

Medical Direction & Oversight for CA AED's

Although AEDs are designed for use by laypeople with minimal training, they are classified as medical devices by the U.S. Food and Drug Administration (FDA) and most cannot be purchased without a prescription from a physician. However a physician is required to serve as the "medical director" of an AED Program. He or she is not expected to be on the scene when AEDs are used, but provides ongoing medical oversight.

The medical director provides the "standing orders" to be followed in the case of a medical emergency. The physician may sign off on training plans and policies and procedures, update them to take into account new treatment recommendations, evaluate data recorded on an AED during a medical emergency, and help assess each use of an AED to suggest any improvements. Also Medical Direction and Oversight creates another layer of protection from lawsuits. **Even if a Prescription is not required, Medical Direction is required in the State of California.**

Below is the full information on the California Code of Regulations regarding AED's. However, here is a brief description of what is necessary to owning an AED.

1. You need Medical Direction/Supervision
2. You need to train your staff in CPR/AED classes
3. You need to call 911 during an emergency.
4. You need to service your AED

Effective January 8, 2009

California Code of Regulations
Title 22. Social Security
Division 9. Prehospital Emergency Medical Services
Chapter 1.8. Lay Rescuer Automated External Defibrillator Regulations

Article 1. Definitions

§ 100031. AED Service Provider.

"AED Service Provider" means any agency, business, organization or individual who purchases an AED for use in a medical emergency involving an unconscious, person who is not breathing. This definition does not apply to individuals who have been prescribed an AED by a physician for use on a specifically identified individual.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

§ 100032. Lay Rescuer

"Lay Rescuer" means any person, not otherwise licensed or certified to use the automated external defibrillator, who has met the training standards of this chapter.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code, Section 1714.21, Civil Code.

§ 100033. Automated External Defibrillator.

"Automated external defibrillator" or "AED" means an external defibrillator that after user activation is capable of cardiac rhythm analysis and will charge and deliver a shock, either automatically or by user interaction, after electronically detecting and assessing ventricular fibrillation or rapid ventricular tachycardia. Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

§ 100034. Cardiopulmonary Resuscitation.

"Cardiopulmonary resuscitation" or "CPR" means a basic emergency procedure for life support, consisting of artificial respiration, manual external cardiac massage, and maneuvers for relief of foreign body airway obstruction.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

§ 100035. Internal Emergency Response Plan.

“Internal Emergency Response Plan” means a written Internal Emergency Response Plan of action which utilizes responders within a facility to activate the “9-1-1” emergency system, and which provides for the access, coordination, and management of immediate medical care to seriously ill or injured individuals.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

§ 100036. Medical Director.

“Medical Director” means a physician and surgeon, currently licensed in California, who provides medical oversight to the AED Service Provider as set forth in Section 100040.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

Article 2. General Training Provisions

§ 100037. Application and Scope.

(a) Any training program, AED Service Provider or vendor may authorize a Lay Rescuer to apply and operate an AED on an unconscious person who is not breathing only if that Lay Rescuer has successfully completed a CPR and AED course according to the standards prescribed by this chapter.

(b) The training standards prescribed by this chapter shall apply to employees of the AED Service Provider and not to licensed, certified or other prehospital emergency medical care personnel as defined by Section 1797.189 of the Health and Safety Code.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.189, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

Article 3. AED Training Program Requirements

§ 100038. Required Topics and Skills.

(a) CPR and AED training shall comply with the American Heart Association or American Red Cross CPR and AED guidelines. The training shall include the following topics and skills:*(ASHI programs have been found acceptable for meeting requirements established by a wide variety of accreditation organizations, professional associations, councils, academies and boards. ASHI resuscitation programs for basic and advanced life support are based on the same scientific guidelines and treatment recommendations used by the American Heart Association (AHA) and American Red Cross (ARC) for course development (2010 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations Circulation)*

(1) basic CPR skills;

(2) proper use, maintenance and periodic inspection of the AED;

(3) the importance of:

(A) early activation of an Internal Emergency Response Plan,

(B) early CPR,

(C) early defibrillation,

(D) early advanced life support, and

(E) internal emergency response plan, if applicable;

(4) overview of the local EMS system, including 9-1-1 access, and interaction with EMS personnel;

(5) assessment of an unconscious patient, to include evaluation of airway and breathing, to determine appropriateness of applying and activating an AED;

(6) information relating to defibrillator safety precautions to enable the individual to administer shock without jeopardizing the safety of the patient or the Lay Rescuer or other nearby persons to include, but not be limited to;

(A) age and weight restrictions for use of the AED,

(B) presence of water or liquid on or around the victim,

(C) presence of transdermal medications, and

(D) implantable pacemakers or automatic implantable cardioverter-defibrillators;

(7) recognition that an electrical shock has been delivered to the patient and that the defibrillator is no longer charged;

(8) rapid, accurate assessment of the patient’s post-shock status to determine if further activation of the AED is necessary; and,

(9) the responsibility for continuation of care, such as continued CPR and repeated shocks, as indicated, until the arrival of more medically qualified personnel.

(b) The Lay Rescuer shall maintain current CPR and AED training, as prescribed in this Chapter.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

§ 100039. Testing.

CPR and AED training for Lay Rescuers shall include a competency demonstration of skills on a manikin, directly observed by an instructor which tests the specified conditions prescribed in Section 100038.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

Article 4. Operational AED Service Provider and Vendor Requirements

§ 100040. Medical Director Requirements

Any AED Service Provider shall have a physician Medical Director who:

- (a) Meets the qualifications of a Medical Director per Section 100036 of this Chapter.
- (b) Shall ensure that AED Service Provider's Lay Rescuer CPR and AED training meets the requirements of this Chapter.
- (c) Shall review each incident where emergency care or treatment on a person in cardiac arrest is rendered and to ensure that the Internal Emergency Response Plan, along with the CPR and AED standards that the Lay Rescuer was trained to, were followed.
- (d) Is involved in developing an Internal Emergency Response Plan and to ensure compliance for training, notification and maintenance as set forth in this Chapter.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

§100041. AED Service Provider Operational Requirements.

(a) An AED Service Provider shall ensure their internal AED programs include all of the following:

- (1) Development of a written Internal Emergency Response Plan which describes the procedures to be followed in the event of an emergency that may involve the use of an AED and complies with the regulations contained in this Chapter. The written Internal Emergency Response Plan shall include, but not be limited to, immediate notification of 9-1-1 and trained office personnel at the start of AED procedures.
- (2) Maintain AEDs in working order and maintain current protocols on the AEDs.
- (3) That all applicable local EMS policies and procedures are followed.
- (4) That Lay Rescuers complete a training course in CPR and AED use and maintain current CPR and AED training that complies with requirements of this Chapter at a minimum of every two years and are familiar with the Internal Emergency Response Plan.
- (5) For every AED unit acquired up to five units, no less than one Lay Rescuer per AED unit shall complete a training course in CPR and AED use that complies with the requirements of this chapter. After the first five AED units are acquired, one Lay Rescuer shall be trained for each additional five AED units acquired. AED Service Providers shall have Lay Rescuers who should be on site to respond to an emergency that may involve the use of an AED unit during normal operating hours.
- (6) That the defibrillator is maintained and regularly tested according to the operation and maintenance guidelines set forth by the manufacturer, and according to any applicable rules and regulations set forth by the governmental authority under the federal Food and Drug Administration and any other applicable state and federal authority.
- (7) That the defibrillator is maintained and regularly tested according to the operation and maintenance guidelines set forth by the manufacturer, and according to any applicable rules and regulations set forth by the governmental authority under the federal Food and Drug Administration and any other applicable state and federal authority.
- (8) That a mechanism exists to ensure that any person, either a Lay Rescuer as part of the AED Service Provider, or member of the general public who renders emergency care or treatment on a person in cardiac arrest by using the service provider's AED activates the emergency medical services system as soon as possible, and reports any use of the AED to the Medical Director and the local EMS agency.
- (9) That there is involvement of a currently licensed California physician and surgeon that meets the requirements of Section 100040 of this Chapter.
- (10) That a mechanism exists that will assure the continued competency of the CPR and AED trained individuals in the AED Service Provider's employ to include periodic training and skills proficiency demonstrations.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code.

Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

§100042. AED Vendor Requirements

Any AED vendor who sells an AED to an AED Service Provider shall notify the AED Service Provider, at the time of purchase, both orally and in writing of the AED Service Provider's responsibility to comply with the regulations contained in this Chapter.

- (a) Notify the local EMS agency of the existence, location, and type of AED at the time it is acquired.
- (b) Provide to the acquirer of the AED all information governing the use, installation, operation, training, and maintenance of the AED.

Note: Authority cited: Sections 1797.107 and 1797.190, Health and Safety Code.

Reference: Sections 1797.5, 1797.190, 1797.196, and 104113, Health and Safety Code. Section 1714.21, Civil Code.

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