SENATE BILL 915

J1

By: Senator Manno

Introduced and read first time: January 31, 2014 Assigned to: Finance and Judicial Proceedings

A BILL ENTITLED

1 AN ACT concerning

2 Public Health – Emergency Use Auto–Injectable Epinephrine Program

3 FOR the purpose of establishing the Emergency Use Auto-Injectable Epinephrine 4 Program in the Department of Health and Mental Hygiene; providing for the $\mathbf{5}$ purpose of the Program; authorizing the Department to adopt certain 6 regulations, collect certain fees, issue and renew certain certificates, and 7 conduct and approve certain training programs relating to the Program; 8 establishing qualifications for applicants for a certain certificate; requiring the 9 Department to issue certain certificates to certain applicants; providing for the contents, replacement, term, and renewal of certain certificates; authorizing 10 certain physicians to prescribe and certain pharmacists to dispense 11 12auto-injectable epinephrine to certain certificate holders; authorizing certain 13 certificate holders to take certain actions; providing that a cause of action may not arise against certain certificate holders for certain acts or omissions under 1415certain circumstances; providing that a cause of action may not arise against 16 certain physicians who prescribe or dispense auto-injectable epinephrine and 17certain paraphernalia to certain certificate holders under certain circumstances; providing that a cause of action may not arise against certain pharmacists who 18 19dispense auto-injectable epinephrine and certain paraphernalia to certain 20certificate holders under certain circumstances; providing for immunity from 21civil liability for certain individuals under certain circumstances; providing for 22the effect of certain provisions of this Act; providing for the construction of this 23Act; requiring certain certificate holders to submit to the Department a certain 24report; requiring the Department to publish a certain report on or before a 25certain date each year; defining certain terms; and generally relating to the 26Emergency Use Auto–Injectable Epinephrine Program.

27 BY adding to28 Article – Health – General

Section 13–7A–01 through 13–7A–10 to be under the new subtitle "Subtitle 7A.
 Emergency Use Auto–Injectable Epinephrine Program"

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law. 4lr1279 CF 4lr2173



	2 SENATE BILL 915
$\frac{1}{2}$	Annotated Code of Maryland (2009 Replacement Volume and 2013 Supplement)
$\frac{3}{4}$	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
5	Article – Health – General
6	SUBTITLE 7A. EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE PROGRAM.
7	13-7A-01.
8 9	(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
10 11 12 13	(B) "AGENT" MEANS AN INDIVIDUAL WHO IS APPOINTED BY A CERTIFICATE HOLDER THAT IS NOT AN INDIVIDUAL TO ADMINISTER AUTO-INJECTABLE EPINEPHRINE IN ACCORDANCE WITH THE PROVISIONS OF THE PROGRAM.
14 15 16	(C) "ANAPHYLAXIS" MEANS A SUDDEN, SEVERE, AND POTENTIALLY LIFE-THREATENING ALLERGIC REACTION THAT OCCURS WHEN AN INDIVIDUAL IS EXPOSED TO AN ALLERGEN.
17 18 19 20	(D) "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.
$\begin{array}{c} 21 \\ 22 \\ 23 \end{array}$	(E) "CERTIFICATE" MEANS A CERTIFICATE ISSUED BY THE DEPARTMENT TO AN AUTHORIZED PERSON TO OBTAIN, STORE, AND ADMINISTER AUTO–INJECTABLE EPINEPHRINE.
$\begin{array}{c} 24\\ 25\\ 26\end{array}$	(F) "CERTIFICATE HOLDER" MEANS A PERSON WHO IS AUTHORIZED BY THE DEPARTMENT TO OBTAIN, STORE, AND ADMINISTER AUTO–INJECTABLE EPINEPHRINE TO BE USED IN AN EMERGENCY SITUATION.
$27 \\ 28 \\ 29$	(G) "PROGRAM" MEANS THE EMERGENCY USE Auto–Injectable Epinephrine Program established under § 13–7A–02 of this subtitle.
30	13-7A-02.

1 (A) THERE IS AN EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE 2 PROGRAM IN THE DEPARTMENT.

THE PURPOSE OF THE PROGRAM IS TO PROVIDE A MEANS OF 3 **(B)** OBTAIN AND 4 AUTHORIZING PERSONS ТО STORE **AUTO-INJECTABLE** 5 EPINEPHRINE AND ADMINISTER AUTO-INJECTABLE EPINEPHRINE то 6 INDIVIDUALS WHO ARE EXPERIENCING ANAPHYLAXIS WHEN PHYSICIAN OR 7 EMERGENCY MEDICAL SERVICES ARE NOT IMMEDIATELY AVAILABLE.

8 **13–7A–03.**

9 **THE DEPARTMENT MAY:**

10(1) ADOPT REGULATIONS FOR THE ADMINISTRATION OF THE11PROGRAM;

12(2)COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF13THE PROGRAM;

14(3)ISSUE AND RENEW CERTIFICATES TO PERSONS MEETING THE15REQUIREMENTS OF THIS SUBTITLE; AND

16(4)(I)CONDUCTEDUCATIONALTRAININGPROGRAMS17DESCRIBED IN § 13–7A –04(E) OF THIS SUBTITLE; AND

18(II) APPROVE EDUCATIONAL TRAINING PROGRAMS19CONDUCTED BY OTHER STATE AGENCIES OR PRIVATE ENTITIES.

20 **13–7A–04.**

21 (A) TO QUALIFY FOR A CERTIFICATE, A PERSON SHALL MEET THE 22 REQUIREMENTS OF THIS SECTION.

23 (B) THE APPLICANT OR AN AGENT OF THE APPLICANT SHALL BE AT 24 LEAST 18 YEARS OLD.

(C) THE APPLICANT SHALL HAVE, OR REASONABLY EXPECT TO HAVE,
RESPONSIBILITY FOR AT LEAST ONE OTHER PERSON AS A RESULT OF THE
INDIVIDUAL'S OCCUPATION OR VOLUNTEER STATUS.

(D) (1) THE APPLICANT OR AGENT OF THE APPLICANT SHALL
 SUCCESSFULLY COMPLETE AN EDUCATIONAL TRAINING PROGRAM APPROVED
 BY THE DEPARTMENT.

SENATE BILL 915

(2) 1 EDUCATIONAL TRAINING PROGRAMS REQUIRED UNDER THIS $\mathbf{2}$ **SUBSECTION SHALL:** 3 **(I) BE CONDUCTED BY:** 4 A PHYSICIAN LICENSED TO PRACTICE MEDICINE 1. IN THE STATE UNDER TITLE 14 OF THE HEALTH OCCUPATIONS ARTICLE; $\mathbf{5}$ 6 2. A NURSE PRACTITIONER WHO IS LICENSED TO 7 PRACTICE REGISTERED NURSING IN THE STATE UNDER TITLE 8 OF THE HEALTH OCCUPATIONS ARTICLE AND IS CERTIFIED AS A NURSE PRACTITIONER 8 BY THE STATE BOARD OF NURSING: 9 10 3. A NATIONALLY RECOGNIZED ORGANIZATION 11 EXPERIENCED IN TRAINING LAYPERSONS IN EMERGENCY MEDICAL TREATMENT; 12OR 13 4. ANY OTHER PERSON APPROVED BY THE 14**DEPARTMENT: AND** 15**(II) INCLUDE TRAINING IN:** 16 1. THE RECOGNITION OF THE SYMPTOMS OF 17ANAPHLYAXIS; 18 2. PROCEDURES THE FOR **EMERGENCY** 19ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; Тне 203. PROPER FOLLOW-UP EMERGENCY 21PROCEDURES AFTER ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; 22AND 23**4**. STANDARDS AND PROCEDURES FOR OBTAINING, 24AND THE PROPER AND SECURE STORAGE OF, AUTO-INJECTABLE EPINEPHRINE. 13-7A-05. 2526AN APPLICANT FOR A CERTIFICATE SHALL: 27SUBMIT AN APPLICATION TO THE DEPARTMENT ON THE (1) 28FORM THAT THE DEPARTMENT REQUIRES; AND

4

SENATE BILL 915

PAY TO THE DEPARTMENT THE APPLICATION FEE SET BY THE 1 (2) $\mathbf{2}$ **DEPARTMENT.** 13-7A-06. 3 (A) THE DEPARTMENT SHALL ISSUE A CERTIFICATE TO ANY APPLICANT 4 $\mathbf{5}$ WHO MEETS THE REQUIREMENTS OF THIS SUBTITLE. 6 **(B) EACH CERTIFICATE SHALL INCLUDE:** 7 (1) THE FULL NAME OF THE CERTIFICATE HOLDER; AND 8 (2) A SERIAL NUMBER. **(**C**)** 9 A REPLACEMENT CERTIFICATE MAY BE ISSUED TO REPLACE A LOST, 10 DESTROYED, OR MUTILATED CERTIFICATE IF THE CERTIFICATE HOLDER PAYS THE CERTIFICATE REPLACEMENT FEE. 11 12THE CERTIFICATE SHALL BE VALID FOR 2 YEARS. **(**D**)** (1) 13 (2) TO RENEW THE CERTIFICATE FOR AN ADDITIONAL 2-YEAR 14TERM, THE APPLICANT OR THE AGENT OF THE APPLICANT SHALL: 15**(I)** SUCCESSFULLY COMPLETE A REFRESHER TRAINING PROGRAM APPROVED BY THE DEPARTMENT; OR 16 **DEMONSTRATE PROFICIENCY TO THE DEPARTMENT.** 17**(II)** 13-7A-07. 18 19 (A) (1) A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE 20STATE MAY PRESCRIBE AUTO-INJECTABLE EPINEPHRINE IN THE NAME OF A 21**CERTIFICATE HOLDER.** 22(2) A PHARMACIST LICENSED TO PRACTICE PHARMACY IN THE STATE OR A PHYSICIAN MAY DISPENSE AUTO-INJECTABLE EPINEPHRINE 2324UNDER A PRESCRIPTION ISSUED TO A CERTIFICATE HOLDER. 25**(B)** A CERTIFICATE HOLDER MAY: ON PRESENTMENT OF A CERTIFICATE, RECEIVE FROM ANY 26(1) 27PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE A PRESCRIPTION FOR AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA
 FOR THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE;

3(2) POSSESS AND STORE PRESCRIBED AUTO-INJECTABLE4EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE5ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; AND

6 (3) IN AN EMERGENCY SITUATION WHEN PHYSICIAN OR 7 EMERGENCY MEDICAL SERVICES ARE NOT IMMEDIATELY AVAILABLE, 8 ADMINISTER AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL WHO IS 9 EXPERIENCING OR BELIEVED IN GOOD FAITH BY THE CERTIFICATE HOLDER TO 10 BE EXPERIENCING ANAPHYLAXIS.

11 **13–7A –08.**

12 (A) A CAUSE OF ACTION MAY NOT ARISE AGAINST A CERTIFICATE 13 HOLDER FOR ANY ACT OR OMISSION IF THE CERTIFICATE HOLDER IS ACTING IN 14 GOOD FAITH WHILE RENDERING EMERGENCY TREATMENT TO AN INDIVIDUAL 15 WHO IS EXPERIENCING OR BELIEVED BY THE CERTIFICATE HOLDER TO BE 16 EXPERIENCING ANAPHYLAXIS UNLESS THE CONDUCT OF THE CERTIFICATE 17 HOLDER AMOUNTS TO GROSS NEGLIGENCE, WILLFUL OR WANTON MISCONDUCT, 18 OR INTENTIONALLY TORTIOUS CONDUCT.

19 A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHYSICIAN **(B)** (1) 20FOR ANY ACT OR OMISSION IF THE PHYSICIAN IN GOOD FAITH PRESCRIBES OR 21DISPENSES AUTO-INJECTABLE **EPINEPHRINE** AND THE NECESSARY 22PARAPHERNALIA FOR THE ADMINISTRATION OF **AUTO-INJECTABLE** 23EPINEPHRINE TO AN INDIVIDUAL CERTIFIED BY THE DEPARTMENT UNDER § 2413–7A–06 OF THIS SUBTITLE.

25A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY (2) 26PHARMACIST FOR ANY ACT OR OMISSION IF THE PHARMACIST IN GOOD FAITH 27AUTO-INJECTABLE AND THE DISPENSES **EPINEPHRINE NECESSARY** 28PARAPHERNALIA FOR THE ADMINISTRATION OF **AUTO-INJECTABLE** 29EPINEPHRINE TO AN INDIVIDUAL CERTIFIED BY THE DEPARTMENT UNDER § 30 13–7A–06 OF THIS SUBTITLE.

(C) THIS SECTION DOES NOT AFFECT ANY IMMUNITIES FROM CIVIL
 LIABILITY OR DEFENSES ESTABLISHED BY ANY OTHER PROVISION OF
 STATUTORY LAW OR BY COMMON LAW TO WHICH A VOLUNTEER, PHYSICIAN, OR
 PHARMACIST MAY BE ENTITLED.

35 **13–7A–09.**

1 (A) THIS SUBTITLE MAY NOT BE CONSTRUED TO CREATE A DUTY ON 2 ANY INDIVIDUAL TO OBTAIN A CERTIFICATE UNDER THIS SUBTITLE, AND AN 3 INDIVIDUAL MAY NOT BE HELD CIVILLY LIABLE FOR FAILING TO OBTAIN A 4 CERTIFICATE UNDER THIS SUBTITLE.

5 (B) AN INDIVIDUAL MAY NOT BE HELD CIVILLY LIABLE IN ANY ACTION 6 ARISING FROM OR IN CONNECTION WITH THE ADMINISTRATION OF 7 AUTO-INJECTABLE EPINEPHRINE BY THE INDIVIDUAL SOLELY BECAUSE THE 8 INDIVIDUAL DID NOT POSSESS A CERTIFICATE ISSUED UNDER THIS SUBTITLE.

9 **13–7A–10.**

10 (A) A CERTIFICATE HOLDER SHALL SUBMIT TO THE DEPARTMENT, ON A 11 FORM REQUIRED BY THE DEPARTMENT, A REPORT OF EACH INCIDENT THAT 12 OCCURRED ON THE CERTIFICATE HOLDER'S PREMISES THAT INVOLVED THE 13 ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE.

14 **(B)** ON OR BEFORE JANUARY 31 OF EACH YEAR, THE DEPARTMENT 15 SHALL PUBLISH A REPORT SUMMARIZING THE INFORMATION OBTAINED FROM 16 THE REPORTS SUBMITTED TO THE DEPARTMENT UNDER SUBSECTION (A) OF 17 THIS SECTION.

18 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect19 October 1, 2014.