SENATE BILL 344

5lr1614 CF 5lr1177

By: **Senators Pugh, Astle, Guzzone, Kagan, and Klausmeier** Introduced and read first time: February 6, 2015 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 Program in the Department of Health and Mental Hygiene; providing for the purpose of the 4 $\mathbf{5}$ Program; authorizing the Department to adopt certain regulations, collect certain 6 fees, issue and renew certain certificates, and approve certain training programs 7 relating to the Program; establishing qualifications for applicants for a certain 8 certificate; requiring the Department to issue certain certificates to certain 9 applicants; providing for the contents, replacement, term, and renewal of certain certificates; authorizing certain physicians to prescribe and certain pharmacists to 10 11 dispense auto-injectable epinephrine to certain certificate holders; authorizing 12certain certificate holders to take certain actions; providing that a cause of action 13 may not arise against certain certificate holders for certain acts or omissions under 14certain circumstances; providing that a cause of action may not arise against certain 15physicians who prescribe or dispense auto-injectable epinephrine and certain 16 paraphernalia to certain certificate holders under certain circumstances; providing 17that a cause of action may not arise against certain pharmacists who dispense 18 auto-injectable epinephrine and certain paraphernalia to certain certificate holders 19under certain circumstances; providing for immunity from civil liability for certain 20individuals under certain circumstances; providing for the effect of certain provisions 21 of this Act; providing for the construction of this Act; requiring certain certificate 22holders to submit to the Department a certain report; requiring the Department to 23publish a certain report on or before a certain date each year; defining certain terms; 24and generally relating to the Emergency Use Auto-Injectable Epinephrine Program.

- 24 and generally relating to the Emergency Ose Auto-Injectable Epinephrine Program.
 25 BY adding to
 26 Article Health General
 27 Section 13–7A–01 through 13–7A–10 to be under the new subtitle "Subtitle 7A.
 28 Emergency Use Auto-Injectable Epinephrine Program"
- 29 Annotated Code of Maryland
- 30 (2009 Replacement Volume and 2014 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

3

Article – Health – General

4 SUBTITLE 7A. EMERGENCY USE AUTO–INJECTABLE EPINEPHRINE PROGRAM.

5 13-7A-01.

6 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 7 INDICATED.

8 **(B)** "AGENT" MEANS AN INDIVIDUAL WHO IS APPOINTED BY A CERTIFICATE AN IS NOT 9 HOLDER THAT INDIVIDUAL ТО ADMINISTER 10 AUTO-INJECTABLE EPINEPHRINE IN ACCORDANCE WITH THE PROVISIONS OF THE 11 **PROGRAM.**

12 (C) "ANAPHYLAXIS" MEANS A SUDDEN, SEVERE, AND POTENTIALLY 13 LIFE-THREATENING ALLERGIC REACTION THAT OCCURS WHEN AN INDIVIDUAL IS 14 EXPOSED TO AN ALLERGEN.

15 **(D)** "AUTO–INJECTABLE EPINEPHRINE" MEANS A PORTABLE, DISPOSABLE 16 DRUG DELIVERY DEVICE THAT CONTAINS A PREMEASURED SINGLE DOSE OF 17 EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.

18 (E) "CERTIFICATE" MEANS A CERTIFICATE ISSUED BY THE DEPARTMENT 19 TO AN AUTHORIZED PERSON TO OBTAIN, STORE, AND ADMINISTER 20 AUTO-INJECTABLE EPINEPHRINE.

21 (F) "CERTIFICATE HOLDER" MEANS A PERSON WHO IS AUTHORIZED BY THE 22 DEPARTMENT TO OBTAIN, STORE, AND ADMINISTER AUTO–INJECTABLE 23 EPINEPHRINE TO BE USED IN AN EMERGENCY SITUATION.

24 (G) "PROGRAM" MEANS THE EMERGENCY USE AUTO-INJECTABLE 25 EPINEPHRINE PROGRAM ESTABLISHED UNDER § 13–7A–02 OF THIS SUBTITLE.

26 **13–7A–02.**

27 (A) THERE IS AN EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE 28 PROGRAM IN THE DEPARTMENT.

29 (B) THE PURPOSE OF THE PROGRAM IS TO PROVIDE A MEANS OF 30 AUTHORIZING PERSONS TO OBTAIN AND STORE AUTO-INJECTABLE EPINEPHRINE

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1 AND ADMINISTER AUTO-INJECTABLE EPINEPHRINE TO INDIVIDUALS WHO ARE 2 EXPERIENCING ANAPHYLAXIS WHEN PHYSICIAN OR EMERGENCY MEDICAL 3 SERVICES ARE NOT IMMEDIATELY AVAILABLE.

4 13-7A-03.

5 **THE DEPARTMENT MAY:**

6 (1) ADOPT REGULATIONS FOR THE ADMINISTRATION OF THE 7 PROGRAM;

8 (2) COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE 9 PROGRAM;

10 (3) ISSUE AND RENEW CERTIFICATES TO PERSONS MEETING THE 11 REQUIREMENTS OF THIS SUBTITLE; AND

12 (4) (I) APPROVE EDUCATIONAL TRAINING PROGRAMS DESCRIBED 13 IN § 13–7A–04(D) OF THIS SUBTITLE; AND

14(II) APPROVE EDUCATIONAL TRAINING PROGRAMS15CONDUCTED BY OTHER STATE AGENCIES OR PRIVATE ENTITIES.

16 **13–7A–04.**

17 (A) TO QUALIFY FOR A CERTIFICATE, A PERSON SHALL MEET THE 18 REQUIREMENTS OF THIS SECTION.

19 (B) THE APPLICANT OR AN AGENT OF THE APPLICANT SHALL BE AT LEAST 20 18 YEARS OLD.

21 (C) THE APPLICANT SHALL HAVE, OR REASONABLY EXPECT TO HAVE, 22 RESPONSIBILITY FOR AT LEAST ONE OTHER PERSON AS A RESULT OF THE 23 INDIVIDUAL'S OCCUPATION OR VOLUNTEER STATUS.

24 (D) (1) THE APPLICANT OR AGENT OF THE APPLICANT SHALL 25 SUCCESSFULLY COMPLETE, AT THE EXPENSE OF THE APPLICANT, AN EDUCATIONAL 26 TRAINING PROGRAM OFFERED BY:

- 27 (I) THE AMERICAN RED CROSS;
- 28 (II) THE AMERICAN CPR CARE ASSOCIATION;

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$\frac{1}{2}$	(III) A NATIONALLY RECOGNIZED ORGANIZATION EXPERIENCED IN TRAINING LAYPERSONS IN EMERGENCY MEDICAL TREATMENT; OR
3	(IV) ANY OTHER PERSON APPROVED BY THE DEPARTMENT.
4 5	(2) THE EDUCATIONAL TRAINING PROGRAM REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION MAY BE AN ONLINE TRAINING PROGRAM.
6	13-7A-05.
7	AN APPLICANT FOR A CERTIFICATE SHALL:
8 9	(1) SUBMIT AN APPLICATION TO THE DEPARTMENT ON THE FORM THAT THE DEPARTMENT REQUIRES; AND
10 11	(2) PAY TO THE DEPARTMENT THE APPLICATION FEE SET BY THE DEPARTMENT.
12	13-7A-06.
13 14	(A) THE DEPARTMENT SHALL ISSUE A CERTIFICATE TO ANY APPLICANT WHO MEETS THE REQUIREMENTS OF THIS SUBTITLE.
15	(B) EACH CERTIFICATE SHALL INCLUDE:
16	(1) THE FULL NAME OF THE CERTIFICATE HOLDER; AND
17	(2) A SERIAL NUMBER.
18 19 20	(C) A REPLACEMENT CERTIFICATE MAY BE ISSUED TO REPLACE A LOST, DESTROYED, OR MUTILATED CERTIFICATE IF THE CERTIFICATE HOLDER PAYS THE CERTIFICATE REPLACEMENT FEE.
21	(D) (1) THE CERTIFICATE SHALL BE VALID FOR 2 YEARS.
$\frac{22}{23}$	(2) TO RENEW THE CERTIFICATE FOR AN ADDITIONAL 2–YEAR TERM, THE APPLICANT OR THE AGENT OF THE APPLICANT SHALL:
$\frac{24}{25}$	(I) SUCCESSFULLY COMPLETE A REFRESHER TRAINING PROGRAM REQUIRED UNDER § 13–7A–04 OF THIS SUBTITLE; OR
26	(II) DEMONSTRATE PROFICIENCY TO THE DEPARTMENT.

1 **13–7A–07.**

2 (A) (1) A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE 3 MAY PRESCRIBE AUTO-INJECTABLE EPINEPHRINE IN THE NAME OF A CERTIFICATE 4 HOLDER.

5 (2) A PHARMACIST LICENSED TO PRACTICE PHARMACY IN THE STATE 6 OR A PHYSICIAN MAY DISPENSE AUTO-INJECTABLE EPINEPHRINE UNDER A 7 PRESCRIPTION ISSUED TO A CERTIFICATE HOLDER.

8 (B) A CERT

A CERTIFICATE HOLDER MAY:

9 (1) ON PRESENTMENT OF A CERTIFICATE, RECEIVE FROM ANY 10 PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE A PRESCRIPTION FOR 11 AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE 12 ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE;

13(2) POSSESS AND STORE PRESCRIBED AUTO-INJECTABLE14EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE ADMINISTRATION OF15AUTO-INJECTABLE EPINEPHRINE; AND

16 (3) IN AN EMERGENCY SITUATION WHEN PHYSICIAN OR EMERGENCY 17SERVICES ARE NOT IMMEDIATELY AVAILABLE, MEDICAL **ADMINISTER** 18 AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL WHO IS EXPERIENCING OR BELIEVED IN GOOD FAITH BY THE CERTIFICATE HOLDER TO BE EXPERIENCING 19 20ANAPHYLAXIS.

21 **13–7A–08.**

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

29(1) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHYSICIAN FOR **(B)** 30 ANY ACT OR OMISSION IF THE PHYSICIAN IN GOOD FAITH PRESCRIBES OR 31 DISPENSES AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY 32 PARAPHERNALIA FOR THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE 33 TO AN INDIVIDUAL CERTIFIED BY THE DEPARTMENT UNDER § 13–7A–06 OF THIS 34 SUBTITLE.

1 (2) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHARMACIST 2 FOR ANY ACT OR OMISSION IF THE PHARMACIST IN GOOD FAITH DISPENSES 3 AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE 4 ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL 5 CERTIFIED BY THE DEPARTMENT UNDER § 13–7A–06 OF THIS SUBTITLE.

6 (C) THIS SECTION DOES NOT AFFECT ANY IMMUNITIES FROM CIVIL 7 LIABILITY OR DEFENSES ESTABLISHED BY ANY OTHER PROVISION OF STATUTORY 8 LAW OR BY COMMON LAW TO WHICH A VOLUNTEER, PHYSICIAN, OR PHARMACIST 9 MAY BE ENTITLED.

10 **13–7A–09.**

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

15AN INDIVIDUAL MAY NOT BE HELD CIVILLY LIABLE IN ANY ACTION **(B)** 16ARISING FROM OR IN CONNECTION WITH THE ADMINISTRATION OF 17AUTO-INJECTABLE EPINEPHRINE BY THE INDIVIDUAL SOLELY BECAUSE THE 18 INDIVIDUAL DID NOT POSSESS A CERTIFICATE ISSUED UNDER THIS SUBTITLE.

19 **13–7A–10.**

20 (A) A CERTIFICATE HOLDER SHALL SUBMIT TO THE DEPARTMENT, ON A 21 FORM REQUIRED BY THE DEPARTMENT, A REPORT OF EACH INCIDENT THAT 22 OCCURRED ON THE CERTIFICATE HOLDER'S PREMISES THAT INVOLVED THE 23 ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE.

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

28 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 29 October 1, 2015.