

HOUSE BILL 1473

J1, F2

(8lr2209)

ENROLLED BILL

— Health and Government Operations/Finance —

Introduced 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~~ K. Young, Pendergrass, Hill, Krebs, Metzgar, Miele, Morales, Platt, and Rosenberg**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this _____ day of _____ at _____ o'clock, _____ M.

Speaker.

CHAPTER _____

1 AN ACT concerning

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

4 FOR the purpose of establishing the Emergency Use Auto–Injectable Epinephrine Program
5 ~~for food service facilities at eligible institutions of higher education~~ at Institutions of
6 Higher Education; providing for the purpose of the Program; authorizing certain
7 eligible institutions of higher education to obtain and store auto–injectable
8 epinephrine under certain circumstances; requiring certain eligible institutions of
9 higher education to designate certain individuals for certain purposes; prohibiting
10 certain eligible institutions of higher education from obtaining or storing
11 auto–injectable epinephrine unless certain employees or individuals hold 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.

Italics indicate opposite chamber/conference committee amendments.



certificates; requiring certain institutions of higher education to maintain a certain copy of a certain certificate; requiring the Maryland Department of Health to adopt certain regulations, collect certain fees, issue and renew certain certificates, approve certain training programs relating to the Program, develop a method by which certain reports may be made, and publish a certain report on or before a certain date each year; authorizing the Department to set certain fees and to establish procedures to apply to the Program; establishing qualifications for applicants for a certain certificate; authorizing an eligible institution to pay the application fee on behalf of the applicant; authorizing certain certificate holders and agents to take certain actions; requiring the Department to issue certain certificates to certain applicants; providing for the contents, replacement, term, and renewal of certain certificates; authorizing certain physicians to prescribe and certain pharmacists and physicians to dispense auto-injectable epinephrine to certain certificate holders; authorizing a certificate holder or an agent to administer auto-injectable epinephrine to a certain individual in certain circumstances; providing that a cause of action may not arise against certain certificate holders ~~or certain agents~~ for certain acts or omissions under certain circumstances; providing for a certain exception under certain circumstances; providing that a cause of action may not arise against certain physicians who prescribe or dispense auto-injectable epinephrine and certain paraphernalia to certain certificate holders and certain eligible institutions under certain circumstances; providing that a cause of action may not arise against certain pharmacists who dispense auto-injectable epinephrine and certain paraphernalia to certain certificate holders and certain eligible institutions under certain circumstances; providing that certain individuals may not be liable for not taking certain actions; providing immunity from civil liability for certain individuals under certain circumstances; requiring certain certificate holders to submit to the Department certain reports; providing for the construction of this Act; requiring the 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 Epinephrine Program at Institutions of Higher Education.

31 BY adding to

32 Article – Health – General

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

34 Emergency Use Auto-Injectable Epinephrine Program ~~for Food Service~~

35 ~~Facilities~~ at Institutions of Higher Education”

36 Annotated Code of Maryland

37 (2015 Replacement Volume and 2017 Supplement)

38 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

39 That the Laws of Maryland read as follows:

40 **Article – Health – General**

41 **SUBTITLE 7A. EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE PROGRAM ~~FOR~~**

42 **~~FOOD SERVICE FACILITIES~~ AT INSTITUTIONS OF HIGHER EDUCATION.**

1 13-7A-01.

2 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
3 INDICATED.

4 (B) "AGENT" MEANS AN INDIVIDUAL WHO:

5 (1) IS AT LEAST 18 YEARS OF AGE;

6 (2) HAS SUCCESSFULLY COMPLETED, AT THE EXPENSE OF THE
7 ~~APPLICANT~~ ELIGIBLE INSTITUTION, AN EDUCATIONAL TRAINING PROGRAM
8 APPROVED BY THE DEPARTMENT UNDER § 13-7A-03 OF THIS SUBTITLE; AND

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

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 INDIVIDUAL TO OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE
20 EPINEPHRINE.

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

24 (G) "ELIGIBLE INSTITUTION" MEANS AN INSTITUTION OF HIGHER
25 EDUCATION THAT HAS A FOOD SERVICE FACILITY OR A RECREATION AND WELLNESS
26 FACILITY ON THE PREMISES AND THAT IS AUTHORIZED UNDER THIS SUBTITLE TO
27 OBTAIN AND STORE AUTO-INJECTABLE EPINEPHRINE.

28 (H) "FOOD SERVICE FACILITY" HAS THE MEANING INDICATED IN § 21-301
29 OF THIS ARTICLE.

30 (I) "PROGRAM" MEANS THE EMERGENCY USE AUTO-INJECTABLE
31 EPINEPHRINE PROGRAM ~~FOR FOOD SERVICE FACILITIES AT INSTITUTIONS OF~~

1 ~~HIGHER EDUCATION~~ AT INSTITUTIONS OF HIGHER EDUCATION ESTABLISHED
2 UNDER § 13-7A-02 OF THIS SUBTITLE.

3 13-7A-02.

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

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

14 (C) (1) SUBJECT TO PARAGRAPH (4) OF THIS SUBSECTION, AN ELIGIBLE
15 INSTITUTION MAY OBTAIN:

16 (I) A PRESCRIPTION FOR A SUPPLY OF AUTO-INJECTABLE
17 EPINEPHRINE FROM A LICENSED PHYSICIAN AS PROVIDED IN § 13-7A-06 OF THIS
18 SUBTITLE; AND

19 (II) A SUPPLY OF AUTO-INJECTABLE EPINEPHRINE FROM A
20 LICENSED PHARMACIST OR A LICENSED PHYSICIAN AS PROVIDED IN § 13-7A-06 OF
21 THIS SUBTITLE.

22 (2) AN ELIGIBLE INSTITUTION SHALL STORE A SUPPLY OF
23 AUTO-INJECTABLE EPINEPHRINE OBTAINED UNDER PARAGRAPH (1)(II) OF THIS
24 SUBSECTION:

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

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

29 (3) AN ELIGIBLE INSTITUTION SHALL DESIGNATE THE EMPLOYEES
30 WHO ARE CERTIFICATE HOLDERS OR DESIGNATED AFFILIATED INDIVIDUALS WHO
31 ARE CERTIFICATE HOLDERS WHO WILL BE RESPONSIBLE FOR THE STORAGE,
32 MAINTENANCE, AND CONTROL OF THE SUPPLY OF AUTO-INJECTABLE EPINEPHRINE.

1 **(4) AN ELIGIBLE INSTITUTION MAY NOT OBTAIN OR STORE**
2 **AUTO-INJECTABLE EPINEPHRINE UNLESS THE ELIGIBLE INSTITUTION HAS AT**
3 **LEAST TWO EMPLOYEES OR DESIGNATED AFFILIATED INDIVIDUALS WHO ARE**
4 **CERTIFICATE HOLDERS.**

5 **(5) AN ELIGIBLE INSTITUTION SHALL MAINTAIN A COPY OF THE**
6 **CERTIFICATE ISSUED TO AN EMPLOYEE OR A DESIGNATED AFFILIATED INDIVIDUAL**
7 **UNDER § 13-7A-05 OF THIS SUBTITLE.**

8 **13-7A-03.**

9 **(A) THE DEPARTMENT SHALL:**

10 **(1) ADOPT REGULATIONS FOR THE ADMINISTRATION OF THE**
11 **PROGRAM;**

12 **(2) COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE**
13 **PROGRAM;**

14 **(3) ISSUE A CERTIFICATE TO, OR RENEW THE CERTIFICATE OF, AN**
15 **INDIVIDUAL MEETING THE REQUIREMENTS OF § 13-7A-04 OF THIS SUBTITLE;**

16 **(4) APPROVE EDUCATIONAL TRAINING PROGRAMS, INCLUDING**
17 **PROGRAMS CONDUCTED BY OTHER STATE AGENCIES OR PRIVATE ENTITIES;**

18 **(5) DEVELOP A METHOD BY WHICH CERTIFICATE HOLDERS MAY**
19 **SUBMIT A REPORT TO THE DEPARTMENT ABOUT EACH INCIDENT THAT OCCURRED**
20 **ON THE PREMISES OF A FOOD SERVICE FACILITY OR A RECREATION AND WELLNESS**
21 **FACILITY AT AN ELIGIBLE INSTITUTION THAT INVOLVED THE ADMINISTRATION OF**
22 **AUTO-INJECTABLE EPINEPHRINE BY A CERTIFICATE HOLDER OR AN AGENT; AND**

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

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

27 **(1) SET AN APPLICATION FEE FOR A CERTIFICATE;**

28 **(2) ESTABLISH A FEE FOR THE RENEWAL OR REPLACEMENT OF A**
29 **CERTIFICATE; AND**

30 **(3) REQUIRE APPLICANTS TO APPLY TO THE PROGRAM IN THE**
31 **MANNER THE DEPARTMENT CHOOSES.**

1 (C) AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE
2 DEPARTMENT UNDER SUBSECTION (A)(4) OF THIS SECTION MAY BE AN ONLINE
3 TRAINING PROGRAM.

4 13-7A-04.

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

6 (1) BE EMPLOYED BY A FOOD SERVICE FACILITY OR A RECREATION
7 AND WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION;

8 (2) SUCCESSFULLY COMPLETE, AT THE EXPENSE OF THE ~~APPLICANT~~
9 ELIGIBLE INSTITUTION, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE
10 DEPARTMENT UNDER § 13-7A-03 OF THIS SUBTITLE;

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

13 (4) ~~PAY~~ SUBJECT TO SUBSECTION (B) OF THIS SECTION, PAY TO THE
14 DEPARTMENT AN APPLICATION FEE REQUIRED UNDER § 13-7A-03 OF THIS
15 SUBTITLE.

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

18 13-7A-05.

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

21 (B) EACH CERTIFICATE SHALL INCLUDE:

22 (1) THE FULL NAME OF THE CERTIFICATE HOLDER; AND

23 (2) A SERIAL NUMBER.

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

27 (D) (1) A CERTIFICATE SHALL BE VALID FOR A TERM OF ~~2 YEARS~~ 1 YEAR.

1 (2) TO RENEW A CERTIFICATE FOR AN ADDITIONAL ~~2-YEAR~~ 1-YEAR
2 TERM, THE RENEWAL APPLICANT SHALL SUCCESSFULLY COMPLETE A REFRESHER
3 EDUCATIONAL TRAINING PROGRAM APPROVED BY THE DEPARTMENT UNDER §
4 13-7A-03 OF THIS SUBTITLE.

5 13-7A-06.

6 (A) (1) A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE
7 MAY PRESCRIBE AUTO-INJECTABLE EPINEPHRINE IN THE NAME OF A CERTIFICATE
8 HOLDER.

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

12 (B) A CERTIFICATE HOLDER MAY:

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

17 (2) POSSESS AND STORE PRESCRIBED AUTO-INJECTABLE
18 EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE ADMINISTRATION OF
19 AUTO-INJECTABLE EPINEPHRINE.

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

25 13-7A-07.

26 (A) (1) ~~A~~ EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION,
27 A CAUSE OF ACTION MAY NOT ARISE AGAINST A CERTIFICATE HOLDER OR AN AGENT
28 FOR ANY ACT OR OMISSION IF THE CERTIFICATE HOLDER OR AGENT IS ACTING IN
29 GOOD FAITH WHILE ADMINISTERING AUTO-INJECTABLE EPINEPHRINE TO AN
30 INDIVIDUAL WHO IS EXPERIENCING OR BELIEVED BY THE CERTIFICATE HOLDER OR
31 AGENT TO BE EXPERIENCING ANAPHYLAXIS EXCEPT WHERE THE CONDUCT OF THE
32 CERTIFICATE HOLDER OR AGENT AMOUNTS TO GROSS NEGLIGENCE, WILLFUL OR
33 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 ELIGIBLE INSTITUTION 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 ANAPHYLAXIS:**

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

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

10 **(B) (1) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHYSICIAN FOR**
 11 **ANY ACT OR OMISSION IF THE PHYSICIAN IN GOOD FAITH PRESCRIBES OR**
 12 **DISPENSES AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY**
 13 **PARAPHERNALIA FOR THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE**
 14 **TO ~~AN INDIVIDUAL CERTIFIED BY THE DEPARTMENT UNDER § 13-7A-05 OF A~~**
 15 **CERTIFICATE HOLDER OR AN ELIGIBLE INSTITUTION UNDER THIS SUBTITLE.**

16 **(2) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHARMACIST**
 17 **FOR ANY ACT OR OMISSION IF THE PHARMACIST IN GOOD FAITH DISPENSES**
 18 **AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE**
 19 **ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE TO ~~AN INDIVIDUAL~~**
 20 **~~CERTIFIED BY THE DEPARTMENT UNDER § 13-7A-05 OF A~~ CERTIFICATE HOLDER OR**
 21 **AN ELIGIBLE INSTITUTION UNDER THIS SUBTITLE.**

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

26 **13-7A-08.**

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

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

35 **13-7A-09.**

1 A CERTIFICATE HOLDER SHALL SUBMIT TO THE DEPARTMENT, IN THE
2 MANNER REQUIRED UNDER § 13-7A-03 OF THIS SUBTITLE, A REPORT OF EACH
3 INCIDENT THAT OCCURRED ON THE PREMISES OF A FOOD SERVICE FACILITY OR A
4 RECREATION AND WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION THAT
5 INVOLVED THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE BY A
6 CERTIFICATE HOLDER OR AN AGENT.

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.