

AMENDED IN SENATE MAY 31, 2016
AMENDED IN ASSEMBLY JANUARY 13, 2016
AMENDED IN ASSEMBLY JANUARY 5, 2016
AMENDED IN ASSEMBLY JANUARY 4, 2016
AMENDED IN ASSEMBLY APRIL 16, 2015
AMENDED IN ASSEMBLY MARCH 26, 2015
CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1386

Introduced by Assembly Member Low

February 27, 2015

An act to add Section 4119.4 to the Business and Professions Code, to amend Section 1714.23 of the Civil Code, and to amend Section 1797.197a of the Health and Safety Code, relating to emergency medical care.

LEGISLATIVE COUNSEL'S DIGEST

AB 1386, as amended, Low. Emergency medical care: epinephrine auto-injectors.

(1) Existing law authorizes a prehospital emergency medical care person, first responder, or lay rescuer to use an epinephrine auto-injector to render emergency care to another person, as specified. Existing law requires the Emergency Medical Services Authority to approve authorized training providers and the minimum standards for training and the use and administration of epinephrine auto-injectors. The existing Pharmacy Law also authorizes a pharmacy to dispense epinephrine auto-injectors to a prehospital emergency medical care

person, first responder, or lay rescuer for the purpose of rendering emergency care in accordance with these provisions. A violation of the Pharmacy Law is a crime.

This bill would permit an “authorized entity,” as defined, to use an epinephrine auto-injector to render emergency care to another person in accordance with these provisions. The bill would also authorize a pharmacy to furnish epinephrine auto-injectors to an authorized entity, as provided. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program. The bill would require an authorized entity to create and maintain a specified operations plan relating to its use of epinephrine auto-injectors, and would require those entities to submit a report to the ~~State Department of Public Health~~ *Emergency Medical Services Authority of each incident that involves the administration of an epinephrine auto-injector, not more than 30 days after each use.* The bill would also require the ~~department to issue~~ *authority to publish* an annual report summarizing ~~and analyzing~~ the reports submitted to the ~~department~~ *authority* pursuant to the bill’s provisions.

(2) Under existing law, everyone is generally responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself. Existing law also provides that a prehospital emergency care person, first responder, or lay rescuer who administers an epinephrine auto-injector to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with specified certification and training requirements and standards.

This bill would provide that an authorized entity is not liable for any civil damages resulting from any act or omission connected to the administration of an epinephrine auto-injector, as specified.

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4119.4 is added to the Business and
2 Professions Code, to read:
3 4119.4. (a) Notwithstanding any other law, a pharmacy may
4 furnish epinephrine auto-injectors to an authorized entity, as
5 defined by Section 1797.197a of the Health and Safety Code, if
6 both of the following requirements are met:
7 (1) The epinephrine auto-injectors are furnished exclusively for
8 use by, or in connection with, an authorized entity.
9 (2) An authorized health care provider provides a prescription
10 that specifies the quantity of epinephrine auto-injectors to be
11 furnished.
12 (b) The pharmacy shall label each epinephrine auto-injector
13 dispensed with all of the following:
14 (1) The name of the person or entity to whom the prescription
15 was issued.
16 (2) The designations “Section 1797.197a Responder” and “First
17 Aid Purposes Only.”
18 (3) The dosage, use, and expiration date.
19 (c) Each dispensed prescription shall include the manufacturer’s
20 product information sheet for the epinephrine auto-injector.
21 (d) Records regarding the acquisition and disposition of
22 epinephrine auto-injectors furnished pursuant to subdivision (a)
23 shall be maintained by the authorized entity for a period of three
24 years from the date the records were created. The authorized entity
25 shall be responsible for monitoring the supply of epinephrine
26 auto-injectors and ensuring the destruction of expired epinephrine
27 auto-injectors.
28 (e) The epinephrine auto-injector dispensed pursuant to this
29 section may be used only for the purpose, and under the
30 circumstances, described in Section 1797.197a of the Health and
31 Safety Code.
32 SEC. 2. Section 1714.23 of the Civil Code is amended to read:
33 1714.23. (a) For purposes of this section, the following
34 definitions shall apply:

1 (1) “Anaphylaxis” means a potentially life-threatening
2 hypersensitivity or allergic reaction to a substance.

3 (A) Symptoms of anaphylaxis may include shortness of breath,
4 wheezing, difficulty breathing, difficulty talking or swallowing,
5 hives, itching, swelling, shock, or asthma.

6 (B) Causes of anaphylaxis may include, but are not limited to,
7 insect stings or bites, foods, drugs, and other allergens, as well as
8 idiopathic or exercise-induced anaphylaxis.

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

13 (b) (1) Any person described in subdivision (b) of Section
14 1797.197a of the Health and Safety Code who administers an
15 epinephrine auto-injector, in good faith and not for compensation,
16 to another person who appears to be experiencing anaphylaxis at
17 the scene of an emergency situation is not liable for any civil
18 damages resulting from his or her acts or omissions in
19 administering the epinephrine auto-injector, if that person has
20 complied with the requirements and standards of Section 1797.197a
21 of the Health and Safety Code.

22 (2) (A) An authorized entity shall not be liable for any civil
23 damages resulting from any act or omission other than an act or
24 omission constituting gross negligence or willful or wanton
25 misconduct connected to the administration of an epinephrine
26 auto-injector by any one of its employees, volunteers, or agents
27 who is a lay rescuer, as defined by paragraph (4) of subdivision
28 (a) of Section 1797.197a of the Health and Safety Code.

29 (B) The failure of an authorized entity to possess or administer
30 an epinephrine auto-injector shall not result in civil liability.

31 (3) This subdivision does not affect any other immunity or
32 defense that is available under law.

33 (c) The protection specified in subdivision (b) shall not apply
34 in a case of personal injury or wrongful death that results from the
35 gross negligence or willful or wanton misconduct of the person
36 who renders emergency care treatment by the use of an epinephrine
37 auto-injector.

38 (d) Nothing in this section relieves a manufacturer, designer,
39 developer, distributor, or supplier of an epinephrine auto-injector
40 of liability under any other applicable law.

1 SEC. 3. Section 1797.197a of the Health and Safety Code is
2 amended to read:

3 1797.197a. (a) For purposes of this section, the following
4 definitions shall apply:

5 (1) "Anaphylaxis" means a potentially life-threatening
6 hypersensitivity or allergic reaction to a substance.

7 (A) Symptoms of anaphylaxis may include shortness of breath,
8 wheezing, difficulty breathing, difficulty talking or swallowing,
9 hives, itching, swelling, shock, or asthma.

10 (B) Causes of anaphylaxis may include, but are not limited to,
11 insect stings or bites, foods, drugs, and other allergens, as well as
12 idiopathic or exercise-induced anaphylaxis.

13 (2) "Authorized entity" means any for-profit, nonprofit, or
14 government entity or organization that employs at least one person
15 or utilizes at least one volunteer or agent that has voluntarily
16 completed a training course as described in subdivision (c).

17 (3) "Epinephrine auto-injector" means a disposable drug delivery
18 system with a spring-activated concealed needle that is designed
19 for emergency administration of epinephrine to provide rapid,
20 convenient first aid for persons suffering from anaphylaxis.

21 (4) "Lay rescuer" means any person who has met the training
22 standards and other requirements of this section but who is not
23 otherwise licensed or certified to use an epinephrine auto-injector
24 on another person.

25 (5) "Prehospital emergency medical care person" has the same
26 meaning as defined in paragraph (2) of subdivision (a) of Section
27 1797.189.

28 (b) A prehospital emergency medical care person or lay rescuer
29 may use an epinephrine auto-injector to render emergency care to
30 another person if all of the following requirements are met:

31 (1) The epinephrine auto-injector is legally obtained by
32 prescription from an authorized health care provider or from an
33 authorized entity that acquired the epinephrine auto-injector
34 pursuant to subdivision (e).

35 (2) The epinephrine auto-injector is used on another, with the
36 expressed or implied consent of that person, to treat anaphylaxis.

37 (3) The epinephrine auto-injector is stored and maintained as
38 directed by the manufacturer's instructions for that product.

39 (4) The person using the epinephrine auto-injector has
40 successfully completed a course of training with an authorized

1 training provider, as described in subdivision (c), and has current
2 certification of training issued by the provider.

3 (5) The epinephrine auto-injectors obtained by prehospital
4 emergency medical care personnel pursuant to Section 4119.3 of
5 the Business and Professions Code shall be used only when
6 functioning outside the course of the person's occupational duties,
7 or as a volunteer, pursuant to this section.

8 (6) The Emergency Medical Services System is activated as
9 soon as practicable when an epinephrine auto-injector is used.

10 (c) (1) The authorized training providers shall be approved,
11 and the minimum standards for training and the use and
12 administration of epinephrine auto-injectors pursuant to this section
13 shall be established and approved, by the authority. The authority
14 may designate existing training standards for the use and
15 administration of epinephrine auto-injectors by prehospital
16 emergency medical care personnel to satisfy the requirements of
17 this section.

18 (2) The minimum training and requirements shall include all of
19 the following components:

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

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

24 (C) Emergency followup procedures, including activation of
25 the Emergency Medical Services System, by calling the emergency
26 9-1-1 telephone number or otherwise alerting and summoning
27 more advanced medical personnel and services.

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

31 (E) Written material covering the information required under
32 this provision, including the manufacturer product information
33 sheets on commonly available models of epinephrine auto-injectors.

34 (F) Completion of a training course in cardiopulmonary
35 resuscitation and the use of an automatic external defibrillator
36 (AED) for infants, children, and adults that complies with
37 regulations adopted by the authority and the standards of the
38 American Heart Association or the American Red Cross, and a
39 current certification for that training.

1 (3) Training certification shall be valid for no more than two
2 years, after which recertification with an authorized training
3 provider is required.

4 (4) The director may, in accordance with regulations adopted
5 by the authority, deny, suspend, or revoke any approval issued
6 under this subdivision or may place any approved training provider
7 on probation upon a finding by the director of an imminent threat
8 to public health and safety, as evidenced by any of the following:

9 (A) Fraud.

10 (B) Incompetence.

11 (C) The commission of any fraudulent, dishonest, or corrupt
12 act that is substantially related to the qualifications, functions, or
13 duties of training program directors or instructors.

14 (D) Conviction of any crime that is substantially related to the
15 qualifications, functions, or duties of training program directors
16 or instructors. The record of conviction or a certified copy of the
17 record shall be conclusive evidence of the conviction.

18 (E) Violating or attempting to violate, directly or indirectly, or
19 assisting in or abetting the violation of, or conspiring to violate,
20 any provision of this section or the regulations promulgated by the
21 authority pertaining to the review and approval of training
22 programs in anaphylaxis and the use and administration of
23 epinephrine auto-injectors, as described in this subdivision.

24 (d) (1) The authority shall assess a fee pursuant to regulation
25 sufficient to cover the reasonable costs incurred by the authority
26 for the ongoing review and approval of training and certification
27 under subdivision (c).

28 (2) The fees shall be deposited in the Specialized First Aid
29 Training Program Approval Fund, which is hereby created in the
30 State Treasury. All moneys deposited in the fund shall be made
31 available, upon appropriation, to the authority for purposes
32 described in paragraph (1).

33 (3) The authority may transfer unused portions of the Specialized
34 First Aid Training Program Approval Fund to the Surplus Money
35 Investment Fund. Funds transferred to the Surplus Money
36 Investment Fund shall be placed in a separate trust account, and
37 shall be available for transfer to the Specialized First Aid Training
38 Program Approval Fund, together with the interest earned, when
39 requested by the authority.

1 (4) The authority shall maintain a reserve balance in the
2 Specialized First Aid Training Program Approval Fund of 5 percent
3 of annual revenues. Any increase in the fees deposited in the
4 Specialized First Aid Training Program Approval Fund shall be
5 effective upon determination by the authority that additional
6 moneys are required to fund expenditures pursuant to subdivision
7 (c).

8 (e) (1) An authorized health care provider may issue a
9 prescription for an epinephrine auto-injector to a prehospital
10 emergency medical care person or a lay rescuer for the purpose of
11 rendering emergency care to another person upon presentation of
12 a current *epinephrine auto-injector certification card issued by the*
13 *authority* demonstrating that the person is trained and qualified to
14 administer an epinephrine auto-injector pursuant to this section or
15 any other law.

16 (2) An authorized health care provider may issue a prescription
17 for an epinephrine auto-injector to an authorized entity if the
18 authorized entity submits evidence it employs at least one person,
19 or utilizes at least one volunteer or agent, who is trained and *has*
20 *a current epinephrine auto-injector certification card issued by*
21 *the authority demonstrating that the person is* qualified to
22 administer an epinephrine auto-injector pursuant to this section.

23 (f) An authorized entity that possesses and makes available
24 epinephrine auto-injectors shall do both of the following:

25 (1) Create and maintain on its premises an operations plan that
26 includes all of the following:

27 (A) The name and contact number for the authorized health care
28 provider who prescribed the epinephrine auto-injector.

29 (B) Where and how the epinephrine auto-injector will be stored.

30 (C) The names of the designated employees or agents who have
31 completed the training program required by this section and who
32 are authorized to administer the epinephrine auto-injector.

33 (D) How and when the epinephrine auto-injector will be
34 inspected for an expiration date.

35 (E) The process to replace the expired epinephrine auto-injector,
36 including the proper disposal of the expired epinephrine
37 auto-injector or used epinephrine auto-injector in a sharps
38 container.

39 ~~(2) Submit to the State Department of Public Health, on a form~~
40 ~~developed by the State Department of Public Health, a report of~~

1 each incident on the authorized entity's premises that involves the
2 administration of an epinephrine auto-injector. The State
3 Department of Public Health shall annually publish a report that
4 summarizes and analyzes all reports submitted to it under this
5 subdivision.

6 (2) *Submit to the authority, in a manner identified by the*
7 *authority, a report of each incident that involves the use of an*
8 *epinephrine auto-injector, not more than 30 days after each use.*
9 *The authority shall annually publish a report that summarizes all*
10 *reports submitted to it under this subdivision.*

11 (g) This section shall not apply to a school district or county
12 office of education, or its personnel, that provides and utilizes
13 epinephrine auto-injectors to provide emergency medical aid
14 pursuant to Section 49414 of the Education Code.

15 (h) This section shall not be construed to limit or restrict the
16 ability of prehospital emergency medical care personnel, under
17 any other statute or regulation, to administer epinephrine, including
18 the use of epinephrine auto-injectors, or to require additional
19 training or certification beyond what is already required under the
20 other statute or regulation.

21 SEC. 4. No reimbursement is required by this act pursuant to
22 Section 6 of Article XIII B of the California Constitution because
23 the only costs that may be incurred by a local agency or school
24 district will be incurred because this act creates a new crime or
25 infraction, eliminates a crime or infraction, or changes the penalty
26 for a crime or infraction, within the meaning of Section 17556 of
27 the Government Code, or changes the definition of a crime within
28 the meaning of Section 6 of Article XIII B of the California
29 Constitution.