

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

PROPOSED

PUBLIC NOTICE

4303 Automatic External Defibrillation

Pursuant to 16 **Del.C.** §9705(p)(1), the Department of Health and Social Services, Division of Public Health, Emergency Medical Services Section, is proposing revisions to the regulations governing automatic external defibrillation (16 **DE Admin. Code** 4303).

The proposed amendments will introduce several important changes to better serve and protect Delawareans. Changes include, but are not limited to, updates to the definitions section, AED/SAED deployment guidelines, and additional technical changes to bring the regulation into compliance with the *Delaware Administrative Code Style Manual*.

Copies of the proposed regulation are available for review in the June 1, 2025, issue of the *Delaware Register of Regulations*, accessible online at: <http://regulations.delaware.gov> or by calling the Division of Public Health at 302-744-4951.

Public comments will be accepted until 4:30 PM on July 1, 2025. Comments will be accepted in written form via email to DHSS_DPH_regulations@delaware.gov, or by U.S. mail to the following address:

Vicki Schultes, Hearing Officer
Division of Public Health
417 Federal Street
Dover, DE 19901

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 Ch. 9705 and 16 **Del.C.** Chapter Ch. 30C.

3.0 Definitions

The following words and terms, when used in this regulation, have the following meaning:

"AED" means an automated external defibrillator, which is 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 or automatically deliver an impulse to restore the sudden cardiac arrest victim to a normal sinus rhythm.

"CPR" means Cardiopulmonary Resuscitation cardiopulmonary resuscitation.

"Delaware Early Defibrillation Program" means a coordinated program provides early access to defibrillation for individuals experiencing sudden cardiac arrest using automated external defibrillation and related care.

"Early defibrillation service" means a person or agency who is registered to provide care to victims of cardiac arrest, who wishes to employ or retain personnel within their organization who are trained in the use of automated external defibrillation and related care.

"Emergency Medical Service" or "EMS" means an ambulance, paramedic or prehospital service that provide urgent prehospital treatment and stabilization for serious illness or injuries and transport to definitive care facilities.

"FDA" means Federal the Food and Drug Administration of the U.S. federal government.

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

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

"SAED" means ~~Semi-Automated External Defibrillator~~. A semi-automatic external defibrillator, an electronic device capable of, of: (1) analyzing cardiac rhythm, (2) determining the need for defibrillation, (3) automatically charging, and (4) advising a provider to deliver an electrical impulse to restore the sudden cardiac arrest victim to a normal sinus rhythm.

"Service" means an organization that provides an early defibrillation program.

"Service Coordinator coordinator" means the appointed possessor of an SAED who coordinates the agency's ~~Early Defibrillation Program~~ an organization'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 Delaware 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~~ individual 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~~ early defibrillation service's State funded defibrillation equipment or any records or documentation associated with that agency's ~~Early Defibrillation Program~~ early defibrillation program.
- 4.3 ~~Semi-Automated External Defibrillators~~ Automated or semi-automated external defibrillators are classified as medical devices by the Delaware Board of Medical Licensure and Discipline.
- 4.4 ~~SAED manufacturers, AED manufacturers and~~ 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 AED/SAED~~ AED/SAED within the boundaries of their ~~jurisdiction~~ jurisdiction.
- 4.6 ~~SAED Providers, SAED agencies and SAED AED/SAED providers, agencies, and~~ training organizations have limited immunity protection as specified in ~~Chapter 41~~ Section 11.0 of this regulation.

5.0 Eligibility

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

6.0 Early Defibrillation Service Requirements

- 6.1 Agencies, schools, ~~corporations~~ corporations, or businesses desiring to provide ~~Early Defibrillation Services~~ 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 The OEMS approved application; and
 - 6.2.2 Other information as required by the OEMS.
- 6.3 Responsibility of the Service
 - 6.3.1 The ~~Service~~ service shall:
 - 6.3.1.1 Appoint a ~~Service Coordinator~~ service coordinator to act as a liaison between the ~~Service~~ 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~~ 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~~ providers, and medical facilities.

8.0 Service Coordinator

A Service Coordinator ~~will~~ shall 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~~ early defibrillation providers are established by the Board of Medical Licensure and Discipline.
- 9.2 Individuals requesting validation as an ~~Early Defibrillation Provider~~ shall: early defibrillation provider shall apply for AED/SAED training through a training agency recognized by the OEMS.
 - 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~~ shall:
 - 10.1.1 Be FDA approved;
 - 10.1.2 Be of the ~~semi-automatic~~ automated type requiring no provider intervention to deliver an electrical impulse, or be of the semi-automated type requiring provider intervention to initiate a defibrillation shock or other device as an electrical impulse approved by the State EMS Medical Director; 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~~ in the service, which results in:
 - 10.2.1.1 Deviation from the original manufacturer's specification; or
 - 10.2.1.2 Deviation from Early Defibrillation Program protocols.
 - 10.2.2 Defibrillation ~~Protocol~~ 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~~ service coordinator.
 - 10.2.4 Defibrillator preventive maintenance will be maintained in accordance with manufacturer's recommendations.
- 10.3 ~~Financial Responsibility~~ Responsibility.
 - 10.3.1 ~~Purchase of SAED~~ AED/SAED units, electrodes or pads, data collection ~~hardware/software~~ hardware/ software, and any required inspections, ~~repairs~~ repairs, or replacement parts shall be the sole responsibility of the service.

11.0 Provisions of Limited Immunity Protections

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

12.0 SAED AED/SAED Deployment Guidelines

- 12.1 ~~SAEDs~~ AEDs/SAEDs are to be used in cases of cardiac arrest and in accordance with manufacturer's guidelines only.

- 12.2 SAED AED/SAED providers shall follow the most current American Heart Association/Emergency Cardiac Association's Emergency Cardiovascular Care Committee guidelines ~~and/or~~ and additional guidelines as promulgated by the State EMS Medical Director.
- 12.3 ~~EMS and First Responder Agencies~~ first responder agencies must transport to the closest appropriate medical facility when a paramedic unit has not arrived on the scene.
- ~~12.3.4~~ EMS and ~~First Responder~~ first responder agencies must contact medical control while enroute for additional orders.
- 12.4 ~~Non-EMS/First Responders~~ 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~~ Non-EMS/first responders must redial 911 until confirmation that help is on the way is established.
- 12.5 ~~Complete the SAED download data management form.~~ the public access AED use report as follows:
- 12.5.1 ~~For non-EMS/First Responders~~ Non-EMS/first responders without download capabilities: capabilities shall complete the public access AED use report and restock the AED/SAED. The AED/SAED shall be placed back in service and ready for use.
- 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.~~
- 12.5.2 Non-EMS/first responders with download capabilities shall complete the public access AED use report, download/print the AED report, and send a copy of all the data to the State AED coordinator.
- 12.5.3 EMS/first responders shall include all AED data in the patient care/police documentation. Police and correction agencies shall forward all AED documentation to the State Coordinator.

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

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

28 DE Reg. 849 (06/01/25) (Prop.)