4300 Emergency Medical Services

4302 Air Medical Ambulance Service

Definitions

"ABEM" American Board of Emergency Medicine

"ABOEM" American Board of Osteopathic Emergency Medicine

"ACLS (Advanced Cardiac Life Support)" A syllabus and certification of the American Heart Association (AHA).

"Aircraft Type" Particular make and model of helicopter or airplane.

"Air Medical Service" A company or entity of a hospital or public service which provides air transportation to patients requiring medical care. This term may be used interchangeably with the term "air medical program" throughout the document.

"**Air Medical Personnel**" Refers only to the patient care personnel involved in an air medical transport.

"Air Medical Team" Refers to the pilot(s) and patient care personnel who are involved in an air medical transport.

"**ALS Mission**" The transport of a patient who receives care during an interfacility or scene response commensurate with the scope of practice of an EMT-Paramedic.

"ALS Provider" A certified provider of skills required for advanced life support.

"**ATLS (Advanced Trauma Life Support)**" A syllabus and certification offered to physicians by the American College of Surgeons.

"**Base Of Operations**" A location from which an aircraft responds to answer a call and to which it returns while awaiting assignment on another call.

"**BLS Mission**" The transport of a patient who receives care during an interfacility or scene response that is commensurate with the scope of practice of an EMT-B. In the state of Delaware, all interfacility air transports must be staffed at a minimum with an EMT-P.

"BLS Provider" A certified provider of skills required for basic life support.

"**BTLS (Basic Trauma Life Support)**" A syllabus offered by the American College of Emergency Physicians to provide a standard of care for the prehospital trauma victim.

"**Certificate**" Signifies a pilot level of competency, i.e., student, private, commercial. It can also refer to the type of service a company is qualified to provide under Federal Aviation Regulations.

"Consortium Program" An air medical service sponsored by more than one health care facility or entity.

"Continuous Quality Improvement (CQI)" CQI is a management strategy that integrates dedication to a quality product into every aspect of the service; it brings together a variety of personnel and management tools to examine the sources of problems within the system. CQI seeks to establish and remedy the root cause of problems by identifying and correcting the system's errors, rather than ascribing fault to individuals.

"**Controlled Air Space**" Air space designated as continental control area, terminal control area, or transition area within which some or all aircraft may be subject to air traffic control.

"**Cross Country (CC)**" Generally when the destination is greater than 25 nautical miles from the departure point or as designated by a geographic boundary. The DSP cross country is 25 nautical miles outside of the state of Delaware.

"DSP" Delaware State Police

"EDIN" See 'EMS Data Information Network'

"Elective Transports" Air medical transports that may not be medically necessary but are done for patient or physician preference; these often are fixed wing, prepaid scheduled transports.

"ELT (Emergency Locator Transmitter)" A radio transmitter attached to the aircraft structure which is designed to locate a downed aircraft without human action after an accident.

1

"EMS Data Information Network" The Internet-based data collection program of the State EMS System.

"FAA" Federal Aviation Administration

"FAR" Federal Aviation Regulation.

2

"Head-strike Envelope" The volume of air space which a person's head would potentially move through during any abrupt aircraft motion.

"Helipad" A small, designated area usually with a prepared surface, on an airport, landing/ take-off area, or apron/ramp used for take-off, landing or parking helicopters.

"Hot Load/unload" The loading or unloading of patient(s) or equipment with rotors turning.

"**IABP (Intra Aortic Balloon Pump)**" A cardiac assist machine which can be retrofitted into some types of aircraft.

"IFR" Instrument Flight Rules

"**Installed Equipment**" Includes all items or systems on the aircraft at the time of certification and any items or systems subsequently added to the aircraft with FAA approval through a Supplemental Type Certificate (STC), FAA Form 8110 or Form 337 action.

"IMC" Instrument meteorological conditions.

"**Independent Program**" Referring to an air medical service not sponsored by a hospital and operating under its own FAA certificate.

"Infection Control" An approach to reducing the risk of disease transmission to care takers, patients and others

"Local" "Day-Local" Less than 25 nautical miles from departure point to destination point with generally the same terrain elevation.

"Night-Local" The urban area of the helicopter base with enough illumination to maintain ground reference.

The DSP local is within the State of Delaware and less than 25 nautical miles outside the State of Delaware.

"Modalities" Treatment plans and equipment used in the delivery of patient care.

"Mutual Aid Agreements" The establishment of appropriate arrangements with EMS systems of other states for the provision of emergency medical services on a reciprocal basis.

"**Out-of-state Program**" A flight program that does not have a base of operations within the borders of the State of Delaware.

"Paramedic" A Nationally Registered or state-certified EMT-P

"**Personnel, Scheduled**" Staff employed by the air medical service with scheduled working hours during which air medical transport is their primary responsibility. This includes those who take call for the primary purpose of being available for air medical transport.

"**Personnel, Non-scheduled**" Staff employed in patient care roles by another department or facility who have received the helicopter orientation and may be utilized as a second crew member, particularly during a specialty transport

"PHTLS" Prehospital Trauma Life Support: A course offered by the American College of Surgeons to provide a standard of care for the prehospital victim.

"PIC" Pilot in command.

"**Point To Point Transport**" Transports that have both an origination and destination point within the State of Delaware.

"Prehospital 911 Service" A service which acts as a supplemental resource to the Delaware State Police in carrying out prehospital scene missions.

"Quality Assurance (QA)" QA is a process of reviewing the quality of care delivered through the examination of known or potential problems. It measures the degree of compliance of the service's personnel with established standards.

"**Specialty Care Mission**" The transport of a patient who requires care by professionals who can be added to the regularly scheduled personnel.

"Specialty Care Provider" A provider of specialty care, such as neonatal, pediatric, etc.

"State Certification, Full" Approval granted, following satisfactory completion of the application process, to an air medical service wishing to provide point to point transport or prehospital 911 service within the state of Delaware. The certification period is three years.

"State Certification, Limited" Approval granted, following satisfactory completion of the air medical program certification process, to an air medical service wishing to provide only one way transport to or from Delaware. The certification period is three years.

"VFR" Visual Flight Rules.

4 DE Reg. 1827 (5/1/01)

5 DE Reg. 1727 (3/1/02)

1.0 Purpose

The purpose of these regulations is to provide minimum standards for the operation of Air Medical Ambulance Services in the State of Delaware. It is the further intent of these regulations to ensure that patients are quickly and safely served with a high standard of care and in a cost-effective manner.

2.0 General Provisions

- 2.1 No person or agency (governmental or private) may operate, conduct, maintain, advertise, engage in or profess to engage in air ambulance services in Delaware unless the agency or person holds a current valid certificate issued by the Division of Public Health (the Division).
- 2.2 Air ambulance services will provide access to its services without discrimination due to race, creed, sex, color, age, religion, national origin, ancestry, or disability. Requests for service for those patients with a potentially life threatening illness or injury, who require rapid transportation, will be honored without prior inquiry as to the patient's ability to pay.
- 2.3 Out of state air ambulance services that provide 'point to point' transport services within the state of Delaware hall be subject to all parts of these regulations (full certification) unless covered by mutual aid agreements entered into with an agency of the State of Delaware, in conjunction with other applicable state laws.
- 2.4 All air ambulance services with a base of operations located within the State of Delaware, or that engage in providing 'prehospital 911 service' regardless of the location of their base of operations, will be subject to all parts of these regulations (full certification).
- 2.5 Pre-hospital scene work shall be conducted only by air ambulance services owned and operated by the State of Delaware, or private air ambulance services which have entered into appropriate agreements with the Division of Public Health and Delaware State Police to provide such services.
- 2.6 All out-of-state flight programs that only provide services consisting of 'one-way' transports either into or out of the State of Delaware, are subject to all requirements of these regulations for certification of the Flight Program. Personnel may maintain appropriate licensure or certification in their home state, in lieu of seeking Delaware licensure/certification. (limited certification)

4 DE Reg. 1827 (5/1/01)

5 DE Reg. 1727 (3/1/02)

3.0 Application Process

- 3.1 An application for a certificate to operate an air ambulance service may be obtained from the Division of Public Health (the Division), Office of Emergency Medical Services (the Office). An application for an original or renewal certificate shall be submitted to the Office and shall include the following:
 - 3.1.1 Name and address of the vendor of the ambulance service or proposed air ambulance service and the name and address under which the service will operate.
 - 3.1.2 Name, address and FAA (Federal Aviation Administration) certification number of the aircraft operator.

- 3.1.3 Submission of the air medical service's mission statement and scope of service to be provided.
- 3.1.4 Experience and qualifications of the applicant to operate an air ambulance service.
- 3.1.5 Description of each aircraft to be used as an air ambulance, including the make, model, year of manufacture, registration number, name, monogram or other distinguishing designation and FAA air worthiness certification.
- 3.1.6 The geographical service area and the location and description of the places from which the air ambulance services is to operate.
- 3.1.7 Name, training, and qualifications of the air ambulance medical director who is responsible for medical care provided by the service.
- 3.1.8 Roster of medical personnel which includes level of certification or licensure.
- 3.1.9 Roster of pilots including training and qualifications.
- 3.1.10 Statement in which the applicant agrees to provide patient specific data to the Division for EMS system quality management program purposes.
- 3.1.11 Other information the Division deems necessary and prescribes as part of the application.
- 3.2 Change of ownership of the air ambulance service requires re-application for certification. An air ambulance certificate holder shall file with the Division an application for renewal of the air ambulance service certificate within 10 business days of acquisition of the service by the new owner.

4 DE Reg. 1827 (5/1/01)

4.0 Certification Process

Within 30 days of receipt of an appropriately completed application from the proposed air ambulance service, the Office will notify the applicant in writing of the approval or disapproval of the application.

- 4.1 Certification Approval
 - 4.1.1 The Division will issue a certificate to operate an air ambulance service. The OEMS may conduct an on-site inspection to confirm that the applicant service is in compliance with these regulations and other applicable laws.
 - 4.1.2 No certificate to operate an air ambulance service shall be issued unless the applicant satisfies the Division that the certification requirements for the air ambulance, medical supplies and equipment, as well as the qualifications of medical and operating personnel, as discussed herein, have been satisfied.
 - 4.1.3 Certification will be granted only to services that meet all Federal Aviation Regulations (FAR's) specific to the operations of the air medical service.
 - 4.1.4 A certificate will be issued for three years from the date of issue and will remain valid for that time period unless revoked or suspended by the Division.
 - 4.1.5 The current certificate shall be posted in a conspicuous place in the air ambulance operations center and on, or in, the aircraft where it is clearly visible.
- 4.2 Denial of Certification
 - 4.2.1 If the Division determines that deficiencies exist which warrant denial of the application, the air medical service shall be provided a list of these deficiencies in writing.
 - 4.2.2 The applicant shall have 30 days from receipt of the denial notice in which to:
 - 4.2.2.1 Respond to the Division with plans to correct the deficiencies.
 - 4.2.2.1.1 After review of an acceptable plan, the Division will conduct a re-inspection consistent with an agreed upon time frame.
 - 4.2.2.1.2 If the Division is satisfied with the results of the re-inspection, The Division will promptly issue a certificate of approval. If the Division determines that deficiencies still exist, the Division will give the applicant written notice of disapproval, which shall identify deficiencies. The applicant shall have 30 days from receipt of the second refusal notice in which to request a review of their application and accompanying documents by the Director of the Division of Public Health or their designee.

4

- 4.2.2.1.2.1 If the result is a denial of application, the applicant may not reapply for a period of six (6) months.
- 4.3 Renewal
 - 4.3.1 The service shall submit to the Division the renewal application postmarked at least 60 days prior to the expiration date of the certificate.
 - 4.3.2 The criteria for certification renewal are the same as the current requirements for original certification.
- 4.4 Inspections
 - 4.4.1 The Division reserves the right to enter and make inspections. All services applying to provide prehospital 911 service will, at a minimum, have an initial inspection prior to execution of the required Memorandum of Agreement allowing them to commence prehospital operations.
 - 4.4.2 Upon request of an agent of the Division during regular business hours, or at other times when a reasonable belief that violations of these regulations may exist, a certificate holder shall produce for inspection, the air ambulance, equipment, personnel and other such items as is determined by the Division's agent.
 - 4.4.3 All records pertaining to the operation of the air medical service must be retained for a minimum of two (2) years.
- 4.5 Investigatory Procedures
 - 4.5.1 Upon receipt of a written complaint describing specific violations of these regulations the Division will:
 - 4.5.1.1 Initiate an investigation of the specific charges.
 - 4.5.1.2 Notify the air ambulance service of the charges and investigation procedures.
 - 4.5.1.3 Conduct and develop a written report of the investigation.
 - 4.5.1.4 Notify the air ambulance service in writing of the results of the investigation with a request for a written response.
 - 4.5.1.5 The Division will conduct an appropriate follow-up investigation.
- 4.6 Grounds for Suspension, Revocation or Refusal of an Air Ambulance Certification
 - 4.6.1 The Division may, in compliance with proper administrative procedure as provided by law, suspend, revoke or refuse to issue certificates for the following reasons:
 - 4.6.1.1 A serious violation of these regulations. A serious violation is one that poses a significant threat to the health and safety of the public.
 - 4.6.1.2 Failure of the certified party or applicant to submit a plan to the Division to correct deficiencies and violations cited by the Division by the deadline requested by the Division.
 - 4.6.1.2.1 The plan must correct the deficiencies within the timeframe specified by the Division.
 - 4.6.1.3 The existence of a pattern of deficiencies or violations over a period of three (3) or more years.
 - 4.6.1.4 Fraud or deceit in obtaining or attempting to obtain certification.
 - 4.6.1.5 Lending a certificate or borrowing or using the certificate of another, or knowingly aiding or abetting the improper granting of a certificate.
 - 4.6.1.6 Incompetence, negligence or misconduct in operating the air ambulance service or in providing emergency medical services (EMS) to patients.
 - 4.6.1.7 Failure to employ or contract for a medical director responsible for the care provided by the air ambulance service.
 - 4.6.1.8 Failure to have appropriate medical equipment and supplies required for certification.
 - 4.6.1.9 Failure of the air ambulance service to have an aircraft equipped in compliance with these regulations.
 - 4.6.1.10 Failure of the aircraft operator to maintain required FAA certifications.

6	TITLE 16 HEALTH AND SOCIAL SERVICES DELAWARE ADMINISTRATIVE CODE		
	4.6.1.11	Failure to employ a sufficient number of certified or licensed personnel to provide services during the time frames identified in the application and approved certification.	
	4.6.1.12	Failure of the air ambulance service to be available during time periods specified upon in the approved certification. Exceptions to this requirement include unsafe weather conditions, commitment to another flight, grounding due to maintenance or other reasons that would prevent commitment to another flight, grounding due to maintenance or other reasons that would prevent response. The air medical service shall maintain a record of each failure to respond to a request for service, and make the record available upon request to the Division. Financial inability to pay does not constitute sufficient grounds to deny response for emergency air service.	
	4.6.1.13	Failure of an air ambulance service to notify the Division of the change of ownership or aircraft operation.	
	4.6.1.14	Abuse or abandonment of a patient.	
	4.6.1.15	Unauthorized disclosure of medical or other confidential information.	
	4.6.1.16	Willful preparation or filing of false medical reports or records, or the inducement of another to do so.	
	4.6.1.17	Destruction of medical records.	
	4.6.1.18	Refusal to render emergency medical services because of a patient's race, sex, creed, national origin, sexual preference, age, disability, medical problem or financial inability to pay.	
	4.6.1.19	Misuse or misappropriation of drugs/ medications.	
	4.6.1.20	Failure to produce requested records for inspection or to permit examination of equipment and facilities shall be grounds for suspension, revocation or denial of certification provided, however, that not certificate shall be suspended, revoked or denied for a period not to exceed sixty days in the event that a dispute regarding the production of such records exists and remains unresolved, except that such suspension or revocation may occur within the sixty day period if the Division determines that such action is necessary to prevent a clear and immediate danger to public health.	
	4.6.1.21	Other reasons as determined by the Division which pose a significant threat to the health and safety of the public.	
	4.6.2 If the D	Division determines that these regulations have been violated, the Division may:	
	4.6.2.1	Place the service on probation until the deficiency is remedied and accepted by the Division.	
	4.6.2.1	.1 This will include a timeframe and method by which the service must demonstrate the deficiency or violation rectified.	
	4.6.2.1	.2 If an air medical service is unable to demonstrate that the deficiency or violation has been rectified within the specified timeframe it must submit a written progress report to the Director of Public Health requesting a deadline extension.	
	4.6	5.2.1.2.1 Failure to comply will result in the 'Probation' status being changed to 'Suspension'.	
	4.6	5.2.1.2.2 Failure to correct the deficiencies or violations within the extension period will result in suspension of the certificate.	
	4.6.2.2	Suspend certification for a period of up to 30 days.	
	4.6.2.2	In circumstances where an alleged violation poses an immediate threat to public health is being investigated, the certification may be suspended during the investigation.	

4.6.2.2.2 The Division must investigate the violation and issue a written report containing the findings of the investigation

- 4.6.2.2.2.1 The report must describe the deficiencies or violations that must be corrected in order to reinstate certification.
- 4.6.2.2.2.2 A hearing must be scheduled within thirty (30) days of the date of suspension.
- 4.6.2.2.3 Upon suspension or revocation of an air ambulance certificate, the service shall cease operations and no person may permit or cause the service to continue.
- 4.6.2.2.4 The air medical service must correct any deficiencies identified to be an immediate danger to public health within the suspension period.
 - 4.6.2.2.4.1 All other deficiencies or violations may be addressed in a correction plan submitted to the Division.
 - 4.6.2.2.4.2 The status of the air medical service certificate will be changed to 'Provisional' for implementation of the corrective plan.
- 4.6.2.3 Revoke certification.
 - 4.6.2.3.1 Violations or deficiencies that resulted in a 'Suspension' status and have not been rectified pursuant to the requirements of those sections will result in the revocation of the air medical service's certificate.
 - 4.6.2.3.2 A hearing will be scheduled within thirty (30) days of the date of revocation.
- 4.6.2.4 Continue current certificate status.
- 4.6.2.5 The Division will provide public notification of their decisions involving probation, suspension-including the length of suspension period, or revocation of an air ambulance service certificate.
- 4.7 Reinstatement Process
 - 4.7.1 When an air medical service has corrected a problem that has resulted in suspension or revocation of their certificate, it shall notify the Division of Public Health in writing, requesting reinstatement.
 - 4.7.2 Based on the recommendations of the Division, a review will be arranged to verify resolution of the problem.
 - 4.7.3 Outcomes of the review will be:
 - 4.7.3.1 Reinstatement of certification
 - 4.7.3.2 Continuation of suspension or revocation.
- 4.8 Right of Appeal
 - 4.8.1 Any air medical ambulance service that has had their reapplication for certification denied or their certification revoked or suspended may appeal the decision.
 - 4.8.2 Written notification of the intent to appeal must be received by the Director of Public Health within thirty (30) days of receipt of notice of such denial, suspension or revocation.
 - 4.8.3 The Director or their designee will conduct a hearing on the Division's action.
 - 4.8.4 Information pertinent to the case will be presented by a member of the Division's investigation committee (or the Office of EMS) and a representative of the air medical service.
 - 4.8.5 The hearing panel will make a recommendation to the Director that the decision stand, be reversed, or modified.
 - 4.8.5.1 Specific recommendation for modification shall be outlined.
 - 4.8.6 The Director of Public Health will make a decision based on the hearing panel's recommendations and will provide written notification of the action to the air medical service.
 - 4.8.7 The Division's action shall not be automatically stayed during the pendency of the appeal.
- 4.9 Voluntary Discontinuation of Service
 - 4.9.1 Certified Air Ambulance Services may not voluntarily discontinue service until ninety (90) days after the certificate holder notifies the Division in writing that the service is to be discontinued.

4.9.2 The Air Ambulance Service shall notify the Division in advance of anticipated temporary discontinuation of service expected to last at least seven (7) consecutive days.

4 DE Reg. 1827 (5/1/01) 5 DE Reg. 1727 (3/1/02)

5.0 Staffing

5.1 Air Medical Personnel Classifications

The aircraft, by virtue of medical staffing and retrofitting of medical equipment, becomes a patient care unit specific to the needs of the patient. Staffing shall be commensurate with the mission statement and scope of care of the air medical service.

5.1.1 Administrative Air Medical Staff

5.1.1.1 Medical Director

The Medical Director of the program is a physician who is responsible for supervising and evaluating the quality of medical care provided by the air medical personnel.

- 5.1.1.1.1 Credentials/Experience
 - 5.1.1.1.1 The Medical Director shall be licensed and authorized to practice medicine in the state in which the air medical service is based unless the flight program is providing primary 911 or 'point to point' transfer services in the State of Delaware. If either of these services is provided, the physician must be licensed in Delaware. The medical director must have educational and clinical experiences in Emergency Medicine as well as other areas of medicine that are commensurate with the mission statement of the air medical service (e.g., adult trauma, pediatrics, neonatal transport, etc.). When specific missions fall outside the scope of expertise of the medical director, specialty care physicians must serve as consultants.
 - 5.1.1.1.2 The medical director shall be experienced in both air and ground emergency medical services (as appropriate to the mission statement) and be familiar with the general concepts of appropriate utilization of air medical services.
 - 5.1.1.1.3 Additionally, the medical director shall have the following educational experiences as appropriate to the mission statement and scope of care of the air medical service:
 - 5.1.1.1.1.4 The Medical Director shall also have education in the following areas:
 - 5.1.1.1.4.1 Specialty education consistent with the mission statement of the air medical service (e.g., Neonatal Resuscitation Certification Program, Pediatric Advanced Life Support, etc. or equivalent education in these areas). Alternately, the medical directors must have immediate access to specialty physicians as consultants.
 - 5.1.1.1.4.2 In-flight patient care capabilities and limitations (e.g., assessment and invasive procedures).
 - 5.1.1.1.1.4.3 Infection control as it relates to prehospital, aircraft and hospital environment.
 - 5.1.1.1.4.4 Stress recognition and management.
 - 5.1.1.1.4.5 Altitude physiology/stressors of flight.
- 5.1.1.1.2 General Areas of Responsibility
 - 5.1.1.2.1 The medical director must be actively involved in the quality assurance/ continuous quality improvement (QA/CQI) program for the service.
 - 5.1.1.1.2.2 The medical director must be involved in administrative decisions affecting medical care for the service.
 - 5.1.1.1.2.3 The medical director must be involved in training and continuing education of all air medical personnel for the service.

8

- 5.1.1.1.2.4 The medical director must be actively involved in the care of critically ill and/or injured patients.
- 5.1.1.1.2.5 The medical director must be actively involved in orienting physicians providing on line (in-flight) medical direction to the policies, procedures and patient care protocols of the air medical service.
- 5.1.1.1.2.6 When applicable, the medical director or his designee sets cabin air pressure altitude limits, for specific disease processes of the patient(s) (through policies and procedures) and maximum altitudes, for specific disease processes of the patient(s) for rotor wing transports.
- 5.1.1.2 Clinical Care Supervisor

The responsibility for supervision of patient care provided by the various clinical care providers (e.g., EMT-B, EMT-P, RN, etc.) will be the responsibility of the medical director, unless the responsibilities are assigned to another professional (flight nurse, flight physician, or flight paramedic) who possesses the knowledge, experience and is legally qualified to provide clinical supervision.

- 5.1.1.2.1 Credentials/Experience
 - The clinical care supervisor must possess the following qualifications:
 - 5.1.1.2.1.1 If the clinical care supervisor is a Physician:
 - 5.1.1.2.1.1.1 ABEM, or ABOEM certified or currency in CPR, ACLS, and Advanced Trauma Life Support (ATLS).
 - 5.1.1.2.1.2 If the clinical care supervisor is a Registered Nurse:
 - 5.1.1.2.1.2.1 Currency in CPR, ACLS and the Flight Nurse Advanced Trauma Course (FNATC).
 - 5.1.1.2.1.2.1.1 ATLS may be audited in lieu of FNATC.
 - 5.1.1.2.1.3 If the clinical care supervisor is a Paramedic:
 - 5.1.1.2.1.3.1 Currency in CPR, ACLS, and PHTLS or BTLS (Advanced).
 - 5.1.1.2.1.4 General Requirements regardless of provider level:
 - 5.1.1.2.1.4.1 Current specialty education consistent with the mission statement of the air medical service (i.e., Neonatal Resuscitation Certification Program, Pediatric Advanced Life Support, etc.). Alternatively, the clinical care supervisor must have immediate access to specialty personnel as consultants.
 - 5.1.1.2.1.4.2 In-flight patient care limitations, e.g., assessment and invasive procedures.
 - 5.1.1.2.1.4.3 Infection control.
 - 5.1.1.2.1.4.4 Stress recognition and management.
 - 5.1.1.2.1.4.5 Altitude physiology/stressors of flight.
 - 5.1.1.2.1.4.6 Appropriate utilization of air medical services.
 - 5.1.1.2.1.4.7 Delaware Emergency Medical Services system.
 - 5.1.1.2.1.4.8 Hazardous materials scene recognition and response (helicopter services).
- 5.1.1.2.2 General Areas of Responsibility
 - 5.1.1.2.2.1 Active involvement in the flight program's QA/ CQI process.
 - 5.1.1.2.2.2 Active involvement in all administrative decisions affecting patient care for the service.
 - 5.1.1.2.2.3 Active involvement in hiring, training, and continuing education of all nonphysician air medical personnel for the service.
 - 5.1.1.2.2.4 Active involvement in the care of the critically ill and/or injured patients.
 - 5.1.1.2.2.5 Ensuring adequate mechanisms are in place for evaluating the clinical practice of the patient care providers.
- 5.1.2 Direct Care Providers
 - 5.1.2.1 General

TITLE 16 HEALTH AND SOCIAL SERVICES			
DELAWARE ADMINISTRATIVE CODE			
5.1.2.1.1 The type of medical care providers staffing each mission shall be directly related to the mission type: advanced life support, specialty care or basic life support.			
5.1.2.1.2 All medical care providers must have current appropriate state licensure or certification which legally allows them to function in their respective professions.			
5.1.2.1.2.1 Delaware based programs and out of state programs providing prehospital 911 service must be staffed with Delaware licensed RN's and Delaware-certified paramedics.			
5.1.2.1.2.2 Out of state programs providing 'point to point' services must be staffed with Delaware licensed RN's. Paramedics must be certified in their state of origin.			
5.1.2.1.2.3 Out of state programs providing 'one way' or mutual aid services must be staffed with providers licensed or certified to practice by their state of origin.			
5.1.2.1.3 Initial and continuing education requirements for all levels of medical care providers are specified in Appendix A.			
5.1.2.1.4 Interhospital/Interfacility Transports			
5.1.2.1.4.1 A minimum of two (2) air medical team members are required to staff interhospital/ interfacility ALS missions. One of the air medical ALS providers must be a member of the regular ALS staff of the air medical ambulance service.			
5.1.2.1.4.2 All air medical team members must be licensed, certified, or permitted according to the appropriate state regulations with current re-licensing, recertification, or re-permitting status.			
5.1.2.1.4.3 A qualified flight physician or flight RN must be designated as the primary care provider during interfacility or interhospital transports.			
5.1.2.1.4.4 A flight paramedic or an approved flight specialty care provider may serve as the second ALS air medical team during an interfacility or interhospital ALS mission.			
5.1.2.1.4.4.1 The specialty care provider must have expertise relative to the needs of the patient.			
5.1.2.1.4.4.2 Point to point interfacility transfers within Delaware must utilize the Delaware receiving facility for Online Medical Control.			
5.1.2.1.4.4.3 In lieu of compliance with paragraph (ii) of this section, this, all physicians providing centralized Medical Control must be Delaware licensed and a status update must be provided to the receiving facility prior to arrival of the patient.			
5.1.2.1.4.4.4 The paramedic on such missions must be certified and function according to their standard treatment protocols.			
5.1.2.1.4.5 One ALS air medical care provider may be considered sufficient staff for ALS missions, where the patient has been categorized and documented as being stable, by the sending physician, and requires 'limited ALS care'.			
5.1.2.1.4.5.1 'Limited ALS care' shall mean patient assessment, monitoring and interventions common to, and within the scope of practice of the paramedic. Patients may require cardiac monitoring and/or intravenous therapy (without medication additives).			
5.1.2.1.4.5.2 A flight paramedic or RN may serve as the single care provider for the transport of stable ALS patients who meet the criteria as established by the operation or agency medical director.			
5.1.2.1.5 Prehospital Scene Responses			
512151 Except as provided below the Delaware State Police (DSP)			

10

5.1.2.1.5.1 Except as provided below, the Delaware State Police (DSP) paramedic service is the primary air medical service authorized to engage in prehospital scene responses and transports in the State of Delaware.

- 5.1.2.1.5.2 A flight paramedic must be a crew member on all prehospital missions.
 - 5.1.2.1.5.2.1 The Aeromedical crew assumes patient care responsibility at the time the patient is secured on the aircraft.
- 5.1.2.1.5.3 Non-scheduled personnel may be added as the second medical team member according to the protocols of the air medical services as long as an orientation has been conducted which includes in-flight treatment protocols, general aircraft safety, emergency procedures, operational policies, and infection control.
- 5.1.2.1.5.4 Air medical ambulance services, other than DSP, may engage in prehospital scene responses and transports under certain unusual conditions that will be defined in a service agreement with the Division and DSP to perform prehospital scene responses and transports, an air medical ambulance service must have previously entered into a service agreement with the Division and the Delaware State Police.
- 5.1.2.1.5.5 All requests for air medical services, other than the DSP, must be initiated by the emergency communications center responsible for managing or coordinating Emergency Medical Services resources in the county where the need for assistance exists.
- 5.1.2.1.5.6 All patient care services provided by the air medical ambulance crew during a prehospital scene response shall be documented using the Delaware Emergency Data Information Network (EDIN). Data provided will be used for descriptive and quality management purposes, including air service utilization review.
 - 5.1.2.1.5.6.1 This shall be provided in addition to any documentation that the service generates internally.
 - 5.1.2.1.5.6.2 The EDIN system is a secure Internet based data management system.
 - 5.1.2.1.5.6.2.1 Access to an Internet connection is necessary to provide the documentation required by these regulations.
- 5.1.2.2 Advanced Life Support (ALS) Mission Providers

An Advanced Life Support (ALS) mission is defined as the transport of a patient who receives care during a prehospital or interfacility/ interhospital transport that is commensurate with the scope of practice of a flight physician, flight nurse or flight paramedic.]

- 5.1.2.3 Specialty Care Mission Providers
 - 5.1.2.3.1 A specialty care mission is defined as the transport of a patient requiring special patient care by one or more professionals who must be added to the regularly scheduled air medical team. Dedicated teams providing specialty-oriented care (e.g., neonatal transport teams, IABP transport teams) must follow the specific mission standards.
 - 5.1.2.3.2 The air medical team must minimally consist of a specially trained physician or registered nurse as the primary caregiver whose expertise must be consistent with the needs of the patient.
 - 5.1.2.3.3 Specialty care missions require at least two air medical team members while a patient(s) is on board. Personnel shall be available for each transport within a reasonable time determined by the service.
 - 5.1.2.3.4 All specialty team members must have received a basic minimum orientation to the air medical service which includes in-flight treatment protocols, general aircraft safety and emergency procedures, operational policies and infection control.
 - 5.1.2.3.5 Specialty care mission personnel must be accompanied by at least one regularly scheduled air medical staff member, of the air medical service, except when independent, dedicated flight specialty teams are used.

- 5.1.2.3.6 Specialty care personnel must be educated in in-flight treatment modalities, altitude physiology, general aircraft safety, and emergency procedures.
- 5.1.2.4 Basic Life Support Mission Providers
 - A Basic Life Support (BLS) mission is generally defined as the transport of a patient who receives care during an interfacility/interhospital transport that is commensurate with the scope of practice of an Emergency Medical Technician-Basic (EMT-B). In the State of Delaware, when such care is provided in the air medical environment, it must be assumed, at a minimum, by a flight Emergency Medical Technician-Paramedic (EMT-P).
- 5.2 Pilot Personnel
 - 5.2.1 There shall be a sufficient number of pilots permanently assigned to the air medical service to provide services approved by the Division of Public Health, and which assures adequate crew rest as per FAA regulations.
 - 5.2.2 All pilots must possess a commercial rotorcraft-helicopter airman's certificate.
 - 5.2.3 Pilot in Command (PIC) must possess 2000 rotorcraft flight hours as PIC prior to assignment with an air medical service or be currently employed by the Delaware State Police (DSP) and have completed a DSP pilot training program.
 - 5.2.4 A planned structure program must be provided for relief pilots, which at a minimum includes specific roles and responsibilities, and familiarization with the region served.
 - 5.2.5 A lead pilot and designated safety officer must be appointed by the FAR 135 certificate holder to insure adherence to operational safety regulations for the program. Adequate training and experience in air medical missions management and evaluation skills must be possessed to carry out these duties.
 - 5.2.6 The pilot has the right to decline or abort any portion of a mission if there is doubt as to the safety of the mission.
 - 5.2.7 The pilot shall meet education and experience requirements as listed in Appendix A. 5.2.7.1 Pilots employed by DSP must comply with the requirements set by that agency.
- 5.3 General Staff Policies Operational policies must be present to address the following areas:
 - 5.3.1 Medical Flight Personnel
 - 5.3.1.1 Minimize duty-related fatigue
 - 5.3.1.2 Hearing protection
 - 5.3.1.3 Crash survivability
 - 5.3.1.3.1 Flame retardant clothing
 - 5.3.1.3.2 Seat belts/shoulder harnesses
 - 5.3.1.3.3 Head-strike protection
 - 5.3.1.3.4 Securement of on-board and carry-on medical equipment
 - 5.3.1.4 Protective clothing and dress codes relative to:
 - 5.3.1.4.1 Mission type
 - 5.3.1.4.2 Infection control
 - 5.3.1.5 Universal infection control
 - 5.3.1.6 Flight status during pregnancy
 - 5.3.1.7 Flight status during acute illnesses (especially respiratory ailments)
 - 5.3.1.8 Flight status while taking medications that may cause dizziness
 - 5.3.1.9 Weight/height and/or lifting abilities if appropriate
 - 5.3.2 Pilot Personnel
 - 5.3.2.1 Minimize duty-related fatigue
 - 5.3.2.2 A policy of the certificate holder that specifies higher weather minimums for new pilots for a time frame based on the pilot's experience, flight time, local environment and personal adaptation. An evaluation tool applied individually to each new pilot by the flight program shall define the time frame.

5 DE Reg. 1727 (3/1/02)

6.0 Aircraft Requirements

- 6.1 Medical Considerations
 - 6.1.1 The aircraft shall have an interior medical configuration that is installed according to FAA criteria. Minimum specifications are listed in APPENDIX B.
 - 6.1.2 The aircraft must be configured in such a way that the air medical personnel have access to the patient for the initiation and/or maintenance of basic advanced life support treatments.
 - 6.1.3 The aircraft must be equipped with medical equipment and supplies consistent with the mission statement and scope of care. Minimum equipment and supplies required are identified in APPENDIX B.
 - 6.1.4 The aircraft design and configuration must not compromise patient stability in during loading, unloading or in-flight operations.
 - 6.1.4.1 The aircraft must have an entry that allows loading and unloading without excessive movement of the patient or compromise to monitoring systems, without interfering with the pilot's vision. The cockpit should be capable of being shielded from light in the patient care area during night operations.
 - 6.1.4.2 The cockpit must be sufficiently isolated, by protective barrier, to minimize distractions from the patient care compartment.
 - 6.1.4.3 The interior of the aircraft must be climate controlled to prevent adverse effects upon the patient from temperature extremes.
 - 6.1.4.4 The avionics shall not interfere with the functioning of medical equipment, nor shall the intravenous lines, manual or mechanical ventilation.
 - 6.1.4.5 Adequate interior lighting shall be available to allow for patient care monitoring. Medical equipment shall not interfere with the avionics.
- 6.2 Aircraft Equipment
 - 6.2.1 The aircraft must be equipped with a 180 degree controllable searchlight of at least 400,000 candle power for rotor-wing aircraft.
 - 6.2.2 Radio capabilities
 - 6.2.2.1 Radios (as range permits) shall be capable of transmitting and receiving communications from:
 - 6.2.2.1.1 Medical control
 - 6.2.2.1.2 Flight operations center
 - 6.2.2.1.3 Air traffic control
 - 6.2.2.1.4 EMS and law enforcement agencies
 - 6.2.2.2 The pilot must be able to control and override radio transmissions from the cockpit in the event of an emergency situation.
 - 6.2.2.3 The flight crew must be able to communicate internally.
 - 6.2.3 The aircraft must be equipped with a functioning emergency locator transmitter (ELT) in compliance with the applicable Federal Aviation Regulations (FARs).
 - 6.2.4 A fire extinguisher must be accessible to air medical personnel and pilot(s) in compliance with applicable FARs.
- 6.3 Maintenance

Maintenance may be provided by an outside vendor who is FAA and manufacturer certified. If an in-house maintenance department is utilized, the following criteria must be met:

- 6.3.1 Credentials/Experience
 - 6.3.1.1 Lead mechanic must possess 2 years of rotorcraft experience as a certified airframe and power plant mechanic prior to assignment with an air medical service.

- 6.3.1.2 The mechanic must be factory schooled or equivalent in an approved program, and FAR 135 qualified to maintain the aircraft designated by the air medical service.
- 6.3.2 Training related to the interior modification of the aircraft:
 - 6.3.2.1 Shall prepare the mechanic for inspection of the installation as well as the removal and reinstallation of special medical equipment.
 - 6.3.2.2 Supplemental training on service and maintenance of medical oxygen systems and a policy as to who maintains responsibility for refilling the medical oxygen system.
- 6.3.3 Staffing of Mechanics
 - 6.3.3.1 A single mechanic on duty or on call 24 hours a day shall be relieved from duty for a period of at least 24 hours during any seven (7) consecutive days, or the equivalent thereof, within any 1 calendar month.
 - 6.3.3.2 Back-up personnel shall be provided to the mechanic during periods of extensive scheduled or unscheduled maintenance or inspection. Complexity of the aircraft and an increased number of flight hours may be considerations for increased mechanic staffing.
 - 6.3.3.3 A policy of the certificate holder shall be in place that documents the disciplinary process for a mechanic.
- 6.3.4 Maintenance Facilities
 - 6.3.4.1 There must be a mechanism/procedure for alerting flight and air medical personnel when the aircraft is not air worthy.
 - 6.3.4.2 A hangar or similar-type facility shall be available for the mechanic to perform heavy maintenance.

4 DE Reg. 1827 (5/1/01)

7.0 Visual Flight Rules (VFR) Weather Issues

- 7.1 VFR weather minimums shall be specified for day and night local, and day and night cross country (CC).
- 7.2 The "local flying area" shall be determined by the operator based upon the operating environment.
- 7.3 There is a system of obtaining pertinent weather information.
 - 7.3.1 The pilot in command (PIC) is responsible for obtaining weather information according to policy which shall address at a minimum:
 - 7.3.1.1 Routine weather checks
 - 7.3.1.2 Weather checks during marginal conditions
 - 7.3.1.3 Weather trending
 - 7.3.2 Communication between pilots, medical personnel, and communication specialists at shift change regarding the most current and forecasted weather is part of a formal briefing.
- 7.4 VFR "response" weather minimums:Recommended minimums to begin a transport shall be no less than:

CONDITIONS	CEILING	VISIBILITY
DAY/LOCAL	500 ft.	1 mile
DAY/CC	1000 ft.	1 mile
NIGHT/LOCAL	800 ft.	2 miles
NIGHT/CC	1000 ft.	3 miles

14

- 7.5 Policies include provisions for patient care and transport alternatives in the event that the aircraft must use alternate landing facilities due to deteriorating weather.
- 7.6 Instrument flight rules, (IFR) Weather Issues When transitioning to an off-airport site after an instrument approach, the following shall apply:
 - 7.6.1 Local VFR weather minimums shall be followed if within a defined local area and if the route and off-airport site are familiar.
 - 7.6.2 Cross-country VFR weather minimums shall be followed if not in defined local area or if not familiar with route and off-airport site.

4 DE Reg. 1827 (5/1/01)

8.0 Helipad

- 8.1 Primary, receiving hospital(s) helipad(s) must be marked (with a painted H or similar landing designation), lighted for night operations, and be equipped with a device to identify wind direction. In addition, there shall be:
 - 8.1.1 Unobstructed approach according to the FAA Advisory circular entitled Heliport Design Advisory Circular, AC 150/5390-2.
 - 8.1.2 Evidence of compliance with local, state, or federal regulations including appropriate and adequate fire retardant chemicals.
 - 8.1.3 Documented on-going safety programs for those responsible for loading and unloading patients or working around the helicopter on the helipad.
 - 8.1.4 Evidence of adequate security-A minimum of one person to prevent bystanders from approaching the helicopter as it lands or lifts off, or perimeter security such as fencing, rooftop etc. A means must exist to monitor the primary helipad if accessible to the public (e.g., through direct visual monitoring or closed circuit TV).
 - 8.1.5 There is limited distance from the helipad, (a limited distance is defined as not requiring intermediary transport of any type from the helipad to the receiving facility), to the hospital in order to minimize the effects to the patient.
 - 8.1.5.1 Patient monitoring shall continue without interruption between the helipad and the hospital.
 - 8.1.5.2 Emergent patient interventions can be performed as needed between helipad and hearing protection is provided for all personnel who assist with patient hot loading and unloading.
 - 8.1.6 Hearing protection is provided for worn by all personnel who assist with patient hot loading and unloading.
- 8.2 Occasional or episodic use of helipad

Helipads used occasionally (at referring or receiving hospitals) shall be reviewed annually by the air medical service for:

- 8.2.1 Identification and removal of obstructions
- 8.2.2 Appropriate lighting (permanent or temporary for night operations)
- 8.2.3 Helicopter ingress/egress limitations
- 8.2.4 Adequate security a minimum of one person to prevent bystanders from approaching the helicopter as it lands or lifts off.
- 8.2.5 Evidence of safety programs (through review of training program records) offered to personnel responsible for operations at the landing site and availability of appropriate fire retardant chemicals.
- 8.3 Temporary scene landings shall be secured
 - 8.3.1 Perimeter lighting with handheld floodlights, emergency vehicles or other lighting source to clearly illuminate the designated landing area at night.
 - 8.3.2 Free of overhead obstruction and ground debris.
 - 8.3.3 Appropriate in size to the type of the aircraft.
 - 8.3.4 Safety programs must be provided to public safety/law enforcement agencies to include:
 - 8.3.4.1 Identifying and designating an appropriate landing zone (LZ).

8.3.4.2 Helicopter safety.

8.3.5 Two-way communications between helicopter and ground personnel.

4 DE Reg. 1827 (5/1/01)

9.0 Communications

- 9.1 The flight crew or a communication specialist must assume the responsibility of receiving and coordinating all requests for the air medical service.
 - 9.1.1 Should a communication specialist be employed, training shall be commensurate with the scope of responsibility of the communications center personnel and include:
 - 9.1.1.1 EMT-B certification or equivalent knowledge and experience.
 - 9.1.1.2 Knowledge of Federal Aviation Regulations and Federal Communications Commission regulations pertinent to the air medical service.
 - 9.1.1.3 General safety rules and emergency procedures pertinent to air medical transportation and flight following procedures.
 - 9.1.1.4 Navigation techniques/terminology and understanding weather interpretation.
 - 9.1.1.5 Types of radio frequency bands used in air medical EMS.
 - 9.1.1.6 Assistance with the materials response and recognition procedure using appropriate reference materials.
- 9.2 Communication policies of the air medical service must reflect:
 - 9.2.1 Aircraft must communicate, when possible, with ground units securing unprepared landing sites prior to landing.
 - 9.2.2 A readily accessible post incident/accident plan must be part of the flight following protocol so that appropriate search and rescue efforts may be initiated in the event the aircraft is overdue, radio communication can not be established nor location verified
 - 9.2.2.1 Written post incident/accident plans are easily identified and readily available.
 - 9.2.2.2 Current phone numbers are easily accessed.
 - 9.2.2.3 An annual drill is conducted to exercise the post incident/accident plan.
- 9.3 Continuous flight following must be monitored and documented and shall consist of the following:
 - 9.3.1 Initial coordination to include communication and documentation of:
 - 9.3.1.1 Time call received
 - 9.3.1.2 Name and phone number of requesting agency
 - 9.3.1.3 Time aircraft departed
 - 9.3.1.4 Pertinent LZ information
 - 9.3.1.5 Number of persons on board
 - 9.3.1.6 Amount of fuel on board
 - 9.3.1.7 Estimated time of arrival (ETA)
 - 9.3.1.8 Diagnosis or mechanism of injury
 - 9.3.1.9 Referring and receiving physician and facilities (for inter facility transports) as per policy of the air medical service
 - 9.3.1.10 Verification of acceptance of patient
 - 9.3.2 Communications during mission shall also be documented accordingly:
 - 9.3.2.1 Direct or relayed communications to communications center (while in flight) specifying locations and ETAs, and deviations, if necessary.
 - 9.3.2.2 Direct or relayed communications to communications center specifying all take-off and landing information.
 - 9.3.2.3 Time between each communication:
 - 9.3.2.3.1 Time between each communication shall not exceed 15 minutes while in flight (If an IFR or VFR flight plan has been filed, may only be able to communicate with air traffic control, (ATC).

- 9.3.2.3.2 Time between communications shall not exceed 45 minutes while on the ground.
- 9.3.2.3.3 Alternate agencies are used to relay communications when direct contact is not possible.
- 9.4 The Communications Center must contain the following:
 - 9.4.1 At least one dedicated phone line for the air medical service.
 - 9.4.2 A system for recording all incoming and outgoing telephone and radio transmissions with time recording and playback capabilities. Recordings are to be kept for 30 days.
 - 9.4.3 Capability to immediately notify air medical team and on-line medical direction (through radio, pager, telephone, etc.).
 - 9.4.4 Back-up emergency power source for communications equipment, or a policy delineating methods for maintaining communications during power outages and in disaster situations.
 - 9.4.5 Communications policy and procedures manual.
- 9.5 All services that will be landing at a healthcare facility helipad within the State must contact AVCOM (302-739-5964) to advise them of their destination and the estimated length of time that they will occupy the helipad. AVCOM must be advised again when the aircraft departs the helipad.

4 DE Reg. 1827 (5/1/01)

5 DE Reg. 1727 (3/1/02)

10.0 Ems System Integration

- 10.1 The air medical service shall be integrated with and communicate with other public safety agencies, including ground emergency service providers. This must include participation in regional quality assurance reviews, regional disaster planning and mass casualty incident drills.
- 10.2 The air medical service must interface (through telephone calls and outreach programs) with existing communications centers, public safety and law enforcement agencies, as well as with local off-line medical directors, as appropriate for prehospital ALS missions.
- 10.3 The air medical service must ensure continuity of care and expeditious treatment of patients by utilizing state EMS medical protocols and procedures, whenever applicable.
- 10.4 All 911 missions must utilize the Delaware paramedic standing orders and (in-state) Delaware Certified Medical Control physicians for on-line Medical Control.
- 10.5 The air medical service shall facilitate integration of all emergency services and transport modalities by supporting joint continuing education programs and operational procedures for:
 - 10.5.1 Disaster response/triage.
 - 10.5.2 Interface of the air medical team with other regional resources.
 - 10.5.3 Safety program consisting of patient preparation and personal safety around the aircraft to include landing zone (LZ) designation for rotary wing services.
 - 10.5.4 Patients considered appropriate for transport by the air medical service.
- 10.6 The service shall promote a timely feedback to referring agency, facility or physician about patient outcome and treatment rendered before, during, and after transport where appropriate.
- 10.7 The flight service shall provide a planned, structured safety program to public safety/ law enforcement agencies and hospital personnel who interface with the air medical service which includes:
 - 10.7.1 Landing zone designation and preparation.
 - 10.7.2 Personal safety in and around the helicopter for all ground personnel.
 - 10.7.3 Procedures for day/night operations, conducted by the air medical team, specific to the aircraft:
 - 10.7.3.1 High and low reconnaissance.
 - 10.7.3.2 Communication and coordination with ground personnel.
 - 10.7.3.3 Approach and departure path selection.

18

TITLE 16 HEALTH AND SOCIAL SERVICES DELAWARE ADMINISTRATIVE CODE

- 10.7.3.4 Procedures for the pilot to ensure safety during ground operations in the landing zone with or without engines running.
- 10.7.3.5 Procedure for the pilot to have ground control during engine start and departure from a landing site.
- 10.8 The service shall maintain records of initial and recurrent training provided by the air medical service to prehospital referring and receiving ground support personnel.

4 DE Reg. 1827 (5/1/01)

5 DE Reg. 1727 (3/1/02)

11.0 Post Incident/accident Plan

- A Post Incident/Accident Plan shall be written and understood by all program personnel and shall include at a minimum:
- 11.1 List of personnel to notify in order of priority (for communication specialist to activate) in the event of a program incident/accident. Two major goals in activating a notification list include:
 - 11.1.1 Provide rapid rescue response.
 - 11.1.2 Insure accurate information dissemination.
- 11.2 Preplanned time frame to activate the post incident/ accident plan for overdue aircraft.
- 11.3 Procedure to secure all documents and tape recordings related to the particular incident/ accident.
- 11.4 Procedure to deal with releasing information to the press.

4 DE Reg. 1827 (5/1/01)

12.0 Professional And Community Education

A professional and community education program and/ or printed information with the target audience to be defined by the air medical service shall include but not be limited to:

- 12.1 Hours of operation, phone number, and procedure to access.
- 12.2 Capabilities of air medical personnel.
- 12.3 Type of aircraft and operational protocols specific to type.
- 12.4 Service area for the aircraft.
- 12.5 Preparation and stabilization of the patient.
- 12.6 Safety program consisting of patient preparation and personal safety around the aircraft to include landing zone (LZ) designation for rotor wing services.
- 12.7 Patients considered appropriate for transport by the air medical service, (Generally, an appropriate transport is one which enhances patient outcome, safety or cost effectiveness over other modes of transport).

13.0 Infection Control

- 13.1 Policies and procedures addressing patient transport issues involving communicable diseases, infectious processes and health precautions for emergency personnel as well as for patients must be current with the local standard of practice, standards of OSHA and as published by the center for Disease Control (CDC).
- 13.2 Policies and procedures must be written and readily available to all personnel of the air medical service.
- 13.3 Additional medical and agency resources pertinent to infection control must be identified and made available in the policy manual to all air medical personnel.
- 13.4 Education programs will include the institution's/ service's infection control resources, programs, policies and CDC recommendations. Policies and procedures will be reviewed on an annual basis.
- 13.5 Air medical personnel transporting patients must practice preventative measures lessening the likelihood of transmission of pathogens. Policies and procedures address:
 - 13.5.1 Personnel health concerns including record of:

13.5.1.1 Physical exams.

- 13.5.1.2 Immunization history air medical personnel are encouraged to have tetanus and hepatitis B immunization.
- 13.5.1.3 Verification of post-vaccination antibody status, if immunized against hepatitis B.
- 13.5.1.4 Annual tuberculosis testing (purified protein derivative).
- 13.5.1.5 Measles, mumps, rubella (MMR) immunization.
- 13.5.2 Management of communicable diseases and infection control in the transport environment is outlined in policies:
 - 13.5.2.1 Use of gloves, eye and mouth protection.
 - 13.5.2.2 Sharps disposal container for contaminated needles and collection container for soiled disposable items on the aircraft.
 - 13.5.2.3 Cleaning and disinfecting with appropriate disinfectant of the patient cabin area, equipment, and personnel's soiled uniforms.
 - 13.5.2.4 Mechanism for identifying those at risk for exposure to an infectious disease.
 - 13.5.2.5 A plan for communication between the air medical service personnel, EMS providers, and hospital when exposure is suspected/confirmed to include what follow-up is necessary.
 - 13.5.2.5.1 Written notification shall go out in an expedient manner.
 - 13.5.2.5.2 Follow-up is documented.
 - 13.5.2.6 A policy for special provisions for transporting infected or possibly infected victims.
 - 13.5.2.7 Proper cleaning or sterilization of all appropriate instruments or equipment.
 - 13.5.2.8 Hand washing before and after each patient.

14.0 Quality Assurance/continuous Quality Improvement

- 14.1 There is an established Quality Assurance/ Continuous Quality Improvement Program which provides on-going monitoring and evaluation of the quality and effectiveness of the air medical ambulance service.
- 14.2 The QA/CQI program shall be comprehensively integrated, including activities related to patient care, communications, aviation, operations and equipment maintenance. The required elements and considerations of the written QA/CQI plan are listed in APPENDIX C.
- 14.3 The Medical Director has the primary responsibility for ensuring timely review of patient care activities and issues, utilizing the medical record and pre-established criteria. A committee consisting of the medical director along with representatives of management, medical and non-medical personnel should be considered as a mechanism for ensuring initiation and continuation of QA/CQI program.
- 14.4 The air medical service has a policy and procedure manual available to all personnel which is reviewed, at least, annually for accuracy, completeness and currency.
- 14.5 The air medical service has established patient care guidelines/standing orders which must be reviewed annually (for content accuracy) by management, QA/CQI committee members and the Medical Director.
- 14.6 The QA/CQI program must be closely linked with risk management, so that concerns related through the risk management program can be followed up through the continuous quality improvement program.

15.0 General Policies

- 15.1 There are well-defined lines of authority with a clear reporting mechanism to upper level management.
- 15.2 Air medical personnel understand the organizational structure and the chain of command.
- 15.3 A policy shall be in place that clearly explains the air medical service's disciplinary process for all levels of staff.
- 15.4 Management policies encourage ongoing communications between all levels and types of air medical service personnel.

TITLE 16 HEALTH AND SOCIAL SERVICES DELAWARE ADMINISTRATIVE CODE There are formal, periodic staff meetings for which minutes are kept on file. There are defined methods for disseminating information between meetings.

- 15.6 For public or private institutions and agencies that contract with an aviation firm to provide air medical services, there shall be a policy that specifies the lines of authority between the medical management team and the aviation management team.
- 15.7 Management sets guidelines for press related issues and marketing activities.
 - 15.7.1 Policies Relating to Patient Management
 - 15.7.1.1 Management ensures, through policy, that all transfers of patient care occur from a lower level of care to an equal or higher level of care except for elective transfers for patient convenience or returning a patient to a referring facility.
 - 15.7.1.2 A patient record shall be maintained on all patients utilizing the services of an air medical ambulance. The record shall be used to document care given during transport, as well as all other relevant patient related factors, such as status prior to, during at the end of transport.
 - 15.7.1.3 A copy of the patient record will be left at the receiving hospital to facilitate continuity of care. A copy will be kept on file by the air medical ambulance service for a period of time to include that of the statue of limitations.
 - 15.7.1.4 The air medical ambulance services has written policies and procedures which indicate what therapies can be performed without on-line medical direction.
 - 15.7.1.5 Inter facility transports require physician referral/acceptance to ensure continuity of care and establish patient care parameters during the transport. Patient transfer protocols must comply with existing Federal requirements.
 - 15.7.1.6 Management ensures an appropriate utilization review process based on:
 - 15.7.1.6.1 Medical benefits to the patient:
 - 15.7.1.6.1.1 Timeliness of the transport as it relates to the patient's clinical status.
 - 15.7.1.6.1.2 Transport to an appropriate receiving facility; an appropriate receiving facility may include:
 - 15.7.1.6.1.2.1 A hospital or facility where the patient has previously undergone specialized treatment and where the patient's previous medical records are located.
 - 15.7.1.6.1.2.2 A facility at too great a distance for ground transport.
 - 15.7.1.6.1.2.3 A facility with a specialized level of care not available in the referring hospital.
 - 15.7.1.6.1.3 Specialized air medical personnel expertise available during transport that would otherwise not be available.
 - 15.7.1.6.1.4 Safety of the transport environment.
 - 15.7.2 Cost of the transport:
 - 15.7.2.1 A structured, periodic review of flights (to determine transport appropriateness or that the mode of transport enhances medical outcome, safety or cost effectiveness over other modes of transport) performed at least semi-annually and resulting in a written report.
 - 15.7.2.2 Hospital or non-hospital based program director/administrator is oriented to FARs that are pertinent to the air medical service.
 - 15.7.3 Policies Pertaining to Safety
 - 15.7.3.1 A Safety Committee shall meet at least quarterly with written reports sent to management and kept on file as dictated by policy. The responsibilities of the safety committee may be assumed by the QA/CQI committee.
 - 15.7.3.2 Written variances relating to "safety" issues will be addressed in Safety Committee meetings. The committee will promote communications between air medical personnel and pilots addressing safety practice, concerns, issues and questions.
 - 15.7.3.3 Recommendations for operational and safety issues will be reviewed by management.

20

15.5

APPENDIX A - EDUCATIONAL REQUIREMENTS

Initial education preparation and requirements will be guided by each air medical ambulance service's mission statement, scope of care provided, levels of care providers, state requirements and medical direction.

I. ALS, RN, MD and SPECIALTY CARE PROVIDERS: Scheduled Crew

Prior to functioning as a provider in an air medical service, all ALS and Specialty care personnel must present documentation of having successfully completed an education program that validates minimum knowledge levels and skill competencies in the following identified areas:

- A. Didactic Component that includes:
 - 1. Advanced airway management
 - 2. Altitude physiology; gas laws; stressors of flight
 - 3. Anatomy, physiology and assessment of the adult, pediatric and neonatal patients
 - 4. Oxygen therapy in the air medical environment

5. Mechanical ventilation and respiratory physiology for adults, pediatric and neonatal patients as appropriate to the mission statement and scope of care provided by the air medical service.

- 6. Respiratory emergencies
- 7. Recognition and management of cardiac emergencies including lethal dysrhythmias

8. Hemodynamic monitoring, pacemaker and automatic implantable cardiac defibrillator (AICD) management

9. Intra-aortic balloon pump, central lines, Swan Ganz and arterial catheters, left and right ventricular devices and extra corporeal membrane oxygenation (ECMO) when applicable

- 10. Environmental emergencies
- 11. High risk obstetric emergencies (bleeding, trauma, medical)
- 12. Neonatal emergencies (respiratory distress, cardiac, surgical)
- 13. Pediatric emergencies (medical, trauma)
- 14. Infection control practices and procedures
- 15. Metabolic/endocrine emergencies
- 16. Adult trauma and burns
- 17. Stress recognition and management
- 18. Toxicology
- 19. Pharmacology
- 20. Disaster and triage management**2
- 21. Survival training, if applicable
- 22. Hazardous materials scene recognition and response**2
- 23. Scene management/rescue/extrication**2
- B. Clinical Component that includes experiences in providing:
 - 1. Critical intensive care
 - 2. Emergency care
 - 3. Neonatal Intensive care
 - 4. Obstetrics
 - 5. Pediatric critical care
 - 6. Prehospital care**2

7. Invasive procedures (or mannequin equivalent) for refreshing specific skills, i.e. endotracheal intubation

*¹Refers to Inter hospital/inter facility providers only

** ²Refers to Prehospital providers only.

NOTE: Specialty Care Providers must have included in their educational programs, additional content material and skills specific for their specialty area.

C. Continuing Education

1. Documentation of each scheduled crew ALS, RN, MD or Specialty care provider completion of a minimum of 48 hours of air medical refresher/continuing education every two years must be kept on file by the air medical ambulance service and submitted to the Office biennially.

2. Continuing education/staff development programs, specific and appropriate to the mission statement and scope of care of the air medical ambulance service, must be provided.

3. Continuing education/staff development programs must include reviews and/or updates of the following areas:

a) Aviation-safety issues

b) Altitude physiology

c) Management of emergency/critical care adults, pediatric and neonatal patients (medical and trauma)

d) Obstetrical emergencies

e) Invasive procedures labs

- f) Stress Management
- g) Infection control

h) Hazardous materials scene recognition and response

i) Survival training, if applicable

j) Current certification must be maintained in the following areas:

(1) CPR (Cardio-pulmonary Resuscitation per guidelines of the American Heart

Association)

(2) ACLS*3

(3) ATLS*³/Flight Nurse Advanced Trauma Course**/PHTLS*** (specific certification depends on level of care provider)

(4) PALS

(5) Neonatal Resuscitation Course (neonatal specialty care providers, only)

*³ Physicians must be either ABEM /ABOEM or ACLS & ATLS certified

**4 Nurses may elect to audit ATLS

***⁵ Paramedics may elect to be certified in Basic Trauma Life Support (BTLS)

4 DE Reg. 1827 (5/1/01) 5 DE Reg. 1727 (3/1/02)

II. Educational Requirements specific to the air medical in-flight environment for all air medical providers.

A. Air medical patient transport considerations (assessment, treatment, preparation, handling, equipment)

1. Day and night flying protocols

2. EMS communications

3. EMS systems

4. General aircraft safety annually to include:

a) aircraft evacuation procedures

b) communications during an emergency situation and knowledge of emergency communication frequencies

c) in-flight and ground fire suppression procedures

d) in-flight emergency and emergency landing procedures (e.g., position, oxygen, securing equipment)

e) safety in and around aircraft including FAA rules and regulations pertinent to safety for air medical team members, patients, and lay individuals

f) specific capabilities, limitations and safety measures for each aircraft used

- g) use of emergency locator transmitter (ELT)
- 5. Ground operations

III. Pilot Training Requirements

A. Initial training shall, at a minimum, consist of:

- 1. Training in specific type of aircraft as follows:
 - a) Less than 100 hours in aircraft type
 - (1) Factory school or equivalent (ground and flight)
 - (2) Twenty-five (25) hours as pilot in command in aircraft type prior to EMS missions
 - (3) Five (5) hours as pilot in command or at the controls prior to EMS missions

(4) Ten (10) hours as pilot in command or at the controls prior to EMS missions if transitioning from a single to a twin engine aircraft

- b) Over 100 hours in aircraft type
 - (1) Part 135 check ride (for Part 135 certificate holders)
 - (2) Five (5) hours local area orientation
- 2. Minimum requirements for area orientation

a) Five (5) hours area orientation of which two hours must be at night as pilot in command or at the controls prior to EMS missions

b) Training hours in aircraft type and area orientation may be combined depending on the experience and background of the pilot

- 3. Terrain and weather considerations specific to the program's geographic area
- 4. Instrument Meteorological conditions (IMC) recovery procedures by reference to instruments

5. A structured orientation must be conducted for relief pilots which at a minimum must include: roles, responsibilities, and familiarization with the region served

6. Orientation to the hospital or health care system associated with the air medical service

7. Orientation to infection control, medical systems installed on the aircraft and patient loading and unloading procedures

8. Orientation to the EMS and public service agencies unique to the specific coverage area

B. Quality assurance and competency must be ensured through methodologies including monthly operational reviews, ensuring pilot proficiency in both standard and emergency procedures. Remediation must be implemented as deficiencies are identified.

C. Annual recurrent training will minimally include:

- 1. Factory or equivalent refresher course
- 2. FAR Part 135 training requirements
- 3. IMC recovery procedures
- 4. Flight by reference to instruments
- 4 DE Reg. 1827 (5/1/01)

APPENDIX B - AIRCRAFT AND EQUIPMENT

The certificate holder must meet all Federal Aviation Regulations specific to the operations of the air medical ambulance service.

A. AIRCRAFT MEDICAL CONFIGURATION STANDARDS

1. Air medical personnel assure that all medical equipment is in working order through checklists.

2. All equipment (including specialized equipment) and supplies must be secured according to FAR's.

3. Personnel must be in seatbelts (and shoulder harnesses if installed) for all take-offs and landings according to FAA regulations.

4. Patients are restrained with straps that must comply with FAA regulations.

5. A policy must be in place to address refusal to transport patients who may be considered a threat to the safety of the flight and/or air medical personnel.

6. Patients under 60 pounds (27 kg), excluding transport isolette patients, shall be provided with an appropriately sized restraining device (for patient's height and weight) which is further secured by a locking device.

7. The pilot(s), flight controls, throttles (RW) and radios are physically protected from an intended or accidental interference by the patient, air medical personnel or equipment and supplies.

8. A minimum of one stretcher shall be provided that can be carried to the patient:

a) The stretcher and the means of securing it for flight must be consistent with FARs.

b) The stretcher shall be large enough to carry the 95th percentile adult American patient, full length in the supine position (the 95th percentile adult American male is 6 ft. and 212 lbs.).

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

d) The head of the stretcher is capable of being elevated at least 30 degrees for patient care and comfort.

9. Medical oxygen system - oxygen is installed according to FAA regulation and is capable of being shut off from inside the aircraft. Medical personnel can determine oxygen status using in-line pressure gauges mounted in the patient care area.

10. Each gas outlet is clearly marked for identification.

11. Supplemental lighting system will be installed in the aircraft for use in situations in which standard lighting is insufficient for patient care.

a) A self-contained lighting system powered by a battery pack or a portable light with a battery source must be available.

b) A means of protecting the cockpit from light in the patient care area shall be provided for night operations or use of red lighting (if not able to isolate the patient care area) to restrict light intensity.

12. Electric power outlet (with a minimum of 750 voltage amperage capacity) is provided, 28 volt DC and/or 115 volt AC, with sufficient output to meet the requirements of the complete specialized equipment package without compromising the operation of any electrical aircraft equipment.

13. No smoking signs are prominently displayed inside the cabin.

14. The air medical personnel "head-strike envelope" is clear of all obstructions.

B. ADDITIONAL OPERATIONAL POLICIES

There shall be specific policies and procedures regarding aircraft operations and evidence of training in the following areas:

- 1. Written patient loading and unloading procedures.
- 2. Specific policies concerning circumstances for hot loading or unloading if practiced.

3. Refueling policies for normal and emergency situations: Refueling with the engine running, rotor turning, and/or passengers on board is not recommended. However, emergency situations of this type can arise. Specific and rigid procedures should be developed by the operator to handles these

occurrences. Refueling policies will address: a) Refueling with engine(s) running or shut down.

b) Refueling with air medical personnel or patient(s) on board.

4. Specific policy to address the combative patient. Additional physical and/or chemical restraints should be available and used for combative patients who potentially endanger himself, the staff or the aircraft.

C. MEDICAL MANAGEMENT and EQUIPMENT REQUIREMENTS

- 1. Airway Maintenance and Oxygen Delivery
 - a) Objectives:

(1) The ability to initiate and maintain an airway with adequate ventilatory support for both adult and pediatric patients must be present.

- (2) Adequate amounts of oxygen must be available for every mission.
- (3) Oxygen flow can be stopped at or near the oxygen source from within the aircraft.
- (4) A variety of oxygen delivery devices which are consistent with the scope of care must

be present.

- (5) The following indicators must be available to personnel while in flight:
 - (a) quantity of oxygen remaining in the onboard oxygen supply system.
 - (b) measurement of oxygen liter flow

(6) There must be a back-up source of oxygen (of sufficient quantity to get safely to the ground for replacement) in the event the main system fails.

(7) Oxygen flow meters and outlets must be padded, flush mounted, or so located to prevent injury to personnel.

- b) Required Equipment:
 - (1) Oral and nasopharyngeal airway adjuncts
 - (2) Oxygen supplies, including PEEP valves, appropriate for age and potential needs of

patients

(3) Bag-Valve-Masks with oxygen reservoirs (assorted sizes appropriate to age of

patients)

(4) Suction equipment (installed and portable) with appropriate suction tubes (sizes and

types)

- (5) Laryngoscope and tracheal intubation equipment
- (6) Chest decompression and cricothyroidotomy equipment
- (7) Pulse Oximeter
- (8) Capnography (wave form)
- (9) And all other equipment required to comply with the Delaware Standard Treatment

Protocols.

- 2. Intravenous Fluids
 - a) Objectives:
 - (1) Fluids and supplies must be readily available.
 - (2) Hangers/hooks are available that secure the IV solutions in place.
 - (3) All hooks are padded and/or flush mounted to prevent injury to personnel.
- (4) Glass IV containers are prohibited unless explicitly required by medication administration specifications.
 - b) Equipment:
 - A variety of IV solutions, tubing and catheters which potentially may be needed must be

carried.

- 3. Medications
 - a) Objectives:
 - (1) Medications must be easily accessible.
 - (2) Controlled substances are to be secured in a manner consistent with state laws.
 - (3) Medications are stored in such a manner as to protect them from temperature

extremes.

b) Equipment and Supplies:

(1) All services whose scope of service include ALS and specialty care missions will carry the drugs required to comply with current Delaware Standard Treatment Protocols.

(2) Medications required by a specific specialty care mission must be carried on board during the mission.

- (3) Appropriate medication administration equipment must be present.
- 4. Cardiac Monitoring, Defibrillation and External Pacing
 - a) Objectives:
 - (1) External cardiac pacing must be available.

(2) Equipment must be secured and positioned so that displays are clearly visible and usable to the attending personnel.

- (3) The aircraft must allow for in-flight, 'effective' CPR.
 - (a) 'Effective' is defined as CPR that produces a compression pulse.

26

TITLE 16 HEALTH AND SOCIAL SERVICES DELAWARE ADMINISTRATIVE CODE

b) Equipment Required:

- (1) Cardiac monitor/Defibrillator and External Cardiac Pacemaker:
- (2) Pediatrics paddles must be present if appropriate to the scope of service.

(3) Extra power sources are available for cardiac monitor, defibrillator and external cardiac pacemaker.

(4) Automatic blood pressure device

4 DE Reg. 1827 (5/1/01)

APPENDIX C – QUALITY MANAGEMENT

1. The service or organization shall have a written QA/CQI plan which includes the following components:

- a) Responsibility/assignment of accountability
- b) Scope of care
- c) Important aspects of care
- d) Indicators
- e) Thresholds for evaluation which are appropriate to the individual service
- f) Methodology
- 2. The service or organization shall regularly hold QA/CQI meetings.

3. The service or organization's monitoring and evaluation process shall have the following characteristics:

- a) Driven by important aspects of care identified by the air medical service's QA/CQI plan
- b) Indicators and control thresholds are used to objectively monitor the important aspects of care
- c) Evidence of QA/CQI studies and evaluation in compliance with written QA/CQI plan
- d) Evidence of reporting QA/CQI activities through established QA/CQI organizational structure
- e) Evidence of on-going re-evaluation of action plans until problem resolution occurs
- 4. Quarterly review shall monitor, at a minimum, the following:
 - a) Reason for transport
 - b) Mechanism of injury or illness
 - c) Medical interventions performed or maintained
 - (1) Time of intervention consistently documented
 - (2) Patient's response to intervention documented
 - (3) Appropriateness of interventions performed or omission of needed interventions

d) Patient's outcome (morbidity and mortality) at the time of arrival at destination (including any change in condition during flight)

- e) Timeliness of the transport
- f) Safety practices
 - (1) Safety issues may be handled through the Safety Committee when a problem is identified.

(2) QA/CQI personnel may collect data and refer to the Safety Committee for action and resolution.

- g) Operational criteria to include at a minimum the following indicators:
 - (1) Number of aborted and canceled flights due to weather
 - (2) Number of aborted and canceled flights due to maintenance

(3) Number of aborted and canceled flights resulting in the use of alternative modes of transport due to patient condition.

5. Utilization appropriateness - the following indicators may trigger a review of the EDIN record by the Office of Emergency Medical Services, or their designate, to determine the medical appropriateness of the transport, based upon patients who are:

a) Discharged home directly from the Emergency Department, or discharged within 24 hours of admission

b) Transported without an IV line or oxygen

c) In cardiopulmonary arrest where CPR is in progress at the referring location

- d) Not transferred from a critical care unit, emergency department, or other specialty care unit.
- e) "Scheduled transports"
- f) Air transported more than once for the same illness or injury within 24 hours

g) Transported from the scene of an injury and fails to meet the criteria outlined in the "Prehospital Trauma Triage Scheme" in Section VI of the State Trauma System Regulations.

h) Transported interfacility, and the receiving facility is not a higher level of care than the referring facility

6. For both QA/CQI and utilization review programs, there shall be evidence of actions taken in problem areas and the evaluation of the effectiveness of that action.

4 DE Reg. 1827 (5/1/01)

APPENDIX D AIR MEDICAL AMBULANCE SERVICE USE REPORT

4 DE Reg. 1827 (5/1/01) 5 DE Reg. 1727 (3/1/02)