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By: Delegates Pena-Melnyk, Angel, B. Barnes, Barron, Bromwell, Cullison, Frush, Hayes, Kelly, Kipke, McDonough, Morgan, Saab, Sample-Hughes, Szeliga, Tarlau, Valentino-Smith, West, and K. Young <u>K. Young, Pendergrass, Hill,</u> Krebs, Metzgar, Miele, Morales, Platt, and Rosenberg

Introduced and read first time: February 9, 2018 Assigned to: Health and Government Operations

Committee Report: Favorable with amendments House action: Adopted Read second time: March 11, 2018

CHAPTER _____

1 AN ACT concerning

Public Health – Emergency Use Auto–Injectable Epinephrine Program for Food Service Facilities at Institutions of Higher Education

4 FOR the purpose of establishing the Emergency Use Auto-Injectable Epinephrine Program $\mathbf{5}$ for food service facilities at eligible institutions of higher education at Institutions of 6 Higher Education; providing for the purpose of the Program; requiring the Maryland 7 Department of Health to adopt certain regulations, collect certain fees, issue and 8 renew certain certificates, approve certain training programs relating to the 9 Program, develop a method by which certain reports may be made, and publish a 10 certain report on or before a certain date each year; authorizing the Department to 11 set certain fees and to establish procedures to apply to the Program; establishing 12qualifications for applicants for a certain certificate; authorizing an eligible 13 institution to pay the application fee on behalf of the applicant; authorizing certain 14 certificate holders and agents to take certain actions; requiring the Department to 15issue certain certificates to certain applicants; providing for the contents, 16replacement, term, and renewal of certain certificates; authorizing certain 17physicians to prescribe and certain pharmacists and physicians to dispense auto-18 injectable epinephrine to certain certificate holders; authorizing a certificate holder 19or an agent to administer auto-injectable epinephrine to a certain individual in 20certain circumstances; providing that a cause of action may not arise against certain 21certificate holders or certain agents for certain acts or omissions under certain 22circumstances; providing that a cause of action may not arise against certain

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 physicians who prescribe or dispense auto-injectable epinephrine and certain $\mathbf{2}$ paraphernalia to certain certificate holders under certain circumstances; providing 3 that a cause of action may not arise against certain pharmacists who dispense auto-4 injectable epinephrine and certain paraphernalia to certain certificate holders under certain circumstances; providing that certain individuals may not be liable for not $\mathbf{5}$ 6 taking certain actions; providing immunity from civil liability for certain individuals $\overline{7}$ under certain circumstances; requiring certain certificate holders to submit to the 8 Department certain reports; providing for the construction of this Act; requiring the 9 Department to publish a certain report on or before a certain date each year; defining certain terms; and generally relating to the Emergency Use Auto-Injectable 10 11 Epinephrine Program at Institutions of Higher Education.

12 BY adding to

- 13 Article Health General
- Section 13–7A–01 through 13–7A–09 to be under the new subtitle "Subtitle 7A.
 Emergency Use Auto–Injectable Epinephrine Program for Food Service
 Facilities at Institutions of Higher Education"
- 17 Annotated Code of Maryland
- 18 (2015 Replacement Volume and 2017 Supplement)
- SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
 That the Laws of Maryland read as follows:
- 21 Article Health General

SUBTITLE 7A. EMERGENCY USE AUTO–INJECTABLE EPINEPHRINE PROGRAM FOR FOOD SERVICE FACILITIES AT INSTITUTIONS OF HIGHER EDUCATION.

24 **13–7A–01.**

25 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 26 INDICATED.

- 27 (B) "AGENT" MEANS AN INDIVIDUAL WHO:
- 28
- (1) IS AT LEAST 18 YEARS OF AGE;

29 (2) HAS SUCCESSFULLY COMPLETED, AT THE EXPENSE OF THE 30 APPLICANT ELIGIBLE INSTITUTION, AN EDUCATIONAL TRAINING PROGRAM 31 APPROVED BY THE DEPARTMENT UNDER § 13–7A–03 OF THIS SUBTITLE; AND

32 (3) IS DESIGNATED BY A CERTIFICATE HOLDER TO ADMINISTER 33 AUTO-INJECTABLE EPINEPHRINE IN ACCORDANCE WITH THE PROVISIONS OF THIS 34 SUBTITLE.

 $\mathbf{2}$

1 (C) "ANAPHYLAXIS" MEANS A SUDDEN, SEVERE, AND POTENTIALLY 2 LIFE-THREATENING ALLERGIC REACTION THAT OCCURS WHEN AN INDIVIDUAL IS 3 EXPOSED TO AN ALLERGEN.

4 (D) "AUTO-INJECTABLE EPINEPHRINE" MEANS A PORTABLE, DISPOSABLE 5 DRUG DELIVERY DEVICE THAT CONTAINS A PREMEASURED SINGLE DOSE OF 6 EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.

7 (E) "CERTIFICATE" MEANS A CERTIFICATE ISSUED BY THE DEPARTMENT 8 TO AN INDIVIDUAL TO OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE 9 EPINEPHRINE.

10 (F) "CERTIFICATE HOLDER" MEANS AN INDIVIDUAL WHO IS AUTHORIZED 11 BY THE DEPARTMENT TO OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE 12 EPINEPHRINE TO BE USED IN AN EMERGENCY SITUATION.

13(G) "ELIGIBLE INSTITUTION" MEANS AN INSTITUTION OF HIGHER14EDUCATION THAT HAS A FOOD SERVICE FACILITY OR A RECREATION AND WELLNESS15FACILITY ON THE PREMISES.

16 (H) "FOOD SERVICE FACILITY" HAS THE MEANING INDICATED IN § 21–301 17 OF THIS ARTICLE.

18 **(I) "PROGRAM" MEANS THE EMERGENCY USE AUTO-INJECTABLE** 19 EPINEPHRINE PROGRAM FOR FOOD SERVICE FACILITIES AT INSTITUTIONS OF 20 HIGHER EDUCATION AT INSTITUTIONS OF HIGHER EDUCATION ESTABLISHED 21 UNDER § 13–7A–02 OF THIS SUBTITLE.

22 **13–7A–02.**

(A) THERE IS AN EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE
 PROGRAM FOR FOOD SERVICE FACILITIES AT INSTITUTIONS OF HIGHER-EDUCATION
 AT INSTITUTIONS OF HIGHER EDUCATION.

(B) THE PURPOSE OF THE PROGRAM IS TO AUTHORIZE INDIVIDUALS
EMPLOYED BY A FOOD SERVICE FACILITY <u>OR A RECREATION AND WELLNESS</u>
<u>FACILITY</u> AT AN ELIGIBLE INSTITUTION TO OBTAIN AND STORE AUTO-INJECTABLE
EPINEPHRINE AND ADMINISTER AUTO-INJECTABLE EPINEPHRINE TO INDIVIDUALS
WHO ARE EXPERIENCING OR ARE BELIEVED TO BE EXPERIENCING ANAPHYLAXIS
WHEN A PHYSICIAN OR EMERGENCY MEDICAL SERVICES ARE NOT IMMEDIATELY
AVAILABLE.

33 **13–7A–03.**

4

HOUSE BILL 1473

1 (A) THE DEPARTMENT SHALL:

2 (1) ADOPT REGULATIONS FOR THE ADMINISTRATION OF THE 3 PROGRAM;

4 (2) COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE 5 PROGRAM;

6 (3) ISSUE A CERTIFICATE TO, OR RENEW THE CERTIFICATE OF, AN 7 INDIVIDUAL MEETING THE REQUIREMENTS OF § 13–7A–04 OF THIS SUBTITLE;

8 (4) APPROVE EDUCATIONAL TRAINING PROGRAMS, INCLUDING 9 PROGRAMS CONDUCTED BY OTHER STATE AGENCIES OR PRIVATE ENTITIES;

10 (5) DEVELOP A METHOD BY WHICH CERTIFICATE HOLDERS MAY 11 SUBMIT A REPORT TO THE DEPARTMENT ABOUT EACH INCIDENT THAT OCCURRED 12 ON THE PREMISES OF A FOOD SERVICE FACILITY <u>OR A RECREATION AND WELLNESS</u> 13 <u>FACILITY</u> AT AN ELIGIBLE INSTITUTION THAT INVOLVED THE ADMINISTRATION OF 14 AUTO-INJECTABLE EPINEPHRINE BY A CERTIFICATE HOLDER OR AN AGENT; AND

15 (6) ON OR BEFORE JANUARY 31 EACH YEAR, PUBLISH A REPORT 16 SUMMARIZING THE INFORMATION OBTAINED FROM REPORTS SUBMITTED TO THE 17 DEPARTMENT UNDER ITEM (5) OF THIS SUBSECTION.

18 **(B) THE DEPARTMENT MAY:**

19 (1) SET AN APPLICATION FEE FOR A CERTIFICATE;

20 (2) ESTABLISH A FEE FOR THE RENEWAL OR REPLACEMENT OF A 21 CERTIFICATE; AND

22 (3) REQUIRE APPLICANTS TO APPLY TO THE PROGRAM IN THE 23 MANNER THE DEPARTMENT CHOOSES.

24 (C) AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE 25 DEPARTMENT UNDER SUBSECTION (A)(4) OF THIS SECTION MAY BE AN ONLINE 26 TRAINING PROGRAM.

27 13-7A-04.

28 (A) TO QUALIFY FOR A CERTIFICATE, AN APPLICANT SHALL:

29 (1) BE EMPLOYED BY A FOOD SERVICE FACILITY <u>OR A RECREATION</u>
 30 <u>AND WELLNESS FACILITY</u> AT AN ELIGIBLE INSTITUTION;

1(2)SUCCESSFULLY COMPLETE, AT THE EXPENSE OF THE APPLICANT2ELIGIBLE INSTITUTION, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE3DEPARTMENT UNDER § 13–7A–03 OF THIS SUBTITLE;

4 (3) SUBMIT AN APPLICATION TO THE DEPARTMENT IN A MANNER 5 REQUIRED BY THE DEPARTMENT UNDER § 13–7A–03 OF THIS SUBTITLE; AND

6 (4) PAY SUBJECT TO SUBSECTION (B) OF THIS SECTION, PAY TO THE 7 DEPARTMENT AN APPLICATION FEE REQUIRED UNDER § 13–7A–03 OF THIS 8 SUBTITLE.

9 (B) AN ELIGIBLE INSTITUTION MAY PAY THE APPLICATION FEE ON BEHALF 10 OF THE APPLICANT.

11 **13–7A–05.**

12 (A) THE DEPARTMENT SHALL ISSUE A CERTIFICATE TO ANY APPLICANT 13 WHO MEETS THE REQUIREMENTS OF § 13–7A–04 OF THIS SUBTITLE.

- 14 (B) EACH CERTIFICATE SHALL INCLUDE:
- 15 (1) THE FULL NAME OF THE CERTIFICATE HOLDER; AND
- 16 (2) A SERIAL NUMBER.

17 (C) A REPLACEMENT CERTIFICATE MAY BE ISSUED TO REPLACE A LOST, 18 DESTROYED, OR MUTILATED CERTIFICATE IF THE CERTIFICATE HOLDER PAYS A 19 CERTIFICATE REPLACEMENT FEE SET BY THE DEPARTMENT.

20

(1) A CERTIFICATE SHALL BE VALID FOR A TERM OF $\frac{2 \text{ YEARS}}{2 \text{ YEARS}}$

(2) TO RENEW A CERTIFICATE FOR AN ADDITIONAL 2-YEAR 1-YEAR
 TERM, THE RENEWAL APPLICANT SHALL SUCCESSFULLY COMPLETE A REFRESHER
 EDUCATIONAL TRAINING PROGRAM APPROVED BY THE DEPARTMENT UNDER §
 13-7A-03 OF THIS SUBTITLE.

25 **13–7A–06.**

(D**)**

26 (A) (1) A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE 27 MAY PRESCRIBE AUTO–INJECTABLE EPINEPHRINE IN THE NAME OF A CERTIFICATE 28 HOLDER.

1 (2) A PHARMACIST LICENSED TO PRACTICE PHARMACY IN THE STATE 2 OR A PHYSICIAN MAY DISPENSE AUTO-INJECTABLE EPINEPHRINE UNDER A 3 PRESCRIPTION ISSUED TO A CERTIFICATE HOLDER.

4

(B) A CERTIFICATE HOLDER MAY:

5 (1) ON PRESENTMENT OF A CERTIFICATE, RECEIVE FROM ANY 6 PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE A PRESCRIPTION FOR 7 AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE 8 ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; AND

9 (2) POSSESS AND STORE PRESCRIBED AUTO-INJECTABLE 10 EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE ADMINISTRATION OF 11 AUTO-INJECTABLE EPINEPHRINE.

12 (C) IN AN EMERGENCY SITUATION WHEN A PHYSICIAN OR EMERGENCY 13 MEDICAL SERVICES ARE NOT IMMEDIATELY AVAILABLE, A CERTIFICATE HOLDER OR 14 AN AGENT MAY ADMINISTER AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL 15 WHO IS EXPERIENCING OR IS BELIEVED IN GOOD FAITH BY THE CERTIFICATE 16 HOLDER OR AGENT TO BE EXPERIENCING ANAPHYLAXIS.

17 **13–7A–07.**

18 A CAUSE OF ACTION MAY NOT ARISE AGAINST A CERTIFICATE HOLDER (A) 19 OR AN AGENT FOR ANY ACT OR OMISSION IF THE CERTIFICATE HOLDER OR AGENT 20IS ACTING IN GOOD FAITH WHILE ADMINISTERING AUTO-INJECTABLE EPINEPHRINE 21TO AN INDIVIDUAL WHO IS EXPERIENCING OR BELIEVED BY THE CERTIFICATE 22HOLDER OR AGENT TO BE EXPERIENCING ANAPHYLAXIS EXCEPT WHERE THE 23CONDUCT OF THE CERTIFICATE HOLDER OR AGENT AMOUNTS TO GROSS 24NEGLIGENCE, WILLFUL OR WANTON MISCONDUCT, OR INTENTIONALLY TORTIOUS 25CONDUCT.

26**(B)** (1) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHYSICIAN FOR 27ANY ACT OR OMISSION IF THE PHYSICIAN IN GOOD FAITH PRESCRIBES OR 28DISPENSES AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY 29PARAPHERNALIA FOR THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE 30 TO AN INDIVIDUAL CERTIFIED BY THE DEPARTMENT UNDER § 13-7A-05 OF THIS SUBTITLE. 31

32 (2) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHARMACIST 33 FOR ANY ACT OR OMISSION IF THE PHARMACIST IN GOOD FAITH DISPENSES 34 AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE 35 ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL 36 CERTIFIED BY THE DEPARTMENT UNDER § 13–7A–05 OF THIS SUBTITLE.

6

1 (C) THIS SECTION DOES NOT AFFECT AND MAY NOT BE CONSTRUED AS 2 AFFECTING ANY IMMUNITIES FROM CIVIL LIABILITY OR DEFENSES ESTABLISHED BY 3 ANY OTHER PROVISION OF LAW OR BY COMMON LAW TO WHICH A PHYSICIAN OR 4 PHARMACIST MAY BE ENTITLED.

5 **13–7A–08.**

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

10 **(B)** AN INDIVIDUAL MAY NOT BE HELD CIVILLY LIABLE IN ANY ACTION 11 CONNECTION WITH ARISING FROM OR IN THE **ADMINISTRATION** OF 12AUTO-INJECTABLE EPINEPHRINE BY THE INDIVIDUAL SOLELY BECAUSE THE 13INDIVIDUAL DID NOT POSSESS A CERTIFICATE ISSUED UNDER THIS SUBTITLE.

14 **13–7A–09.**

A CERTIFICATE HOLDER SHALL SUBMIT TO THE DEPARTMENT, IN THE MANNER REQUIRED UNDER § 13–7A–03 OF THIS SUBTITLE, A REPORT OF EACH INCIDENT THAT OCCURRED ON THE PREMISES OF A FOOD SERVICE FACILITY <u>OR A</u> <u>RECREATION AND WELLNESS FACILITY</u> AT AN ELIGIBLE INSTITUTION THAT INVOLVED THE ADMINISTRATION OF AUTO–INJECTABLE EPINEPHRINE BY A CERTIFICATE HOLDER OR AN AGENT.

21 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 22 October 1, 2018.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.