

RESOLUTION 08-05-2012

DIGEST

Epinephrine Auto-Injectors: Training and Authorization for Emergency Use

Adds Health and Safety Code section 1797.197a and Civil Code section 1714.23 and amends Business and Professions Code section 4119.2 to create a training program and standards that would allow a lay rescuer to administer epinephrine (EpiPen).

RESOLUTIONS COMMITTEE RECOMMENDATION

APPROVE IN PRINCIPLE

History:

No similar resolutions found.

Reasons:

The resolution adds Health and Safety Code section 1797.197a and Civil Code section 1714.23 and amends Business and Professions Code section 4119.2 to create a training program and standards that would allow lay rescuers to administer epinephrine (EpiPen). This resolution should be approved in principle because it would allow those who have met all of the training standards to obtain a prescription for an EpiPen and administer it.

The purpose of the proposed resolution is to allow first responders, school nurses, group leaders overseeing the welfare of others, or a lay rescuer to have and administer an EpiPen. The current problem is that, unless someone is authorized to use an EpiPen, it cannot be administered by a non-physician on someone who is going into anaphylactic shock, unless it is prescribed to that person. This resolution would allow those that have met all of the training requirements, such as first responders, troop leaders, teachers, emergency response teams, lay rescuers, to be able to have and administer an EpiPen and be able to save lives.

TEXT OF RESOLUTION

RESOLVED, that the Conference of California Bar Associations recommends that legislation be sponsored to add Health and Safety Code section 1797.197a and Civil Code section 1714.23, and amend Business and Professions Code section 4119.2 to read as follows:

- 1 § 1797.197a
- 2 (a) An "epinephrine auto-injector," as used in Division 2.5 of this Code, means a
- 3 disposable drug delivery system with a spring-activated concealed needle that is designed for
- 4 emergency administration of epinephrine to provide rapid, convenient first aid for persons
- 5 suffering from a potentially fatal reaction to anaphylaxis. It includes such brand names as
- 6 EpiPen and Twinject. The injector consists of a 0.3 mL (or less) single-dose injectable
- 7 epinephrine solution of between 2:1000 (0.5 gm/mL) and 1:1000 (1 mg/mL).
- 8 (b) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic
- 9 reaction to a substance, such as insect stings or bites, foods, drugs, and other allergens, as well as
- 10 idiopathic or exercise-induced anaphylaxis. Symptoms of anaphylaxis may include shortness of

11 breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling,
12 shock or asthma.

13 (c) A "lay rescuer" means any person, not otherwise licensed or certified to use an
14 epinephrine auto-injector on another, who has met the training standards and other requirements
15 of this Section.

16 (d) The "authorized training providers," the minimum "training" standards, and the
17 minimum standards for the use and administration of epinephrine auto-injectors pursuant to this
18 provision, shall be established or approved by the California Emergency Medical Services
19 (EMS) Authority, the local Emergency Medical System Agency and/or by the county
20 Department of Health, in consultation with such agencies and organizations as the manufacturer,
21 the State Department of Health Services, the American Academy of Allergy, Asthma and
22 Immunology, the American Academy of Pediatrics, the American Heart Association, the
23 American Red Cross, and the California Medical Association. The minimum training and
24 requirements shall include the components set forth in subdivision (e)(4) of this Section. The
25 standards mentioned herein shall be minimum standards applicable to any regulations or
26 standards of a school district or county office of education's regulations for provision of
27 emergency epinephrine auto-injectors under Section 49414 of the Education Code.

28 (e) In order to ensure public safety, any prehospital emergency care personnel or first
29 responder, as defined pursuant to paragraph (2) of subdivision (a) of Section 1797.189, and
30 Divisions 2.5 (commencing at Section 1797) and 9 (commencing at Section 10000, including but
31 not limited to Section 10026) of Title 22 of the Code of Regulations, or a lay rescuer, who
32 acquires an epinephrine auto-injector, may use it to render emergency care to another, providing
33 compliance with the following requirements:

34 (1) The epinephrine auto-injector must be legally obtained on prescription from an
35 authorized health care provider, who may prescribe it to any person meeting the definition of
36 subdivision (d) and for the purposes described in this provision, upon that person's presentation
37 to the prescribing physician of a current certificate demonstrating the person is trained and
38 qualified under this provision to administer epinephrine auto-injector as a prehospital emergency
39 care person, first responder or lay rescuer.

40 (2) The epinephrine auto-injector must be used on another, with the expressed or implied
41 consent of that person, for the indicated purposes as described in subdivisions (a) and (b).

42 (3) The epinephrine auto-injector used must be stored and maintained as directed by the
43 manufacturer's instructions for that product.

44 (4) The user must have successfully completed a course of training by an authorized
45 training provider, as described herein, and have a current certification of training issued by such
46 a provider. The minimum training established pursuant to this provision shall include all of the
47 following:

48 (A) Techniques for recognizing circumstances, signs and symptoms of anaphylaxis.

49 (B) Standards and procedures for proper storage and emergency use of epinephrine auto-
50 injectors.

51 (C) Emergency follow-up procedures, including activation of the Emergency Medical
52 System, by calling the emergency 911 phone number or otherwise alerting and summoning more
53 advanced medical personnel and services.

54 (D) Compliance with all regulations governing the training, indications, use and
55 precautions concerning epinephrine auto-injectors.

56 (E) Written material covering the information required under this provision, including the
57 manufacturer's product information sheet on the particular epinephrine auto-injector in
58 possession of the user.

59 (F) Completion of a training course in cardiopulmonary resuscitation and the use of an
60 automatic external defibrillator (AED) for infants, children and adults that complies with
61 regulations adopted by the EMS Authority and the standards of the American Heart Association
62 or the American Red Cross, and a current certification for that training.

63 (G) Training certification for no more than two years, after which there must be
64 recertification by an authorized training provider.

65
66 § 1714.23

67 (a) For purposes of this Section, the following definitions shall apply:

68 (1) An "epinephrine auto-injector," as used in Division 2.5 of this Code, means a
69 disposable drug delivery system with a spring-activated concealed needle that is designed for
70 emergency administration of epinephrine to provide rapid, convenient first aid for persons
71 suffering from a potentially fatal reaction to anaphylaxis. It includes such brand names as
72 EpiPen, and the injector consists of a 0.3 mL (or less) single-dose injectable epinephrine solution
73 of between 2:1000 (0.5 gm/mL) and 1:1000 (1 mg/mL) a 1:2000.

74 (2) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic
75 reaction to a substance, such as insect stings or bites, foods, drugs, and other allergens, as well as
76 idiopathic or exercise-induced anaphylaxis. Symptoms of anaphylaxis may include shortness of
77 breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling,
78 shock or asthma.

79 (b) Any person described in subdivision (e) of Section 1797.197a of the Health and
80 Safety Code, who at the scene of an emergency situation administers in good faith and not for
81 compensation an epinephrine auto-injector to another who appears to be experiencing
82 anaphylaxis, shall not be liable for any civil damages as a result of any acts or omissions in
83 rendering such emergency care if that person administering the epinephrine auto-injector is
84 otherwise in compliance with the requirements of Section 1797.197a of the Health and Safety
85 Code.

86 (c) This Section shall not be construed to grant immunity from civil damages to any
87 person whose conduct in rendering such emergency care constitutes gross negligence.

88 (d) In order to encourage such emergency care and to promote authorized training
89 providers, as described in subdivision (d) of Section 1797.197a of the Health and Safety Code, to
90 train those persons described in subdivision (e) of that statute concerning the minimum standards
91 for the use and administration of epinephrine auto-injectors, no local agency, entity of state or
92 local government, or other public or private organization which sponsors, authorizes, supports,
93 develops, advises or consults concerning, finances or supervises such standards and training,
94 including but not limited to the California Emergency Medical Services (EMS) Authority, the
95 local Emergency Medical System Agency and/or by the county Department of Health, the State
96 Department of Health Services, the American Academy of Allergy, Asthma and Immunology,
97 the American Academy of Pediatrics, the American Heart Association, the American Red Cross,
98 and the California Medical Association, and no such authorized training provider, shall be liable
99 for any civil damages alleged to result from such standards or training.

100 (e) Nothing in this Section shall relieve a manufacturer, designer, developer, distributor
101 or supplier of an epinephrine auto-injector of any liability under any applicable statute or rule of
102 law.

103
104 § 4119.2

105 (a) Notwithstanding any other provision of law, a pharmacy may furnish epinephrine
106 auto-injectors to a school district or county office of education pursuant to Section 49414 of the
107 Education Code if all of the following are met:

108 (1) The epinephrine auto-injectors are furnished exclusively for use at a school district
109 site or county office of education.

110 (2) A physician and surgeon provides a written order that specifies the quantity of
111 epinephrine auto-injectors to be furnished.

112 (b) Records regarding the acquisition and disposition of epinephrine auto-injectors
113 furnished pursuant to subdivision (a) shall be maintained by both the school district or county
114 office of education for a period of three years from the date the records were created. The school
115 district or county office of education shall be responsible for monitoring the supply of auto-
116 injectors and assuring the destruction of expired auto-injectors.

117 (c) Notwithstanding any other provision of law, a pharmacy may furnish epinephrine
118 auto-injectors to a person described in subdivision (e) to Section 1797.197a of the Health and
119 Safety Code, upon prescription of a physician made out to that person as a currently certified
120 trained and qualified prehospital emergency care person, first responder or lay rescuer authorized
121 to administer epinephrine auto-injector to another in an emergency situation. The following
122 requirements must be met:

123 (1) A physician and surgeon may only issue a prescription for epinephrine auto-injector
124 to a person described in subdivision (e) to Section 1797.197a, for purposes of use as a qualified
125 prehospital emergency care person, first responder or lay rescuer to be administered to another in
126 an emergency situation upon presentation of a current certificate demonstrating the person is
127 trained and qualified to do so under Section 1797.197a of the Health and Safety Code. The
128 prescription shall specify that the dispensed epinephrine auto-injector is for "EMS Purposes
129 Only" and the named recipient is a "Section 1797.197a Responder." The physician and surgeon
130 must specify the quantity of epinephrine auto-injectors to be furnished. A new prescription must
131 be written for any additional epinephrine auto-injectors required.

132 (2) The epinephrine auto-injector prescription dispensed by the pharmacy shall reflect the
133 name of the recipient, the designation "Section 1797.197a Responder," and "EMS Purposes
134 Only," in addition to dosage, use and expiration date. Included with each dispensed prescription
135 shall be the manufacturer's product information sheet for the product.

136 (3) The person described in subdivision (e) to Section 1797.197a of the Health and Safety
137 Code receiving the epinephrine auto-injector under these provisions must make and maintain a
138 record for five years reflecting dates of receipt, use and destruction of each auto-injector, the
139 name of any person to whom epinephrine was administered and the circumstances, and the
140 manner of any destruction of the auto-injector.

141 (4) The epinephrine auto-injector issued under these provisions may only be used for the
142 purposes and under the circumstances described in Section 1797.197a of the Health and Safety
143 Code.

(Proposed new language underlined; language to be deleted stricken.)

PROPONENT: Los Angeles County Bar Association

STATEMENT OF REASONS

Existing Law: Only a physician is authorized to prescribe epinephrine auto-injectors to patients with a known allergy, who is at risk for a lethal anaphylactic reaction to a substance. No one other than that patient may administer it to him or herself, even if the patient is unconscious. Even if an EpiPen is available at the scene of an emergency, it may not be given to anyone else.

This Resolution: Would create a training program and standards for the safe and proper use of epinephrine auto-injectors, make them available to trained first responders and group leaders, and allow them to use it on a person suffering from a potentially fatal anaphylaxis, without facing civil liability for trying save a life.

The Problem: Despite Good Samaritan protection fostering trained first responders and group supervisors to provide emergency care--first aid, cardiopulmonary resuscitation and automatic external defibrillation--for someone with a life-threatening allergic reaction, there is effectively nothing anyone can do to prevent cardio-pulmonary shutdown unless the anaphylaxis victim has an EpiPen and is able to self-administer epinephrine before losing consciousness. Epinephrine saves lives. Unless specifically used by and for the person for whom it was prescribed, it may not administered by non-physicians--even if an auto-injector is on the scene. This is a problem encountered by school nurses for students who have not been prescribed an EpiPen, group leaders overseeing the welfare of others on an outing, as well as first responders at the scene of an emergency. It's not just wilderness situations--death from anaphylaxis can occur in the middle of the city within minutes. EpiPens require a prescription and can only be used by that person on him or herself. If given by anyone else, outside of on a physician's direction, it's illegal and subjects the rescuer to major liability exposure. Anaphylaxis is a pervasive lethal threat, both to those with known allergies and those who suddenly become sensitized to a substance--be it a simple bee sting, ingestion of shell fish or being around peanuts. Most people connected within the Emergency Medical System recognize the need for and favor this long overdue legislation. Like first aid, CPR and AEDs, people can be effectively trained in the indication and safe use of EpiPens.

IMPACT STATEMENT

This resolution will not conflict with any other law, statute or rule. It augments and facilitates the present statutory scheme for first aid, CPR and AED emergency services with Good Samaritan immunity (22 Cal. Code Reg. §§ 1797.100 et seq., 1797.200 et seq., 10000 et seq.; Division 2.5, Health and Safety Code (Health & Safety Code, §§ 1797.196, 1797.197, 1797.189); Civ. Code, §§1714.2, 1714.21). It will broaden the provision concerning epinephrine auto-injectors in a school setting (Educ. Code, § 49414) and the enabling provision calling for guidelines by the EMS Authority (Health & Safety Code, § 1797.197). Financial impact is minimal, and may even prove a source of revenue from training.

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