First Regular Session Seventieth General Assembly STATE OF COLORADO

REREVISED

This Version Includes All Amendments Adopted in the Second House HOUSE BILL 15-1232

LLS NO. 15-0792.01 Yelana Love x2295

HOUSE SPONSORSHIP

Ginal and Landgraf,

Todd,

SENATE SPONSORSHIP

House Committees Public Health Care & Human Services Appropriations Senate Committees Health & Human Services Appropriations

A BILL FOR AN ACT

101 **CONCERNING THE EMERGENCY USE OF EPINEPHRINE AUTO-INJECTORS**

102

BY AUTHORIZED ENTITIES, AND, IN CONNECTION THEREWITH,

103 MAKING AN APPROPRIATION.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <u>http://www.leg.state.co.us/billsummaries.</u>)

The bill permits entities and organizations other than schools to acquire and stock epinephrine auto-injectors. A health care practitioner may prescribe, and a health care practitioner or pharmacist may dispense, epinephrine auto-injectors in the name of an authorized entity where allergens capable of causing anaphylaxis may be present. Each employee, SENATE 3rd Reading Unamended April 27, 2015

> Reading Unamended April 24, 2015

2nd

Reading Unamended April 2, 2015

3rd

Amended 2nd Reading April 1, 2015

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agent, or other individual of the authorized entity must complete a training program before using an epinephrine auto-injector. A trained employee, agent, or other individual of the authorized entity may either provide or administer an epinephrine auto-injector to a person who the employee, agent, or other individual believes in good faith is experiencing anaphylaxis.

An authorized entity may keep an emergency public access station (EPAS) containing epinephrine auto-injectors under the general oversight of a medical professional who is capable of communicating with a user in real time before the EPAS may be unlocked to dispense an epinephrine auto-injector.

The bill exempts from civil and criminal liability:

- ! An authorized entity that possesses and makes available an epinephrine auto-injector or an EPAS and the entity's employees, agents, and other individuals;
- ! An individual or entity that conducts the anaphylaxis training program;
- ! An individual who prescribes or dispenses an epinephrine auto-injector;
- ! An individual who provides or administers an epinephrine auto-injector;
- A medical professional who consults a user of an EPAS and makes an epinephrine auto-injector stored in the EPAS available to the user; and
- ! An individual who uses an EPAS.

1 Be it enacted by the General Assembly of the State of Colorado:

- 2 SECTION 1. In Colorado Revised Statutes, add article 47 to title
- 3 25 as follows:

4	ARTICLE 47
5	Use of Epinephrine Injectors by Authorized Entities
6	25-47-101. Definitions. As used in this article:
7	(1) "Administer" means to directly apply an epinephrine
8	AUTO-INJECTOR TO THE BODY OF AN INDIVIDUAL.
9	(2) "AUTHORIZED ENTITY" MEANS AN ENTITY OR ORGANIZATION,
10	OTHER THAN A SCHOOL DESCRIBED IN SECTION 22-1-119.5, C.R.S., OR A
11	HOSPITAL LICENSED OR CERTIFIED PURSUANT TO SECTION $25-1.5-103(1)$

(a) (I) (A) OR 25-1.5-103 (1) (a) (II), AT WHICH ALLERGENS CAPABLE OF
 CAUSING ANAPHYLAXIS MAY BE PRESENT. THE TERM INCLUDES BUT IS NOT
 LIMITED TO RECREATION CAMPS, COLLEGES AND UNIVERSITIES, DAY CARE
 FACILITIES, YOUTH SPORTS LEAGUES, AMUSEMENT PARKS, RESTAURANTS,
 PLACES OF EMPLOYMENT, SKI AREAS, AND SPORTS ARENAS.

6 (3) "EMERGENCY PUBLIC ACCESS STATION" OR "EPAS" MEANS A 7 LOCKED, SECURE CONTAINER USED TO STORE EPINEPHRINE 8 AUTO-INJECTORS FOR USE UNDER THE GENERAL OVERSIGHT OF A MEDICAL 9 PROFESSIONAL, WHICH ALLOWS A LAY RESCUER TO CONSULT WITH A 10 MEDICAL PROFESSIONAL IN REAL TIME BY AUDIO, TELEVIDEO, OR OTHER 11 SIMILAR MEANS OF ELECTRONIC COMMUNICATION. UPON AUTHORIZATION 12 OF THE CONSULTING MEDICAL PROFESSIONAL, AN EPAS MAY BE 13 UNLOCKED TO MAKE AN EPINEPHRINE AUTO-INJECTOR AVAILABLE.

14 (4) "EPINEPHRINE AUTO-INJECTOR" MEANS A SINGLE-USE DEVICE
15 USED FOR THE AUTOMATIC INJECTION OF A PREMEASURED DOSE OF
16 EPINEPHRINE INTO THE HUMAN BODY.

17 (5) "HEALTH CARE PRACTITIONER" MEANS A PERSON AUTHORIZED
18 BY LAW TO PRESCRIBE ANY DRUG OR DEVICE, ACTING WITHIN THE SCOPE
19 OF HIS OR HER AUTHORITY.

20 (6) "MEDICAL PROFESSIONAL" MEANS A PHYSICIAN OR OTHER
21 PERSON AUTHORIZED BY APPLICABLE LAW TO PRESCRIBE DRUGS IN THIS
22 STATE OR ANOTHER STATE.

23 (7) "PHARMACIST" HAS THE MEANING SET FORTH IN SECTION
24 12-42.5-102 (28), C.R.S.

25 (8) "PROVIDE" MEANS TO SUPPLY ONE OR MORE EPINEPHRINE
26 AUTO-INJECTORS TO AN INDIVIDUAL.

27 25-47-102. Stock supply of epinephrine auto-injectors -

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emergency administration. (1) NOTWITHSTANDING ANY PROVISION OF
 LAW TO THE CONTRARY:

3 (a) Prescribing to an authorized entity permitted. A HEALTH
4 CARE PRACTITIONER MAY DIRECT THE DISTRIBUTION OF EPINEPHRINE
5 AUTO-INJECTORS FROM AN IN-STATE PRESCRIPTION DRUG OUTLET TO
6 AN AUTHORIZED ENTITY FOR USE IN ACCORDANCE WITH THIS ARTICLE, AND
7 HEALTH CARE PRACTITIONERS MAY DISTRIBUTE EPINEPHRINE
8 AUTO-INJECTORS TO AN AUTHORIZED ENTITY; AND

9 (b) Authorized entities permitted to maintain supply. An
10 AUTHORIZED ENTITY MAY ACQUIRE AND STOCK A SUPPLY OF EPINEPHRINE
11 AUTO-INJECTORS PURSUANT TO A PRESCRIPTION ISSUED IN ACCORDANCE
12 WITH THIS SECTION.

13 (2) EPINEPHRINE AUTO-INJECTORS MUST BE STORED:

14 (a) IN A LOCATION THAT WILL BE READILY ACCESSIBLE IN AN15 EMERGENCY;

16 (b) ACCORDING TO THE APPLICABLE INSTRUCTIONS FOR USE; AND
17 (c) IN COMPLIANCE WITH ANY ADDITIONAL REQUIREMENTS THAT
18 MAY BE ESTABLISHED BY THE DEPARTMENT OF HEALTH.

(3) AN AUTHORIZED ENTITY SHALL DESIGNATE EMPLOYEES OR
AGENTS WHO HAVE COMPLETED THE TRAINING REQUIRED BY SECTION
25-47-104 TO BE RESPONSIBLE FOR THE STORAGE, MAINTENANCE,
CONTROL, AND GENERAL OVERSIGHT OF EPINEPHRINE AUTO-INJECTORS
ACQUIRED BY THE AUTHORIZED ENTITY.

24 25-47-103. Use of epinephrine auto-injectors. (1) AN
25 EMPLOYEE OR AGENT OF AN AUTHORIZED ENTITY OR OTHER INDIVIDUAL
26 WHO HAS COMPLETED THE TRAINING REQUIRED BY SECTION 25-47-104
27 MAY USE EPINEPHRINE AUTO-INJECTORS PRESCRIBED PURSUANT TO

1 SECTION 25-47-102 TO PROVIDE OR ADMINISTER AN EPINEPHRINE 2 AUTO-INJECTOR TO ANY INDIVIDUAL WHO THE EMPLOYEE, AGENT, OR 3 OTHER INDIVIDUAL BELIEVES IN GOOD FAITH IS EXPERIENCING 4 ANAPHYLAXIS, REGARDLESS OF WHETHER THE INDIVIDUAL HAS A 5 PRESCRIPTION FOR AN EPINEPHRINE AUTO-INJECTOR OR HAS PREVIOUSLY 6 BEEN DIAGNOSED WITH AN ALLERGY, OR TO PROVIDE AN EPINEPHRINE 7 AUTO-INJECTOR TO A FAMILY MEMBER, FRIEND, COLLEAGUE, CAREGIVER, 8 OR PERSON WITH A SIMILAR RELATIONSHIP WITH THE INDIVIDUAL; AND

9 (2) THE ADMINISTRATION OF AN EPINEPHRINE AUTO-INJECTOR IN
10 ACCORDANCE WITH THIS SECTION IS NEITHER THE PRACTICE OF MEDICINE
11 NOR OF ANY OTHER PROFESSION THAT REQUIRES LICENSURE.

12 **25-47-104.** Training. (1) AN EMPLOYEE, AGENT, OR OTHER 13 INDIVIDUAL MUST COMPLETE AN ANAPHYLAXIS TRAINING PROGRAM 14 BEFORE USING AN EPINEPHRINE AUTO-INJECTOR. THE TRAINING MUST BE 15 CONDUCTED BY A NATIONALLY RECOGNIZED ORGANIZATION EXPERIENCED 16 IN TRAINING LAYPERSONS IN EMERGENCY HEALTH TREATMENT OR BY AN 17 INDIVIDUAL OR ENTITY APPROVED BY THE DEPARTMENT OF HEALTH. THE 18 DEPARTMENT OF HEALTH MAY APPROVE SPECIFIC ENTITIES OR 19 INDIVIDUALS TO CONDUCT TRAINING OR MAY APPROVE SPECIFIC CLASSES 20 BY INDIVIDUALS OR ENTITIES. THE TRAINING MAY BE CONDUCTED ON-LINE 21 OR IN-PERSON AND, AT A MINIMUM, MUST COVER:

(a) How to recognize the signs and symptoms of severe
 Allergic reactions, including anaphylaxis;

(b) THE STANDARDS AND PROCEDURES FOR THE STORAGE ANDADMINISTRATION OF AN EPINEPHRINE AUTO-INJECTOR; AND

26 (c) EMERGENCY FOLLOW-UP PROCEDURES.

27 (2) The individual or entity that conducts the

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ANAPHYLAXIS TRAINING PROGRAM SHALL ISSUE A CERTIFICATE, ON A
 FORM DEVELOPED OR APPROVED BY THE DEPARTMENT OF HEALTH, TO
 EACH PERSON WHO SUCCESSFULLY COMPLETES THE ANAPHYLAXIS
 TRAINING PROGRAM.

5 **25-47-105. Reporting.** AN AUTHORIZED ENTITY THAT POSSESSES 6 AND MAKES AVAILABLE EPINEPHRINE AUTO-INJECTORS SHALL SUBMIT TO 7 THE DEPARTMENT OF HEALTH, ON A FORM DEVELOPED BY THE 8 DEPARTMENT OF HEALTH, A REPORT OF EACH INCIDENT ON THE 9 AUTHORIZED ENTITY'S PREMISES THAT INVOLVES THE ADMINISTRATION OF 10 AN EPINEPHRINE AUTO-INJECTOR PURSUANT TO SECTION 25-47-103. THE 11 DEPARTMENT OF HEALTH SHALL ANNUALLY PUBLISH A REPORT THAT 12 SUMMARIZES AND ANALYZES ALL REPORTS SUBMITTED TO IT UNDER THIS 13 SECTION.

14 25-47-106. Emergency public access stations - life-saving
15 allergy medication. (1) NOTWITHSTANDING ANY LAW TO THE
16 CONTRARY:

(a) A MEDICAL PROFESSIONAL MAY PRESCRIBE A STOCK SUPPLY OF
EPINEPHRINE AUTO-INJECTORS TO ANY AUTHORIZED ENTITY FOR STORAGE
IN AN EPAS, AND MAY PLACE A STOCK SUPPLY OF EPINEPHRINE
AUTO-INJECTORS IN AN EPAS MAINTAINED BY AN AUTHORIZED ENTITY;
(b) A MEDICAL PROFESSIONAL MAY CONSULT THE USER OF AN
EPAS AND MAKE THE EPINEPHRINE AUTO-INJECTORS STORED IN THE EPAS
AVAILABLE TO THE USER; AND

(c) ANY PERSON MAY USE AN EPAS TO ADMINISTER OR PROVIDE
AN EPINEPHRINE AUTO-INJECTOR TO AN INDIVIDUAL BELIEVED IN GOOD
FAITH TO BE EXPERIENCING ANAPHYLAXIS OR TO PROVIDE AN EPINEPHRINE
AUTO-INJECTOR TO A FAMILY MEMBER, FRIEND, COLLEAGUE, CAREGIVER,

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1 OR PERSON WITH A SIMILAR RELATIONSHIP WITH THE INDIVIDUAL.

2 (2) THE USE OF AN EPAS IN ACCORDANCE WITH THIS ARTICLE IS
3 NEITHER THE PRACTICE OF MEDICINE NOR OF ANY OTHER PROFESSION THAT
4 REQUIRES LICENSURE.

5 25-47-107. Good samaritan protections - liability. (1) THE
6 FOLLOWING INDIVIDUALS AND ENTITIES ARE IMMUNE FROM CRIMINAL
7 LIABILITY AND FROM SUIT IN ANY CIVIL ACTION BROUGHT BY ANY PERSON
8 FOR INJURIES OR RELATED DAMAGES THAT RESULT FROM AN ACT OR
9 OMISSION TAKEN PURSUANT TO THIS ARTICLE:

10 (a) AN AUTHORIZED ENTITY THAT POSSESSES AND MAKES
11 AVAILABLE EPINEPHRINE AUTO-INJECTORS OR AN EPAS AND THE ENTITY'S
12 EMPLOYEES, AGENTS, AND OTHER INDIVIDUALS;

(b) AN AUTHORIZED ENTITY THAT DOES NOT POSSESS OR MAKE
AVAILABLE EPINEPHRINE AUTO-INJECTORS OR AN EPAS AND THE ENTITY'S
EMPLOYEES, AGENTS, AND OTHER INDIVIDUALS;

16 (c) AN INDIVIDUAL OR ENTITY THAT CONDUCTS AN ANAPHYLAXIS
 17 TRAINING PROGRAM;

18 (d) AN INDIVIDUAL WHO PRESCRIBES OR DISPENSES AN
19 EPINEPHRINE AUTO-INJECTOR;

20 (e) AN INDIVIDUAL WHO ADMINISTERS OR PROVIDES AN
21 EPINEPHRINE AUTO-INJECTOR;

(f) A MEDICAL PROFESSIONAL WHO CONSULTS THE USER OF AN
EPAS AND MAKES THE EPINEPHRINE AUTO-INJECTORS STORED IN THE
EPAS AVAILABLE TO THE USER; OR

25 (g) AN INDIVIDUAL WHO USES AN EPAS.

26 (2) IMMUNITY UNDER SUBSECTION (1) OF THIS SECTION DOES NOT
 27 APPLY TO ACTS OR OMISSIONS THAT ARE GROSSLY NEGLIGENT OR WILLFUL

1 AND WANTON.

(3) THIS SECTION DOES NOT ELIMINATE, LIMIT, OR REDUCE ANY
OTHER IMMUNITY OR DEFENSE THAT MAY BE AVAILABLE UNDER STATE
LAW, INCLUDING THE PROTECTIONS SET FORTH IN SECTION 13-21-108,
C.R.S. PROVIDING OR ADMINISTERING AN EPINEPHRINE AUTO-INJECTOR BY
AN ENTITY OR INDIVIDUAL IS DEEMED EMERGENCY CARE OR EMERGENCY
ASSISTANCE FOR PURPOSES OF SECTION 13-21-108, C.R.S.

8 (4) AN AUTHORIZED ENTITY LOCATED IN THIS STATE THAT 9 PROVIDES OR ADMINISTERS AN EPINEPHRINE AUTO-INJECTOR OUTSIDE OF 10 THIS STATE IS NOT LIABLE FOR ANY RESULTING INJURIES OR RELATED 11 DAMAGES IF THE AUTHORIZED ENTITY:

12 (a) WOULD NOT BE LIABLE FOR THE INJURIES OR RELATED
13 DAMAGES IF THE EPINEPHRINE AUTO-INJECTOR HAD BEEN PROVIDED OR
14 ADMINISTERED IN THIS STATE; OR

(b) IS NOT LIABLE FOR INJURIES OR RELATED DAMAGES UNDER THE
LAW OF THE STATE WHERE THE AUTHORIZED ENTITY PROVIDED OR
ADMINISTERED THE EPINEPHRINE AUTO-INJECTOR.

18 25-47-108. Health care professionals - hospitals - obligations
19 under state and federal law. Nothing in this article limits the
20 Obligations of a health care professional or hospital under
21 STATE OR FEDERAL LAW IN PRESCRIBING, STORING, OR ADMINISTERING
22 DRUGS OR DEVICES.

23 SECTION 2. In Colorado Revised Statutes, 12-36-117, amend
24 (1.8) as follows:

12-36-117. Unprofessional conduct. (1.8) A licensee shall IS not
 be subject to disciplinary action by the board for issuing standing orders
 and protocols regarding the use of epinephrine auto-injectors in a public

1 or nonpublic school in accordance with the requirements of section 2 22-1-119.5, C.R.S., or for the actions taken by a school nurse or by any 3 designated school personnel who administer epinephrine auto-injectors 4 in accordance with the requirements of section 22-1-119.5, C.R.S., OR 5 FOR PRESCRIBING EPINEPHRINE AUTO-INJECTORS IN ACCORDANCE WITH 6 THE REQUIREMENTS OF ARTICLE 47 OF TITLE 25, C.R.S. 7 **SECTION 3.** In Colorado Revised Statutes, 12-38-125, add (1) 8 (o) as follows: 9 **12-38-125.** Exclusions. (1) No provision of this article shall be 10 construed to prohibit: 11 (0) A PRESCRIPTION BY AN ADVANCED PRACTICE NURSE WITH 12 PRESCRIPTIVE AUTHORITY FOR THE USE OF EPINEPHRINE AUTO-INJECTORS 13 BY AN AUTHORIZED ENTITY IN ACCORDANCE WITH ARTICLE 47 OF TITLE 25, 14 C.R.S. 15 SECTION 4. In Colorado Revised Statutes, 12-42.5-102, amend 16 (42) (b) (XV) as follows: 12-42.5-102. Definitions. As used in this article, unless the 17 18 context otherwise requires or the term is otherwise defined in another part 19 of this article: 20 (42) (b) "Wholesale distribution" does not include: 21 (XV) The distribution, donation, or sale by a manufacturer or 22 wholesaler of a stock supply of epinephrine auto-injectors to public 23 schools or nonpublic schools for emergency use by designated school 24 personnel in accordance with the requirements of section 22-1-119.5, 25 C.R.S., OR TO OTHER ENTITIES FOR EMERGENCY USE IN ACCORDANCE WITH 26 THE REQUIREMENTS OF ARTICLE 47 OF TITLE 25, C.R.S. 27 **SECTION 5.** Appropriation. For the 2015-16 state fiscal year,

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\$23,736 is appropriated to the department of public health and environment for use by the disease control and environmental epidemiology division. This appropriation is from the general fund and is based on an assumption that the division will require an additional 0.4 FTE. To implement this act, the division may use this appropriation for costs to implement this act.

SECTION 6. Safety clause. The general assembly hereby finds,
determines, and declares that this act is necessary for the immediate
preservation of the public peace, health, and safety.