

SENATE BILL 965

J1
SB 898/16 – FIN

7lr3018

By: **Senator Klausmeier**

Introduced and read first time: February 3, 2017

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Auto-Injectable Epinephrine – Certification for Emergency**
3 **Administration**

4 FOR the purpose of establishing requirements for an authorized entity to obtain and store
5 a supply of auto-injectable epinephrine; prohibiting an authorized entity from
6 obtaining and storing auto-injectable epinephrine unless the authorized entity has
7 a certain number of certain employees or certain affiliated individuals; requiring an
8 authorized entity to maintain a copy of a certain certificate issued to certain
9 individuals; establishing qualifications for an individual to obtain a certificate to
10 obtain, store, and administer auto-injectable epinephrine to be used in an emergency
11 situation; establishing the term of a certain certificate; authorizing the Department
12 of Health and Mental Hygiene to adopt certain regulations; requiring the
13 Department to approve certain training programs; providing for the contents and
14 renewal of certain certificates; authorizing certain physicians to prescribe and
15 certain pharmacists and physicians to dispense auto-injectable epinephrine to
16 certain certificate holders or authorized entities; authorizing certain certificate
17 holders or authorized entities to take certain actions; authorizing a certificate holder
18 to administer auto-injectable epinephrine to a certain individual in a certain
19 situation; providing that a cause of action may not arise against certain certificate
20 holders or authorized entities for certain acts or omissions under certain
21 circumstances; providing a certain exception to a certain immunity; providing that a
22 cause of action may not arise against certain physicians who prescribe or dispense
23 auto-injectable epinephrine to certain certificate holders or authorized entities
24 under certain circumstances; providing that a cause of action may not arise against
25 certain pharmacists who dispense auto-injectable epinephrine to certain certificate
26 holders or authorized entities under certain circumstances; providing for immunity
27 from civil liability for certain individuals under certain circumstances; providing for
28 the effect of certain provisions of this Act; providing for the application of this Act;
29 providing for the construction of this Act; defining certain terms; and generally
30 relating to certification for obtaining, storing, and administering auto-injectable
31 epinephrine.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 BY adding to

2 Article – Health – General

3 Section 13–7A–01 through 13–7A–09 to be under the new subtitle “Subtitle 7A.

4 Emergency Administration of Auto–Injectable Epinephrine”

5 Annotated Code of Maryland

6 (2015 Replacement Volume and 2016 Supplement)

7 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
8 That the Laws of Maryland read as follows:

9 **Article – Health – General**

10 **SUBTITLE 7A. EMERGENCY ADMINISTRATION OF AUTO–INJECTABLE**
11 **EPINEPHRINE.**

12 **13–7A–01.**

13 **(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS**
14 **INDICATED.**

15 **(B) “AFFILIATED INDIVIDUAL” MEANS AN INDIVIDUAL WHO:**

16 **(1) IS AT LEAST 18 YEARS OF AGE;**

17 **(2) HAS AN UNPAID AND CLOSE ASSOCIATION WITH AN AUTHORIZING**
18 **ENTITY;**

19 **(3) HAS SUCCESSFULLY COMPLETED, AT THE EXPENSE OF THE**
20 **APPLICANT, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE**
21 **DEPARTMENT; AND**

22 **(4) IS DESIGNATED BY AN AUTHORIZED ENTITY TO OBTAIN, STORE,**
23 **AND ADMINISTER AUTO–INJECTABLE EPINEPHRINE IN ACCORDANCE WITH THE**
24 **PROVISIONS OF THIS SUBTITLE.**

25 **(C) “ANAPHYLAXIS” MEANS A SUDDEN, SEVERE, AND POTENTIALLY**
26 **LIFE–THREATENING ALLERGIC REACTION THAT OCCURS WHEN AN INDIVIDUAL IS**
27 **EXPOSED TO AN ALLERGEN.**

28 **(D) (1) “AUTHORIZED ENTITY” MEANS AN ENTITY:**

29 **(I) AT WHICH ALLERGENS CAPABLE OF CAUSING ANAPHYLAXIS**
30 **MAY BE PRESENT; AND**

(II) THAT IS AUTHORIZED UNDER THIS SUBTITLE TO OBTAIN AND STORE AUTO-INJECTABLE EPINEPHRINE.

(2) "AUTHORIZED ENTITY" INCLUDES:

(I) A COLLEGE OR UNIVERSITY;

(II) A DAY CARE FACILITY;

(III) A FOOD SERVICE FACILITY;

(IV) AN AMUSEMENT PARK; AND

(V) A YOUTH SPORTS LEAGUE.

(3) "AUTHORIZED ENTITY" DOES NOT INCLUDE A YOUTH CAMP AS DEFINED IN § 14-401 OF THIS ARTICLE.

(E) "AUTO-INJECTABLE EPINEPHRINE" MEANS A PORTABLE, DISPOSABLE DRUG DELIVERY DEVICE THAT CONTAINS A PREMEASURED SINGLE DOSE OF EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.

(F) "CERTIFICATE" MEANS A CERTIFICATE ISSUED BY AN EDUCATIONAL PROGRAM APPROVED BY THE DEPARTMENT TO AN INDIVIDUAL TO OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE EPINEPHRINE.

(G) "CERTIFICATE HOLDER" MEANS AN INDIVIDUAL WHO:

(1) IS AT LEAST 18 YEARS OLD; AND

(2) IS AUTHORIZED TO OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE EPINEPHRINE TO BE USED IN AN EMERGENCY SITUATION.

13-7A-02.

THIS SUBTITLE DOES NOT APPLY TO:

(1) THE EMERGENCY AND ALLERGY TREATMENT PROGRAM UNDER SUBTITLE 7 OF THIS TITLE;

(2) PUBLIC ELEMENTARY AND SECONDARY SCHOOLS; OR

(3) NONPUBLIC ELEMENTARY AND SECONDARY SCHOOLS.

13-7A-03.

(A) SUBJECT TO SUBSECTION (C) OF THIS SECTION, AN AUTHORIZED ENTITY MAY OBTAIN:

(1) A PRESCRIPTION FOR A SUPPLY OF AUTO-INJECTABLE EPINEPHRINE FROM A LICENSED PHYSICIAN AS PROVIDED IN § 13-7A-07 OF THIS SUBTITLE; AND

(2) A SUPPLY OF AUTO-INJECTABLE EPINEPHRINE FROM A LICENSED PHARMACIST OR A LICENSED PHYSICIAN AS PROVIDED IN § 13-7A-07 OF THIS SUBTITLE.

(B) (1) AN AUTHORIZED ENTITY SHALL STORE A SUPPLY OF AUTO-INJECTABLE EPINEPHRINE OBTAINED UNDER SUBSECTION (A)(2) OF THIS SECTION:

(I) IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS; AND

(II) IN A LOCATION THAT IS READILY ACCESSIBLE TO EMPLOYEES OR AFFILIATED INDIVIDUALS IN AN EMERGENCY SITUATION.

(2) AN AUTHORIZED ENTITY SHALL DESIGNATE THE EMPLOYEES WHO ARE CERTIFICATE HOLDERS OR AFFILIATED INDIVIDUALS WHO ARE CERTIFICATE HOLDERS WHO WILL BE RESPONSIBLE FOR THE STORAGE, MAINTENANCE, AND CONTROL OF THE SUPPLY OF THE AUTO-INJECTABLE EPINEPHRINE.

(C) (1) AN AUTHORIZED ENTITY MAY NOT OBTAIN OR STORE AUTO-INJECTABLE EPINEPHRINE UNLESS THE AUTHORIZED ENTITY HAS AT LEAST TWO:

(I) EMPLOYEES WHO ARE CERTIFICATE HOLDERS; OR

(II) DESIGNATED AFFILIATED INDIVIDUALS WHO ARE CERTIFICATE HOLDERS.

(2) AN OWNER OF AN AUTHORIZED ENTITY WHO IS A CERTIFICATE HOLDER SHALL BE DEEMED TO BE AN EMPLOYEE FOR PURPOSES OF THE REQUIREMENT UNDER PARAGRAPH (1) OF THIS SUBSECTION.

(D) AN AUTHORIZED ENTITY SHALL MAINTAIN A COPY OF THE CERTIFICATE ISSUED TO AN EMPLOYEE OR AN AFFILIATED INDIVIDUAL UNDER § 13-7A-06 OF THIS SUBTITLE.

1 13-7A-04.

2 THE DEPARTMENT:

3 (1) MAY ADOPT REGULATIONS TO CARRY OUT THIS SUBTITLE; AND

4 (2) SHALL APPROVE EDUCATIONAL TRAINING PROGRAMS,
5 INCLUDING PROGRAMS CONDUCTED BY OTHER STATE AGENCIES OR PRIVATE
6 ENTITIES.

7 13-7A-05.

8 (A) TO QUALIFY FOR A CERTIFICATE, AN INDIVIDUAL SHALL MEET THE
9 REQUIREMENTS OF THIS SECTION.

10 (B) (1) THE APPLICANT SHALL SUCCESSFULLY COMPLETE, AT THE
11 EXPENSE OF THE APPLICANT, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY
12 THE DEPARTMENT.

13 (2) THE EDUCATIONAL TRAINING PROGRAM REQUIRED UNDER
14 PARAGRAPH (1) OF THIS SUBSECTION MAY BE AN ONLINE TRAINING PROGRAM.

15 13-7A-06.

16 (A) AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE
17 DEPARTMENT SHALL ISSUE A CERTIFICATE TO ANY APPLICANT WHO MEETS THE
18 REQUIREMENTS OF THIS SUBTITLE.

19 (B) (1) THE CERTIFICATE SHALL BE VALID FOR 2 YEARS.

20 (2) TO RENEW THE CERTIFICATE FOR AN ADDITIONAL 2-YEAR TERM,
21 THE APPLICANT SHALL SUCCESSFULLY COMPLETE A REFRESHER EDUCATIONAL
22 TRAINING PROGRAM APPROVED BY THE DEPARTMENT.

23 13-7A-07.

24 (A) (1) A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE
25 MAY PRESCRIBE AUTO-INJECTABLE EPINEPHRINE IN THE NAME OF:

26 (I) A CERTIFICATE HOLDER; OR

27 (II) SUBJECT TO SUBSECTION (C) OF THIS SECTION, AN
28 AUTHORIZED ENTITY.

(2) A PHARMACIST LICENSED TO PRACTICE PHARMACY IN THE STATE OR A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE MAY DISPENSE AUTO-INJECTABLE EPINEPHRINE UNDER A PRESCRIPTION ISSUED TO A CERTIFICATE HOLDER OR AN AUTHORIZED ENTITY.

(B) A CERTIFICATE HOLDER MAY:

(1) ON PRESENTMENT OF A CERTIFICATE, RECEIVE FROM ANY PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE A PRESCRIPTION FOR AUTO-INJECTABLE EPINEPHRINE; AND

(2) POSSESS AND STORE PRESCRIBED AUTO-INJECTABLE EPINEPHRINE.

(C) AN AUTHORIZED ENTITY MAY:

(1) ON PRESENTMENT OF A CERTIFICATE OF AN EMPLOYEE OF THE AUTHORIZED ENTITY OR AN AFFILIATED INDIVIDUAL, RECEIVE FROM ANY PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE A PRESCRIPTION FOR AUTO-INJECTABLE EPINEPHRINE; AND

(2) POSSESS AND STORE THE PRESCRIBED AUTO-INJECTABLE EPINEPHRINE.

(D) IN AN EMERGENCY SITUATION WHEN A PHYSICIAN OR EMERGENCY MEDICAL SERVICES ARE NOT IMMEDIATELY AVAILABLE, A CERTIFICATE HOLDER OR AN AUTHORIZED ENTITY MAY MAKE AVAILABLE AND A CERTIFICATE HOLDER MAY ADMINISTER AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL WHO IS EXPERIENCING OR IS BELIEVED IN GOOD FAITH BY THE CERTIFICATE HOLDER TO BE EXPERIENCING ANAPHYLAXIS.

13-7A-08.

(A) (1) A CAUSE OF ACTION MAY NOT ARISE AGAINST A CERTIFICATE HOLDER OR AN AUTHORIZED ENTITY FOR ANY ACT OR OMISSION IF THE CERTIFICATE HOLDER OR AUTHORIZED ENTITY IS ACTING IN GOOD FAITH WHILE MAKING AVAILABLE OR ADMINISTERING AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL WHO IS EXPERIENCING OR BELIEVED BY THE CERTIFICATE HOLDER OR AUTHORIZED ENTITY TO BE EXPERIENCING ANAPHYLAXIS EXCEPT WHERE THE CONDUCT OF THE CERTIFICATE HOLDER OR AUTHORIZED ENTITY AMOUNTS TO GROSS NEGLIGENCE, WILLFUL OR WANTON MISCONDUCT, OR INTENTIONALLY TORTIOUS CONDUCT.

1 **(2) THE PROVISIONS OF PARAGRAPH (1) OF THIS SUBSECTION DO**
2 **NOT APPLY IF A CERTIFICATE HOLDER OR AN AUTHORIZED ENTITY THAT MAKES**
3 **AVAILABLE OR A CERTIFICATE HOLDER WHO ADMINISTERS AUTO-INJECTABLE**
4 **EPINEPHRINE TO AN INDIVIDUAL WHO IS EXPERIENCING OR IS BELIEVED BY THE**
5 **CERTIFICATE HOLDER OR AUTHORIZED ENTITY TO BE EXPERIENCING**
6 **ANAPHYLAXIS:**

7 **(I) FAILS TO FOLLOW STANDARDS AND PROCEDURES FOR**
8 **STORAGE AND ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; OR**

9 **(II) ADMINISTERS AUTO-INJECTABLE EPINEPHRINE THAT IS**
10 **BEYOND THE MANUFACTURER'S EXPIRATION DATE.**

11 **(B) (1) A CAUSE OF ACTION MAY NOT ARISE AGAINST A PHYSICIAN FOR**
12 **ANY ACT OR OMISSION IF THE PHYSICIAN IN GOOD FAITH PRESCRIBES OR**
13 **DISPENSES AUTO-INJECTABLE EPINEPHRINE TO A CERTIFICATE HOLDER OR AN**
14 **AUTHORIZED ENTITY UNDER THIS SUBTITLE.**

15 **(2) A CAUSE OF ACTION MAY NOT ARISE AGAINST A PHARMACIST FOR**
16 **ANY ACT OR OMISSION IF THE PHARMACIST IN GOOD FAITH DISPENSES**
17 **AUTO-INJECTABLE EPINEPHRINE TO A CERTIFICATE HOLDER OR AN AUTHORIZED**
18 **ENTITY UNDER THIS SUBTITLE.**

19 **(C) THIS SECTION DOES NOT AFFECT AND MAY NOT BE CONSTRUED AS**
20 **AFFECTING ANY IMMUNITIES FROM CIVIL LIABILITY OR DEFENSES ESTABLISHED BY**
21 **ANY OTHER PROVISION OF THE CODE OR BY COMMON LAW TO WHICH A PHYSICIAN**
22 **OR PHARMACIST MAY BE ENTITLED.**

23 **13-7A-09.**

24 **(A) THIS SUBTITLE MAY NOT BE CONSTRUED TO CREATE A DUTY ON ANY**
25 **INDIVIDUAL TO OBTAIN A CERTIFICATE UNDER THIS SUBTITLE, AND AN INDIVIDUAL**
26 **MAY NOT BE HELD CIVILLY LIABLE FOR FAILING TO OBTAIN A CERTIFICATE UNDER**
27 **THIS SUBTITLE.**

28 **(B) AN INDIVIDUAL MAY NOT BE HELD CIVILLY LIABLE IN ANY ACTION**
29 **ARISING FROM OR IN CONNECTION WITH THE ADMINISTRATION OF**
30 **AUTO-INJECTABLE EPINEPHRINE BY THE INDIVIDUAL SOLELY BECAUSE THE**
31 **INDIVIDUAL DID NOT POSSESS A CERTIFICATE ISSUED UNDER THIS SUBTITLE.**

32 **SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect**
33 **October 1, 2017.**