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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, *to amend Section 49414 of the Education 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. *Existing law requires school districts, county offices of education, and charter schools to provide emergency epinephrine auto-injectors, as defined, to school nurses and trained personnel who have volunteered to use epinephrine auto-injectors under emergency circumstances, as specified, and authorizes school nurses and trained personnel to use epinephrine auto-injectors to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction.*

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 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 authority to publish an annual report summarizing the reports submitted to the authority pursuant to the bill’s provisions. *The bill would define the term “epinephrine auto-injector” for purposes of these provisions and other related provisions that authorize the use of epinephrine auto-injectors, as specified.*

(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. *The bill would also exempt an authorizing physician and surgeon from certain sanctions for the issuance of an epinephrine auto-injector under those provisions, except 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)

1 shall be maintained by the authorized entity for a period of three
2 years from the date the records were created. The authorized entity
3 shall be responsible for monitoring the supply of epinephrine
4 auto-injectors and ensuring the destruction of expired epinephrine
5 auto-injectors.

6 (e) The epinephrine auto-injector dispensed pursuant to this
7 section may be used only for the purpose, and under the
8 circumstances, described in Section 1797.197a of the Health and
9 Safety Code.

10 (f) *For purposes of this section, “epinephrine auto-injector”*
11 *means a disposable delivery device designed for the automatic*
12 *injection of a premeasured dose of epinephrine into the human*
13 *body to prevent or treat a life-threatening allergic reaction.*

14 SEC. 2. Section 1714.23 of the Civil Code is amended to read:
15 1714.23. (a) For purposes of this section, the following
16 definitions shall apply:

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

19 (A) Symptoms of anaphylaxis may include shortness of breath,
20 wheezing, difficulty breathing, difficulty talking or swallowing,
21 hives, itching, swelling, shock, or asthma.

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

25 (2) “Epinephrine auto-injector” means a disposable drug delivery
26 ~~system with a spring-activated concealed needle that is designed~~
27 ~~for emergency administration of epinephrine to provide rapid,~~
28 ~~convenient first aid for persons suffering from anaphylaxis.~~ *delivery*
29 *device designed for the automatic injection of a premeasured dose*
30 *of epinephrine into the human body to prevent or treat a*
31 *life-threatening allergic reaction.*

32 (b) (1) Any person described in subdivision (b) of Section
33 1797.197a of the Health and Safety Code who administers an
34 epinephrine auto-injector, in good faith and not for compensation,
35 to another person who appears to be experiencing anaphylaxis at
36 the scene of an emergency situation is not liable for any civil
37 damages resulting from his or her acts or omissions in
38 administering the epinephrine auto-injector, if that person has
39 complied with the requirements and standards of Section 1797.197a
40 of the Health and Safety Code.

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

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

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

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

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

(e) An authorizing physician and surgeon is not subject to professional review, liable in a civil action, or subject to criminal prosecution for the issuance of a prescription or order pursuant to this section, unless the physician and surgeon's issuance of the prescription or order constitutes gross negligence or willful or malicious conduct.

SEC. 3. Section 49414 of the Education Code is amended to read:

49414. (a) School districts, county offices of education, and charter schools shall provide emergency epinephrine auto-injectors to school nurses or trained personnel who have volunteered pursuant to subdivision (d), and school nurses or trained personnel may use epinephrine auto-injectors to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction.

(b) For purposes of this section, the following terms have the following meanings:

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity to a substance.

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

4 (B) Causes of anaphylaxis may include, but are not limited to,
5 an insect sting, food allergy, drug reaction, and exercise.

6 (2) “Authorizing physician and surgeon” may include, but is
7 not limited to, a physician and surgeon employed by, or contracting
8 with, a local educational agency, a medical director of the local
9 health department, or a local emergency medical services director.

10 (3) “Epinephrine auto-injector” means a disposable ~~drug delivery~~
11 ~~system with a spring-activated needle that is designed for~~
12 ~~emergency administration of epinephrine to provide rapid,~~
13 ~~convenient first aid for persons suffering a potentially fatal reaction~~
14 ~~to anaphylaxis.~~ *delivery device designed for the automatic injection*
15 *of a premeasured dose of epinephrine into the human body to*
16 *prevent or treat a life-threatening allergic reaction.*

17 (4) “Qualified supervisor of health” may include, but is not
18 limited to, a school nurse.

19 (5) “Volunteer” or “trained personnel” means an employee who
20 has volunteered to administer epinephrine auto-injectors to a person
21 if the person is suffering, or reasonably believed to be suffering,
22 from anaphylaxis, has been designated by a school, and has
23 received training pursuant to subdivision (d).

24 (c) Each private elementary and secondary school in the state
25 may voluntarily determine whether or not to make emergency
26 epinephrine auto-injectors and trained personnel available at its
27 school. In making this determination, a school shall evaluate the
28 emergency medical response time to the school and determine
29 whether initiating emergency medical services is an acceptable
30 alternative to epinephrine auto-injectors and trained personnel. A
31 private elementary or secondary school choosing to exercise the
32 authority provided under this subdivision shall not receive state
33 funds specifically for purposes of this subdivision.

34 (d) Each public and private elementary and secondary school
35 in the state may designate one or more volunteers to receive initial
36 and annual refresher training, based on the standards developed
37 pursuant to subdivision (e), regarding the storage and emergency
38 use of an epinephrine auto-injector from the school nurse or other
39 qualified person designated by an authorizing physician and
40 surgeon.

(e) (1) Every five years, or sooner as deemed necessary by the Superintendent, the Superintendent shall review minimum standards of training for the administration of epinephrine auto-injectors that satisfy the requirements of paragraph (2). For purposes of this subdivision, the Superintendent shall consult with organizations and providers with expertise in administering epinephrine auto-injectors and administering medication in a school environment, including, but not limited to, the State Department of Public Health, the Emergency Medical Services Authority, the American Academy of Allergy, Asthma and Immunology, the California School Nurses Organization, the California Medical Association, the American Academy of Pediatrics, Food Allergy Research and Education, the California Society of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, the Sean N. Parker Center for Allergy Research, and others.

(2) Training established pursuant to this subdivision shall include all of the following:

- (A) Techniques for recognizing symptoms of anaphylaxis.
- (B) Standards and procedures for the storage, restocking, and emergency use of epinephrine auto-injectors.
- (C) Emergency followup procedures, including calling the emergency 911 telephone number and contacting, if possible, the pupil's parent and physician.
- (D) Recommendations on the necessity of instruction and certification in cardiopulmonary resuscitation.
- (E) Instruction on how to determine whether to use an adult epinephrine auto-injector or a junior epinephrine auto-injector, which shall include consideration of a pupil's grade level or age as a guideline of equivalency for the appropriate pupil weight determination.
- (F) Written materials covering the information required under this subdivision.

(3) Training established pursuant to this subdivision shall be consistent with the most recent Voluntary Guidelines for Managing Food Allergies In Schools and Early Care and Education Programs published by the federal Centers for Disease Control and Prevention and the most recent guidelines for medication administration issued by the department.

1 (4) A school shall retain for reference the written materials
2 prepared under subparagraph (F) of paragraph (2).

3 (f) A school district, county office of education, or charter school
4 shall distribute a notice at least once per school year to all staff
5 that contains the following information:

6 (1) A description of the volunteer request stating that the request
7 is for volunteers to be trained to administer an epinephrine
8 auto-injector to a person if the person is suffering, or reasonably
9 believed to be suffering, from anaphylaxis, as specified in
10 subdivision (b).

11 (2) A description of the training that the volunteer will receive
12 pursuant to subdivision (d).

13 (g) (1) A qualified supervisor of health at a school district,
14 county office of education, or charter school shall obtain from an
15 authorizing physician and surgeon a prescription for each school
16 for epinephrine auto-injectors that, at a minimum, includes, for
17 elementary schools, one regular epinephrine auto-injector and one
18 junior epinephrine auto-injector, and for junior high schools, middle
19 schools, and high schools, if there are no pupils who require a
20 junior epinephrine auto-injector, one regular epinephrine
21 auto-injector. A qualified supervisor of health at a school district,
22 county office of education, or charter school shall be responsible
23 for stocking the epinephrine auto-injector and restocking it if it is
24 used.

25 (2) If a school district, county office of education, or charter
26 school does not have a qualified supervisor of health, an
27 administrator at the school district, county office of education, or
28 charter school shall carry out the duties specified in paragraph (1).

29 (3) A prescription pursuant to this subdivision may be filled by
30 local or mail order pharmacies or epinephrine auto-injector
31 manufacturers.

32 (4) An authorizing physician and surgeon shall not be subject
33 to professional review, be liable in a civil action, or be subject to
34 criminal prosecution for the issuance of a prescription or order
35 pursuant to this section, unless the physician and surgeon's issuance
36 of the prescription or order constitutes gross negligence or willful
37 or malicious conduct.

38 (h) A school nurse or, if the school does not have a school nurse
39 or the school nurse is not onsite or available, a volunteer may
40 administer an epinephrine auto-injector to a person exhibiting

1 potentially life-threatening symptoms of anaphylaxis at school or
2 a school activity when a physician is not immediately available.
3 If the epinephrine auto-injector is used it shall be restocked as soon
4 as reasonably possible, but no later than two weeks after it is used.
5 Epinephrine auto-injectors shall be restocked before their expiration
6 date.

7 (i) A volunteer shall initiate emergency medical services or
8 other appropriate medical followup in accordance with the training
9 materials retained pursuant to paragraph (4) of subdivision (e).

10 (j) A school district, county office of education, or charter school
11 shall ensure that each employee who volunteers under this section
12 will be provided defense and indemnification by the school district,
13 county office of education, or charter school for any and all civil
14 liability, in accordance with, but not limited to, that provided in
15 Division 3.6 (commencing with Section 810) of Title 1 of the
16 Government Code. This information shall be reduced to writing,
17 provided to the volunteer, and retained in the volunteer's personnel
18 file.

19 (k) A state agency, the department, or a public school may
20 accept gifts, grants, and donations from any source for the support
21 of the public school carrying out the provisions of this section,
22 including, but not limited to, the acceptance of epinephrine
23 auto-injectors from a manufacturer or wholesaler.

24 ~~SEC. 3.~~

25 *SEC. 4.* Section 1797.197a of the Health and Safety Code is
26 amended to read:

27 1797.197a. (a) For purposes of this section, the following
28 definitions shall apply:

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

31 (A) Symptoms of anaphylaxis may include shortness of breath,
32 wheezing, difficulty breathing, difficulty talking or swallowing,
33 hives, itching, swelling, shock, or asthma.

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

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

(3) “Epinephrine auto-injector” means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis. *delivery device designed for the automatic injection of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction.*

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

(5) “Prehospital emergency medical care person” has the same meaning as defined in paragraph (2) of subdivision (a) of Section 1797.189.

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

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

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

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

(4) The person using the epinephrine auto-injector has successfully completed a course of training with an authorized training provider, as described in subdivision (c), and has current certification of training issued by the provider.

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

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

(c) (1) The authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors pursuant to this section shall be established and approved, by the authority. The authority

1 may designate existing training standards for the use and
2 administration of epinephrine auto-injectors by prehospital
3 emergency medical care personnel to satisfy the requirements of
4 this section.

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

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

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

11 (C) Emergency followup procedures, including activation of
12 the Emergency Medical Services System, by calling the emergency
13 9-1-1 telephone number or otherwise alerting and summoning
14 more advanced medical personnel and services.

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

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

21 (F) Completion of a training course in cardiopulmonary
22 resuscitation and the use of an automatic external defibrillator
23 (AED) for infants, children, and adults that complies with
24 regulations adopted by the authority and the standards of the
25 American Heart Association or the American Red Cross, and a
26 current certification for that training.

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

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

35 (A) Fraud.

36 (B) Incompetence.

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

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

5 (E) Violating or attempting to violate, directly or indirectly, or
6 assisting in or abetting the violation of, or conspiring to violate,
7 any provision of this section or the regulations promulgated by the
8 authority pertaining to the review and approval of training
9 programs in anaphylaxis and the use and administration of
10 epinephrine auto-injectors, as described in this subdivision.

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

15 (2) The fees shall be deposited in the Specialized First Aid
16 Training Program Approval Fund, which is hereby created in the
17 State Treasury. All moneys deposited in the fund shall be made
18 available, upon appropriation, to the authority for purposes
19 described in paragraph (1).

20 (3) The authority may transfer unused portions of the Specialized
21 First Aid Training Program Approval Fund to the Surplus Money
22 Investment Fund. Funds transferred to the Surplus Money
23 Investment Fund shall be placed in a separate trust account, and
24 shall be available for transfer to the Specialized First Aid Training
25 Program Approval Fund, together with the interest earned, when
26 requested by the authority.

27 (4) The authority shall maintain a reserve balance in the
28 Specialized First Aid Training Program Approval Fund of 5 percent
29 of annual revenues. Any increase in the fees deposited in the
30 Specialized First Aid Training Program Approval Fund shall be
31 effective upon determination by the authority that additional
32 moneys are required to fund expenditures pursuant to subdivision
33 (c).

34 (e) (1) An authorized health care provider may issue a
35 prescription for an epinephrine auto-injector to a prehospital
36 emergency medical care person or a lay rescuer for the purpose of
37 rendering emergency care to another person upon presentation of
38 a current epinephrine auto-injector certification card issued by the
39 authority demonstrating that the person is trained and qualified to

1 administer an epinephrine auto-injector pursuant to this section or
2 any other law.

3 (2) An authorized health care provider may issue a prescription
4 for an epinephrine auto-injector to an authorized entity if the
5 authorized entity submits evidence it employs at least one person,
6 or utilizes at least one volunteer or agent, who is trained and has
7 a current epinephrine auto-injector certification card issued by the
8 authority demonstrating that the person is qualified to administer
9 an epinephrine auto-injector pursuant to this section.

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

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

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

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

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

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

22 (E) The process to replace the expired epinephrine auto-injector,
23 including the proper disposal of the expired epinephrine
24 auto-injector or used epinephrine auto-injector in a sharps
25 container.

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

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

35 (h) This section shall not be construed to limit or restrict the
36 ability of prehospital emergency medical care personnel, under
37 any other statute or regulation, to administer epinephrine, including
38 the use of epinephrine auto-injectors, or to require additional
39 training or certification beyond what is already required under the
40 other statute or regulation.

1 ~~SEC. 4.~~
2 *SEC. 5.* No reimbursement is required by this act pursuant to
3 Section 6 of Article XIII B of the California Constitution because
4 the only costs that may be incurred by a local agency or school
5 district will be incurred because this act creates a new crime or
6 infraction, eliminates a crime or infraction, or changes the penalty
7 for a crime or infraction, within the meaning of Section 17556 of
8 the Government Code, or changes the definition of a crime within
9 the meaning of Section 6 of Article XIII B of the California
10 Constitution.