

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 9705 (p)(1) (16 **Del.C.** §9705 (p)(1))
16 **DE Admin. Code** 4303

FINAL

ORDER

4303 Automatic External Defibrillation

NATURE OF THE PROCEEDINGS:

The Delaware Department of Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Regulations Governing Automatic External Defibrillation. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Delaware Code**, Ch. 101 and authority as prescribed by 16 **Delaware Code**, Section 9705 (p)(1).

On August 1, 2013 (Volume 17, Issue 2), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Del.C.** §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by September 3, 2013, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying "Summary of Evidence."

SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Automatic External Defibrillation were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations*.

Entities offering written comments include:

IAED Grassroots (International Academies of Emergency Dispatch)

Public comments and the DHSS (Agency) responses are as follows:

IAED Grassroots (International Academies of Emergency Dispatch):

...placement of an AED within the State of Delaware. 4.6 The OEMS will be responsible for notifying the jurisdictional *public safety answering point* of the placement of an SAED within the boundaries of their jurisdiction. 5.0 Eligibility* 5.1 Any agency, organization...

...placement of an SAED within the State of Delaware. 4.5 The OEMS shall be responsible for notifying the jurisdictional *public safety answering point* of the placement of an SAED within the boundaries of their jurisdiction 4.6 SAED Providers, SAED agencies and SAED...

Agency Response: The Agency appreciates and acknowledges these comments. The term "public safety answering point" has been in the AED regulations since the inception of the AED program. Dispatch centers in each jurisdiction of the state identify themselves by a different name, i.e. Fire Board, Kent Center, etc., thus, the state prefers using the generally accepted universal term of "public safety answering point" instead of specifically delineating each dispatch center.

The public comment period was open from August 1, 2013 through September 3, 2013.

Based on comments received during the public comment period no changes have been made to the proposed regulation. The regulation has been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

FINDINGS OF FACT:

Based on public comments received, no changes were made to the proposed regulations. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Automatic External Defibrillation are adopted and shall become effective October 11, 2013, after publication of the final regulation in the *Delaware Register of Regulations*.

Rita M. Landgraf, Secretary

4303 Delaware Early Defibrillation Program

4.0 Purpose

4.1 This regulation establishes:

- 4.1.1 The criteria for training and right to practice of emergency responders to administer automatic external cardiac defibrillation in an out-of-hospital environment;
- 4.1.2 Standards identified by the State Emergency Medical Services Medical Director for certification of Early Defibrillation Services through the Office of Emergency Medical Services; and,
- 4.1.3 Procedures to assure equipment and training standardization, quality assurance and improvement and uniform data collection.

2.0 Authority

This regulation is written and promulgated by the Delaware Department of Health and Social Services, pursuant to 16 **Del.C.**, Chapter 97.

3.0 Definitions

“ABEM”: American Board of Emergency Medicine.

“ACLS”: Advanced Cardiac Life Support.

“Board”: The Delaware State Board of Medical Practice.

“CPR”: Cardiopulmonary Resuscitation.

“Certification”: Recognition by the Office of Emergency Medical Services that an agency, organization or business has met the requirements to provide Early Defibrillation services.

“Defibrillation”: The administration of electrical impulses to the heart to stop and/or convert ventricular fibrillation or pulseless ventricular tachycardia into a viable rhythm.

“Department”: The Department of Health and Social Services.

“Division”: The Division of Public Health.

“EMS”: Emergency Medical Services.

“Early Defibrillation Provider”: A member or employee of an Early Defibrillation Service who has completed training in SAED operation and use under the requirements set forth in this regulation.

“Early Defibrillation Service”: Any agency, organization or company, certified as such by the State Office Of Emergency Medical Services, that employs or retains providers who have completed an SAED training program to use semi-automatic defibrillation equipment.

“FDA”: Federal Food and Drug Administration.

“First Responder Team”: An organized group of individuals within a corporation, business or agency designated by that agency to respond to emergency situations.

“Medical Control”: Physician direction, through protocols, supervision and quality control of Early Defibrillation Services and/or Providers by the State Office Of Emergency Medical Services Medical Director.

“Office or OEMS”: The State Office of Emergency Medical Services.

“Protocol”: Currently approved and accepted procedures describing specific steps a provider must follow in assessing and treating a patient.

“Renewal”: Periodic training and demonstration of competence in the application and use of semi-automatic defibrillation equipment.

“Right to Practice”: An Early Defibrillation Provider is granted the right to practice as such by the State EMS Medical Director upon the completion of an approved initial or renewal SAED training course and when functioning as a member of an approved Early Defibrillation Service. The right to practice can be suspended or revoked by the State EMS Medical Director.

“SAED”: Semi-Automatic External Defibrillator. A device capable of, (1) analyzing a cardiac rhythm, (2) determining the need for defibrillation, (3) automatically charging, and, (4) advising a provider to deliver a defibrillation electrical impulse.

“Service Coordinator”: A designated appointee from an Early Defibrillation Service responsible for administration of the Early Defibrillation Program for their respective Service.

“Service Director”: President, Chief Executive Officer or any other individual who is administratively responsible for a corporation, business or agency.

~~“State Coordinator”~~: An individual appointed by the Director, State Office of Emergency Medical Services to administer the Early Defibrillation Program at the State level.

~~“State Medical Director”~~: The State Office of Emergency Medical Services Medical Director, who provides medical control, supervision, and quality control for the Early Defibrillation Program.

~~“Training /Certifying Agency/Center”~~: Any training facility, approved by the State Medical Director, that engages in the training of Early Defibrillation Providers in accordance with the requirements set forth in this regulation.

~~“Ventricular Fibrillation”~~: A lethal disturbance in the normal rhythm of the heart characterized by rapid, irregular and ineffective twitching of the lower chambers, or ventricles, of the heart.

~~“Ventricular Tachycardia”~~: A potentially lethal dysrhythmia originating in the ventricles of the heart. A pulse may or may not be present.

4.0 General Provisions

- 4.1 This regulation applies to any organization or individuals participating in the Delaware Early Defibrillation Program.
- 4.2 Early Defibrillation Services shall not allow any individual who does not meet the requirements established in this regulation to operate SAED equipment.
- 4.3 The OEMS, or its designee, shall retain the right to inspect any Early Defibrillation Service's defibrillation equipment and any records or documentation associated with the Early Defibrillation Program.
- 4.4 Automatic External Defibrillators are classified as medical devices by the Board.
- 4.5 SAED manufacturers, their representatives or agents are required to notify the OEMS of the sale and placement of an AED within the State of Delaware.
- 4.6 The OEMS will be responsible for notifying the jurisdictional public safety answering point of the placement of an SAED within the boundaries of their jurisdiction.

5.0 Eligibility

- 5.1 Any agency, organization or business, within the State of Delaware, routinely providing Basic Life Support services, First Responder services or maintains an organized First Responder Team on the premises, is eligible to become an Early Defibrillation Service.
- 5.2 Any agency, organization or business from another state providing Basic Life Support services, First Responder Services or maintains an organized First Responder Team on the premises routinely operating within the State of Delaware, is eligible to become an Early Defibrillation Service as approved by the State Emergency Medical Services Medical Director.

6.0 Medical Direction

- 6.1 Program Medical Director
 - 6.1.1 The Early Defibrillation Program shall be under medical supervision of the State EMS Medical Director or his/her designee.
 - 6.1.2 The State EMS Medical Director shall be responsible for:
 - 6.1.2.1 Overseeing medical and training operations for the program;
 - 6.1.2.2 Approve the appointment of personnel responsible for medical supervision and training of early defibrillation providers;
 - 6.1.2.3 Approve SAED training courses for instructors and instructor trainers.
 - 6.1.2.4 Approve initial training and renewal courses for program providers;
 - 6.1.2.5 Establish and assure compliance with Quality Assurance/Quality Improvement (QA/QI) policies, practices and procedures
 - 6.1.2.6 Establish Early Defibrillation Program medical protocols.
 - 6.1.3 The Medical Director is granted the authority to suspend or revoke an Early Defibrillation Provider's right to practice with cause.

7.0 Early Defibrillation Service Requirements

- 7.1 Agencies, corporations or businesses desiring to provide Early Defibrillation Services must make application to the OEMS prior to implementation of the program.
- 7.2 Information to be provided with the application package shall include:

- 7.2.1 OEMS-approved application;
- 7.2.2 Other information as required by the OEMS.
- 7.3 Upon approval, Early Defibrillation Services will be issued a certificate with a unique service identification number by the OEMS.
 - 7.3.1 The copy of the certificate must be displayed in the immediate proximity of each SAED held by the Early Defibrillation Provider agency.
- 7.4 Triennial Re-certification
 - 7.4.1 Application for re-certification as an Early Defibrillation Service must be filed every three (3) years with the OEMS on forms prescribed and issued by the Office.
 - 7.4.1.1 The OEMS shall be responsible for issuing applications for re-certification to the Early Defibrillation Services within 90 days of certification expiration date.
- 7.5 Responsibility of the Service.
 - 7.5.1 The Service shall:
 - 7.5.1.1 Appoint a Service Coordinator to act as a liaison between the Service and the State Coordinator;
 - 7.5.1.2 Services must notify the OEMS of changes of any information contained in the original application within 14 days of the changes. This includes changes in the Service Coordinator or changes in equipment or operational procedure.
 - 7.5.1.3 Ensure defibrillators used by the service are of the type specified by this regulation.
 - 7.5.1.4 The Service shall supply appropriate resources to providers to assure the capability to comply with the reporting procedures required under this regulation.
- 7.6 Service De-certification
 - 7.6.1 The State EMS Medical Director may decertify an Early Defibrillation Service if the Service:
 - 7.6.1.1 Fails to comply with this regulation, or;
 - 7.6.1.2 Ceases to provide emergency response service.
- 7.7 Service Re-certification
 - 7.7.1 The State EMS Medical Director may grant re-certification as an Early Defibrillation Service to an agency provided such agency re-applies for certification under the procedure for initial certification as outlined in this section.

8.0 State Coordinator Responsibilities

- 8.1 The OEMS Director will appoint the State Coordinator.
- 8.2 The State Coordinator shall:
 - 8.2.1 Be responsible for administration and oversight of the Early Defibrillation Program.
 - 8.2.2 Establish Early Defibrillation Program regulations and administrative policies and ensure their enforcement.
 - 8.2.3 Review and evaluate written reports from Service Coordinators pertinent to data collection, statistical analysis and make recommendations for program improvement.
 - 8.2.4 On a quarterly basis, submit summary reports to the OEMS Director which shall include:
 - 8.2.4.1 Summary of data collected pertinent to patient age, sex, percentage of patients the SAED determined defibrillation was indicated and patient outcome;
 - 8.2.4.2 Variances received pertinent to regulations/policies and/or protocols utilized by providers, services or administration;
 - 8.2.4.3 Documented equipment malfunctions, and;
 - 8.2.4.4 Recommendations for modifications to the program and/or administrative regulations and policies.
 - 8.2.5 On an annual basis, submit a program report to the OEMS Director, which shall include:
 - 8.2.5.1 Information required in Section 8.2.4, and;
 - 8.2.5.2 Report of the programs medical director.
 - 8.2.6 In cooperation with the State EMS Medical Director and Service Coordinators, the State Coordinator shall:
 - 8.2.6.1 Ensure the Early Defibrillation Program is in compliance with this regulation;
 - 8.2.6.2 Establish QA/QI evaluation policies for the program and ensure said policies are enforced;
 - 8.2.6.3 Ensure compliance with the findings and recommendations of the QA/QI program;
 - 8.2.6.4 Immediately notify the State EMS Medical Director and the Service Coordinator if the competency of a provider puts the safety and welfare of the public at risk.

- 8.2.7 ~~Act as a liaison between the OEMS and the recognized training agencies, Training Centers, services, providers and medical facilities.~~

9.0 Service Coordinator

- 9.1 ~~The Service Coordinator will be appointed by the Service Director and shall:~~
 - 9.1.1 ~~Successfully completed an SAED training course;~~
 - 9.1.2 ~~Ensure all patient data reports are forwarded to the State Coordinator within 72 hours;~~
 - 9.1.3 ~~Assure that patient data reports are left at the receiving medical facility emergency department in a timely manner but no longer than 10 hours after the delivery of the patient to the facility;~~
 - 9.1.4 ~~Act as a liaison with the State Coordinator;~~
 - 9.1.5 ~~Assure that Early Defibrillation Providers receive appropriate training in:~~
 - 9.1.5.1 ~~The use and maintenance of the agency's SAED;~~
 - 9.1.5.2 ~~SAED program data collection, report writing and quality improvement.~~
 - 9.1.6 ~~Oversee training operations for the agency and maintain organizational training reports;~~
 - 9.1.7 ~~Annually submit training records with a list of all providers in the organization to the State Coordinator no later than January 30;~~
 - 9.1.8 ~~Ensure SAED equipment is maintained according to manufacturer and protocol specifications.~~
 - 9.1.9 ~~Ensure service compliance with this regulation;~~
 - 9.1.10 ~~Provide continuing education opportunities annually for Early Defibrillation Providers;~~
 - 9.1.11 ~~Verify credentials of personnel functioning as an early defibrillation provider within the agency represented;~~
 - 9.1.12 ~~Review each use of the AED;~~
 - 9.1.13 ~~Provide recommendations to the State Coordinator for improvements to the program.~~

10.0 Early Defibrillation Provider Requirements

- 10.1 ~~Guidelines for the validation of credentials of Early Defibrillation Providers are established by the Board of Medical Practice.~~
- 10.2 ~~Permission to participate as an Early Defibrillation Provider is approved by the Service Coordinator.~~
- 10.3 ~~Individuals requesting validation as an Early Defibrillation Provider shall:~~
 - 10.3.1 ~~Be at least 16 years of age at time of application;~~
 - 10.3.2 ~~Apply for SAED training through an SAED training agency recognized by the OEMS;~~
 - 10.3.3 ~~Present evidence to the Service Coordinator of satisfactory completion of an approved SAED training program.~~
- 10.4 ~~Each Early Defibrillation Provider is responsible for:~~
 - 10.4.1 ~~Maintaining employment or membership with an approved Early Defibrillation Service;~~
 - 10.4.2 ~~Complete an approved SAED renewal training program a minimum of every twenty-four (24) months;~~
 - 10.4.3 ~~Participate in continuing education programs as outlined in this regulation.~~
- 10.5 ~~Each Early Defibrillation Provider shall meet the following performance responsibilities.~~
 - 10.5.1 ~~Ensure duties are performed in accordance with the protocols established by the State Emergency Medical Services Medical Director;~~
 - 10.5.2 ~~Collect all data pertinent to patient care;~~
 - 10.5.3 ~~Complete required documentation of provider intervention in all cases of SAED use.~~
 - 10.5.4 ~~Leave a completed data report of SAED use with the patient care report at the time of delivery to the receiving medical facility or within 10 hours thereof.~~

11.0 Early Defibrillation Provider Training Requirements

- 11.1 ~~Program Supervision~~
 - 11.1.1 ~~Direction and supervision of an SAED training program will be managed by a training agency recognized by the OEMS and shall:~~
 - 11.1.1.1 ~~Ensure training programs comply with the requirements of this regulation;~~
 - 11.1.1.2 ~~Approve/disapprove program instructor qualification criteria;~~
 - 11.1.1.3 ~~Review criteria used to determine successful completion of the SAED training program;~~
 - 11.1.1.4 ~~Issue course completion cards to individuals who have successfully completed the training program.~~

11.2 Instructor Requirements.

11.2.1 Initial training and renewal courses shall be conducted by instructors who meet the following minimum standards for approval as SAED instructors and to maintain instructor status:

11.2.1.1 Are approved by a training agency recognized by the OEMS;

11.2.1.2 Are CPR Instructors as authorized by the training agency;

11.2.1.3 Have prior teaching experience in out-of-hospital emergency care;

11.2.1.4 Have successfully completed an SAED instructor training program approved by the State EMS Medical Director;

11.2.1.5 Have instructor participation in a minimum of two (2) SAED training courses per calendar year.

11.3 SAED Training Curriculum.

11.3.1 The SAED training curriculum shall include at a minimum, basic theory and practice in the following subject areas:

11.3.1.1 Introduction to early defibrillation;

11.3.1.2 Patient assessment and evaluation;

11.3.1.3 Cardiac anatomy and physiology;

11.3.1.4 Cardiac defibrillation and program protocols;

11.3.1.5 CPR and its relationship to defibrillation;

11.3.1.6 Skills practice;

11.3.1.7 Practical skills demonstration.

11.3.2 SAED training curricula must be submitted to the OEMS for approval by the State EMS Medical Director.

11.4 Instructor administrative requirements.

11.4.1 At the completion of each course the instructor shall:

11.4.1.1 Sign the class roster verifying student demonstration of skills;

11.4.1.2 Submit to the appropriate Service Coordinator for retention:

11.4.1.2.1A record of the class roster;

11.4.1.2.2A list of students successfully completing the course;

11.4.1.2.3A record of student performance.

11.5 Training Sites

11.5.1 Early Defibrillation initial, renewal and continuing education courses will be scheduled by the Service at a site appropriate for training and coordinated with an approved training center.

11.6 Continuing Education

11.6.1 Each Early Defibrillation Service shall provide continuing education on an annual basis.

11.6.2 Continuing education may consist of, but is not limited to:

11.6.2.1 Case reviews;

11.6.2.2 CPR renewal as necessary;

11.6.2.3 Provider demonstration of competent performance in the protocols and equipment in a simulated cardiac arrest situation;

11.6.2.4 Review of documentation and SAED equipment features;

11.6.2.5 Additional training as required by the Service or State EMS Medical Director.

11.6.3 Continuing education shall be no less than 2 hours annually.

12.0 Provider Right to Practice

12.1 Early defibrillation providers trained under the provisions outlined in Section 11 and affiliated with a recognized Early Defibrillation Service per Section 7 receive the right to practice as an Early Defibrillation provider under the Medical Direction provisions of Section 6.

12.2 The State EMS Medical Director may propose to suspend or revoke the right to practice of an Early Defibrillation Provider with cause.

12.3 The State EMS Medical Director must provide the provider with prior written notice of the proposed action and the opportunity for a hearing if the Medical Director deems:

12.3.1 The provider did not meet the eligibility requirements as outlined in this regulation;

12.3.2 The right to practice was obtained through error or fraud;

12.3.3 Provisions of this regulation were violated;

12.3.4 The Early Defibrillation Provider has engaged in conduct detrimental to the health or safety of a patient or to members of the general public during a period of emergency care or transport.

12.4 Emergency Suspension of the Right to Practice

12.4.1 The State EMS Medical Director may summarily suspend a provider's right to practice when there is a risk of serious harm or death if a provider retains his right to practice.

12.4.2 The State Coordinator may recommend to the State EMS Medical Director to suspend a provider's right to practice for a period not to exceed sixty (60) days.

12.4.3 The OEMS shall:

12.4.3.1 Provide written notice to the provider of the suspension which will:

12.4.3.1.1 Outline proposed additional action or actions and;

12.4.3.1.2 Contain a written notice of the right to request a hearing.

12.4.3.2 Conduct an investigation coordinated with the Service Coordinator.

12.4.3.3 Provide the opportunity for a prompt hearing on the summary suspension.

12.5 Provider Right to a Hearing

12.5.1 In the event the State EMS Medical Director proposes to suspend or revoke a provider's right to practice, the applicant or provider may request a hearing, in writing, to the OEMS within ten (10) days after date of notice.

12.5.2 The OEMS shall:

12.5.2.1 Schedule a hearing no later than twenty (20) working days after receiving a request for hearing.

12.5.2.1.1 The hearing committee shall be comprised of the State Paramedic Administrator, a county EMS Medical Director from a county other than one in which the provider works, the State Coordinator and a Service Coordinator;

12.5.2.1.2 The State Paramedic Administrator will preside over the hearing;

12.5.2.1.3 The Service Coordinator will be from a service other than the provider's.

12.5.2.2 Issue a final decision, in writing to the provider, within ten (10) working days after the hearing.

13.0 Defibrillation Equipment

13.1 Defibrillator Model

13.1.1 Defibrillators acceptable for use in the State of Delaware will:

13.1.1.1 Be FDA approved;

13.1.1.2 Be of the semi-automatic type requiring provider intervention to initiate a defibrillation shock;

13.1.1.3 Be capable of automatically collecting data;

13.1.1.4 Be capable of producing a printed summary report as approved by the State EMS Medical Director.

13.1.2 Defibrillators must be approved by the State EMS Medical Director prior to purchase.

13.1.3 SAED's utilizing alternate waveform technologies are approved for use provided that the treatment algorithm has been approved by the FDA.

13.2 Defibrillator Modifications

13.2.1 No modifications are to be made to defibrillation equipment, by a provider or the service, which results in:

13.2.1.1 Deviation from the original manufacturer's specifications;

13.2.1.2 Deviation from Early Defibrillation Program protocols.

13.2.2 Protocol changes may only be authorized by the State EMS Medical Director.

13.2.3 Necessary defibrillator modifications shall be coordinated by the Service Coordinator.

13.3 Defibrillator Preventative Maintenance/Repairs

13.3.1 All components of the defibrillator and integrated data recording system shall be inspected by a qualified service technician at least one (1) time per calendar year or as recommended by the manufacturer to ensure:

13.3.1.1 The equipment meets original manufacturer's specifications, and;

13.3.1.2 The equipment maintains the currently approved program protocols.

13.3.2 The battery and data recording systems of the SAED shall be maintained and replaced in accordance with manufacturer's specifications.

13.3.3 All maintenance and repairs shall be performed by a qualified service technician recognized by the manufacturer.

~~13.3.4 Early Defibrillation Services shall maintain written records of all maintenance, repairs and inspections performed on defibrillation equipment.~~

~~13.4 Defibrillator Pre-hospital Use~~

~~13.4.1 In the event any non-EMS/Fire or police service provider agency employs a SAED, the local 911/emergency response system must be immediately activated.~~

~~13.4.2 During pre-hospital use of SAED equipment, the following guidelines will be used:~~

~~13.4.2.1 Providers may use only self-adhering electrodes or pads with the SAED;~~

~~13.4.2.2 Monitoring electrodes or pads shall be attached to the patient, and;~~

~~13.4.2.3 The integrated data recording system shall be in operation;~~

~~13.4.2.4 Data recording will begin upon initial application of the SAED and may not be terminated until:~~

~~13.4.2.4.1 The patient is disconnected from the SAED either by service providers upon spontaneous return of patient cardiac function, or;~~

~~13.4.2.4.2 The patient is disconnected by paramedics or hospital personnel during transfer to a cardiac monitor.~~

~~13.5 Financial Responsibility~~

~~13.5.1 Purchase of SAED units, electrodes or pads, data collection hardware/software, and any required inspections, repairs or replacement parts shall be the sole responsibility of the service.~~

~~4 DE Reg. 1543 (03/01/01)~~

~~**Appendix
The Delaware Early Defibrillation Program Regulations
Early Defibrillation Program Protocols**~~

~~**1.0 The protocols are designed under which the early defibrillation provider may administer defibrillation as a component of their emergency care to the cardiac arrest victim. Voice contact with an on-line medical control physician is not required for certified personnel to implement this protocol.**~~

~~**2.0 This protocol is specific to the type of defibrillator used in the program.**~~

~~**3.0 The provider standing orders are as follows:**~~

~~3.1 The indication for the application and/or use of the SAED is cardiac arrest.~~

~~3.2 Assess the scene for safety. Also assess the surroundings for a possible cause of the arrest.~~

~~3.3 Establish that cardiac arrest has occurred. Before the SAED can be attached, the patient must be:~~

~~3.3.1 Unresponsive;~~

~~3.3.2 Pulseless; and~~

~~3.3.3 Apneic~~

~~3.4 Begin resuscitation efforts, including Cardiopulmonary Resuscitation (CPR). Make certain that 911 has been called.~~

~~3.5 Connect the patient to the SAED. Do not delay for the purpose of placing adjunct airway devices or mechanical CPR devices.~~

~~3.6 Stop CPR, clear away from the patient, and initiate analysis of the patient's cardiac rhythm. If the SAED determines that defibrillation is indicated, the unit shall automatically charge to 200 joules and prompt the provider to deliver the shock. It is the provider's responsibility to assure that all individuals are clear from the patient prior to delivery of the counter shock.~~

~~NOTE: Different energy levels are acceptable in AED's using alternate waveform technology providing the AED and treatment algorithm have been approved by the FDA.~~

~~3.7 Immediately re-analyze the RHYTHM, and if indicated, deliver a second counter shock at 300 joules.~~

~~3.8 Again, re-analyze the RHYTHM, and if indicated, deliver a third counter shock at 360 joules.~~

~~3.9 If no pulse is present, perform CPR for one (1) minute. At the end of one minute check for a pulse, and if no pulse, re-analyze the RHYTHM and, if indicated, defibrillate at 360 joules.~~

~~3.10 Immediately re-analyze the RHYTHM, and if indicated, deliver a second counter shock at 360 joules.~~

~~3.11 Immediately re-analyze the RHYTHM, and if indicated, deliver a third counter shock at 360 joules.~~

~~3.12 If no pulse is present, continue CPR.~~

- 3.13 ~~If a paramedic unit has not yet arrived on the scene, transport to the closest appropriate medical receiving facility should commence without delay. Contact medical control while en route for additional orders, such as additional countershocks.~~
- 3.14 ~~For non-EMS SAED providers, continue CPR and repeat rhythm analysis and shock sequence until EMS arrives. Re-contact the 911 center to assure that help is on the way.~~
- 3.15 ~~Complete the data management form.~~

4303 Automatic External Defibrillation

1.0 Purpose

- 1.1 This regulation establishes:
 - 1.1.1 The criteria for administering semi-automatic external cardiac defibrillation by the general public in the pre-hospital environment.
 - 1.1.2 The State Emergency Medical Director's standards and training requirements for authorized semi-automatic external defibrillation equipment throughout the State of Delaware.
 - 1.1.3 The procedures to assure quality assurance and uniform data collection.

2.0 Authority

This regulation is written and promulgated by the Delaware Department of Health and Social Services pursuant to 16 Del.C. Chapter 9705 and 16 Del.C. Chapter 30C.

3.0 Definitions

"CPR": Cardiopulmonary Resuscitation

"FDA": Federal Food and Drug Administration

"First Responder Team": An organized group of individuals within a Public Access Defibrillation agency designated by that agency to respond to emergency situations.

"Office or OEMS": The Delaware State Office of Emergency Medical Services

"SAED": Semi-Automatic External Defibrillator. A device capable of, (1) analyzing cardiac rhythm, (2) determining the need for defibrillation, (3) automatically charging, and (4) advising a provider to deliver an electrical impulse.

"Service Coordinator": The appointed possessor of an SAED who coordinates the agency's Early Defibrillation Program.

"State Coordinator": The Director of the State Office of Emergency Medical Services appointee who administers the Early Defibrillation Program at the state level.

"State Medical Director": The State Office of Emergency Medical Services State EMS Medical Director who provides medical control supervision and quality control for the Early Defibrillation Program.

"The Board": The Delaware Board of Medical Licensure and Discipline.

4.0 General Provisions

- 4.1 This regulation applies to any organization or individuals participating in the Delaware Early Defibrillation Program.
- 4.2 The OEMS, or its designee, shall retain the right to inspect any Early Defibrillation Service's state funded defibrillation equipment or any records or documentation associated with that agency's Early Defibrillation Program.
- 4.3 Semi-Automated External Defibrillators are classified as medical devices by the Delaware Board of Medical Licensure and Discipline.
- 4.4 SAED manufacturers, their representatives or agents are required to notify the OEMS of the sale and placement of an SAED within the State of Delaware.
- 4.5 The OEMS shall be responsible for notifying the jurisdictional public safety answering point of the placement of an SAED within the boundaries of their jurisdiction
- 4.6 SAED Providers, SAED agencies and SAED training organizations have limited immunity protection as specified in Chapter 11 of this regulation.

5.0 Eligibility

- 5.1 Any individual, agency, school, organization or business, within the State of Delaware is eligible to become an Early Defibrillation Service.
- 5.2 Any agency, school, organization or business from another state operating within the State of Delaware, is eligible to become an Early Defibrillation Service as approved by the State Emergency Medical Services Medical Director.

6.0 Early Defibrillation Service Requirements

- 6.1 Agencies, schools, corporations or businesses desiring to provide Early Defibrillation Services must make application to the OEMS prior to implementation of the program.
- 6.2 Information to be provided with the application package shall include:
 - 6.2.1 OEMS approved application;
 - 6.2.2 Other information as required by the OEMS
- 6.3 Responsibility of the Service
 - 6.3.1 The Service shall:
 - 6.3.1.1 Appoint a Service Coordinator to act as a liaison between the Service and the State Coordinator
 - 6.3.1.2 Services must notify the OEMS of changes of any information contained in the original application within 14 days of the changes. This includes changes in the Service Coordinator or changes in equipment or operational procedure.
 - 6.3.1.3 Ensure defibrillators used by the service are of the type specified by this regulation.
 - 6.3.1.4 The Service shall supply appropriate resources to providers to assure the capability to comply with the reporting procedures required under this regulation.

7.0 State Coordinator Responsibilities

- 7.1 A State Coordinator shall be appointed by the State EMS Director.
- 7.2 Act as a liaison between the OEMS and the recognized training agencies, services, providers and medical facilities.

8.0 Service Coordinator

Will have successfully completed an SAED training course;

9.0 Early Defibrillation Provider Requirements

- 9.1 Guidelines for the validation of credentials of Early Defibrillation Providers are established by the Board of Medical Licensure and Discipline.
- 9.2 Individuals requesting validation as an Early Defibrillation Provider shall:
 - 9.2.1 Apply for SAED training through an SAED training agency recognized by the OEMS;

10.0 Defibrillation Equipment

- 10.1 Defibrillators acceptable for use in the State of Delaware will:
 - 10.1.1 Be FDA approved;
 - 10.1.2 Be of the semi-automatic type requiring provider intervention to initiate a defibrillation shock or other device as approved by the State EMS Medical Director.
 - 10.1.3 Be capable of automatically collecting data;
 - 10.1.4 Be capable of producing a printed summary report as approved by the State EMS Medical Director.
 - 10.1.5 SAED's utilizing alternate waveform technologies are approved for use provided that the treatment algorithm has been approved by the FDA.
- 10.2 Defibrillation Equipment Modification
 - 10.2.1 No modifications are to be made to defibrillation equipment, by a provider on the service, which results in:
 - 10.2.1.1 Deviation from the original manufacturer's specification;
 - 10.2.1.2 Deviation from Early Defibrillation Program protocols.
 - 10.2.2 Defibrillation Protocol changes may only be authorized by the State EMS Medical Director.
 - 10.2.3 Necessary defibrillator modifications shall be coordinated by the Service Coordinator.
 - 10.2.4 Defibrillator preventive maintenance will be maintained in accordance with manufacturer's recommendations

10.3 Financial Responsibility

10.3.1 Purchase of SAED units, electrodes or pads, data collection hardware/software and any required inspections, repairs or replacement parts shall be the sole responsibility of the service.

11.0 Provisions of Limited Immunity Protections

Persons using an SAED in attempt to resuscitate another person have limited immunity protection under 16 Del.C. Chapter 3005C.

12.0 SAED Deployment Guidelines

12.1 SAEDs are used in cases of cardiac arrest.

12.2 SAED providers shall follow the most current American Heart Association/Emergency Cardiac Care Committee guidelines and/or additional guidelines as promulgated by the State EMS Medical Director.

12.3 EMS and First Responder Agencies must transport to the closest appropriate medical facility when a paramedic unit has not arrived on the scene.

12.3.1 EMS and First Responder agencies must contact medical control while enroute for additional orders.

12.4 Non-EMS/First Responders must continue CPR and repeat rhythm analysis until EMS arrives.

12.4.1 Non-EMS/First Responders must re-contact 911 assuring help is on the way.

12.5 Complete the SAED download data management form.

12.5.1 For non-EMS/First Responders without download capabilities:

12.5.1.1 Turn the SAED over to the responding EMS agency for data download.

12.5.1.2 After the data has been downloaded and printed out have the EMS agency return the SAED to the owner agency.

12.5.1.3 Send a hard copy of all data downloads to the State AED Coordinator.

4 DE Reg. 1543 (03/01/01)

17 DE Reg. 438 (10/01/13) (Final)