensed in the State of Tennessee and another licensed medical provider (i.e., EMT-P, Respiratory Therapist, Nurse, or Physician licensed in the State of Tennessee). The composition of the medical team may be altered for specialty missions upon order of the medical director of the air ambulance service.
3. On a fixed-wing flight mission only, the air ambulance service medical director may allow transport of patients in the presence of only one medical professional; the minimum level of licensure in such a situation would be that of EMT-P.

(c) Medical crew training and qualifications

1. The service medical director shall make a determination that each regular medical crew member serving on an air ambulance is physically fit for duty by ensuring the service has documentation that each regular crew member has had a pre-employment and annual medical examination.
2. A Registered Nurse serving as a medical crew member on an air ambulance shall meet the following qualifications:
 - (i) Have three years of registered nursing experience in critical care nursing, or two years fulltime flight paramedic experience and one year critical care nursing experience;
 - (ii) Possess a current Tennessee nursing license, unless exempted by T.C.A. § 63-7-102(8);
 - (iii) Obtain certification as an Emergency Medical Technician within twelve (12) months of employment; and
 - (iv) Obtain advance nursing certification within twelve (12) months of employment through one of the following programs:
 - (I) Certified Emergency Nurse; or
 - (II) Critical Care Registered Nurse; or
 - (III) Certified Flight Registered Nurse.
3. An EMT-Paramedic serving as a medical crew member on an air ambulance shall meet the following qualifications:

- (i) Possess a current Tennessee EMT-P license and have three years experience as an EMT-P in an advanced life support service;
 - (ii) Obtain advanced paramedic certification within twenty-four (24) months of employment through one of the following programs:
 - (I) Critical Care Paramedic; or
 - (II) Certified Flight Paramedic.
4. Each medical crew member on an air ambulance shall have and maintain certification in Advanced Cardiac Life Support, Pediatric Advanced Life Support or equivalent (Emergency Nursing Pediatric Course, PEPP), and in neonatal resuscitation.
5. Each medical crew member on an air ambulance shall attend and maintain training in one of the following:
- (i) Trauma Nurse Advanced Trauma Course;
 - (ii) International Trauma Life Support;
 - (iii) Prehospital Trauma Life Support; or,
 - (iv) Trauma Nurse Core Course.
- (d) Each fixed wing air ambulance service shall have an air medical consultant who shall be a physician licensed within the jurisdiction of the base of operations and shall advise on the restrictions and medical requirements for patient transport.
- (e) Each helicopter air ambulance service shall have a Medical Control Physician who shall be available to provide on line medical control continuously via radio or telephone who shall be board certified or eligible for board certification by a professional association or society in General or Trauma Surgery, Internal medicine, Pediatrics, Emergency Medicine, Family Practice, or Aerospace Medicine.
- (f) Air Medical Communications specialist qualifications and duties:
1. Each air medical communications specialist shall meet the following qualifications:
 - (i) At a minimum, be licensed as an Emergency Medical Technician; or
 - (ii) Be a higher level licensed health care professional with at least two years of emergency medical or emergency communications experience; and
 2. Have initial and recurrent training for medical coordination and telecommunications.
 3. Air medical communications specialists shall be certified through the National Association of Air Medical Communication Specialists (NAACS) or obtain such certification within twelve (12) months of employment.
 - (i) Air medical communication specialists shall coordinate helicopter air ambulance service flights.

4. Air medical communications specialists shall not be required to work more than sixteen (16) hours in any one twenty-four (24) hour period.

(g) Duty time for medical crew members on an air ambulance shall not exceed twenty-four (24) consecutive hours or more than forty-eight (48) hours within a seventy-two (72) hour period. The air ambulance service shall provide the medical flight crew adequate rest and meal time. Personnel must have at least eight (8) hours of rest with no work-related interruptions prior to any scheduled shift of twelve (12) hours or more in the air transport environment.

(6) Flight Coordination

(a) Each air ambulance service operations office director shall maintain an Operations Manual detailing policies and procedures and shall ensure that it is available for reference in the operations office. Personnel shall be familiar and comply with policies contained within the manual which shall include:

1. Criteria for medical conditions including indications or contraindications for transfer;
2. Procedures for call verification and advisories to the requesting party;
3. Radio and telephone communications procedures;
4. Policies and procedures for accidents and incidents;
5. Procedures for informing the requesting party of operations procedure, ambulance arrival, termination of mission and delayed responses, including the following:
 - (i) Estimated Time of Arrival includes time of operations acceptance to time of landing on scene; and
 - (ii) Any deviation from ETA greater than 5 minutes will be reported to the requesting agency;
6. Procedures shall be established for communications failure or overdue transports;
7. Emergency protocols for alerting search and rescue; and
8. Utilization of the Air Medical Communication Safety Questionnaire (as approved by the board).

(7) Telecommunications

(a) The operations center for an air ambulance service operating in Tennessee shall include radio and telephone equipment to enable personnel to contact the helicopters and crew. Telecommunications devices shall include the following:

1. EMS Communications on the established frequencies of 155.205 MHz, 155.340 MHz, and/or upon such specific channels or frequencies as may be designated within each region as approved and published as a supplement to the State EMS Telecommunications Plan;

2. Direct telephone circuits accessible by air communication; and
 3. Recording equipment for both telephone and radio messages and instant message recall.
- (8) Helicopter Air Ambulance Response and Destination Guidelines and Procedures.
- (a) Medical necessity shall govern air ambulance service response, including medical responsibility and destination coordination, to emergency medical situations.
 - (b) Medical Necessity.
 1. The medical director for the helicopter air ambulance service shall determine whether there is a medical necessity to transport a patient by air ambulance. Medical necessity will be met if the following conditions occur:
 - (i) At the time of transport the patient has an actual or anticipated medical or surgical need requiring transport or transfer that would place the patient at significant risk for loss of life or impaired health without helicopter transport; or
 - (ii) Patient meets the criteria of the trauma destination guidelines; or
 - (iii) Available alternative methods may impose additional risk to the life or health of the patient; or,
 - (iv) Speed and critical care capabilities of the helicopter are essential; or,
 - (v) The patient is inaccessible to ground ambulances; or,
 - (I) Patient transfer is delayed by entrapment, traffic congestion, or other barriers; or,
 - (II) Necessary advanced life support is unavailable or subject to response time in excess of twenty (20) minutes.
 - (vi) Specialty Missions with specialized medical care personnel, special medical products and equipment, emergency supplies, and special assistance for major casualty incidents or disasters, or mutual aid to other aero medical services are medically necessary when their availability might lessen aggravation or deterioration of the patient's condition.
 - (c) The incident commander or his designee will coordinate the transfer of medical responsibility to the medical flight crew by emergency services responsible for the patient at the scene of the incident.
 1. If a helicopter air ambulance lands on a scene and it is determined through patient assessment and coordination between ground and air medical personnel that it is not medically necessary to transport the patient by helicopter, the appropriate ground EMS agency will transport the patient.
 2. Interfacility transfers shall not be initiated unless an appropriate physician at the receiving facility has accepted the patient for transfer.

(d) Patient destination shall be established pursuant to Rule 1200-12-01-.21.

(9) Records and Reports

(a) The air ambulance service shall maintain records including the following:

1. A record for each patient transported including:

- (i) Name of the person transported;
- (ii) Date of transport;
- (iii) Origin and destination of transport;
- (iv) Presenting illness, injury, or medical condition necessitating air ambulance service;
- (v) Attending and medical personnel;
- (vi) Accessory ground ambulance services;
- (vii) Medical facilities transferring and receiving the patient;
- (viii) Documentation of treatment during transport; and
- (ix) A copy shall be provided to the receiving facility.

2. Each air ambulance service shall report the number of air ambulance transfers performed annually on the form provided for such purposes to the Division of Emergency Medical Services.

(b) Each air ambulance service shall retain patient records for at least ten years.

(10) Utilization Review (UR)

(a) The air ambulance service management shall ensure appropriate utilization review process based on:

1. Chart review of medical benefits delivered to a random sample of patients, including the following:

- (i) Timeliness of the transport as it relates to the patient's clinical status;
- (ii) Transport to an appropriate receiving facility;
- (iii) On scene transports (Rotor Wing) – the following types of criteria are used in the triage plan for on-scene transports:
 - (I) Anatomic and physiological identifiers;
 - (II) Mechanism of injury identifiers;
 - (III) Situational identifiers;

(IV) Pediatric and Geriatric Patients;

(iv) Specialized medical transport personnel expertise available during transport are otherwise unavailable;

2. Structured, periodic review of transports shall be performed at least semi-annually and result in a written report; and
3. The service shall list criteria used to determine medical appropriateness. It will maintain records of such reviews for two years.

(11) Quality Improvement (QI)

- (a) The service shall have an established Quality Improvement program, including, at a minimum, the medical director(s) and management.
- (b) The service shall conduct an ongoing Quality Improvement program designed to assess and improve the quality and appropriateness of patient care provided by the air medical service.
- (c) The service shall have established patient care guidelines/standing orders. The QI committee and medical director(s) shall periodically review such guidelines/standing orders.
- (d) The Medical Director(s) is responsible for ensuring timely review of patient care, utilizing the medical record and pre-established criteria.
- (e) Operational criteria shall include at least the following quantity indicators:
 - (i) Number of completed transports;
 - (ii) Number of air medical missions aborted and canceled due to weather; and
 - (iii) Number of air medical missions aborted and canceled due to patient condition and use of alternative modes of transport.
- (f) For both QI and utilization review programs, the air ambulance service shall record procedures taken to improve problem areas and the evaluation of the effectiveness of such action.
- (g) For both QI and utilization review programs, the air ambulance service shall report results to its sponsoring institution(s) or agency (if applicable) indicating that there is integration of the medical transport service's activities with the sponsoring institution or agency (if applicable).

(12) Compliance. Compliance with the foregoing regulations shall not relieve the air ambulance operator from compliance with other statutes, rules, or regulations in effect for medical personnel and emergency medical services, involving licensing and authorizations, insurance, prescribed and proscribed acts and penalties.

- (13) Separation of Services. Air ambulance service shall constitute a separate class of license and authorization from the Board and Department.

Authority: T.C.A. §§ 68-140-504 and 68-140-507.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Tim Bell				X	
Susan M. Breeden	X				
Jeffrey L. Davis	X				
Julie A. Dunn, M.D.	X				
Larry Q. Griffin				X	
Kevin Mitchell	X				
Ronald E. Mitchell, Sr.	X				
Dennis W. Parker	X				
Lawrence Potter	X				
James E. Ross				X	
Sullivan K. Smith				X	
Robert Webb	X				
Jackie Wilkerson	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Division of Emergency Medical Services on 12/16/2009, and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 10/27/2009

Rulemaking Hearing(s) Conducted on: (add more dates). 12/16/2009

Date: March 31, 2010

Signature: Lucille F. Bond

Name of Officer: Lucille F. Bond

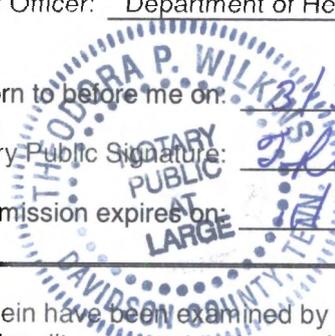
Assistant General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: 3/31/2010

Notary Public Signature: Thudora P. Wilkerson

My commission expires on: 7/2011



All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Robert E. Cooper, Jr.
 Robert E. Cooper, Jr.
 Attorney General and Reporter
6-10-11
 Date

Department of State Use Only

Filed with the Department of State on: 06/30/2011

Effective on: 09/28/2011

Tre Hargett
Tre Hargett
Secretary of State

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PUBLICATIONS

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

PUBLIC HEARING COMMENTS

RULEMAKING HEARING

Division of Emergency Medical Services

Bureau of Health Licensure and Regulation

Chapter 1200-12-01-.05

Air Ambulance Standards

The Division received two (2) written comments from the public prior to the December 16, 2009 rulemaking hearing. There were four (4) verbal comments and one (1) written comment received at the rulemaking hearing.

Written Comments:

Susan K. Hannasch, Esq., submitted written comments on behalf of Vanderbilt University regarding the University's concern about the following in the proposed rules:

- 1) As submitted for rulemaking hearing, the proposed rules required specific sanitary supplies, bedpans and a urinal, to be included as medical supplies on both helicopter and fixed-wing patient transports. The Board voted to change the proposed rules to require those sanitary supplies on fixed-wing air ambulance flights only.
- 2) Vanderbilt expressed concern that the portable oxygen capacity as stated in the proposed rules would not be sufficient to assure a continuous supply of oxygen for the patient during transport by the air ambulance to the emergency room. It suggested that proposed Rule 1200-12-01-.05(3)(a)1 be changed to require helicopter ambulance flight missions to include a "portable medical oxygen system with at least 1000 psi capacity." The Board voted to change proposed language at Rule 1200-12-01-.05(2)(f) to read: "Medical oxygen equipment on board capable of adjustable flow from 2 to 15 liters per minute..." It also voted to change proposed language at Rule 1200-12-01-.05(3)(a)1 to read as follows: "Portable medical oxygen system with a usable supply of at least 300 liters of oxygen;" and
- 3) Vanderbilt expressed concern that the proposed rules as presented for rulemaking did not include a provision for environmental control to be maintained via functioning air conditioner and heater on helicopter ambulance flight missions. The Board's action regarding this matter will be discussed below.

Debra Barnes, Memphis Medical Center Air Ambulance Service, known as "Hospital Wing," submitted the comments on behalf of her service regarding its concern about the following in the proposed rules:

- 1) As submitted for rulemaking hearing, the proposed rules required "an adult cricothyromy kit" to be included as medical equipment on both fixed-wing and helicopter flight missions. Ms. Barnes expressed concern that such equipment should not be required for helicopter wing flight missions. The Board voted to change the proposed language at Rule 1200-12-01-.05(2)(d)4 to read as follows: "Alternative advanced airway devices as approved by the service medical director;"
- 2) As submitted, the proposed rules required that a bedpan, urinal, towelettes, and tissues be included as sanitary medical supplies on both fixed-wing and helicopter wing flight missions. Ms. Barnes

expressed concern that such supplies need not be required for helicopter flight missions. The Board voted to change the proposed language at Rule 1200-12-01-.05(2)(g)1-4 to require the above-referenced sanitary supplies on fixed-wing flight missions only.

3) As submitted for rulemaking hearing, the proposed rules required that a clinical thermometer be included on all air ambulance flight missions as a patient assessment device for adult and/or pediatric patients. Ms. Barnes suggested the addition of the terminology, "or temperature strips." The Board voted to accept this change.

4) As submitted for rulemaking hearing, the proposed rules required a surgical airway device be included as a trauma supply on all air ambulance flight missions. Ms. Barnes suggested that a surgical airway device be a required trauma supply only if approved by the service medical director. The Board voted to change to language of the Rule 1200-12-01-.05(2)(j)4 to state that a surgical airway device shall be required as a trauma supply "as approved by medical direction."

5) As submitted for rulemaking hearing, the proposed rules included that each helicopter flight mission include a lower extremity traction device as a trauma supply. Ms. Barnes pointed out that such equipment is not currently carried on rotor wing aircrafts and suggested that the language be changed to "pelvic stabilization device." The Board voted not to make this change.

6) As submitted for rulemaking hearing, the proposed rules included a requirement at Rule 1200-12-01-.05(5)4(ii) that the service medical director require each medical crew member to complete and maintain documentation of initial and annual training (both didactic and hands-on) in "emergency cricothyotomy." Ms. Barnes suggested that the language be changed to include the following: "if approved by service medical director." The Board voted not to make this change.

7) As submitted for rulemaking hearing, the proposed rule included a requirement at Rule 1200-12-01-.05(5)(c)2(i) that a Registered Nurse serving as a medical crew member have three years of registered nursing experience in critical care nursing, or two years fulltime flight paramedic experience and one year critical care nursing experience. Ms. Barnes suggested that the requirement be changed to two years fulltime flight paramedic experience and one year critical care nursing experience. The Board voted not to make this change.

8) As submitted for rulemaking hearing, the proposed rule included a requirement at Rule 1200-12-01-.05(c)5(i) that a medical crew member must obtain advanced paramedic certification with one alternative being a critical care paramedic, "or equivalent." Ms. Barnes stated that the terminology "or equivalent" be eliminated because of ambiguity. The Board voted to make this change.

9) As submitted for rulemaking hearing, the proposed rule included the requirement at Rule 1200-12-01-.05(c)7 that each medical crew member on an air ambulance shall attend and maintain training in at least one of number of delineated courses. Ms. Barnes stated that "Advanced Trauma Life Support" can only be attended and maintained at a physician level, and should be removed from the flight nurse and paramedic sections. She also stated that "Basic Trauma Life Support" is now "International Trauma Life Support and the "Trauma Nurse Care Course" should be the "Trauma Nurse Core Course." The Board voted to accept these changes as well as changing "Flight Nurse Advanced Trauma Care Course" to "Trauma Nurse Advanced Trauma Course."

Verbal Comments:

Mark Wilkinson, MD, from "Wings," made the following verbal comments:

1) As submitted for rulemaking hearing, the proposed rule included qualifications for the Medical Director of a helicopter air ambulance service at Rule 1200-12-01-.05(5)(a)2(i)-(v). Dr. Wilkinson suggested that the terminology "unless Board Certified or Board Eligible in emergency medicine" be added at sections (iii) and (v). The EMS Board voted to accept this change.

2) As submitted for rulemaking hearing, the proposed rule required at Rule 1200-12-01-.05(c)5 that members of the medical crew on a air ambulance mission must obtain advanced paramedic certification

within 12 months of employment. Dr. Wilkinson suggested that this grace period was too short. The Board voted to change the proposed rule to allow members of the medical crew twenty-four (24) months to obtain advanced paramedic certification.

3) Dr. Wilkinson suggested that the qualifications for the Medical Control Physician found at proposed Rule 1200-12-01-.05(5)(e) be changed to reflect those found at Rule 1200-12-01(5)(c). The Board voted not to make this change.

4) Dr. Wilkinson stated that he agreed with Vanderbilt, as discussed above, regarding the oxygen requirement for helicopter air ambulance flight missions found at Rule 1200-12-01-.05(3)(a)1. The Board's action regarding this matter is discussed above under section (2) of the discussion of written comments submitted by counsel for Vanderbilt University.

Neil Worf (Vanderbilt Life Flight), Rhonda Phillippi (COPEC), and Tim Pickering (Air Evac) commented verbally regarding the fact that the proposed rules do not include a requirement that helicopter air ambulances must be climate controlled via functioning air conditioning and heater. After making his verbal comments, Mr. Pickering submitted written comments reflecting a summary of the same. As stated above, Vanderbilt University submitted written comments regarding this matter.

1) Mr. Worf, Ms. Phillippi and Vanderbilt University all contend that climate control on helicopter air ambulances via functioning air conditioning and heater is related to medical care and the lack of same is detrimental to patient care.

2) Mr. Pickering stated that the benefit of a functioning air conditioner on helicopter air ambulances is not backed by patient care data. It is his position that a functioning air conditioner is an equipment issue rather than one of medical care. He further stated only the Federal Aviation Authority can mandate helicopter equipment. He asserted that because a functioning air conditioner on a helicopter air ambulance is equipment a state cannot mandate such and the matter is preempted by federal law.

3) The Board voted to defer whether or not to regulate climate control on helicopter air ambulances pending a ruling from the United States Department of Transportation as to whether it is related to medical care or is considered helicopter equipment. The Office of General Counsel, Tennessee Department of Health is to request a ruling from the DOT.

Regulatory Flexibility Addendum

Pursuant to T.C.A. § 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

Regulatory Flexibility Analysis

- (1) Every effort has been made to assure that the proposed rules do not overlap, duplicate, or conflict with other federal, state, or local government rules.
- (2) The proposed rules exhibit clarity, conciseness, and lack of ambiguity.
- (3) The proposed rules are not written with special consideration for the flexible compliance and/or requirements because the licensing boards have, as their primary mission, the protection of the health, safety and welfare of Tennesseans. However, the proposed rules are written with a goal of avoiding unduly onerous regulations.
- (4) The compliance requirements throughout the proposed rules are as “user-friendly” as possible while still allowing the Board to achieve its mandated mission in regulating the air ambulance services. There is sufficient notice between the rulemaking hearing and the final promulgation of rules to allow services and providers to come into compliance with the proposed rules.
- (5) Compliance requirements are not consolidated or simplified for small businesses in the proposed rules for the protection of the health, safety and welfare of Tennesseans.
- (6) The standards required in the proposed rules are very basic and do not necessitate the establishment of performance standards for small businesses.
- (7) There are no unnecessary entry barriers or other effects in the proposed rules that would stifle entrepreneurial activity or curb innovation.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council:

Tennessee Department of Health, Board of Emergency Medical Services

Rulemaking hearing date: Dec. 16, 2009

Types of small businesses that will be directly affected by the proposed rules:

These rule changes only affect licensed air ambulance services. Their impact on small businesses is expected to be negligible.

Types of small businesses that will bear the cost of the proposed rules:

The rule changes impact licensed air ambulance services and would have minimal affect on any small businesses.

Types of small businesses that will directly benefit from the proposed rules:

It is unlikely that the attached rules would affect small businesses.

Description of how small business will be adversely impacted by the proposed rules:

The rule changes should have little adverse impact on small business as they primarily affect air ambulance services.

Alternatives to the proposed rule that will accomplish the same objectives but are less burdensome, and why they are not being proposed:

The Department of Health, Division of Emergency Medical Services does not believe there are less burdensome alternatives to the proposed rule amendments.

Comparison of the proposed rule with federal or state counterparts:

Federal: The Division of Emergency Medical Services has made every effort possible to assure that the proposed rules do not conflict with the Federal Aviation Act of 1958 or the Airline Deregulation Act of 1958 or duplicate rules and regulations promulgated thereunder.

State: The proposed rule amendments will have no state counterpart because the Department of Health, Board of Emergency Medical Services is the only agency charged with regulating air ambulance services.

Impact on Local Governments

Pursuant to T.C.A. 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

These amendments to the rules are not expected to have any impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

1200-12-01-05(1) Definitions – The current rule includes definitions of “crew member,” “flight crew member,” “flight coordinator,” “public use air ambulance service,” regular medical crew members,” and “special equipment” that have been eliminated from the new rule. The new rule includes definitions of “air medical communications specialist,” “medical crew member,” “special medical equipment,” and “utilization review” that were not included in the old rule.
1200-12-01-05(2) Air Ambulance Design and Navigational Equipment – This section is included in the old rule but has been eliminated from the new rule.
1200-12-01-05(3) Air Ambulance Medical Equipment and Supplies – This section was included in the old rule but has been moved to 1200-12-01-.05(2) Medical Equipment and Supplies. In the old rule, 1200-12-01-.05(3)(a) delineated medical equipment and supplies required on fixed-wing air medical missions. In the old rule, 1200-12-01-05(3)(b) delineated medical equipment and supplies required on helicopter air medical missions. The new rule delineates one list of medical equipment and supplies required on both fixed-wing and helicopter air medical missions with a few exceptions as noted in the rule.
1200-12-01-.05(2)(d) Airway devices for adult and pediatric patients. At 1200-12-01-.05(3)(a)4 the old rule required that oropharyngeal airways be provided for infants, children, and adults on fixed-wing air medical flights. At 1200-12-01-.05(b)4 the old rule requires that airway maintenance devices shall be provided for adult and pediatric patients including oropharyngeal airways, endotracheal tubes, laryngoscope with assorted blades, and accessory items for intubation. The new rule has eliminated these requirements substituting instead that all air medical missions (both fixed-wing and helicopter) include the following airway devices for adult and pediatric patients: oropharyngeal airways; endotracheal tubes; laryngoscope with assorted blades and accessory items for intubation and alternative advanced airway devices, as approved by the service medical director.
1200-12-01-.05(2)(f) regarding medical oxygen equipment. At 1200-12-01-.05(3)(a)(6) the old rule required medical oxygen equipment on fixed-wing air ambulance missions as follows: oxygen equipment capable of adjustable flow from 2 to 15 liters per minute; masks and supply tubing for adult and pediatric patients shall allow administration of variable oxygen concentrations from 24% to 95% fraction inspired oxygen; and medical oxygen provided for 150% of the scheduled flight time by a unit secured within the aircraft. This requirement was eliminated from the new rules. Instead, both fixed-wing and helicopter flight missions must have medical oxygen equipment on board capable of adjustable flow from 2 to 15 liters per minute including the following: masks and supply tubing capable of administering variable oxygen concentrations from 24% to 95% fraction inspired oxygen for both adult and pediatric patients; and medical oxygen to allow for treatment 150% of estimated transport.
Rule 1200-12-01-.05(3)(a) refers to medical oxygen equipment specifically required on helicopter flight missions. Old rule 1200-12-01-.05(b)6 required medical oxygen equipment on helicopter flight missions as follows: oxygen equipment capable of adjustable flow from 2 to 15 liters per minute; masks and supply tubing for adult and pediatric patients shall allow administration of variable oxygen concentrations from 24% to 95% fraction inspired oxygen; an installed oxygen system shall supply a minimum 1,800 liter supply; and a portable system that shall supply at least 300 liters. This requirement has been eliminated in the new rules. Instead, the new rule 1200-12-01-.05(2)(f) states requirements for medical oxygen equipment as discussed above. Additionally, new rule 1200-12-01-.05(3)(a) requires medical oxygen equipment on helicopter medical missions as follows: medical oxygen equipment capable of an adjustable flow from 2 to 15 liters per minute including a portable oxygen system with a usable supply of at least 300 liters of oxygen and a backup source of oxygen that shall be delivered via a non-gravity dependent delivery source and may be the required portable tank if it is carried in the patient care area during flight.
Rule 1200-02-01-.05(2)(g) requires the following sanitary supplies only on fixed-wing medical flights: bedpan, urinal, towelettes, and tissues. The following sanitary supplies are required on both fixed-wing and helicopter flights: emesis bags, plastic trash disposable bags; and non-latex gloves. These requirements are in the new rule only. At 1200-12-01-.05(3)(a)7 the old rule required the following sanitary supplies on fixed-wing flights: urinal, towelettes, tissues, emesis bags, and plastic trash disposable bags. This requirement has been eliminated. The old rules do not refer to requirements for sanitary supplies on helicopter flight missions.
Rule 1200-12-01-.05(2)(i) refers to patient assessment devices required on both fixed-wing and helicopter flight missions. Old rule 1200-12-01-.05(3)(a) 9 requires the following devices for adult and pediatric patient assessment on fixed-wing flight missions: flashlight and/or penlight; stethoscope; sphygmomanometer and blood pressure cuffs, and dressings and bandages. This requirement has been modified in the new rule. Old

<p>rule 1200-12-01-.05(b)8 requires the following devices for adult and pediatric patient assessment on helicopter flight missions: sphygmomanometer and blood pressure cuffs; stethoscope; Doppler stethoscope, and electrocardiographic monitor/recorder and defibrillator. This requirement has been modified in the new rule which requires the following patient assessment devices for adult and/or pediatric patients on both fixed-wing and helicopter flight missions: flashlight and/or penlight; stethoscope and Doppler stethoscope; sphygmomanometer and blood pressure cuffs; electro-cardiographic monitor/recorder and defibrillator; with transcutaneous pacemaker, having a back-up power source; pulse oximetry; capnography, both continuous and portable; transport ventilator; and clinical thermometer or temperature strips.</p>
<p>Rule 1200-12-01-.05(2)(j) refers to trauma supplies required on fixed-wing and helicopter flight missions. Old rule 1200-12-01-.05(3)(b)9 requires the following trauma devices on helicopter flight missions only: sterile dressings, roller bandages, pneumatic antishock trousers, and semi-rigid cervical collars. The new rule eliminated the requirement for pneumatic antishock trousers. It requires the following on both fixed-wing and helicopter flight missions: sterile dressings; roller bandages; device for chest decompressions; surgical airway device as approved by medical direction; and semi-rigid immobilization devices.</p>
<p>Rule 1200-12-01-.05(3)(b) requires that a lower extremity traction device be required as a trauma supply on helicopter flight missions. The old rule does not include this requirement.</p>
<p>Rule 1200-12-01-.05(5)(2)(m) requires that both fixed-wing and helicopter flight missions include an isolette that shall be capable of being opened from its secured position within the aircraft be included as neonatal transport equipment. The old rule does not include this requirement.</p>
<p>Rule 1200-12-01-.05(4) Air Ambulance Safety Equipment, Procedures and Training and Standards – This section is included in the old rule but has been eliminated from the new rule.</p>
<p>Rule 1200-12-01-.05(5) Air Ambulance Personnel and Qualifications – This section is included in the old rules but has been eliminated. Rule 1200-12-01-.05(4) Air Ambulance Personnel Qualifications and Duties has been substituted in its place.</p>
<p>Rule 1200-12-01-.05(5)(a) Air Ambulance Personnel and Qualifications – Pilot – This section is included in the old rules and is totally and completely eliminated in the new rules.</p>
<p>Rule 1200-12-01-.05(4)(a) Air Ambulance Personnel Qualifications and Duties – Medical Director Qualifications and Duties – This section has been moved from Rule 1200-12-01-.05(d) in the old rules.</p>
<p>Rule 1200-12-01-.05(4)(a)1 requires that a Medical Director for a helicopter air ambulance must be certified in advanced Cardiac Life Support unless board certified or board eligible in emergency medicine; certified in Pediatric Advanced Life Support or equivalent unless board certified or board eligible in emergency medicine including certification in a neonatal resuscitation program and possess adequate knowledge regarding altitude physiology/stressors in flight. The old rule does not include the above.</p>
<p>Rule 1200-12-01-.05(4)(a)3 includes the duties of the Medical Director for a helicopter air ambulance service. The old rule does not include the above.</p>
<p>Rule 1200-12-01-.05(4)(a)4 includes that the service Medical Director shall establish mission specific and clinical procedures and requirements that he require specific hands-on and didactic training in delineated procedures for the medical crew. The old rule does not include this requirement.</p>
<p>Rule 1200-12-01-.05(4)(b)3 includes a requirement that on a fixed-wing flight mission only, the service medical director may allow transport of patients in the presence of only one medical professional, the minimum level of licensure in such a situation would be that of an EMT-P. The old rule does not include same.</p>
<p>Rule 1200-12-01-.05(4)(c)2(i) requires a registered nurse serving as a medical crew member on air ambulance to have three years of registered nursing experience in critical care nursing, or two years fulltime flight paramedic experience and one year critical care nursing experience. The old rule does not include this provision.</p>
<p>Rule 1200-12-01-.05(4)(c)2(iv)(III) allows a Registered Nurse serving as a medical crew member on an air ambulance to obtain advance nursing certification within 12 months of employment through several alternative programs. The new rule includes a program for a “Certified Flight Registered Nurse.” The old rule does not include the above-referenced alternative program.</p>
<p>Rule 1200-12-01-.05(4)(c)4 requires an EMT-P serving as an air ambulance medical crew member to possess a current Tennessee EMT-P license and have three years experience as an EMT-P in an advanced life-support service. The old rule does not include the above.</p>
<p>Rule 1200-12-01-.05(4)(c)5 requires an EMT-P serving as a medical crew member on an air ambulance to obtain advanced paramedic certification within twenty-four months of employment through one of the following programs: Critical Care Paramedic or Certified Flight Paramedic. The old rule does not include the above.</p>
<p>Rule 1200-12-01-.05(4)(c)6 requires each medical crew member on an air ambulance to have and maintain certification in Advanced Cardiac Life Support, Pediatric Advanced Life Support, or equivalent (Emergency Nursing Pediatric Course, PEPP), and in neonatal resuscitation. The old rule does not include the above.</p>
<p>Rule 1200-12-01-.05(4)(c)7 requires each medical crew member on an air ambulance to attend and maintain</p>

training in one of the following: Trauma Nurse Advanced Trauma Course; International Trauma Life Support; Prehospital Trauma Life Support; or Trauma Nurse Core Course. The old rule does not include the above.
Rule 1200-12-01-.05(4)(d) includes qualifications and duties of an air medical consultant for each fixed wing air ambulance service. The old rule does not include the above.
Rule 1200-12-01-.05(4)(e) includes qualifications and duties of a Medical Control Physician who will be available to each helicopter air ambulance service. The old rule does not include the above.
Rule 1200-12-01-.05(4)(f) includes qualifications of the Air Medical Communications specialist. The old rule does not include the above.
Rule 1200-12-01-.05(6) Flight Coordination and Telecommunications is deleted and replaced by Rule 1200-12-01-.05(6) Flight Coordination and Rule 1200-12-01-.05(7) Telecommunications.
Rule 1200-12-01-.05(6)(a) sets forth the requirement that the air ambulance service operations office director shall maintain an Operations Manual setting forth policies and procedures and the policies it shall include. The old rule did not include the above.
Rule 1200-12-01-.05(7)(a) sets forth a requirement for an operations center for an air ambulance service operating in Tennessee. It also delineates telecommunications devices which includes recording equipment for "instant message recall" which was not included in the old rule.
Rule 1200-12-01-.05(8) Helicopter Air Ambulance Response Destination Guidelines and Procedures sets for that medical necessity shall govern air ambulance service response and states that the medical director for a helicopter air ambulance service shall determine whether or not medical necessity exists using specific criteria. The old rule does not include the above.
Rule 1200-12-01-.05(8)(c) allows the incident commander or his designee to coordinate the transfer of medical responsibility to the medical flight crew by emergency services responsible for the patient at the scene of the incident. The old rule does not include the above.
Rule 1200-12-01-.05(9)(a) delineates records and reports that must be maintained by the air ambulance service for each patient transported by the service including documentation of treatment during transport. Additionally, a copy of the report must be provided to the receiving facility. Said requirements are not included in the old rule.
Rule 1200-12-01-.05(9)(b) requires each air ambulance service to retain patient records for 10 years. The old rule requires that medical records be retained for 5 years.
Rule 1200-12-01-.05(10) Utilization Review -- This rule sets forth a requirement and process for utilization review. The old rule does not include this requirement.
Rule 1200-12-01-.05(11) Quality Improvement -- This rule sets for a requirement and process for quality improvement. The old rule does not include this requirement.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

1. The Airline Deregulation Act ("ADA"), which is part of the Federal Aviation Act, particularly section 49 USC § 41713(b)(1), provides that a State, political subdivision of a state, or political authority of at least two states is not allowed to enact a law or regulation having the force and effect of law related to price, route, or services of an air carrier that may provide air transportation under this subpart.
2. Air ambulances are included in those air carriers under the jurisdiction of the FAA.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Vanderbilt Life Flight, Air Evac, Tennessee Emergency Medical Services for Children, Wings, Memphis Medical Center Air Ambulance Service and all other air ambulance services

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

Med-Trans Corp. v. Benton, et al, 581 F.Supp.2d 721 (2008). – This North Carolina case is considered to be definitive regarding state regulation of air ambulances. It generally concludes that issues related to the area of aviation safety such as issues of aviation safety related equipment and safety related training are preempted by federal law. **However, laws and regulations relating primarily to medical care are not preempted.** See also Air Evac EMS, Inc. v. Robinson, 486 F. Supp. 2d 713 (M.D. Tenn. 2007).

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

None

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Joseph Phillips, Director, Division of Emergency Medical Services and Richard Land, Director of Ambulance Service Licensure, Division of Emergency Medical Services

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Joseph Phillips, Director
Division of Emergency Medical Services

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Joseph Phillips, Director Division of Emergency Medical Services 227 French Landing, Suite 303 Nashville, TN 37243 (615) 741-2584 Joseph.Phillips@tn.gov	Lucille F. Bond Assistant General Counsel Office of General Counsel Tennessee Department of Health 220 Athens Way, Suite 210 Nashville, TN 37243 (615) 741-1611 Lucille.F.Bond@tn.gov
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(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None

(Rule 1200-12-1-.04, continued)

- (b) Any EMS professional who has filed the required information for permanent retirement of his or her license shall be permitted to use the appropriate title:
1. For emergency medical technicians, EMT Retired or EMTR.
 2. For emergency medical technician–paramedics, EMT-Paramedic Retired, or EMT-PR.

(12) Reinstatement of a retired EMS professional license.

- (a) A reinstatement applicant whose license has been retired two years or less may reinstate his or her license by completing the following requirements:
1. Payment of all past due renewal fees, reinstatement, and state regulatory fees pursuant to Rule 1200-12-1-.06; and
 2. Submission of documentation to prove satisfactory health and good character.
- (b) If a reinstatement applicant's license has been retired for more than two years, an applicant must complete refresher training requirements and written and practical examinations that have been approved by the board for the level of licensure for which reinstatement has been applied.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-140-504, 68-140-506, 68-140-508, 68-140-509, 68-140-511, 68-140-517, 68-140-518, and 68-140-525. **Administrative History:** Original rule filed March 20, 1974; effective April 19, 1974. Amendment filed February 4, 1976; effective March 5, 1976. Repeal and new rule filed February 8, 1983; effective May 16, 1983. Amendment filed November 30, 1984, effective February 12, 1985. Amendment filed August 22, 1985; effective September 21, 1985. Amendment filed February 21, 1986; effective May 13, 1986. Amendment filed September 18, 1986; effective December 29, 1986. Amendment filed April 8, 1987; effective May 23, 1987. Amendment filed June 30, 1987; effective August 14, 1987. Amendment filed October 22, 1987; effective December 6, 1987. Amendment filed January 17, 1989; effective March 3, 1989. Amendment filed September 24, 1990; effective November 8, 1990. Amendment filed October 21, 1993; effective January 4, 1994. Amendment filed April 13, 1994; effective June 27, 1994. Amendment filed August 5, 1996; effective October 19, 1995. Amendment filed August 29, 2003; effective November 12, 2003. Amendment filed December 16, 2005; effective March 1, 2006. Amendments filed April 13, 2006; effective June 27, 2006. Amendment filed September 21, 2007; effective December 5, 2007.

~~**1200-12-1-.05 AIR AMBULANCE STANDARDS.** All air ambulance service providers and crew members operating in Tennessee must comply with Chapter 140 of Title 68 of the Tennessee Code Annotated and this Rule. Failure to comply shall subject the service providers and/or its personnel to disciplinary action pursuant to T.C.A. §68-140-511.~~

1200-12-1-.05 Air Ambulance Standards - All air ambulance service providers and crew members operating in Tennessee must comply with Chapter 140 of Title 68 of the Tennessee Code Annotated and this Rule. Failure to comply shall subject the service provider and/or its personnel to disciplinary action pursuant to T.C.A. 68-140-511.

~~(1) Definitions—As used in this Rule, the following terms shall have the following meanings:~~

- ~~(a) Crew Member—Any person employed by an air ambulance service with the intent to function in the performance of duties aboard any aircraft during flight.~~
- ~~(b) Flight crew member—Any person employed by an air ambulance service with the intent to be engaged as the pilot of an aircraft.~~

(Rule 1200-12-1-.05, continued)

- ~~(c) Flight coordinator — Any person functioning for an air ambulance service with duties for initial acknowledgement of requests, telecommunications, and flight following.~~
- ~~(d) Public Use Air Ambulance Service — Any service conducted by a local or state government unit and/or associated with operations for police patrol or fire fighting, conducted without compensation for patient transport.~~
- ~~(e) Regular Medical Crew Members — Any person with the intent to be engaged in day-to-day flight mission assignment as distinguished from a medical crew member who is employed to serve on an occasional flight mission or as a specialty crew member.~~
- ~~(f) Special Equipment — Any device or number of devices and supplies which shall be approved by the medical director of an air ambulance service for the medical care of a particular patient.~~
- ~~(g) Specialty Crew Members — Any person substituted by the medical director of an air ambulance service for a Specialty Mission.~~
- ~~(h) Specialty Mission — An assignment for air ambulance service for which the specified needs of a particular patient require the substitution of particular medical care providers and/or equipment as may be approved by the medical director.~~

(1) Definitions - As used in this Rule, the following terms shall have the following meanings:

- (a) "Air Medical Communications Specialist" means any person employed by an air ambulance service coordinating acknowledgement of medical requests, medical destination, and medical communications during air medical response and patient transfer.
- (b) "Medical Crew Member" means any person employed by an air ambulance service for the purpose of providing care to patients transported by and receiving medical care from an air ambulance service.
- (c) "Special Medical Equipment" means any device which shall be approved by the air ambulance service medical director for the medical care of an individual patient on an air ambulance.
- (d) "Specialty Crew Member" means any person the air ambulance service medical director assigns for a regular medical crew member for a specialty mission.
- (e) "Specialty Mission" means an air ambulance service assignment necessitating the medical director to substitute special medical care providers and/or equipment to meet the specified needs of an individual patient.
- (f) "Utilization Review" means the critical evaluation of health care processes and services delivered to patients to ensure appropriate medical outcome, safety and cost effectiveness.

~~(2) Air Ambulance Design and Navigational Equipment.~~

- ~~(a) All fixed wing aeromedical aircraft shall comply with all applicable Federal Aviation Regulations for the type of operation and aircraft, and shall be designed for the provision of patient care as follows:~~

(Rule 1200-12-1-.05, continued)

- ~~1. Aircraft doors shall accommodate passage of a supine litter patient without rotation of more than 30 degree roll or 45 degree pitch.~~
 - ~~2. At least 30 inches (76cm) of vertical head space shall exist above the head of the stretcher with sufficient attendant access from at least one side of the litter without obstruction.~~
 - ~~3. Lighting for the patient area shall afford necessary observation by medical personnel. Fixed or portable lamps may be used to comply with this standard.~~
- ~~(b) Civil helicopter aeromedical programs that are licensed or authorized or operating in the State of Tennessee shall operate in compliance with Federal Aviation Regulations, 14 C.F.R. Parts 91 and 135. Public use aeromedical programs shall comply with applicable Federal Aviation Regulations, 14 C.F.R. Parts 91 and 135.~~
- ~~(c) All helicopters performing aeromedical missions shall be equipped with avionics and instruments necessary to enable the pilot to execute an instrument approach under instrument meteorological conditions and shall include:~~
- ~~1. Two very high frequency transceivers, notwithstanding the provisions of applicable Federal Aviation Regulations regarding inoperable equipment. One transceiver shall be capable of operating on the designated EMS frequency;~~
 - ~~2. Two very high frequency omnidirectional ranging (VOR) receivers;~~
 - ~~3. One nondirectional beacon (NDB) receiver;~~
 - ~~4. One glide slope receiver;~~
 - ~~5. Transponder meeting requirements of FAA TSO C-112, (Mode S), or C74b or TSO C74C as appropriate; and~~
 - ~~6. FAA approved navigational aids and current IFR charts for the area of operations.~~

(2) Medical Equipment and Supplies. The medical director for the emergency medical service shall ensure that the following medical equipment and supplies are provided on each fixed-wing or helicopter flight mission:

- (a) Litter or stretcher with at least three sets of restraining straps;
- (b) An installed and a portable suction apparatus, each of which has the capacity to deliver adequate suction, including sterile suction catheters and a rigid suction tip for both adult and pediatric patients;
- (c) Bag/valve/mask resuscitator(s) with clear masks and an oxygen reservoir with connections capable of achieving 95% fraction inspired oxygen to provide resuscitation for both adult and pediatric patients;
- (d) Airway devices for adult and pediatric patients including the following:
 1. Oropharyngeal airways;
 2. Endotracheal tubes;

(Rule 1200-12-1-.05, continued)

3. Laryngoscope with assorted blades and accessory items for intubation; and,

4. Alternative advanced airway devices as approved by the service medical director;

(e) Resuscitation board suitable for cardiac compression, unless a rigid stretcher or spine board is employed for patient transfer;

(f) Medical oxygen equipment on board capable of adjustable flow from 2 to 15 liters per minute including the following:

1. Masks and supply tubing capable of administering variable oxygen concentrations from 24% to 95% fraction inspired oxygen for both adult and pediatric patients;

2. Medical oxygen to allow for treatment during 150% of estimated transport time; and,

(g) Sanitary supplies including the following:

1. Bedpan (fixed-wing flight mission only);

2. Urinal (fixed-wing flight mission only);

3. Towelettes (fixed-wing flight mission only);

4. Tissues (fixed-wing flight mission only);

5. Emesis bags;

6. Plastic trash disposable bags; and,

7. Non-latex gloves;

(h) Sheets and blankets for each patient transported;

(i) Patient assessment devices for adult and pediatric patients, including:

1. Flashlight and/or penlight;

2. Stethoscope and Doppler stethoscope;

3. Sphygmomanometer and blood pressure cuffs;

4. Electro-cardiographic monitor/recorder and defibrillator, with transcutaneous pacemaker, having a back-up power source;

5. Pulse oximetry;

(Rule 1200-12-1-.05, continued)

6. Capnography, both continuous and portable;
 7. Transport ventilator; and
 8. Clinical thermometer or temperature strips;
- (j) Trauma supplies, including:
1. Sterile dressings;
 2. Roller bandages;
 3. Device for chest decompression;
 4. Surgical airway device as approved by medical direction; and
 5. Semi-rigid immobilization devices;
- (k) Intravenous fluids and administration devices;
- (l) Appropriate medications including the advanced life support medications described in Rule 1200-12-01-.03; and
- (m) Neonatal transport equipment that shall conform to the standards adopted in the Tennessee Perinatal Care System Guidelines for Transportation, Tennessee Department of Health, Women's Health & Genetice Section, Fifth Edition, 2006 or successor publication.
1. Isolette shall be capable of being opened from its secured position within the aircraft.

~~(3) Air Ambulance Medical Equipment and Supplies.~~

- ~~(a) Fixed-Wing Medical Equipment and Supplies—The following medical equipment and supplies shall be provided on each flight aboard the aircraft and shall be stored and secured within the flight compartment by suitable restraints.~~
- ~~1. Litter—A litter or stretcher with at least two sets of restraining straps shall be supplied, secured as required by the supplemental type certification for the aircraft utilized.~~
 - ~~2. Suction Apparatus—A suction device shall be provided, capable of 12 inches mercury vacuum. Sterile suction catheters and a rigid suction tip shall be provided for adult and pediatric patients.~~
 - ~~3. Bag/Valve/Mask Resuscitator—Bag/Mask resuscitator(s) shall be provided for the adult or pediatric patient, with clear masks and an oxygen reservoir and connections to achieve 95% fraction inspired oxygen.~~
 - ~~4. Airways—Oropharyngeal airways shall be provided for infants, children, and adults.~~

(Rule 1200-12-1-.05, continued)

- ~~5. Resuscitation Board — Unless a rigid stretcher or spineboard is employed for patient transfer, a suitable board for cardiac compression shall be provided.~~
 - ~~6. Medical Oxygen Equipment — Oxygen equipment shall be furnished capable of adjustable flow from 2 to 15 liters per minute. Masks and supply tubing for adult and pediatric patients shall allow administration of variable oxygen concentrations from 24% to 95% fraction inspired oxygen. Medical oxygen shall be provided for 150% of the scheduled flight time by a unit secured within the aircraft.~~
 - ~~7. Sanitary Supplies — Sanitary supply items provided for fixed-wing flights shall include a bedpan, urinal, towelettes, tissues, emesis bags, and plastic trash disposable bags.~~
 - ~~8. Sheets and Blankets — Sheets and blankets shall be provided for each patient transported.~~
 - ~~9. Patient Assessment Devices — Devices for adult and pediatric patient assessment shall be provided, including:
 - ~~(i) Flashlight and/or penlight,~~
 - ~~(ii) Stethoscope,~~
 - ~~(iii) Sphygmomanometer and blood pressure cuffs, and~~
 - ~~(iv) Dressings and bandages.~~~~
 - ~~10. Medications deemed suitable by the aeromedical consultant shall be provided as appropriate for the crew and patient.~~
- ~~(b) Helicopter Medical Equipment and Supplies — Unless the service's Medical Director approves substitution of special equipment for specialty missions, the following medical equipment and supplies shall be provided on each helicopter, and all equipment shall be stored and secured by suitable restraints:~~
- ~~1. Litter — A litter or stretcher with at least two sets of restraining Amps shall be supplied, secured as required by the supplemental type certification for the aircraft utilized~~
 - ~~2. Suction Apparatus — An installed and portable suction device shall be provided, capable of 12 inches mercury vacuum. Sterile suction catheters and a rigid suction tip shall be provided for adult and pediatric patients.~~
 - ~~3. Bag/Valve/Mask Resuscitator — Bag/Mask resuscitator(s) shall be provided for the adult and pediatric patient, with clear masks and an oxygen reservoir and connections to achieve 95% fraction inspired oxygen.~~
 - ~~4. Airway — Maintenance devices shall be provided for adult and pediatric patients including oropharyngeal airways, endotracheal tubes, laryngoscope with assorted blades, and accessory items for intubation.~~
 - ~~5. Resuscitation Board — Unless a rigid stretcher or spineboard is employed for patient transfer, a suitable board for cardiac compression shall be provided.~~
 - ~~6. Medical Oxygen Equipment — Oxygen equipment shall be furnished capable of adjustable flow from 2 to 15 liters per minute. Masks and supply tubing for adult~~

(Rule 1200-12-1-.05, continued)

~~and pediatric patients shall allow administration of variable oxygen concentrations from 24% to 95% fraction inspired oxygen. An installed oxygen system shall supply a minimum 1,800 liter supply. A portable system shall supply at least 300 liters.~~

- ~~7. Protective Cover — A protective cover shall be supplied for each patient.~~
- ~~8. Patient Assessment Devices — Devices and supplies shall be available for adult and pediatric patient assessment, to include:

 - ~~(i) Sphygmomanometer and blood pressure cuffs,~~
 - ~~(ii) Stethoscope,~~
 - ~~(iii) Doppler stethoscope, and~~
 - ~~(iv) Electrocardiographic monitor/recorder and defibrillator.~~~~
- ~~9. Trauma Supplies — Sterile dressings, roller bandages, pneumatic antishock trousers, and semi-rigid cervical collars shall be supplied.~~
- ~~10. Intravenous fluids and administration devices shall be provided.~~
- ~~11. Medications — Appropriate medications including the advanced life support medications described in a Rule 1200-12-1-.03(2)(b) shall be provided.~~
- ~~12. Neonatal transport equipment shall conform to the standards adopted in the Tennessee Perinatal Care System Guidelines for Transportation, Tennessee Department of Health and Environment, Maternal and Child Health Section, September, 1985 or successor publication.~~

(3) In addition to the medical equipment and supplies required on either a fixed wing or helicopter flight mission as described in paragraph (2) above, the medical director for the emergency medical service shall ensure that the following medical equipment and supplies are provided on each helicopter flight mission:

(a) Medical oxygen equipment capable of adjustable flow from 2 to 15 liters per minute which shall include:

1. Portable medical oxygen system with a usable supply of at least 300 liters of oxygen; and
2. A backup source of oxygen that shall be delivered via a non-gravity dependent delivery source which may be the required portable tank if it is carried in the patient care area during flight;

(b) Trauma supplies, including:

1. Lower extremity traction device; and
2. Semi-rigid cervical collars.

(Rule 1200-12-1-.05, continued)

~~(4) Air Ambulance Safety Equipment, Procedures and Training and Standards. Each aeromedical service shall assure that aircraft are equipped to promote safe scene access, that procedures are established for safe operation, and that adequate training has been conducted for personnel in placement and use of emergency equipment and emergency and safety procedures.~~

~~(a) Safety and Survival Equipment shall be required on all helicopter air ambulances which shall include:~~

- ~~1. Illumination of the tail of the aircraft.~~
- ~~2. Search light of at least 300,000 candlepower for night scene and landing area illumination.~~
- ~~3. Survival kit with signaling devices and personal survival items.~~

~~(b) Landing Zone Preparation Procedures shall be published for distribution to ground ambulance services specifying the following minimum requirements:~~

- ~~1. An 80 by 80 foot square perimeter shall be required for day operations; a 100 by 100 foot square perimeter shall be required for night operations.~~
- ~~2. Landing areas shall be clear of trees, wire or other obstructions.~~
- ~~3. Landing areas shall be clear of loose debris.~~
- ~~4. Touchdown areas shall be smooth and as level as possible.~~
- ~~5. Perimeter obstructions—Wires, trees, poles, lights, and other hazards must be marked or clearly identified to the pilot.~~
- ~~6. Night landing areas shall be clearly identified by lights at the perimeter boundary.~~

~~(c) Safety Training shall be provided by each helicopter air ambulance service for all Flight Crew Members, Medical Crew Members, Specialty Crew Members, and Flight Coordinators.~~

~~1. Safety training provided annually shall include the following:~~

- ~~(i) Ground emergency procedures,~~
- ~~(ii) Inflight safety procedures,~~
- ~~(iii) Aircraft safety equipment~~
- ~~(iv) Hazardous material identification training,~~
- ~~(v) Emergency shut down aircraft engines,~~
- ~~(vi) Electrical shut down of the aircraft,~~
- ~~(vii) Use of the emergency locator transmitter,~~
- ~~(viii) Emergency use of the aircraft avionics system to include appropriate emergency frequencies,~~

(Rule 1200-12-1-.05, continued)

- ~~(ix) Demonstrated ability to use onboard fire equipment to include engine and cabin fire extinguishers,~~
- ~~(x) Emergency exits of the aircraft,~~
- ~~(xi) Passenger safety briefings,~~
- ~~(xii) Roles and responsibilities for patient safety and flight duties, and~~
- ~~(xiii) Crash protection and survival techniques.~~

~~2. Flight coordinators and ground support personnel functioning for an air ambulance service shall be trained to promote safe operations, to include:~~

- ~~(i) Helipad safety precaution,~~
- ~~(ii) Landing zone standards and scene control,~~
- ~~(iii) Radio communications,~~
- ~~(iv) Fire prevention and fire suppression, and~~
- ~~(v) Accident and incident notification and documentation.~~

~~3. Instruction materials shall be offered by the air ambulance service that will familiarize other EMS providers within their response area with the requirements for establishing landing zones, control of the landing area, and ground to air communications.~~

(4) Each air ambulance service shall offer its instruction materials to other EMS providers within its response area to familiarize them with its requirements for control of helicopter access and ground to air communications on the scene.

~~(5) Air Ambulance Personnel and Qualifications.~~

~~(a) Pilot~~

- ~~1. For all air ambulances the pilot shall possess a minimum commercial pilot's certificate with an instrument rating and in a category appropriate to the aircraft utilized and meet all applicable Federal Aviation Regulations for the type of operation and aircraft.~~
- ~~2. For all helicopter air ambulance services:~~
 - ~~(i) Each pilot shall possess a Commercial Helicopter Certificate with Instrument Helicopter ratings and 3000 hours of flight time which shall include the following:~~
 - ~~(I) 2000 hours of flight time in helicopters with at least 1000 hours in turbine helicopters;~~
 - ~~(II) 200 hours of night flight time of which 100 hours must have been helicopter flight time.~~

(Rule 1200-12-1-.05, continued)

- ~~(ii) An instrument flight and night flight proficiency check will be required before accepting missions.~~
- ~~(iii) Pilot training shall include factory school or equivalent. Flight time shall include five hours of local orientation for all pilots, of which two hours shall be night time flight.~~
- ~~(iv) Each pilot shall successfully complete an instrument proficiency check ride every six months.~~
- ~~(v) Pilot staffing shall consist of four permanently assigned pilots per regularly deployed aircraft and a sufficient number of relief pilots for adequate coverage.~~
- ~~(vi) No pilot shall receive compensation on a "per flight" incentive nor shall patient factors which may unduly influence flight acceptance be communicated to the pilot before a flight plan and departure status are confirmed.~~

~~(b) Medical Crew~~

- ~~1. Each patient transported by a fixed-wing air ambulance shall be accompanied by either a physician, a registered nurse, or an EMT or an EMT-P, meeting recommendations of the American Medical Association Air Ambulance Guidelines (U.S. Department of Transportation Publication DOT HS 806 703, Revised May, 1986, or its successor publication), and so recognized by a letter of authorization from the service's aeromedical consultant.~~
- ~~2. Each transport of patients by a helicopter air ambulance shall require staffing by a regular medical crew which as a minimum standard shall consist of one Registered Nurse licensed in the State of Tennessee and another licensed or certified medical provider (i.e., EMT-P, Respiratory Therapist, Nurse, or Physician). The composition of the medical team may be altered for specialty missions upon order of the medical director of the air ambulance service.~~
- ~~3. All regular medical crew members serving on helicopter air ambulances shall be determined physically fit for duty by the program medical director.
 - ~~(i) An annual medical examination shall be documented.~~
 - ~~(ii) A preplacement Class II FAA Flight Physical certificate or equivalent physical examination shall be documented.~~~~
- ~~4. Registered Nurse Qualifications A Registered Nurse serving as a regular medical crew member on a helicopter air ambulance shall meet the following criteria:
 - ~~(i) Have three years of registered nursing experience with two years experience in critical care nursing.~~
 - ~~(ii) Possess current licensure as a registered nurse in Tennessee unless exempted by T.C.A. §63-7-102(8).~~
 - ~~(iii) Enroll in an EMT training course within twelve months of employment and obtain state certification as an Emergency Medical Technician.~~~~

(Rule 1200-12-1-.05, continued)

- ~~(iv) Obtain and maintain advanced nursing certification within twelve months of employment through one of the following programs:
 - ~~(I) Certified Emergency Nurse.~~
 - ~~(II) Critical Care Registered Nurse.~~~~
- ~~5. EMT Paramedic Qualifications — An EMT Paramedic serving as a regular medical crew member on a helicopter air ambulance shall be certified and have three years experience as an EMT-P, with two years experience as a paramedic in an advanced life support service.~~
- ~~6. Physician Qualifications — The qualifications of a physician serving as a regular medical crew member on a helicopter air ambulance shall be determined by the medical director. At a minimum, each physician shall:
 - ~~(i) Hold current certification in the advanced trauma life support course, and~~
 - ~~(ii) Hold current certification in advanced cardiac life support.~~~~
- ~~7. Each regular medical crew member on a helicopter air ambulance shall have and maintain certification in Advanced Cardiac Life Support and Pediatric Advanced Life Support, or obtain certification within six months of employment and restrict flight duty by accompanying another certified provider until so certified.~~
- ~~8. Each regular medical crew member on a helicopter air ambulance shall have and maintain training in an Advanced Trauma Life Support, Flight Nurse Advanced Trauma Care Course, Basic Trauma Life Support, Pre-hospital Trauma Life Support course, or Trauma Nurse Core Course, or obtain training within six months of employment and restrict flight duty by accompanying another trained provider until so trained.~~
- ~~9. Each regular medical crew member shall complete and document training in mission specific procedures as established by the medical director and such federal, state or local agencies with authority to regulate air ambulance services.~~
- ~~10. Medical crew members on a helicopter air ambulance shall not exceed 24 hours of consecutive duty time or more than 48 hours of duty time within a 72 hour period. Adequate provision for crew rest and time for meals shall be provided for the medical flight crew.~~
- ~~11. Specialty crew members shall be trained in safety procedures and appropriate aeromedical procedures commensurate with the mission.~~
- ~~(c) Aeromedical Consultant — On all fixed-wing air ambulance services an aeromedical consultant, who must be a physician licensed to practice within the jurisdiction of the base of operations, shall advise on the restrictions and medical requirements for patient transport.~~
- ~~(d) Medical Director — All helicopter air ambulance services shall have medical direction from a physician who shall be:
 - ~~1. Licensed in the State of Tennessee; and~~~~

(Rule 1200-12-1-.05, continued)

- ~~2. Board certified or eligible for Board certification by a professional association or society in a Surgical Specialty, Internal Medicine, Pediatrics, Emergency Medicine, Family Practice, or Aerospace Medicine; and~~
 - ~~3. Certified in Advanced Cardiac Life Support; and~~
 - ~~4. Certified in Advanced Trauma Life Support.~~
- ~~(e) Medical Control Physician—Reserved for future use.~~
- ~~(f) All helicopter air ambulance services shall have flights coordinated by designated flight coordinators.~~
- ~~1. As a minimum qualification flight coordinators shall be certified Emergency Medical Technicians with at least two years of emergency medical or emergency communications experience.~~
 - ~~2. Flight coordinators shall have training in FAA approved procedures for flight coordination and telecommunications, which shall include:

 - ~~(i) Map reading, aeronautical chart interpretation and basic navigation and flight planning;~~
 - ~~(ii) Weather terminology and procedures for flight service weather advisories;~~
 - ~~(iii) Flight following and ground-to-air telecommunications; and~~
 - ~~(iv) Procedures for accident and incident policies.~~~~
 - ~~3. Flight coordinators shall not be required to work more than 16 hours in any one 24 hour period or more than 72 hours in any work week.~~

(5) Air Ambulance Personnel Qualifications and Duties

(a) Medical Director Qualifications and Duties

1. Each helicopter air ambulance service shall employ a Medical Director who is responsible for providing medical direction for the helicopter air ambulance service.
2. The Medical Director for a helicopter air ambulance service must be a physician having the following qualifications:

 - (i) Currently licensed in the State of Tennessee;
 - (ii) Board certified or eligible for Board certification by a professional association or society in General or Trauma Surgery, Family Practice, Internal medicine, Pediatrics, Emergency Medicine, or Aerospace Medicine;
 - (iii) Certification in Advanced Cardiac Life Support (unless Board certified or eligible for Board certification in Emergency Medicine);

(Rule 1200-12-1-.05, continued)

- (iv) Certification in Advanced Trauma Life Support; and
 - (v) Certification in Pediatric Advanced Life Support or equivalent (unless Board certified or eligible for Board certification in Emergency Medicine), including the following:
 - (I) Certification in a Neonatal Resuscitation Program; and
 - (II) Possess adequate knowledge regarding altitude physiology/stressors of flight.
 - 3. Duties of the Medical Director for a helicopter air ambulance service shall include the following:
 - (i) Active involvement in the Quality Improvement process;
 - (ii) Active involvement in the hiring, training and continuing education of all medical personnel for the service; and
 - (iii) Responsibility for on-line medical control or involved in orienting and collaborating with physicians providing on-line medical direction according to the policies, procedures and patient care protocols of the medical transport service.
 - 4. The service Medical Director shall establish mission specific and clinical procedures. He shall require each medical crew member to complete and maintain documentation of initial and annual training in such procedures, which shall at least include didactic and hands-on components for the following clinical procedures:
 - (i) Pharmacological Assisted Intubation – Adult and Pediatric;
 - (ii) Emergency cricothyrotomy;
 - (iii) Alternative airway management – Adult and Pediatric;
 - (iv) Chest decompression; and
 - (v) Intraosseous Access – Adult and Pediatric.
- (b) The medical crew shall include:
 - 1. Each patient transported by a fixed-wing ambulance shall be accompanied by either a physician, a registered nurse, or an EMT-P licensed in the State of Tennessee.
 - 2. Each transport of patients by a helicopter air ambulance shall require staffing by a regular medical crew which as a minimum standard shall consist of one Registered Nurse licensed in the State of Tennessee and another licensed medical provider (i.e., EMT-P, Respiratory Therapist, Nurse, or Physician licensed in the State of Tennessee). The composition

(Rule 1200-12-1-.05, continued)

of the medical team may be altered for specialty missions upon order of the medical director of the air ambulance service.

3. On a fixed-wing flight mission only, the air ambulance service medical director may allow transport of patients in the presence of only one medical professional; the minimum level of licensure in such a situation would be that of EMT-P.

(c) Medical crew training and qualifications

1. The service medical director shall make a determination that each regular medical crew member serving on an air ambulance is physically fit for duty by ensuring the service has documentation that each regular crew member has had a pre-employment and annual medical examination.

2. A Registered Nurse serving as a medical crew member on an air ambulance shall meet the following qualifications:

- (i) Have three years of registered nursing experience in critical care nursing, or two years fulltime flight paramedic experience and one year critical care nursing experience;

- (ii) Possess a current Tennessee nursing license, unless exempted by T.C.A. § 63-7-102(8);

- (iii) Obtain certification as an Emergency Medical Technician within twelve (12) months of employment; and

- (iv) Obtain advance nursing certification within twelve (12) months of employment through one of the following programs:

- (I) Certified Emergency Nurse; or

- (II) Critical Care Registered Nurse; or

- (III) Certified Flight Registered Nurse.

3. An EMT-Paramedic serving as a medical crew member on an air ambulance shall meet the following qualifications:

- (i) Possess a current Tennessee EMT-P license and have three years experience as an EMT-P in an advanced life support service;

- (ii) Obtain advanced paramedic certification within twenty-four (24) months of employment through one of the following programs:

- (I) Critical Care Paramedic; or

- (II) Certified Flight Paramedic.

(Rule 1200-12-1-.05, continued)

4. Each medical crew member on an air ambulance shall have and maintain certification in Advanced Cardiac Life Support, Pediatric Advanced Life Support or equivalent (Emergency Nursing Pediatric Course, PEPP), and in neonatal resuscitation.
5. Each medical crew member on an air ambulance shall attend and maintain training in one of the following:
 - (i) Trauma Nurse Advanced Trauma Course;
 - (ii) International Trauma Life Support;
 - (iii) Prehospital Trauma Life Support; or,
 - (iv) Trauma Nurse Core Course.
- (d) Each fixed wing air ambulance service shall have an air medical consultant who shall be a physician licensed within the jurisdiction of the base of operations and shall advise on the restrictions and medical requirements for patient transport.
- (e) Each helicopter air ambulance service shall have a Medical Control Physician who shall be available to provide on line medical control continuously via radio or telephone who shall be board certified or eligible for board certification by a professional association or society in General or Trauma Surgery, Internal medicine, Pediatrics, Emergency Medicine, Family Practice, or Aerospace Medicine.
- (f) Air Medical Communications specialist qualifications and duties:
 1. Each air medical communications specialist shall meet the following qualifications:
 - (i) At a minimum, be licensed as an Emergency Medical Technician;
or
 - (ii) Be a higher level licensed health care professional with at least two years of emergency medical or emergency communications experience; and
 2. Have initial and recurrent training for medical coordination and telecommunications.
 3. Air medical communications specialists shall be certified through the National Association of Air Medical Communication Specialists (NAACS) or obtain such certification within twelve (12) months of employment.
 - (i) Air medical communication specialists shall coordinate helicopter air ambulance service flights.
 4. Air medical communications specialists shall not be required to work more than sixteen (16) hours in any one twenty-four (24) hour period.

(Rule 1200-12-1-.05, continued)

(g) Duty time for medical crew members on an air ambulance shall not exceed twenty-four (24) consecutive hours or more than forty-eight (48) hours within a seventy-two (72) hour period. The air ambulance service shall provide the medical flight crew adequate rest and meal time. Personnel must have at least eight (8) hours of rest with no work-related interruptions prior to any scheduled shift of twelve (12) hours or more in the air transport environment.

~~(6) Flight Coordination and Telecommunications. A flight coordination office shall be provided for each helicopter air ambulance service for processing requests, initiating responses, telecommunications, and flight following. This office shall be physically isolated from emergency room or admitting areas to minimize distractions. This office shall be staffed 24 hours per day on a continuous basis.~~

~~(a) Operations Manual for Flight Control Office — A detailed manual of policies and procedures shall be available for reference in the flight coordination office. Personnel shall be familiar and comply with policies contained within the manual, which shall include:~~

- ~~1. Procedures for acceptance of requests and referral or denial of service,~~
- ~~2. Geographical boundaries and features for the service area,~~
- ~~3. Criteria for the medical conditions and indications or contraindications for flight~~
- ~~4. Procedures for call verification and advisories to the requesting party,~~
- ~~5. Acceptable destinations and landing areas,~~
- ~~6. Weather advisory procedures and policies for minimum flight operations,~~
- ~~7. Procedures for pilot and flight crew assignment and notification including resters for personnel,~~
- ~~8. Radio and telephone communications procedures,~~
- ~~9. Policies and procedures for accidents and incidents,~~
- ~~10. Procedures for informing requesting party of flight procedures, helicopter arrival, and termination of flight,~~
- ~~11. Flight following procedures which shall assure air/ground position reports at intervals not to exceed fifteen minutes.~~

~~(i) Information for each flight following shall be recorded on an appropriate form.~~

~~(ii) Position reporting shall use a map or aeronautical reference system with established locational descriptions.~~

~~12. Procedures shall be established for communications failure or overdue aircraft.~~

~~13. Emergency protocols shall be established for downed aircraft search and rescue.~~

~~(b) Telecommunications — The flight coordination center for a helicopter air ambulance service shall include radio and telephone equipment to enable personnel to contact the~~

(Rule 1200-12-1-.05, continued)

~~helicopters and crew and promote safe operations. Telecommunications devices shall include the following:~~

- ~~1. EMS Communications on the established frequencies of 155.205 MHz, 155.340 MHz, and/or upon such specific channels or frequencies as may be designated within each region as are approved and published as a supplement to the State EMS Telecommunications Plan,~~
- ~~2. Direct telephone circuits accessible by flight coordination personnel, and~~
- ~~3. Tape logging or recording equipment for both telephone and radio messages.~~

(6) Flight Coordination

(a) Each air ambulance service operations office director shall maintain an Operations Manual detailing policies and procedures and shall ensure that it is available for reference in the operations office. Personnel shall be familiar and comply with policies contained within the manual which shall include:

1. Criteria for medical conditions including indication or contraindications for transfer;
2. Procedures for call verification and advisories to the requesting party;
3. Radio and telephone communications procedures;
4. Policies and procedures for accidents and incidents;
5. Procedures for informing the requesting party of operations procedure, ambulance arrival, termination of mission and delayed responses, including the following:
 - (i) Estimated Time of Arrival includes time of operations acceptance to landing on scene; and
 - (ii) Any deviation from ETA greater than 5 minutes will be reported to the requesting agency;
6. Procedures shall be established for communications failure or overdue transports;
7. Emergency protocols for alerting search and rescue; and
8. Utilization of the Air Medical Communication Safety Questionnaire (as approved by the board).

~~(7) Helicopter Air Ambulance Response and Destination Guidelines and Procedures. Response to emergency medical situations by helicopter air ambulance services shall be governed by medical necessity. Procedures for initiation of requests, medical responsibility and destination coordination shall be governed by this Rule.~~

~~(a) Medical Necessity~~

(Rule 1200-12-1-.05, continued)

- ~~1. Helicopter air ambulance response is appropriate when the information available at the time of transport indicates the patient has an anticipated medical or surgical need requiring transport or transfer and without helicopter transport the patient would be placed at significant risk for loss of life or impaired health; and,
 - ~~(i) Available alternative methods may impose additional risk to the life or health of the patient; or~~
 - ~~(ii) Available alternative methods would make ambulance services unavailable or severely limited in the community service area; or~~
 - ~~(iii) Where speed and critical care capabilities of the helicopter are essential; or~~
 - ~~(iv) Where the patient is inaccessible to ground ambulances or distance to a hospital from the scene would require unnecessarily prolonged ground travel time; or~~
 - ~~(v) Where the patient transfer is delayed in entrapment, traffic congestion, or other barriers; or~~
 - ~~(vi) Where advanced life support is unavailable or subject to response time in excess of twenty minutes.~~~~
 - ~~2. Specialty Missions with specialized medical care personnel, medical products and equipment, emergency supplies, and special assistance for major casualty incidents or disasters, or mutual aid to other aeromedical services are medically necessary when their availability might decrease the risk of aggravation or deterioration of the patient's condition.~~
- ~~(b) Request Initiation Procedures—Procedures for initiation of requests shall be established in writing to include documentation of the following:~~
- ~~1. Means of access,~~
 - ~~2. Call criteria and incident criteria, and~~
 - ~~3. Notification to the requesting party of the estimated time of arrival of the helicopter.~~
- ~~(c) Medical Responsibility—Medical responsibility will be assumed by the medical flight crew personnel upon arrival at the scene.~~
- ~~(d) Interfacility transfers shall not be initiated unless an appropriate physician at the receiving institution has accepted the patient for transfer.~~
- ~~(e) Destination—The destination of a patient shall be established pursuant to Rule 1200-12-1-.11(7).~~

(7) Telecommunications

- (a) The operations center for an air ambulance service operating in Tennessee shall include radio and telephone equipment to enable personnel to contact the helicopters and crew. Telecommunications devices shall include the following:

(Rule 1200-12-1-.05, continued)

1. EMS Communications on the established frequencies of 155.205 MHz, 155.340 MHz, and/or upon such specific channels or frequencies as may be designated within each region as approved and published as a supplement to the State EMS Telecommunications Plan;
2. Direct telephone circuits accessible by air communication; and
3. Recording equipment for both telephone and radio messages and instant message recall.

~~(8) Records and Reports~~

~~(a) Fixed-wing aircraft records shall include the following:~~

~~1. A record on each patient transported providing:~~

- ~~(i) Name of the person transported,~~
- ~~(ii) Date of flight,~~
- ~~(iii) Origin and destination of flight,~~
- ~~(iv) Presenting illness or injury, or medical condition necessitating air ambulance service,~~
- ~~(v) Flight crew and medical personnel,~~
- ~~(vi) Accessory ground ambulance services, and~~
- ~~(vii) Medical facilities transferring and receiving the patient.~~

~~2. Each fixed-wing air ambulance service shall report the number of air ambulance transfers performed annually, on the form provided for such purposes to the Division of Emergency Medical Services.~~

~~(b) Helicopter Air Ambulance Services — Records and reports shall be required for the dispatch, personnel, flights, patient care and incidents or accidents involving any helicopter air ambulance.~~

~~1. Tape recordings of telecommunications shall be retained for at least thirty days.~~

~~2. Flight following or related equipment records shall be retained for at least 30 days.~~

~~3. A patient record shall include the patient's name, date of transport, origin and destination of flight chief complaint, documentation of treatment during transport, and medical care providers. A copy shall be provided to the receiving facility.~~

~~(c) All records of medical services shall be retained for at least five years.~~

(8) Helicopter Air Ambulance Response and Destination Guidelines and Procedures.

(a) Medical necessity shall govern air ambulance service response, including medical responsibility and destination coordination, to emergency medical situations.

(Rule 1200-12-1-.05, continued)

(b) Medical Necessity.

1. The medical director for the helicopter air ambulance service shall determine whether there is a medical necessity to transport a patient by air ambulance. Medical necessity will be met if the following conditions occur:

(i) At the time of transport the patient has an actual or anticipated medical or surgical need requiring transport or transfer that would place the patient at significant risk for loss of life or impaired health without helicopter transport; or

(ii) Patient meets the criteria of the trauma destination guidelines; or

(iii) Available alternative methods may impose additional risk to the life or health of the patient; or,

(iv) Speed and critical care capabilities of the helicopter are essential; or,

(v) The patient is inaccessible to ground ambulances; or,

(I) Patient transfer is delayed by entrapment, traffic congestion, or other barriers; or,

(II) Necessary advanced life support is unavailable or subject to response time in excess of twenty (20) minutes.

(vi) Specialty Missions with specialized medical care personnel, special medical products and equipment, emergency supplies, and special assistance for major casualty incidents or disasters, or mutual aid to other aeromedical services are medically necessary when their availability might lessen aggravation or deterioration of the patient's condition.

(c) The incident commander or his designee will coordinate the transfer of medical responsibility to the medical flight crew by emergency services responsible for the patient at the scene of the incident.

1. If a helicopter air ambulance lands on a scene and it is determined through patient assessment and coordination between ground and air medical personnel that it is not medically necessary to transport the patient by helicopter, the appropriate ground EMS agency will transport the patient.

2. Interfacility transfers shall not be initiated unless an appropriate physician at the receiving facility has accepted the patient for transfer.

(d) Patient destination shall be established pursuant to Rule 1200-12-01-.21.

~~(9) Compliance. Compliance with the foregoing regulations shall not relieve the air ambulance operator from compliance with other statutes, rules, or regulations in effect for medical~~

(Rule 1200-12-1-.05, continued)

~~personnel and emergency medical services, involving licensing and authorizations, insurance, prescribed and proscribed acts and penalties.~~

(9) Records and Reports

(a) The air ambulance service shall maintain records including the following:

1. A record for each patient transported including:

(i) Name of the person transported;

(ii) Date of transport;

(iii) Origin and destination of transport;

(iv) Presenting illness, injury, or medical condition necessitating air ambulance service;

(v) Attending and medical personnel;

(vi) Accessory ground ambulance services;

(vii) Medical facilities transferring and receiving the patient;

(viii) Documentation of treatment during transport; and

(ix) A copy shall be provided to the receiving facility.

2. Each air ambulance service shall report the number of air ambulance transfers performed annually on the form provided for such purposes to the Division of Emergency Medical Services.

(b) Each air ambulance service shall retain patient records for at least ten years.

~~(10) Separation of Services. Ground ambulance services, categorized in accordance with rule 1200-12-1-.14 shall remit a separate application and fee for operation of an air ambulance service, and air ambulance service shall constitute a separate class of license and authorization from the Board and Department.~~

(10) Utilization Review (UR)

(a) The air ambulance service management shall ensure appropriate utilization review process based on:

1. Chart review of medical benefits delivered to a random sample of patients, including the following:

(i) Timeliness of the transport as it relates to the patient's clinical status;

(Rule 1200-12-1-.05, continued)

- (ii) Transport to an appropriate receiving facility;
 - (iii) On scene transports (Rotor Wing) – the following types of criteria are used in the triage plan for on-scene transports:
 - (I) Anatomic and physiological identifiers;
 - (II) Mechanism of injury identifiers;
 - (III) Situational identifiers;
 - (IV) Pediatric and Geriatric Patients;
 - (iv) Specialized medical transport personnel expertise available during transport are otherwise unavailable;
2. Structured, periodic review of transports shall be performed at least semi-annually and result in a written report; and
3. The service shall list criteria used to determine medical appropriateness. It will maintain records of such reviews for two years.

(11) Quality Improvement (QI)

- (a) The service shall have an established Quality Improvement Program, including, at a minimum, the medical director(s) and management.
- (b) The service shall conduct an ongoing Quality Improvement program designed to assess and improve the quality and appropriateness of patient care provided by the air medical service.
- (c) The service shall have established patient care guidelines/standing orders. The QI committee and medical director(s) shall periodically review such guidelines/standing orders.
- (d) The Medical Director(s) is responsible for ensuring timely review of patient care, utilizing the medical record and pre-established criteria.
- (e) Operational criteria shall include at least the following quantity indicators:
 - (i) Number of completed transports;
 - (ii) Number of air medical missions aborted and canceled due to weather; and
 - (iii) Number of air medical missions aborted and canceled due to patient condition and use of alternative modes of transport.
- (f) For both QI and utilization review programs, the air ambulance service shall record procedures taken to improve problem areas and the evaluation of the effectiveness of such action.

(Rule 1200-12-1-.05, continued)

- (g) For both QI and utilization review programs, the air ambulance service shall report results to its sponsoring institution(s) or agency (if applicable) indicating that there is integration of the medical transport service's activities with the sponsoring institution or agency (if applicable).
- (12) Compliance. Compliance with the foregoing regulations shall not relieve the air ambulance operator from compliance with other statutes, rules, or regulations in effect for medical personnel and emergency medical services, involving licensing and authorizations, insurance, prescribed and proscribed acts and penalties.
- (13) Separation of Services. Air ambulance service shall constitute a separate class of license and authorization from the Board and Department.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-140-504, and 68-140-507. **Administrative History:** Original rule filed March 20, 1974; effective April 19, 1974. Amendment filed November 30, 1984; effective February 12, 1985. Amendment filed February 4, 1988; effective March 20, 1988. Amendment filed June 28, 1988; effective August 12, 1988. Amendment filed August 11, 1993; effective October 25, 1993. Amendment filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed January 7, 1997; effective March 23, 1997.

1200-12-1-.06 SCHEDULE OF FEES.

- (1) The fees are as follows:
- (a) Application fee for licensure or certification - A fee to be paid by all applicants as indicated, including those seeking licensure by reciprocity. It must be paid each time an application for licensure is filed.
 - (b) Endorsement/verification - A fee paid for each level of certification or endorsement as may be recognized by the Board within each category of personnel license.
 - (c) Examination fee - A fee paid each time an applicant requests to sit for any initial, retake, or renewal test or examination, written or practical.
 - (d) License fee - A fee to be paid prior to the issuance of the initial license.
 - (e) License Renewal fee - A fee to be paid by all license holders. This fee also applies to personnel who may reinstate an expired or lapsed license.
 - (f) Reinstatement fee - A fee to be paid when an individual fails to timely renew a license or certification.
 - (g) Replacement license or permit fee - A fee to be paid when a request is made for a replacement when the initial license has been changed, lost, or destroyed.
 - (h) Volunteer non-profit ambulance services eligible for reduced license fees under paragraph (5) shall be provided by all volunteer personnel and shall not assess any fees for their services, and shall be primarily supported by donations or governmental support for their charitable purposes.
- (2) All fees shall be established pursuant to the rules approved by the Board.
- (3) All fees for initial licensing or certification shall be submitted to the Division of Emergency Medical Services to the attention of the Revenue Control office. Fees shall be payable by check or money order payable to the Tennessee Department of Health.