

4300 Emergency Medical Services

4301 Advanced Life Support Interfacility Transportation

1.0 Definitions

“911 ALS Organization” means an EMS organization that has been designated to provide ALS services to calls originating from a 911 center.

“ACLS” means American Heart Association Advanced Cardiac Life Support course.

“Advanced Life Support” The advanced level of prehospital and interhospital health care that includes basic life support functions plus cardiac monitoring, defibrillation, administration of specific medications, drugs and solutions, intravenous therapy, and other authorized treatments and procedures.

“Advertising” means any information communicated by oral, written, electronic, or any graphic means including flyers, newspapers, business cards, letterhead, radio, television, telephone directories, or internet websites. It also includes ambulance markings. It does not include novelty items such as pens, pencils and mugs.

“Air Medical Service” means an organization that provides medical transportation utilizing either fixed wing or rotor-wing vehicles.

“ALS” is Advanced Life Support

“ALS-IFT” means Advanced Life Support – Interfacility Transport

“ALS-ITO” means an organization or service that provides Advanced Life Support - Interfacility Transport.

“Ambulance” means any publicly or privately owned vehicle, as certified by the State Fire Prevention Commission, that is specifically designed, constructed or modified and equipped, and intended to be used for and is maintained or operated for the transportation upon the streets and highways of this state for persons who are sick, injured, wounded, or otherwise incapacitated or helpless.

“BCLS” means American Heart Association Basic Cardiac Life Support course

“Board of Medical Practice” is the body that oversees medical practice in Delaware under 24 Del.C. 19.

“BOMP” see Board of Medical Practice

“Certification Process” means the process by which a paramedic certified in another state may receive reciprocity to function in the State of Delaware. (Refer to Appendix A).

“Cost per Unit Hour” is a ratio measure of fiscal performance. It is calculated by summing all costs associated with providing a service (i.e. staffing, fuel, vehicle expenses, supply^o) for a particular period and dividing by the number of unit hours that were produced by the service during the same period.

“Designation” means status provided by the Division of Public Health to an ambulance service allowing them to provide Advanced Life Support Interfacility Transportation.

“Designation Probation” Organization may provide ALS Interfacility Transportation but performance will be monitored as recommended changes are implemented. Continued infractions may result in suspension or revocation of service designation.

“Designation Reinstatement” The Organization may resume provision of ALS-IFT in the State of Delaware.

“Designation Revocation” The Organization may not provide ALS Interfacility Transport services in the State of Delaware for a period of one year before re-applying for ALS-ITO Designation.

“Designation Suspension” The Organization may not provide ALS Interfacility Transport services until recommended changes are implemented and reviewed by the OEMS.

“Division” Refers to the Division of Public Health

“EDIN” See ‘Emergency Data Information Network’

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“Emergency Call” Any request for medical assistance that is received by a 911 Public Safety Access Point (PSAP).

“Emergency Data Information Network” Internet based data collection system for the State EMS system.

“Emergency Medical Technician” means a person who has been trained in basic emergency care procedures and has been certified by the Delaware Fire Prevention Commission to perform them in the State of Delaware.

“Inter-facility Transportation” means the movement of a patient between two medical facilities.

“Medical Facility” An agency, institution, or establishment where people receive acute, inpatient, outpatient, or long term health care.

“Non-911 ALS Organization” means an organization that is approved to provide ALS services to calls that do not originate from a 911 center.

“OEMS” Office of Emergency Medical Services, Division of Public Health

“Office” Refers to the Office of Emergency Medical Services, Division of Public Health

“Optional ALS Skill” means a skill, procedure, or medication that has been approved by the BOMP for use by ALS-ITO paramedics. Optional skills are only for use by ‘non-911’ organizations.

“Organization” means an ALS Interfacility Transportation Organization

“Organization Medical Director” Medical Director hired or contracted to oversee the medical care provided by an ALS-ITO.

“PALS” American Heart Association Pediatric Advanced Life Support course

“Paramedic” means a person who has been trained in advanced life support procedures and has been certified by the Division of Public Health and the Board of Medical Practice to perform them in the State of Delaware.

“Patient Contact Activity” means any activity involving contact between a patient and an ALS-ITO provider involving assessment, treatment, and/or transportation services being provided to the patient by the provider.

“PHTLS” The National Association of EMTs and the Committee on Trauma of the American College of Surgeons Prehospital Trauma Life Support course.

“Physician” means an individual authorized to practice medicine in Delaware under 24 Del.C. 17.

“PSAP” Public Safety Access Point. Location / agency that receives 911 calls for public safety assistance.

“Registered Nurse” An individual authorized to practice registered nursing in Delaware under 24 Del.C. 17.

“Unit Hour” A basic EMS productivity measure. A unit that is staffed and available for service for one hour generates ‘a unit hour’.

4 DE Reg. 1525 (3/1/01)**2.0 Purpose**

The purpose of these regulations is to permit the use of paramedics, under the oversight of the Division of Public Health, to manage patients while in transit between medical facilities or within a healthcare system. It includes approval of an organization to provide a service with a paramedic, as well as define their scope of practice and medical oversight. Data reporting to the Division of Public Health is included for the purposes of evaluating the performance of the State EMS system, of which Inter-facility Transport is a component, regardless of the level of medical care provided.

4 DE Reg. 1525 (3/1/01)**3.0 Authority**

This regulation is promulgated under the authority of 16 Del.C., Ch. 97 and 98.

The statewide paramedic program, a “coordinated advanced life support system under qualified medical supervision”, was established under the direction of the Office of Emergency Medical Services, Division of Public Health, Department of Health and Social Services (16 **Del.C.** §9801 (a)). “Except for those activities and responsibilities for basic life support and other emergency services which are under the jurisdiction of the State Fire Prevention Commission, the Office [of EMS] shall have jurisdiction over the development, implementation, and maintenance of a statewide paramedic system (16 **Del.C.** §9803)”.

The transfer of patients to specialty care, or rehabilitation, or follow-up care centers is within the scope of the State EMS system (16 **Del.C.** §9705 (j)) The use of paramedics to facilitate these transfers] is a function of the statewide paramedic program (16 **Del.C.** §9801 (g)).

Other functions of the Office of EMS as it relates to advanced life support interfacility transportation are found in 16 **Del.C.**, Ch. 97. The OEMS was created with the responsibility of providing assistance and advice for activities related toward the planning, development, improvement and expansion of emergency medical services (16 **Del.C.** §9704 (a)). This includes ‘monitoring and evaluating transportation services in Delaware to assure that patients in the EMS system have access to effective and efficient transportation to appropriate treatment facilities’ (16 **Del.C.** §9705 (d)).

The OEMS is primary staff to the Delaware Emergency Medical Services Oversight Council (DEMSOC) in addition to functioning as the body having jurisdiction over the state paramedic program. In this capacity, the Office shares the responsibility for “monitoring the [State] EMS system to ensure that all elements are functioning in a coordinated, effective, and efficient manner in order to reduce morbidity and mortality for the citizens of Delaware and to ensure quality of emergency medical services (16 **Del.C.** §9703).

4 DE Reg. 1525 (3/1/01)

4.0 General Provisions

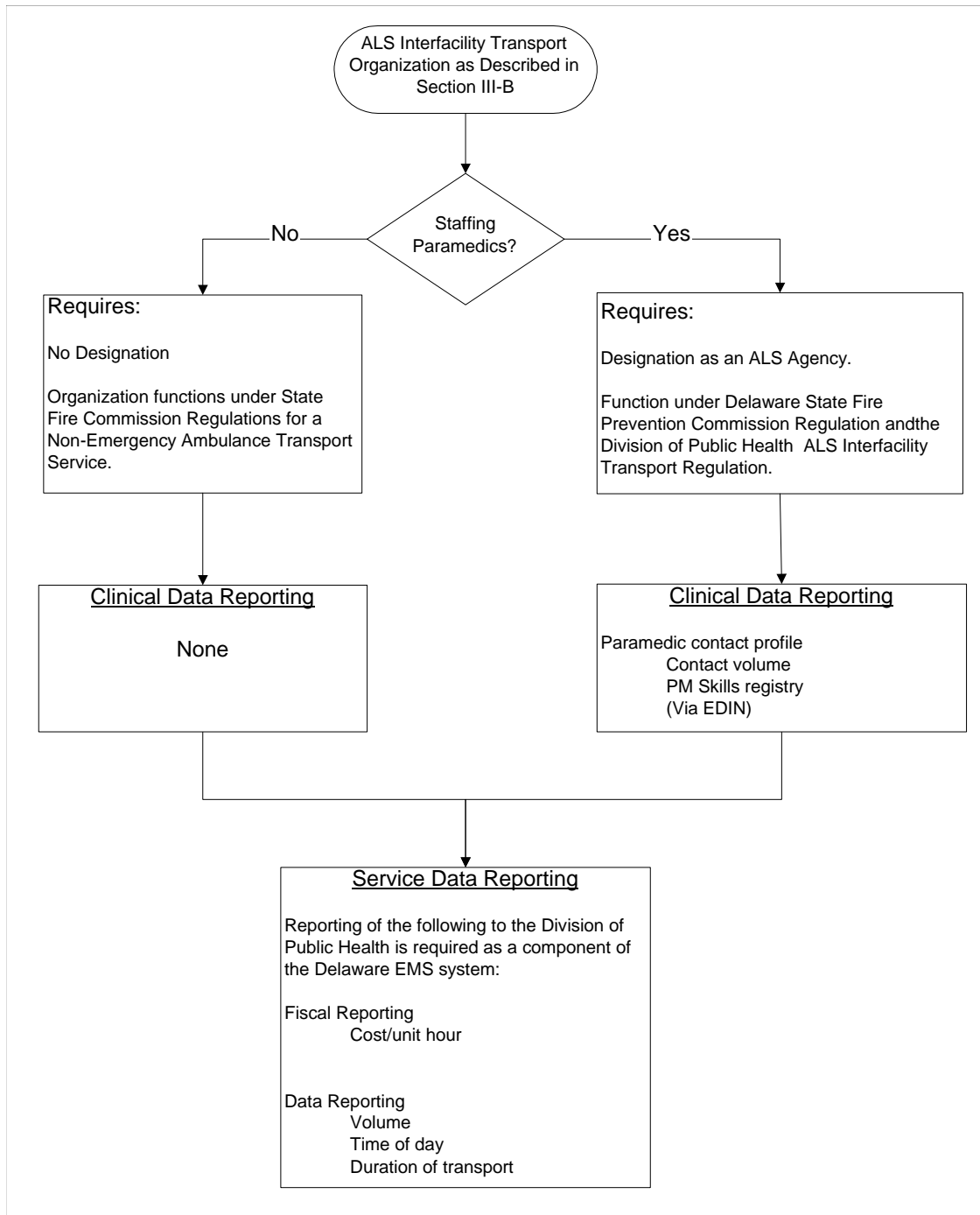
- 4.1 ALS Interfacility Transport Organizations will provide access to their services without discrimination due to race, color, creed, sex, nationality, age, or disability.
- 4.2 All organizations employing the services of paramedics to provide ALS Interfacility Transportation in the State of Delaware are subject to all of the provisions and limitations of this regulation and oversight by the Division of Public Health except:
 - 4.2.1 Organizations owned or operated by or under the jurisdiction of the federal government and used exclusively for government purposes.
 - 4.2.2 Agencies or organizations whose ambulances travel through Delaware, regardless of frequency exclusively for the purpose of interstate travel where patients are neither discharged nor picked up in the State.
 - 4.2.3 An organization based outside of Delaware that transports patients to and from Delaware for diagnostic or therapeutic services within the same calendar day.
- 4.3 No person, agency or organization may operate, conduct, maintain, advertise, engage in or profess to engage in Advanced Life Support Interfacility Transportation services in Delaware utilizing paramedics as advanced life support providers unless the agency or person holds a current designation certificate from the Division of Public Health with the exception of:
 - 4.3.1 Organizations owned or operated by or under the jurisdiction of the federal government and used exclusively for government purposes.
 - 4.3.2 Organizations whose units travel through Delaware, regardless of frequency, exclusively for the purpose of interstate travel where patients are neither picked up nor dropped off in the State.
 - 4.3.3 An organization based outside of Delaware that exclusively transports a patient to and from a Delaware location for diagnostic or therapeutic service within the same calendar day.
- 4.4 If a vehicle is used to provide transportation services, or an organization provides transportation services that are both excepted and non-excepted under these regulations, its ambulance, clinical providers, and operator shall comply with the regulations when not operating as an excepted service or organization.

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- 4.5 If the Division of Public Health believes that an ambulance is picking up or discharging patients and is required to be functioning under these regulations, the Division, or a appointed representative, may require the crew and management to provide information sufficient to determine whether the organization is required to comply with the regulation or is exempt.
- 4.6 Organizations that provide Interfacility Transportation Services that originate within the State of Delaware but do not utilize paramedics for Advanced Life Support Inter-facility Transports, must comply with the following sections of these regulations only:
- 4.6.1 Data Reporting
- 4.7 Communication
- 4.7.1 All communication regarding this regulation should be made to:
Delaware Division of Public Health
Office of Emergency Medical Services
Blue Hen Corporate Center
Suite 4H
655 Bay Rd.
Dover, DE 19901
- 4.8 Public Information
- 4.8.1 The Division of Public Health shall maintain a current list of designated Advanced Life Support Interfacility Transport Organizations (ALS-ITO) and shall provide this list as requested. The list shall contain the name of the ALS-ITO and their unit designations that will be used in radio communications.
- 4.8.2 The Delaware Freedom of Information Act shall govern responses to requests for public records of the Division of Public Health.

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Figure 1. Application of ALS-IFT Regulations



5.0 Patient Service Expectations

5.1 Each ALS-ITO shall provide each patient:

- 5.1.1 Considerate and respectful care
- 5.1.2 Information necessary in order to give informed consent for treatment, transport, or both.
- 5.1.3 The opportunity to refuse treatment or transport when competent to do so.
- 5.1.4 Reasonable privacy concerning a patient's transportation and care.
- 5.1.5 Confidentiality of all communication and records related to patient transportation and care except as otherwise required by law.
- 5.1.6 Reasonable response to a request for service once the ALS-ITO is engaged to provide service.

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- 5.1.7 Reasonable continuity of care once the ALS-ITO is engaged to provide service.
- 5.1.8 An opportunity to examine and receive an explanation of the patient's bill.
- 5.1.9 An environment in the ambulance that is free from hazards and annoyances to include but not limited to:
 - 5.1.9.1 Smoking
 - 5.1.9.2 Loud radio
 - 5.1.9.3 Loud conversation by the crew.

5.1.10 Information that the ALS-IFT units in Delaware are regulated by the Division of Public Health. Communication should be directed to the Division of Public Health, Office of Emergency Medical Services, Blue Hen Corporate Center, Suite 4H, 655 Bay Rd., Dover DE 19901. Phone number (302) 739-6637.

4 DE Reg. 1525 (3/1/01)**6.0 Designation****6.1 Purpose**

To qualify an organization to provide Advanced Life Support services in the State of Delaware under 16 **Del.C.** §9809(b).

6.2 Eligibility

To be eligible to apply for ALS-ITO designation, an organization shall:

6.2.1 Be qualified to conduct business in the State of Delaware.

6.2.1.1 Evidenced by a Delaware business license, unless a non-profit corporation.

6.2.2 Possess a permit from the Delaware Fire Prevention Commission as either an Emergency or Non-Emergency BLS Ambulance Service.^{1,2}

6.2.3 Own or operate at least one ambulance that is certified by the Delaware State Fire Prevention Commission (DSFPC).

6.2.4 Employ drivers with a valid motor vehicle license.

6.2.5 Have insurance coverage as outlined in Section VIII – I of these regulations.

6.2.6 Have computer equipment and Internet access that is compatible for integration into the Delaware Emergency Data Information Network.

6.2.7 Apply for Designation.

6.3 Application

An organization seeking Designation to provide ALS-IFT in Delaware shall submit a completed application on the required form to the Division of Public Health.

6.3.1 Submit a completed application on the required form to the Division of Public Health.

6.3.2 A completed application will contain:

6.3.2.1 The Organization's:

6.3.2.1.1 Name

6.3.2.1.2 Main physical business address.

6.3.2.1.3 Billing address

6.3.2.1.4 Telephone number

6.3.2.1.5 Fax number

6.3.2.1.6 Name of the principal contact person for communication with the Division of Public Health.

6.3.2.1.7 Name of the principal contact person for daily operations.

6.3.2.1.8 Entity type

1. Delaware Fire Prevention Commission BLS Regulation

2. This regulation requires the Organization to maintain an office of operations within the State of Delaware.

6.3.2.2 Documentation that the Organization is qualified to do business in Delaware and a signed agreement that it will take all actions necessary to remain qualified to do business in Delaware.

6.3.2.3 All trade names that the organization, its parent, or subsidiary has done business under.

6.3.2.4 Information about management personnel and owners:

6.3.2.4.1 Names

6.3.2.4.2 Addresses

6.3.2.4.3 Telephone numbers

6.3.2.4.4 Titles

6.3.2.5 Street addresses of any locations from which the organization intends to operate, including:

6.3.2.5.1 Location from which units are dispatched.

6.3.2.5.2 Location where records are kept.

6.3.2.5.3 Location where crews are quartered.

6.3.2.5.4 Location where ambulances are parked or stored

6.3.2.6 Information about employees who may be providing health care:

6.3.2.6.1 Name

6.3.2.6.2 Documentation of the following certifications:

6.3.2.6.2.1 Delaware Paramedic certification, or Delaware EMT-B certification.

6.3.2.6.2.2 BCLS

6.3.2.6.2.3 Delaware Emergency Vehicle Operator card or equivalent as approved by the Delaware Fire Prevention Commission.³

6.3.2.6.2.4 Motor vehicle license

6.3.2.6.3 Non-Delaware certified providers must receive reciprocity before they may function in Delaware^{4,5}.

6.3.2.7 Information about the Organization Medical Director

6.3.2.7.1 Name

6.3.2.7.2 Address

6.3.2.7.3 Telephone number

6.3.2.7.4 E-mail address

6.3.2.7.5 Evidence of Credentials

6.3.2.7.5.1 Delaware medical license.

6.3.2.7.5.2 Board certification in an appropriate specialty approved by the State Medical Director.

6.3.2.7.6 A description of their role, responsibilities, and authority within the Organization.

6.3.2.8 Information about the ambulances

6.3.2.7.1A list of the units that will be utilized for ALS-IFT with tag, VIN, and unit designation.

6.3.2.7.2 Documentation from the Delaware State Fire Prevention Commission that each ambulance that the Organization intends to use for ALS-IFT has received a permit for service in the State of Delaware.

6.3.2.7.3A diagram of the numbering, lettering, and symbols that will be displayed on the units.

6.3.2.9 A copy of the operational policies of the organization. These should include but are not limited to policies governing responses, transport practices, security of Controlled Dangerous Substances (CDS), and training.

3. DSFPC BLS Regulation Part. VII, Operational Requirements Sec. C (3)

4. 16 Del. C. §§ 9809-9810

5. Refer to Appendix A for certification process.

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6.3.2.10 Insurance Information

6.3.2.10.1A certificate of liability insurance that verifies that coverage that complies with Section VIII - I is in effect and lists:

The Division of Public Health-Office
of Emergency Medical Services
Blue Hen Corporate Center
Suite 4H
655 Bay Rd.
Dover DE 19901

as a party entitled to notification ten days prior to any of the following changes to the insurance policies required by regulation:

6.3.2.10.1.1 Non-renewal or cancellation

6.3.2.10.1.2 Changes in coverage or level of insurance.

6.3.2.10.2A certificate of motor vehicle insurance that identifies by VIN all motor vehicles covered under the insurance policy.

6.3.2.11A description of the Quality Management activities in the company or organization.

6.3.2.11.1 Include samples of reports describing activities related to:

6.3.2.11.1.1 Clinical performance

6.3.2.11.1.2 Operational performance

6.3.2.12A signed written statement that:

6.3.2.12.1 There has been no attempt for the purpose of obtaining or attempting to obtain a designation, to knowingly and willfully:

6.3.2.12.1.1 Falsify, conceal, or omit a material fact,

6.3.2.12.1.2 Make any false, fictitious, incomplete, or fraudulent statements or representations,

6.3.2.12.1.3 Make or use any false writing, document, or entry knowing the same to contain any false, fictitious, or fraudulent statements.

6.3.2.12.2 The signer is authorized by the Organization identified on the application to sign the application form to execute the sworn statement.

6.3.2.13 Any additional information that the Division of Public Health may consider necessary.

6.3.3 The application shall be signed by:

6.3.3.1 If a sole proprietorship, the owner,

6.3.3.2 If a partnership, a duly authorized partner,

6.3.3.3 If a corporation, a duly authorized corporate official,

6.3.3.4 If a limited liability company, a duly authorized member.

6.4 Review

6.4.1 The application must be completed and returned with all accompanying materials to the Division of Public Health either in person or by certified mail.

6.4.2 The Division of Public Health will review the application of the proposed ALS-ITO and conduct an on-site inspection and review to determine whether the applicant organization is in compliance with these regulations and other applicable laws.

6.4.2.1 The inspection/review may include any or all of the following:

6.4.2.1.1 Inspection of the supporting documents,

6.4.2.1.2A survey to inspect the ambulance service facilities, vehicles, and/or equipment,

6.4.2.1.3A conference with the applicant(s).

6.4.3 The applicant will be notified of the status of their application by certified letter.

6.4.3.1 Approval

6.4.3.1.1A Designation certificate will be provided from the Division of Public Health if all requirements are met as discussed herein.

6.4.3.1.2The current certificate, or a facsimile, shall be posted in a conspicuous place in each office of operations and in each ambulance that is used for ALS-IFT in the State of Delaware.

6.4.3.2 Denial

6.4.3.2.1If the Division determines that deficiencies exist which warrant the disapproval of the application, written notice will be given to the applicant with the disapproval notice.

6.4.3.2.2The applicant will have thirty (30) days from the receipt of the disapproval notice in which to respond to the Division with plans to correct the deficiencies.

6.4.3.2.3After review of an acceptable plan, the Division will conduct a re-inspection consistent with an agreed upon time frame.

6.4.3.2.4If the Division is satisfied with the results of the re-inspection, a certificate of Designation will be issued.

6.4.3.2.5If the deficiencies still exist, the Division will give the applicant a written notice of disapproval that shall identify the deficiencies.

6.4.3.2.6The applicant shall have thirty (30) days from receipt of the second written notice in which to appeal the decision to the Secretary of the Department of Health and Social Services or his/her designee.

6.4.4Before accepting a Designation, the Organization shall notify the Division of Public Health in writing of any changes in the information submitted in the application regarding:

6.4.4.1 The ambulances

6.4.4.2 Personnel

6.4.4.3 Ownership

6.4.4.4 Any other material in the application.

6.5 Designation Term

6.5.1Designation as a Delaware ALS-ITO is valid for a term of three years.

6.5.2The Designation expires at midnight of the expiration date.

6.5.3A revoked or surrendered designation certificate expires immediately upon notification.

6.5.4All ALS-IFT services must cease and desist at the time Designation expires.

6.6 Designation transfer

6.6.1ALS-ITO Designation may not be transferred without the written approval of the Division of Public Health.

6.6.2The owner(s) of a Designated ALS-ITO wishing to transfer or acquire the assets or stocks of another company may submit a letter of intent for the purposes of transferring the organization and designation to the successor organization.

6.7 Merger/Acquisition

A prospective purchaser of the stock or assets of an Organization, with the written permission of the current ownership may apply to the Division of Public Health for a preliminary determination of the eligibility of the prospective purchaser to receive ALS-ITO Designation under Section V.

6.8 Sale/Cessation of Operations

6.8.1An ALS-ITO sold without a transfer of Designation shall cease ALS operations at midnight of the day before ownership is transferred.

6.8.2An Organization ceasing operations shall return the ALS-ITO Designation certificate to the Division of Public Health within fourteen (14) days of the cessation date.

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7.0 Re-designation

7.1 Review Process

7.1.1The Organization shall submit the application postmarked no later than sixty (60) days before the certificate expiration date.

7.1.2The organization will complete an application with a cover letter identifying any changes from the previous review.

7.1.3The criteria for designation renewal are the same as for original designation.

4 DE Reg. 1525 (3/1/01)**8.0 Inspection Surveys**

8.1 The Division of Public Health, or a duly appointed representative, reserves the right to enter and make inspections at least quarterly and shall conduct, at a minimum, an annual inspection survey to ensure compliance with these regulations. Additional inspections may be conducted upon complaint or a reasonable belief that violations may exist.

8.2 Survey visits may be made to any location used or occupied by the organization during regular business hours, or at other times when a reasonable belief that violations of these regulations may exist.

8.2.1 Upon request of an authorized agent of the Division of Public Health, the designated organization shall produce for inspection:

8.2.1.1 The ambulances used for ALS-IFT.

8.2.1.2 Equipment

8.2.1.3 Personnel

8.2.1.4 Records required by these regulations

8.2.1.5 Any other items as determined by the agent.

8.2.2 Authorized representatives of the Division of Public Health may survey an ambulance used for ALS-IFT whenever it is in service.

8.3 Survey visits shall, at the discretion of an authorized representative of the Division of Public Health, include:

8.3.1 A review of all required records.

8.3.2 Conferences with the staff.

8.3.3 Audit of business locations, vehicles, equipment and qualifications of staff.

8.4 The ALS-ITO shall be notified in writing of the results of the inspection.

4 DE Reg. 1525 (3/1/01)**9.0 Organization Requirements****9.1 Statute / Regulatory Compliance**

The Organization must comply with the requirements of all parts of this regulation and associated federal, state, and local statutes and regulations.

9.2 Medical Director

9.2.1 The Organization shall retain the services of a Delaware licensed physician who agrees to assume the physician responsibilities for the Organization and providers as defined in 16 Del.C. §9806 (b) and will comply with all required areas of this regulation.

9.2.2 Role and Function – the role and responsibilities of the medical director include:

9.2.2.1 Provide medical oversight and quality control of interfacility advanced life support.

9.2.2.2 Establish and ensure compliance with standing orders and treatment protocols.

9.2.2.3 Provide review and evaluate the medical interventions of the paramedics.

9.2.2.4 Monitor the EMS providers for skill degradation and recommend appropriate remedies to the provider organization.

9.2.2.5 Offer technical assistance to the EMS providers they serve as medical director.

9.2.2.6 Oversee the training and certification of the ALS providers.

9.2.2.7 Determine policy guiding transport priority classifications (i.e. emergency vs. non-emergency response and transportation determinants).

9.2.2.8 Investigate issues related to clinical proficiency.

9.2.2.9 Serve as a liaison with the State Medical Director's Office.

9.3 Air Medical Service

A non-exempt Organization that will be providing Air Medical ALS-IFT must comply with the requirements of the OEMS Regulation for Air Medical Ambulance Services in addition to the ALS Interfacility Transport Regulations.

9.4 Provider Certification

All EMS providers must be certified to function in Delaware.⁶ The following are requirements for certification in Delaware.⁷

9.4.1 Paramedic

9.4.1.1 NREMT-P, BCLS, ACLS, PALS, PHTLS/ BTLs, and Emergency Vehicle Operator (or equivalent as determined by the State Fire Prevention Commission).

9.4.1.1.1 Flight crews are excepted from the EVO requirement.

9.4.2 Emergency Medical Technician

9.4.2.1 NREMT-B (or Delaware EMT-B), BCLS, and Emergency Vehicle Operator (or equivalent as determined by the State Fire Prevention Commission).

9.5 Ambulances

9.5.1 The Delaware State Fire Prevention Commission must permit each transport ambulance for use in the State of Delaware.

9.5.2 Units that are used exclusively for advanced life support services may be marked "Advanced Life Support", "Critical Care Transport", or "Mobile Intensive Care" to describe the level of service provided.

9.5.2.1 This marking is not required.

9.5.2.2 Units that are used for Basic Level Transportation as well as Advanced Life Support Transport services may not be marked as above.

9.5.2.3 If marked, all markings must be 3-in. (minimum) reflective lettering.

9.5.3 In instances of vehicular conditions that may precipitate or aggravate a medical condition or create a potential hazard to public health, the vehicle may not be driven with passengers or patients on board until repairs are completed. These conditions include but are not limited to:

9.5.3.1 Carbon monoxide hazards

9.5.3.1.1 An occupant complains of symptoms or has been affected by carbon monoxide as a result of riding in the ambulance.

9.5.3.1.2 Carbon monoxide levels that have been detected at a level of 9ppm in the interior of the ambulance.

9.5.3.1.3 A mechanical condition exists that may present a carbon monoxide hazard to the occupants.

9.5.3.2 Specific mechanical defects or hazards including:

9.5.3.2.1 Faulty brakes

9.5.3.2.2 Tire wear

9.5.3.2.3 Any other mechanical condition that may pose a threat, direct or indirect, to public health.

9.5.4 Equipment Requirements

9.5.4.1 The following equipment must be carried aboard each ambulance used for ALS Interfacility Transport.

9.5.4.1.1 All equipment required by the Delaware State Fire Prevention Commission.⁸

9.5.4.1.2 All equipment needed to provide any and all care under the protocols of the Delaware ALS Standing Orders⁹.

9.5.4.1.3 All medications listed in the Delaware Paramedic Formulary and those included in the Standing Orders as an 'Optional Skill' (See Section XIII).

9.5.4.2 Equipment must be stowed or secured in a manner as to prevent it from becoming injury-producing projectiles in the event of a crash.

9.6 Security of Narcotics and other Controlled Dangerous Substances

6. 16 Del. C. §9809 (a)

7. Refer to Appendix A for the certification process.

8. DSFPC BLS Regulation Appendix A

9. Refer to the OEMS ALS Standard Equipment list.

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9.6.1 All medications falling under Schedule II, III, and IV of the Controlled Dangerous Substance Act of 1970 that are stored or carried on board the unit must be secured under double lock with the exceptions:

9.6.1.1 Medications brought on board an ambulance by medical facility personnel for possible use during a transport must be secured according to the policies of that facility and may not be stored aboard the unit after the facility personnel are returned to the medical facility and have separated themselves from the transport team.

9.6.1.2 Medications carried on the charge provider's person do not require double lock security.

9.6.2 Keys to access the secured medications must be in the possession of the charge clinical provider, or the responsible person, on the ambulance at all times.

9.7 Data Reporting

9.7.1 The following data must be reported to the Division of Public Health on a continuous basis.

9.7.1.1 Clinical

9.7.1.1.1 All Paramedic activity related to a patient contact must be reported through the Delaware Emergency Data Information Network (EDIN)¹⁰.

9.7.1.1.2 In the event that EDIN is out of service, all records will be maintained in paper form using the Delaware Paramedic Report until EDIN is available again. The paper records will be entered into EDIN at such time that the system is available.

9.7.1.2 Volume

8.7.1.2.1 An EDIN Interfacility Report shall be completed for each transport performed by the ALS-ITO.

9.7.1.3 Any data as requested by the Division of Public Health for the purposes of system quality management or system performance evaluation.

9.7.2 The following data pertaining to the operation, or portion of the operation, related to ALS interfacility transportation must be reported to the Division of Public Health on a quarterly basis, within thirty (30) days of the end of the quarter. The Division of Public Health will use these data for the purposes of monitoring the transportation services as required in 16 **Del.C.** §9705(d) as well as provide them to the Delaware EMS Oversight Council for the purposes of determining the overall statewide EMS system performance as required by 16 **Del.C.** §9703 (e).

9.7.2.1 Fiscal

9.7.2.1.1 Cost per unit hour

9.7.2.2 Operational

9.7.2.2.1 Unit hour production

9.7.2.2.2 Transport volume

9.7.2.3 Any data as requested by the Division of Public Health for the purposes of system quality management or system performance evaluation.

9.8 Records / Documentation

The following records, or a copy, must be maintained at the Delaware operations office for all providers participating in the organization's ALS-IFT operation.

9.8.1 Personnel

9.8.1.1 The Organization shall maintain a current list of the following personnel: EMS providers, registered nurses, any other medical personnel employed.

9.8.1.2 The list shall include the employee's full name, certification number, level, date of issue, and date of expiration.

9.8.2 Training

9.8.2.1 Training records for each employee shall contain evidence of:

9.8.2.1.1 Initial orientation and competency assessment,

9.8.2.1.2 Continuing education, and

9.8.2.1.3 All other training required as part of this regulation.

9.8.2.2 Training records should be maintained to document the date training was provided, course outline, attendance, instructor's name and qualifications.

9.8.3 Continuing Education

9.8.3.1 Credit for continuing education programs must be applied for through the OEMS prior to the course being held as per the OEMS Education policy.

9.8.4 Records retention

9.8.4.1 All records pertaining to the operation of the ALS-ITO must be retained for a minimum period of two (2) years.

9.8.4.2 Medical records documenting patient care provided by the organization (i.e. patient care reports) must be retained for a minimum of seven (7) years.

9.9 Insurance coverage

9.9.1 An ALS-ITO may not be designated to provide service in Delaware unless it maintains continuous insurance of the following types and amounts:

9.9.1.1 General liability insurance of not less than \$1 million.¹¹

9.9.1.2 Motor vehicle liability insurance coverage not less than \$1 million individual and \$3 million aggregate per occurrence.¹²

9.9.1.3 Worker Compensation coverage in the amount required by 19 **Del.C.** §2306.

9.9.2 The general liability coverage must provide payment of damages as a result of:

9.9.2.1 Any bodily injury to, death of, individuals in accidents resulting from any cause which the ALS-ITO is liable,

9.9.2.2 Property damage, or loss of property, including personal property resulting from any cause for which the Organization is liable.

9.9.3 The financial responsibility requirements for motor vehicle liability coverage shall conform to 21 **Del.C.** §2901.

9.9.4 The financial responsibility for the worker's compensation insurance shall comply with 19 **Del.C.** §§ 2321-2334.

4 DE Reg. 1525 (3/1/01)

10.0 Operations

10.1 Designation

10.1.1 An agency must be designated¹³ as an ALS Interfacility Transport Organization by the Delaware Department of Health and Social Services, Division of Public Health in order to:

10.1.1.1 Provide ALS services during any medical transport originating in Delaware.

10.1.1.2 Advertise as a Delaware Advanced Life Support Organization.¹⁴

10.1.1.2.1 All advertisements and invoices shall contain the legal name and the phrase "A Designated Delaware ALS Interfacility Transport Organization".

10.1.1.2.1.1 Advertisements may also include the words "Mobile Intensive Care Service", "Critical Care Transport Service", or "Advanced Life Support".

10.1.1.2.1.2 An ALS-ITO utilizing paramedics shall not include the words "Paramedics" or "Paramedic Service" on any of their advertisements.

10.1.1.2.2 Advertisements include but are not limited to business cards, letterhead, newsletters, brochures, flyers, etc.

10.2 Scope of Services

10.2.1 ALS Interfacility Transportation is defined as the medically necessary transportation of a patient requiring the provision of medical care that exceeds the scope of practice of an EMT-Basic that originates at a Delaware medical facility with a destination at another medical facility.

11.

12.DSFPC BLS Regulation Part X, Sec. A (5)

13.Refer to Section V for the designation process.

14.Comply with 16 **Del.C.** §9809 (c)

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10.2.2 Operations as an ALS Interfacility Transport Organization are limited to 'non-911' emergency and non-emergency transports with the following exceptions:

10.2.2.1As a component of a disaster plan.

10.2.2.2As part of a 'mutual aid' agreement approved by the OEMS.

10.2.2.2.1The agreement must specifically address:

10.2.2.2.1.1Remuneration for services rendered,

10.2.2.2.1.2Response time performance.

10.2.2.3At an incident where the ALS-IFT unit coincidentally arrived before the jurisdiction 911 organization.

10.2.3 In instances where the crew of an uncommitted ALS-ITO ambulance chooses to render care at a '911' incident before the jurisdictional '911' ALS agency is present on scene, the following procedures shall apply:

10.2.3.1The ALS-ITO unit shall immediately contact the jurisdictional PSAP and report the nature and location of the incident.

10.2.3.2The ALS-ITO personnel shall provide medical care within their scope of practice to any persons in need of it until a jurisdictional EMS unit arrives at the scene.

10.2.3.3Patient care responsibilities and scene control shall be deferred to the jurisdictional authorities as they arrive or as they request.

10.2.3.4The ALS-ITO unit may, but will not be required to, provide transportation services if a request is made by the Incident Commander and this request is approved by a representative of the jurisdictional ALS agency.

10.2.3.4.1The responsibility for providing the service remains with the jurisdictional ALS agency until it is accepted by the ALS-ITO.

10.2.3.5Documentation of the patient contact must be completed using the appropriate EDIN form at the time of transfer to the receiving medical facility.

10.2.4 A 911-ALS organization or PSAP may not direct emergency calls to an ALS-ITO unless a mutual aid agreement, approved by the OEMS, exists between the jurisdictional 911 ALS service and the ALS-ITO.

10.2.4.1The agreement must specifically address:

10.2.4.1.1Remuneration for services rendered,

10.2.4.1.2Response time performance requirements.

10.3 Standing Orders

10.3.1 Use

10.3.1.1The scope of practice for paramedics providing ALS Interfacility Transport services is defined by the Delaware Paramedic Standing Orders.

10.3.1.1.1The State Medical Director and the Board of Medical Practice (BOMP) must approve any changes to the paramedic scope of practice (Refer to Section XII of these regulations).

10.3.2 Protocol Variances

10.3.2.1If a paramedic performs a function that is outside of the scope of practice as defined by the Delaware Paramedic Standing Orders, the following activity must occur:

10.3.2.1.1The Organization Medical Director must be notified of the violation immediately.

10.3.2.1.2The paramedic must submit a written report of the incident to the Organization Medical Director within twenty-four (24) hours of the incident.

10.3.2.1.3The Organization Medical Director shall notify the State Medical Director's Office of any and all incidents of potential protocol violations within five (5) working days of receiving the incident report.

10.3.2.2The Organization Medical Director and/ or the company shall investigate the incident and provide a written report of the investigation and its conclusions to the State Medical Director through the Organization Medical Director within fourteen calendar days of the incident.

10.3.2.3The State Medical Director will review the incident based on the reports and issue a recommendation for action if appropriate.

10.3.2.3.1 The State Medical Director reserves the right to initiate an independent investigation.

10.3.2.3.2 The State Medical Director may immediately suspend the paramedic's certification for a period of thirty days in order to prevent a clear and imminent danger to public health¹⁵.

10.3.2.4 A review may also be initiated by a written complaint to the Division of Public Health – Office of Emergency Medical Services.

10.4 Crew Configuration

10.4.1 The crew shall consist of at least two providers.

10.4.1.1 At least one provider must be a certified Delaware paramedic.

10.4.1.2 The other provider must at least be a Delaware EMT-B.

10.4.1.2.1 The EMT-B may not function as a primary care provider.

10.4.2 An ALS-ITO may not transport patients requiring care that is beyond the scope of practice of a Delaware paramedic unless the patient is accompanied by a healthcare provider authorized under Delaware law to provide the required level of care in compliance with federal medical transport/transfer regulations.

10.5 Personnel Identification

10.5.1 All personnel shall display identification that includes their photograph, last name, and position/ certification level.

10.5.2 All EMTs and paramedics must carry a Delaware issued certification card at all times while on duty.

10.5.3 Identification must be visible on the front of the outermost garment.

10.5.4 All personnel shall only display insignia for valid certification and personal identification.

10.5.5 Agencies shall provide assurance that their personnel do not wear or display identification that suggests affiliation with another agency, service, organization, department, or company other than the ALS-ITO or a healthcare facility that is involved in the patient's care.

10.6 Ambulance Operation

10.6.1 Ambulances are to be operated in accordance with 21Del.C. §4106 by licensed operators possessing a Delaware emergency vehicle operator (EVO) card or an equivalent as determined by the Delaware State Fire Prevention Commission.¹⁶

10.6.2 Lights and sirens are to be used by ALS-IFT vehicles only in the following situations:

10.6.2.1 Enroute to an emergency call as determined and documented by the transferring physician,

10.6.2.2 Transporting a Priority 1 patient as determined and documented by the transferring physician.

10.6.2.3 Transporting a patient meeting the criteria determined by the Organization Medical Director as requiring emergency transportation.

10.7 Medical Control

10.7.1 Authority

10.7.1.1 The transferring physician is responsible for providing medical control for the patient transfer until the patient reaches the destination facility.

11.0 Designation Review

11.1 Purpose

To provide a mechanism to identify conditions that may affect public health and protect public health until the problems are resolved.

11.2 Cause

15.16 Del.C. §9806 (6)

16. DSFPC BLS Regulation Part VII, Operational Requirements Sec. C (2)

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The Division of Public Health may, in compliance with proper administrative procedures as provided by the law, suspend, revoke, or refuse to issue designation certificates for any of the following reasons:

11.2.1 A serious violation of these regulations. (Defined as one that poses a significant threat to the health and safety of the public.)

11.2.2 Revocation of permit as a BLS Ambulance Service by the Delaware State Fire Prevention Commission.¹⁷

11.2.3 Failure to submit a reasonable timetable to correct deficiencies and violations cited by the Division.

11.2.4 The existence of a continuing pattern of deficiencies.

11.2.5 Fraud or deceit in obtaining or attempting to obtain certification.

11.2.6 Lending a certificate or borrowing or using the certificate of another, or knowingly aiding or abetting the improper granting of a certificate.

11.2.7 Incompetence, negligence, or misconduct in operating or providing ALS Interfacility Transport services. This includes but is not limited to patterns such as a failure to follow medical command or a failure to respond to a transport request.

11.2.8 Failure to employ or contract for a medical director responsible for services as outlined in this regulation.

11.2.9 Failure to have appropriate medical equipment and supplies required for certification.

11.2.10 Failure of the ALS Interfacility Transport Organization to notify the Division of Public Health of a change of ownership.

11.2.11 Abuse or abandonment of a patient.

11.2.12 Unauthorized disclosure of medical or other confidential material.

11.2.13 Willful preparation or filing of false medical reports or records, or the inducement of another to do so.

11.2.14 Destruction of medical records.

11.2.15 Failure to provide data to the Division of Public Health as required, either through EDIN or via report.

11.2.16 Refusal to render services on the basis of a patient's race, color, creed, gender or sexual orientation, nationality, age, or disability.

11.2.17 Misuse or misappropriation of drugs/ medications.

11.2.18 Failure to produce requested records for inspection or to permit the examination of equipment shall be grounds for suspension or revocation or the denial of certification. However the certificate shall not be suspended, revoked or denied for a period of longer than sixty (60) days in the event that a dispute regarding the production of these records exists and remains unresolved. Such suspension, revocation, or denial may occur for the entire sixty (60) day period if the Division determines that such action is necessary to prevent a clear and immediate danger to public health.

11.2.19 Conviction of the Organization or owner(s) of a crime, including Medicare or Medicaid fraud, relating adversely to the person's capability of owning or operating the Organization.

11.2.20 Non-compliance with COBRA/EMTALA.

11.2.21 Other reasons as determined by the Division which pose a significant threat to public health and safety.

11.3 Initiation

11.3.1 The Designation Review Process can be initiated by:

11.3.1.1 A written or verbal complaint indicating a violation of these regulations.

11.3.1.2 Failure to participate in data reporting.

11.3.1.3 Failure to correct deficiencies identified by the Division of Public Health.

11.4 Investigation

11.4.1 Upon initiation of the Designation Review Process the Division of Public Health will:

17. Refer to DSFPC Regulation of BLS Ambulance Services Part XI

11.4.1.1 Receive written notification of the violation from the identifying agent accompanied by supporting documentation.

11.4.1.2 Convene an investigation panel

11.4.1.2.1 The panel will consist of the Paramedic Administrator (OEMS), the State Medical Director and any other subject matter expert deemed appropriate.

11.4.1.3 The panel will initiate an investigation of the allegation(s).

11.4.1.3.1 The ALS Interfacility Transport Organization will be notified in writing with a request for its written response.

11.4.1.3.2 The investigation panel will conduct an appropriate follow-up investigation.

11.4.1.4 The Investigation Panel will submit its report and recommendation to the Director of the Division of Public Health.

11.4.1.4.1 Panel Recommendations

11.4.1.4.1.1 The panel may recommend any of the following actions:

11.4.1.4.1.1.1 Designation Probation

11.4.1.4.1.1.1.1 The Investigation Panel will determine the recommended length of probation and include recommended conditions that must be met by the end of the probationary period.

11.4.1.4.1.1.1.2 If adopted by the Division Director, these conditions will be verified by a representative of the Division of Public Health at the end of the probationary period or at an earlier time as requested in writing by the Organization.

11.4.1.4.1.1.1.2.1 The Division of Public Health will confirm reinstatement in writing before operations may resume.

11.4.1.4.1.1.1.3 Additional infractions occurring during the probation period will result in an immediate review for Designation Suspension by the Division of Public Health.

11.4.1.4.1.1.1.4 Failure to meet the conditions will result in a review for Designation Suspension by the Division of Public Health.

11.4.1.4.1.1.2 Designation Suspension

11.4.1.4.1.1.2.1 The Investigation Panel will recommend the length of suspension and any conditions to be met for reinstatement.

11.4.1.4.1.1.2.2 If adopted by the Division Director, the Organization may not provide ALS services in Delaware for the duration of the suspension.

11.4.1.4.1.1.2.2.1 A representative of the Division of Public Health must verify that any conditions for reinstatement have been met before ALS services may be resumed.

11.4.1.4.1.1.2.2.2 The Division of Public Health will confirm reinstatement in writing before operations may resume.

11.4.1.4.1.1.3 Designation Revocation

11.4.1.4.1.1.3.1 The Investigation Panel will recommend revocation and any conditions to be met before the Organization may reapply for designation.

11.4.1.4.1.1.3.2 If adopted by the Division Director, the Organization may not provide ALS services in Delaware and may not re-apply for ALS-ITO Designation for a period of not less than one year from the date of Revocation.

11.4.1.4.1.1.3.2.1 The Division of Public Health will verify that any conditions have been met as part of the re-application process.

11.4.1.4.1.2 If probation, suspension or revocation is not recommended the Investigation Panel may recommend follow up monitoring or reporting.

11.4.1.5 The Division Director will provide written notification to the ALS Interfacility Transport Organization of the results of the investigation and the disposition of the Organization's designation.

11.4.1.6 The involved Organization will have the right to contest any decision of the Division of Public Health. Written notification of the intent to contest must be made to the Director of the Division of Public Health within thirty (30) days of notification of action.

11.4.1.6.1 The Division Director shall offer a public hearing to review the decision in accordance with 29 Del.C.101.

11.4.1.6.2 The Division Director shall name a hearing officer and schedule a hearing in accordance with 29 Del.C. 101.

11.5 Appeals

11.5.1 The involved Organization will have the right to appeal any decision of the Director of the Division of Public Health. Written notification of the intent to appeal must be made to the Secretary of the Department of Health and Social Services within thirty (30) days of notification of action.

4 DE Reg. 1525 (3/1/01)

12.0 Certification Review

12.1 Initiation

12.1.1 The Organization Medical Director may initiate a review of medical performance on the basis of a variance, complaint, or EDIN review.

12.1.2 The Division of Public Health may also initiate a review on the basis of a variance, complaint, or an EDIN review.

12.2 Investigation

12.2.1 The Organization Medical Director performs the initial investigation.

12.2.1.1 The Organization Medical Director shall remove the paramedic from patient care status pending a review of the incident by the State Medical Director's Office.

12.2.2 Findings of this investigation will be forwarded to the State Medical Director's Office within ten working days of completion of the investigation.

12.2.2.1 The State Medical Director has the authority to suspend the paramedic's certification for up to 30 days in order to prevent a clear and imminent danger to public health¹⁸.

12.2.3 The State Medical Director will review the incident and forward findings and recommendations to the Board of Medical Practice¹⁹.

12.2.3.1 Issues concerning nursing performance will be addressed by the State Medical Director with the organization's clinical nursing supervisor and/ or to the Board of Nursing.

12.2.4 The BOMP will review the incident and decide appropriate action.

4 DE Reg. 1525 (3/1/01)

13.0 Scope of Practice Expansion

13.1 Purpose

The environment and the needs of patients who are moving within the health care system are different from those of patients who are being transported into the healthcare system. This section provides a mechanism for expanding the scope of practice of paramedics functioning in the Interfacility transport component of the EMS system in order to meet these needs.

13.2 Limitations

13.2.1 Optional Skills that are approved for use in 'non-911' transport services may be used only in 'non-911' transports.

13.2.2 At no time may they be used during '911' transports without BOMP approval.

13.3 Review

13.3.1 Proposal

13.3.1.1 A proposal of the new protocol shall be submitted to the State Medical Director's Office from the Organization's Medical Director. The proposal shall include a description of the skill, procedure, or medication, a description of the need and any supporting documentation, the training that will be required and the credentials of the person or agency that will providing it, and the methods that will be used to evaluate proficiency.

13.3.2 Protocol Review Process

18.16 Del.C. §9806 (6)

19.16 Del.C. §9812

13.3.2.1 The State Medical Director will review the proposal and have the option of setting up a meeting with the writer to discuss the proposal.

13.3.2.2 If the proposal is denied, the State Medical Director will notify the Organization of the denial in writing with the reasons for denial or,

13.3.2.3 The State Medical Director will attach a recommendation to it and forward the request to the Board of Medical Practice (BOMP).

13.3.2.4 The BOMP will review the proposal and determine whether the proposed skill, procedure, or medication will be added to the Delaware Standing Orders as an 'Optional ALS Skill'.

4 DE Reg. 1525 (3/1/01)

14.0 'Optional Skills'

14.1 Skills that have been designated an "Optional Skill" may be used by paramedics employed by an ALS-ITO that has been approved by the State Medical Director to use the skill, procedure, or medication.

14.2 The Organization Medical Director will need to supply the following information to the State Medical Director before the paramedics employed by the ALS-ITO may function under the expanded Standing Orders:

14.2.1 A list of the trained providers.

14.2.2 Documentation of the initial training provided and skill verification.

14.2.3 A schedule for annual continuing education on the optional skill.

4 DE Reg. 1525 (3/1/01)