

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
Emergency Medical Services

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" means Cardiopulmonary Resuscitation

"FDA" means Federal Food and Drug Administration

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

"Office or OEMS" means the Delaware State Office of Emergency Medical Services

"SAED" means 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" means the appointed possessor of an SAED who coordinates the agency's Early Defibrillation Program.

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

"State Medical Director" means 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" means 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

TITLE 16 HEALTH AND SAFETY

DELAWARE ADMINISTRATIVE CODE

- 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 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 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:
 - 7.1.1 Be appointed by the State EMS Director.
 - 7.1.2 Act as a liaison between the OEMS and the recognized training agencies, services, providers and medical facilities.

8.0 Service Coordinator

A 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)