

**California Code of Regulations
Title 22. Social Security
Division 9. Prehospital Emergency Medical Services
Chapter 1.9. Lay Rescuer Epinephrine Auto-injector Training Certification
Standards**

Article 1. Definitions.

§ 100044 Anaphylaxis.

“Anaphylaxis” means a potentially life-threatening hypersensitivity or allergic reaction.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code.

§ 100044.1. Approved Training Program.

“Approved training program” means a training program that is approved by the EMS Authority to provide epinephrine auto-injector training.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code.

§ 100044.2. Authorized Health Care Provider.

“Authorized Health Care Provider” means a currently licensed health care professional who is legally authorized in California to issue a prescription for or dispense an epinephrine auto-injector to an individual who meets the requirements of Section 100046 of this Chapter.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code.

§ 100044.3. Authorized Training Provider.

“Authorized training provider” or “instructor” means an individual who is authorized by an approved training program to provide epinephrine auto-injector training as approved by the EMS Authority and who meets the requirements set forth in Section 100050 of this Chapter.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code.

§ 100044.4. Automated External Defibrillator.

“Automated external defibrillator” or “AED” means an external defibrillator capable of cardiac rhythm analysis which 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: Section 1797.107, Health and Safety Code. Reference: Sections 1797.5, 1797.190, 1797.196, 1797.197 and 1797.197a, Health and Safety Code and Section 1714.23, Civil Code.

§ 100044.5. Cardiopulmonary Resuscitation.

“Cardiopulmonary resuscitation” (CPR) means ensuring adequate circulation either spontaneously or by means of closed chest cardiac compression, establishing and maintaining an open airway, and ensuring adequate ventilation equivalent to current standards promulgated by the American Heart Association’s (AHA) Guidelines for CPR and Emergency Cardiovascular Care (ECC) or the American Red Cross.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code; and Section 1714.23, Civil Code.

§ 100044.6. Certification of Training.

“Certification of training” means the certification card issued by the EMS Authority to an individual who satisfies the requirements outlined in Section 100046.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code.

§ 100044.7. Epinephrine Auto-injector.

“Epinephrine auto-injector” means a disposable drug delivery system with a spring-activated needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a and Section 1714.23, Civil Code.

§ 100044.8. Lay Rescuer.

“Lay rescuer” means any person who has met the training standards and other requirements of this Chapter but who is not otherwise licensed or certified to use an epinephrine auto-injector on another person.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code; and Section 1714.23, Civil Code.

§ 100044.9. Prehospital Emergency Medical Care Person.

“Prehospital emergency medical care person” means any of the following: authorized registered nurse, mobile intensive care nurse, nurse practitioner, nurse midwives, clinical nurse specialist, nurse anesthetists, physician assistant, emergency medical technician, advanced emergency medical technician, paramedic, lifeguard, firefighter, peace officer, or a physician and surgeon who provides prehospital emergency medical care or rescue services.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.56, 1797.80, 1797.82, 1797.84, 1797.182, 1797.183, 1797.189, 1797.197 and 1797.197a, Health and Safety Code; and Section 1714.23, Civil Code.

§ 100044.10. Training Program Director.

“Training program director” means the person who is designated in the application as the director and who provides oversight of the approved training program as set forth in Section 100049 of this Chapter.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code.

Article 2. Certification Requirements.

§ 100045. Application and Scope.

(a) Upon certification by the EMS Authority as defined in Section 100044.6 a lay rescuer, or off-duty prehospital emergency medical care personnel are authorized to administer an epinephrine auto-injector to treat a person who is suffering or reasonably believed to be suffering from anaphylaxis under the following conditions:

(1) The epinephrine auto-injector is legally obtained by prescription from an authorized health care provider who may issue a prescription for an epinephrine auto-injector to a person described in this subdivision for the purpose of rendering emergency care to another person upon presentation of current and valid certification card issued by the EMS Authority, and

(2) The epinephrine auto-injector is used on an individual, with the express or implied consent of that person, to treat anaphylaxis, and

(3) The epinephrine auto-injector is stored and maintained as directed by the manufacturer’s instructions for that product, and

(4) The emergency medical services system is activated as soon as practical when an epinephrine auto-injector is used.

(b) Certified persons shall make, maintain, and make available to EMSA upon request a record for five years reflecting:

(1) Dates of receipt, use and destruction of each auto-injector dispensed, and

(2) The name of any person to whom epinephrine was administered by using an auto-injector, and

(3) The circumstances and manner of disposal of any auto-injectors.

(c) The training standards prescribed by this Chapter shall apply to lay rescuers and off duty prehospital emergency medical care personnel.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code, 4119.3 of the Business and Professions Code.

§ 100046. Certification Requirements.

(a) An individual who meets all of the following criteria shall be eligible for certification by the EMS Authority:

(1) Successful completion of training from an epinephrine auto-injector training program approved pursuant to Section 100047 of this Chapter, and

(2) Course completion document provided by the training program and signed by the class instructor and,

(3) Current certification in CPR and AED for infants, children and adults equivalent to the current standards of the American Red Cross and/or the AHA Guidelines for CPR and ECC and,

(4) Payment of all fees pursuant to Section 100054 of this Chapter and,

(5) Submit the State of California Epinephrine Certification Application form #1.9app

(6/2015) herein incorporated by reference.

(b) Currently licensed California health care professionals including physician assistants, registered nurses, nurse practitioners, nurse midwives, clinical nurse specialists, nurse anesthetists, mobile intensive care nurses and currently licensed or certified California paramedics and advanced emergency medical technicians (AEMTs) shall be deemed to have met the requirement for training and are eligible for certification under this Chapter and may apply to the EMS Authority for a certification card using the State of California Epinephrine Certification Application form # 1.9app (6/2015).

(c) California emergency medical technicians, lifeguards, firefighters and peace officers in this state who have current documentation of successfully completed training in the administration of epinephrine by auto-injector, approved by a local EMS agency or the EMS Authority, are eligible for certification under this Chapter and may apply to the EMS Authority for a certification card using the State of California Epinephrine Certification Application form # 1.9app (6/2015).

(d) The effective date of the certification shall be the day the certification is issued by the EMS Authority.

(e) The certification card shall be valid for two (2) years from the last day of the month in which it was issued.

(f) The requirements and process for renewal of the certification are the same as that for the initial certification as described in Section 100046 (a)(1)-(5), (b) and (c).

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code.

Article 3. Training Program Requirements.

§ 100047. Procedures for Training Program Approval.

(a) Prospective training programs shall submit a written request for training program approval to the EMS Authority.

(b) The EMS Authority shall receive and review the following prior to program approval:

(1) A statement verifying that the course content meets the requirements set forth in Section 100048 of this Chapter, and

(2) An outline of course objectives, and

- (3) A final written and skills competency examination, and
- (4) The name and qualifications of the program director, and
- (5) The training program address and phone number, and
- (6) A copy of the training course curriculum including any workbooks, videos, textbooks, or handouts if used in the course, and
- (7) The required fees for program review, and
- (8) A copy of a course completion document to be provided to students who successfully complete training which shall contain all of the following elements:
 - (A) The name of the training program, and
 - (B) The name of the individual completing the course, and
 - (C) The course completion date, and
 - (D) A signature line for the class instructor, and
 - (E) Course name.
- (c) All program materials and student records specified in this chapter shall be subject to periodic review, evaluation and monitoring by the EMS Authority.
- (d) Any person or agency conducting a training program shall notify the EMS Authority in writing within thirty (30) calendar days of any change in program director, instructor, and change of address, phone number, and contact person.
- (e) Any change to the curriculum once approved, shall be submitted for review and approval by the EMS Authority and shall include the requirements of Section 100048 Subsections (a) and (b) (1)-(12) and subsection (a)(2) of Section 100054
- (f) The EMS Authority may request additional materials or documentation as a condition of course approval.
- (g) The requirements and process for renewal of approval are the same as that for the initial approval.
- (1) The training program shall submit an application for renewal at least sixty (60) calendar days before the expiration date of their approval in order to maintain continuous approval.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code

§ 100048. Course Content Requirements.

- (a) Training in the administration of epinephrine shall result in the lay rescuer demonstrating competency in the assessment, management and administration of epinephrine to an individual suspected of having an anaphylactic reaction.
- (b) The following topics and skills shall be included in the training:
 - (1) Common causative agents,
 - (2) Recognition of symptoms of anaphylaxis,
 - (3) Recognition of signs of anaphylaxis,
 - (4) Acquisition and disposal of epinephrine auto-injectors,
 - (5) Maintenance and quality assessment of epinephrine auto-injectors,
 - (6) Emergency use of an epinephrine auto-injector
- (A) Indications,

- (B) Contraindications,
 - (C) Adverse effects,
 - (D) Administration by auto-injector,
 - (E) Dosing,
 - (F) Drug actions,
 - (G) Proper storage, handling and disposal of used/or expired injectors,
 - (7) Consent law,
 - (8) Good Samaritan law,
 - (9) Emergency Care Plans,
 - (10) Activation of the EMS system by calling 9-1-1,
 - (11) Commonly available models of epinephrine auto-injectors,
 - (12) Record keeping requirement as specified in Section 100045(b).
- (c) At the completion of training, the student shall successfully complete a competency based written and skills examination which shall include all the course content requirements listed in subsection (b) of this Section.
- Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code

§ 100049. Director Requirements.

- (a) Each training program shall have a program director that shall be qualified by education and experience in methods, materials, and evaluation of instruction.
- (b) Duties of the program director shall include but not be limited to:
- (1) Administering the training program, and
 - (2) Approving course content, and
 - (3) Approving all written examinations and the final skills examination, and
 - (4) Approving all instructor(s), and
 - (5) Assuring all aspects of the training program are in compliance with this Chapter and other related laws.
 - (6) Provide to the EMS Authority a list of all instructors at least every thirty (30) calendar days or,
 - (7) Notify the EMS Authority of any changes to the approved instructor list within fifteen (15) calendar days.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code

§ 100050. Instructor Requirements.

- (a) Each instructor shall:
- (1) Be authorized by an approved training program, and
 - (2) Be approved by the training program director as qualified to teach by education and experience in methods, materials, and evaluation of instruction, and
 - (3) Possess current certification in first aid, CPR and AED.
- (b) Upon completion of each epinephrine auto-injector course the instructor shall provide the individual with a signed course completion document.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code

§ 100051. Notification of Program Approval.

(a) The EMS Authority shall notify the training program within twenty-one (21) working days of receiving its request that:

- (1) The request has been received, and
- (2) The request contains or does not contain the information requested in Section 100047 of this Chapter, and
- (3) What information, if any, is missing from the request.

(b) Program approval or disapproval shall be made in writing by the EMS Authority to the applying training program within sixty (60) days of receiving all application information. The training program shall complete all modifications to an application or program required by the EMS Authority before approval can be given.

(c) The EMS Authority shall establish the effective date of training program approval in writing once the training program is reviewed and found in compliance with all program requirements. The EMS Authority shall issue a certificate of approval to the training program with the effective date and an expiration date.

(d) Program approval shall be for four (4) years from the last day of the month in which the approval is given and shall be reviewed by the EMS Authority for approval every four (4) years or sooner at the discretion of the EMS Authority.

(e) Approved training programs shall notify the EMS Authority in writing, and within thirty (30) calendar days of any change in name, address, phone number, hours of instruction, or program director.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code

§ 100052. Withdrawal of Program Approval.

(a) Failure to comply with any requirement for program approval, use of any unqualified teaching personnel, or noncompliance with any other applicable provision of this Chapter may result in probation, suspension, revocation, or denial of renewal of program approval by the EMS Authority.

(b) Notification of noncompliance and action to place on probation, suspend, or revoke shall be done as follows:

(1) The EMS Authority shall notify the approved training program course director in writing, by registered mail, of the provisions of this Chapter with which the training program is not in compliance.

(2) Within fifteen (15) working days of receipt of the notification of noncompliance, the approved training program shall submit in writing, by registered mail, to the EMS Authority one of the following:

- (A) Evidence of compliance with this Chapter, or
- (B) A plan for meeting compliance with the provisions of this Chapter within sixty (60) calendar days from the day of receipt of the notification of noncompliance.

(3) Within thirty (30) calendar days from the mailing date of the noncompliance notification the EMS Authority shall notify the approved training program in writing, by registered mail, of the decision to accept the evidence of compliance, accept the plan for meeting compliance, place on probation, suspend or revoke the training program approval.

(4) If the EMS Authority decides to suspend, revoke, or place a training program on probation the notification specified in the subsection (b) (3) of this Section shall include the beginning and ending dates of the probation or suspension and the terms and conditions for lifting of the probation or suspension or the effective date of the revocation which shall not be less than sixty (60) calendar days from the date of the EMS Authority's letter of decision to the approved training program.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code

§ 100053. Certification Card.

(a) The EMS Authority shall issue a certification card to each individual who satisfies the requirements of Section 100046

(b) The certification card shall contain all of the following:

(1) The name of the individual completing the course

(2) The course completion date

(3) Certification expiration date

(4) Certification number

(5) The title of the card shall be listed as: Epinephrine Auto-injector Certification.

(6) The signature of the certified Health and Safety Code Section 1797.197a Responder, affirming the statement: "I understand the scope of my authority and responsibilities as a trained Health and Safety Code Section 1797.197a Responder, and will possess and only employ epinephrine consistent with that Health and Safety Code Section 1797.197a training and applicable law, including activation of the Emergency Medical Services System and record keeping."

Note: Authority cited: Sections 1797.107, Health and Safety Code. Reference: Sections, 1797.197 and 1797.197a, Health and Safety Code.

Article 4. Fees.

§ 100054. Fees.

(a) Each epinephrine training program submitting a written request for program approval shall include a fee of:

(1) Five hundred (\$500) dollars for approval and re-approval of a training program.

(2) Two hundred and fifty (\$250) dollars for any changes in the course content or curriculum occurring outside of the renewal period.

(b) Each individual submitting an application for certification, recertification, or request for a replacement card shall include a fee of:

(1) Fifteen (\$15) dollars.

(c) All fees are nonrefundable.

Note: Authority cited: Section 1797.107, Health and Safety Code. Reference: Sections 1797.197 and 1797.197a, Health and Safety Code