

INITIAL STATEMENT OF REASONS
CHAPTER 1.9 LAY RESCUER EPINEHPRINE AUTO-INJECTOR TRAINING
CERTIFICATION STANDARDS

PROBLEM STATEMENT

The Legislature added Section 4119.3 of the Business and Professions Code, Section 1714.23 of the Civil Code and Section 1797.197a of the Health and Safety Code (HSC) because it found death from anaphylaxis to be a pervasive yet preventable problem in the community. The Legislature found that expanding the number of trained individuals who may respond in an emergency and providing access to epinephrine auto-injectors along with civil liability protection would reduce the number of preventable deaths related to anaphylaxis. Section 1797.197a of the HSC requires the promulgation of regulations by the Emergency Medical Services Authority (EMSA) relating to emergency medical care: epinephrine auto-injectors, as reasonable and proper to carry out the purposes and intent of Senate Bill 669 (Chapter 725, Statutes of 2013).

The major provisions of 1797.197a charge the EMSA with establishing minimum training and standards for certification of off-duty prehospital emergency medical care persons and lay rescuers in the use and administration of the epinephrine auto-injector to render emergency care to another person who may be experiencing anaphylaxis. The Section does not clarify or make specific the minimum training and standards; the procedure for the approval of a training program; subject matter areas required in a training program curriculum; or the procedure and requirements for a lay person to become certified by the EMSA in the use and administration of an epinephrine auto-injector.

Finally, Section 1797.197a also grants the EMSA the ability to charge a fee for review of epinephrine auto-injector training programs and establishes the Specialized First Aid Training Program Approval Fund into which these fees shall be deposited. This Section, however, does not specify what the fee(s) shall be but leaves that to the discretion of the EMSA.

PURPOSE

The purpose of these regulations is to protect the health and safety of the public by defining the procedures that enable the lay person to receive certification in the use and administration of an epinephrine auto-injector to a member of the general public who is suffering from a severe allergic emergency, while also providing civil liability protection. These regulations will protect the health and safety of the public by establishing minimum training standards, including CPR and AED, for epinephrine auto-injector training programs. The regulations also authorize the EMSA to review and approve training programs that will train the lay public in the use and administration of an epinephrine auto-injector.

BENEFIT

The broad objective of the regulation is to provide training to the general public in the use and administration of an epinephrine auto-injector. The specific benefit from the regulation is to protect the health and safety of the public by allowing the lay public and off-duty prehospital medical care personnel, who meet the prescribed qualifications, to use and administer an epinephrine auto-injector to any person suffering from an allergic emergency while also providing civil liability protection. The regulations improve the chances of a person suffering a severe allergic emergency to receive immediate, potentially lifesaving medical care.

PURPOSE AND NECESSITY

ARTICLE 1. DEFINITIONS

These definitions are necessary to ensure that the terms used in the regulations will be clear to readers, including the general public, and particularly to the persons affected by these regulations adopted by the EMSA, which are found in Title 22 of the California Code of Regulations (CCR).

ARTICLE 2. CERTIFICATION REQUIREMENTS

The provisions in this article provide the minimum standards to be met and procedures to be followed in order to receive and maintain epinephrine auto-injector certification with the EMS Authority.

Section 100054. Application and Scope.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to the extent and conditions under which a lay person or off-duty prehospital emergency medical care personnel are authorized to administer an epinephrine auto-injector.

NECESSITY

An off-duty emergency medical care person or lay rescuer may use an epinephrine auto-injector to render emergency care to another person if they meet specified requirements as stated in Statute.

It is imperative for the health and safety of the public to ensure the lay rescuer or off-duty prehospital emergency medical care personnel understand their authorized skills and be aware that they are not licensed to practice medicine but only certified to provide immediate medical care in the instance of an anaphylaxis emergency through the use and administration of an epinephrine auto-injector.

Also, to meet the requirements in Statute, specifically Section 4119.3 (b) of the Business and Professions Code, we have included specific record keeping requirements for certified individuals.

Section 100055. Certification Requirements.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to the criteria that shall be met for certification eligibility.

NECESSITY

The certification requirements listed in Statute require that an individual using the epinephrine auto-injector must have current certification of training issued by an EMSA authorized training provider and current training in CPR and AED to render care to another person.

Providing the specific certification requirements in the regulations is the most effective way of ensuring an individual is aware of the policy and procedures required to become certified in the use and administration of the epinephrine auto-injector.

Completion of training is not required for currently licensed California health care providers as specified, as their medical training encompasses and exceeds the training standards described in this chapter of regulations.

Emergency medical technicians, lifeguards and peace officers in this state have the ability to take epinephrine auto-injector training as an optional skill within their scope of practice. Completion of training is not required if current documentation of successfully completed training in the administration of epinephrine by auto-injector is provided.

ARTICLE 3. TRAINING PROGRAM REQUIREMENTS.

The provisions in this article provide the minimum standards to be met and procedures to be followed in order to receive and maintain training program approval. The provisions specify the requirements for program approval, review, reporting, renewal, required course content and training program fees.

Section 100056. Procedures for Training Program Approval.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to training program approval in order to ensure that only qualified training programs meeting the minimum standards are available to all persons completing the training.

NECESSITY

The EMSA is authorized in statute to approve training providers wishing to offer an epinephrine auto-injector training program. To ensure the lay person or off-duty prehospital emergency medical care personnel receives the proper training and in turn provides the appropriate care to an anaphylaxis patient, the EMSA has established minimum standards and requirements to become an approved training program.

These requirements will ensure the training program is providing a comprehensive program through the use of current materials, required course content, the storing of student records, and continued review by the EMSA.

For EMSA to maintain continued review ensuring proper training and compliance, EMSA must be kept up to date on changes made within the program in a timely manner. Therefore, upon a change in the training program director, instructor, address, phone number and contact person, EMSA is requiring notification in writing within thirty (30) days. This section is consistent with other chapters of regulations promulgated by the EMSA concerning training program approval notification.

Section 100057. Course Content Requirements.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to the minimum course content which is required to be in a training program curriculum.

NECESSITY

In part, course content requirements are provided for in Statute. EMSA is tasked with expanding upon the requirements listed in statute establishing minimum required course content for training and the use and administration of an epinephrine auto-injector for authorized training providers.

To accomplish this task, EMSA convened a workgroup of subject matter experts and interested parties. The workgroup provided additional specific and detailed components a training program should provide in its curriculum to ensure the layperson and off-duty emergency medical care personnel have obtained the knowledge and skills necessary to render emergency care to a person suffering from anaphylaxis.

The course content requirements are based upon standards contained in the documents specified in the section below titled "Technical, Theoretical, and/or Empirical Study, Reports, or Documents."

Section 100058. Director Requirements.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to ensuring the training program director is qualified through education and experience to provide for the administration of the training program and provide for the functions of administrative direction, program coordination, and program instruction.

NECESSITY

The role of the training program director is to provide oversight and administration of the approved training program. Therefore, to ensure a quality and comprehensive training program is provided, it is necessary that the director meet specific qualifications in

education and experience, and is aware of their functions and duties in program administration.

To ensure the training program director is approving and using qualified instructors EMSA requires a list of all instructors at least every thirty (30) days. This is consistent with other chapters of regulations promulgated by the EMSA.

For record keeping purposes and to ensure each student receives their certification card in a timely manner, each program director will submit their class roster and appropriate fees within thirty (30) days to the EMSA.

Section 100059. Instructor Requirements.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to ensuring the training program instructor has the essential skills and knowledge to teach an epinephrine auto-injector class according to the training standards approved by the EMSA.

NECESSITY

This section is necessary to establish prerequisite qualifications, and specify functions and duties required of a training program instructor to ensure the instructor has the experience, knowledge and skills necessary to provide a quality and comprehensive course. Certain instructor requirements are necessary for screening purposes, to verify that an individual who completes the required training has additionally met the requirement of certification in CPR and AED.

For record keeping purposes and to ensure each student receives their certification card in a timely manner, each training instructor will submit their class roster within fifteen (15) days to the program director to be forwarded to the EMSA.

Section 100060. Notification of Program Approval.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to the process and requirements for EMSA in notifying a training program of approval or disapproval by providing timeframes for program review, notification of deficiencies, and maintaining EMSA approval.

NECESSITY

Once a prospective training program submits its application this section provides EMSA with specific guidelines that EMSA must follow in notifying the training program of approval or disapproval. Requiring specific guidelines of EMSA will keep EMSA on track ensuring prospective training programs will be approved or notified of deficiencies in a timely manner and make the process and requirements available to the prospective training programs. This process is consistent with other chapters of regulations promulgated by the EMSA concerning training program approval notification.

Section 100061. Withdrawal of Program Approval.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to the probation, suspension, revocation, or denial of renewal of program approval when an approved training program is found to be noncompliant with any requirements or minimum standard set by the EMSA.

NECESSITY

It's essential for the health and safety of the public that all training programs comply with the requirements and minimum standards set by the EMSA for continued approval or be faced with probation, suspension, revocation, or denial of renewal of program approval. Should the EMSA find a training program is out of compliance this section specifies the timelines and notification guidelines EMSA and the training program must follow. Providing EMSA and the training program with the required process and requirements maintains the integrity and consistency of the process. This process is consistent with other chapters of regulations promulgated by the EMSA concerning withdrawal of training program approval.

Section 100062. Certification Card.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to the certification cards for individuals who successfully complete an epinephrine auto-injector training program.

NECESSITY

To demonstrate that a person is trained and qualified to administer an epinephrine auto-injector as a lay person or off-duty prehospital medical care personnel, certification cards will be issued by the EMSA. This section specifies the data elements required to be on the certification card, including a control number in order to maintain uniformity and protect against fraudulent cards. The individual is required to sign the certification card as further affirmation that they understand their authorized skills.

ARTICLE 4. FEES.

The provisions in this article establish a schedule of fees for the review, approval and renewal for the epinephrine auto-injector training programs, and for certification of lay rescuers, prehospital emergency medical care personnel, currently licensed health care professionals, certified California paramedics and advanced emergency medical technicians and emergency medical technicians, lifeguards, firefighters and peace officers.

Section 100063. Fees.

SPECIFIC PURPOSE

The specific purpose of this section is to clarify, interpret and make specific HSC Section 1797.197a with regard to setting a schedule of fees to support the epinephrine auto-injector training programs review, approval and renewing requirements, and to establish a schedule a fees to become certified by the EMSA for training programs, individuals completing the training, currently licensed health care professionals, certified California paramedics and advance emergency medical technicians and emergency medical technicians, lifeguards, firefighters and peace officers.

NECESSITY

The epinephrine auto-injector program is entirely funded through revenues collected from the fees charged to training programs and individuals taking the course. The Statute creates the Specialized First Aid Training Program Approval Fund and authorizes the EMS Authority to assess a reasonable fee sufficient to cover the costs incurred by the EMSA for the ongoing review, approval and certification of training providers however, Statute does not specify what the fee(s) shall be leaving that to the discretion of the EMSA.

Because this program is the first of its kind we have had to estimate fees for individual certification and training program review based upon the potential response from training programs and individuals. Once implemented, EMSA will do a periodic review of the epinephrine auto-injector program fees to determine if changes need to be made through regulation.

The EMSA estimated a program review cost of \$500 per training program with an estimated 10 training programs to be reviewed throughout the entire state every year, the estimated revenue generated will be \$5,000. This fee was based on workload including: Conducting ongoing review, approval, and renewal of training programs; Management of certified laypersons; publicizing the availability of the lay public to receive state approved epinephrine auto-injector training; costs to produce and mail certification cards to trained individuals; Provide technical support to the public; and Maintain the database of approved training providers and certified individuals. The \$250 fee for changes made outside of the biannual renewal period takes into account the additional time and workload incurred for review and administration.

Estimating an EMS Authority certification card cost of \$15 per card and potentially 9,000 individuals receiving or renewing their training annually, estimated revenues of \$135,000 are predicted. Given that there are approximately 80,000 EMTs and EMT-Paramedics currently licensed throughout the state, an estimate of 9,000 training providers and individuals who will seek certification, both new and renewals, every year is a reasonable estimate, as EMTs and EMT-Paramedics are not the only population who may reasonably have the responsibility to care for others. Other populations throughout the state may include camp counselors, park and forest rangers, wilderness guides, team coaches, and lifeguards.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS

EMSA relied on input from a working group comprised of various stakeholders and interested parties that provided information and subject matter expertise from operational, educational, administrative and medical perspectives.

The groups and organizations that participated in the workgroup include: A representative from Senator Huff's office, author of SB 669, the California BAR Association, the San Francisco Bay Food Allergy Network, Epi-Expert, Emergency Medical Services Safety Services, California Department of Education, California Medical Association, Emergency Nurses Organization, Food Allergy Research and Education, Emergency Medical Director Association of California, American Red Cross, Emergency Medical Services Administration Association of California and the American Academy of Allergy Asthma and Immunology.

The documents relied upon include:

"World Allergy Organization (WAO) Guidelines for the Assessment and Management of Anaphylaxis," WAO Journal, February 2011.

"World Allergy Organization Anaphylaxis Guidelines: 2013 Update of the Evidence Base," *International Archives of Allergy and Immunology* 2013; 162(3): 193-204.

Guidelines for the Diagnosis and Management of Food Allergy in the United States: A Summary for Patients, Families and Caregivers. National Institute of Allergy and Infectious Diseases (NIAID).

The American Red Cross Scientific Advisory Council (ARC SAC): Use of Epinephrine Auto-Injectors for Anaphylaxis. January 2012.

California Department of Education (CDE): Training Standards for the administration of epinephrine auto-injectors with Education Code Section 49414.

All documents are available on the EMSA website www.emsa.ca.gov/public_comment

ECONOMIC IMPACT ASSESSMENT/ANAYLSIS

The Creation or Elimination of Jobs within the State of California

The regulations are designed to make specific the training standards for the proper use of epinephrine auto-injectors and which makes these auto-injectors available by prescription to individuals who have successfully completed the training. The regulations will increase the number of people who can legally obtain the medication and administer its use in a medical emergency and be granted civil liability protection. As no such approved training programs currently exist in California, the regulations afford an opportunity for the creation of training programs. Therefore, the EMSA has determined that this regulatory proposal will likely create an unknown number of jobs for providers of epinephrine auto-injector training in the State of California.

The Creation of New Businesses or the Elimination of Existing Businesses Within the State of California

The regulations are designed to make specific the training standards for the proper use of epinephrine auto-injectors and which makes these auto-injectors available by prescription to individuals who have successfully completed the training. The regulations will increase the number of people who can legally obtain the medication and administer its use in a medical emergency and be granted civil liability protection. As no such approved training programs currently exist in California, the regulations afford an opportunity for the creation of training programs. Therefore, the EMSA has determined that this regulatory proposal will likely create an unknown number of new businesses providing training in epinephrine auto-injector use and administration and would not eliminate any existing businesses in the State of California.

The Expansion of Businesses Currently Doing Business Within the State of California

The regulations are designed to make specific the training standards for the proper use of epinephrine auto-injectors and which makes these auto-injectors available by prescription to individuals who have successfully completed the training. The regulations will increase the number of people who can legally obtain the medication and administer its use in a medical emergency and be granted civil liability protection. The regulations are likely to result in the expansion of businesses currently doing business within the state because while there are currently no epinephrine auto-injector training programs in existence in the state meeting the provisions of Section 1797.107 of the Health and Safety Code, there are other training programs providing lay rescuer training in other topic areas such as first aid, CPR and AED that may expand their course offerings to include training in epinephrine auto-injectors.

Benefits of the Regulations to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The proposed regulations will benefit California residents and worker safety by allowing a person suffering an allergic emergency to receive potentially lifesaving medical care by providing the lay person with a process to obtain a prescription for an epinephrine auto-injector that they may use and administer to any person in an allergic emergency situation. It also increases public safety by specifying the minimum training standards and requirements to be met in order to use and administer an epinephrine auto-injector. The proposed regulations are not anticipated to benefit or negatively impact the state's environment.

Results of the Economic Impact Analysis/Assessment

The EMSA concludes that it is (1) unlikely that the proposal will eliminate any jobs public safety personnel or epinephrine training providers, (2) likely that the proposal will create an unknown number of jobs for providers of epinephrine auto-injector training, (3) likely that the proposal will create an unknown number of new businesses providing training in epinephrine auto-injector use and administration, (4) unlikely that the proposal will eliminate any existing businesses, and (5) likely that the proposed

regulations will result in the expansion of businesses currently doing business within the state.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS.

EMSA has not identified any alternatives that would lessen any adverse impact on small businesses.

EVIDENCE SUPPORTING FINDING OF ADVERSE ECONOMIC IMPACT ON ANY BUSINESS

EMSA has determined that these regulations are not likely to result in adverse economic impact on any business due to the voluntary nature of these regulations which establish training standards and certification. These regulations do not mandate that any individual or business complete the training and certification, and no individual or business is required to offer the training as established in these regulations.

FOR FURTHER INFORMATION

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