By: Delegates Metzgar, Cullison, Anderton, Arikan, Cox, Forbes, Guyton, Hartman, Hill, Hornberger, Lisanti, McComas, Rose, Shoemaker, Szeliga, and Wilson

Introduced and read first time: February 7, 2020 Assigned to: Health and Government Operations

Committee Report: Favorable House action: Adopted Read second time: March 10, 2020

CHAPTER _____

1 AN ACT concerning

Public Health – Emergency Use Auto–Injectable Epinephrine Program – Revisions

- 4 FOR the purpose of altering the name of the Emergency Use Auto–Injectable Epinephrine Program at Institutions of Higher Education to be the Emergency Use $\mathbf{5}$ 6 Auto–Injectable Epinephrine Program; authorizing food service facilities to store and 7 make available for administration auto-injectable epinephrine for a certain purpose 8 under the Program; altering the purpose of the Program; authorizing participating 9 food service facilities, except under certain circumstances, to obtain a certain 10 prescription for and supply of auto-injectable epinephrine; requiring participating 11 food service facilities to store a supply of auto-injectable epinephrine in a certain manner; requiring participating food service facilities to designate certain employees 1213 or individuals for a certain purpose; requiring participating food service facilities to maintain a copy of a certain certificate; providing that a participating food service 1415facility may pay a certain fee on behalf of a certain applicant; providing that either entity may pay a certain application fee if a food service facility is part of an eligible 16 17institution; providing that certain individuals may not be liable for not taking certain 18 actions; providing immunity from civil liability for certain individuals under certain 19 circumstances; providing for the construction of certain provisions of this Act; 20altering certain definitions; defining certain terms; and generally relating to the 21 Emergency Use Auto–Injectable Epinephrine Program.
- 22 BY repealing and reenacting, with amendments,

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.



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$egin{array}{c} 1 \\ 2 \\ 3 \\ 4 \\ 5 \\ 6 \end{array}$	 Article – Health – General Section 13–7A–01 through 13–7A–04 and 13–7A–07 through 13–7A–09 to be under the amended subtitle "Subtitle 7A. Emergency Use Auto–Injectable Epinephrine Program" Annotated Code of Maryland (2019 Replacement Volume)
$7\\ 8\\ 9\\ 10\\ 11$	BY repealing and reenacting, without amendments, Article – Health – General Section 13–7A–05 and 13–7A–06 Annotated Code of Maryland (2019 Replacement Volume)
$\begin{array}{c} 12\\ 13 \end{array}$	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
14	Article – Health – General
$\begin{array}{c} 15\\ 16\end{array}$	Subtitle 7A. Emergency Use Auto–Injectable Epinephrine Program [at Institutions of Higher Education].
17	13–7A–01.
18	(a) In this subtitle the following words have the meanings indicated.
19	(b) "Agent" means an individual who:
20	(1) Is at least 18 years of age;
$21 \\ 22 \\ 23$	(2) Has successfully completed, at the expense of the [eligible institution] PARTICIPATING FACILITY , an educational training program approved by the Department under § 13–7A–03 of this subtitle; and
$\begin{array}{c} 24 \\ 25 \end{array}$	(3) Is designated by a certificate holder to administer auto-injectable epinephrine in accordance with the provisions of this subtitle.
$\frac{26}{27}$	(c) "Anaphylaxis" means a sudden, severe, and potentially life-threatening allergic reaction that occurs when an individual is exposed to an allergen.
28 29 30	(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.
$\frac{31}{32}$	(e) "Certificate" means a certificate issued by the Department to an individual to obtain, store, and administer auto–injectable epinephrine.
33	(f) "Certificate holder" means an individual who is authorized by the Department

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1 to obtain, store, and administer auto-injectable epinephrine to be used in an emergency 2 situation.

3 (g) "Eligible institution" means an institution of higher education that has a food 4 service facility or a recreation and wellness facility on the premises and that is authorized 5 under this subtitle to obtain and store auto-injectable epinephrine.

6 (h) "Food service facility" has the meaning indicated in § 21–301 of this article.

7 (i) "PARTICIPATING FACILITY" MEANS A RECREATION OR WELLNESS 8 FACILITY AT AN ELIGIBLE INSTITUTION OR A FOOD SERVICE FACILITY, INCLUDING 9 A FOOD SERVICE FACILITY AT AN ELIGIBLE INSTITUTION, IN THE STATE THAT 10 VOLUNTARILY PARTICIPATES IN THE PROGRAM.

11 (J) "Program" means the Emergency Use Auto–Injectable Epinephrine Program 12 [at Institutions of Higher Education] established under § 13–7A–02 of this subtitle.

13 13–7A–02.

14 (a) There is an Emergency Use Auto-Injectable Epinephrine Program [at 15 Institutions of Higher Education].

16 (b) The purpose of the Program is to authorize individuals employed by a [food 17 service facility or a recreation and wellness facility at an eligible institution] 18 **PARTICIPATING FACILITY** to obtain and store auto-injectable epinephrine and 19 administer auto-injectable epinephrine to individuals who are experiencing or are believed 20 to be experiencing anaphylaxis when a physician or emergency medical services are not 21 immediately available.

(c) (1) Subject to paragraph (4) of this subsection, [an eligible institution]
 EACH PARTICIPATING FACILITY may obtain:

(i) A prescription for a supply of auto-injectable epinephrine from a
licensed physician as provided in § 13–7A–06 of this subtitle; and

- 26 (ii) A supply of auto-injectable epinephrine from a licensed 27 pharmacist or a licensed physician as provided in § 13–7A–06 of this subtitle.
- 28 (2) [An eligible institution] **EACH PARTICIPATING FACILITY** shall store 29 a supply of auto–injectable epinephrine obtained under paragraph (1)(ii) of this subsection:
- 30
- (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.

1 (3) [An eligible institution] EACH PARTICIPATING FACILITY shall 2 designate the employees who are certificate holders or designated affiliated individuals who 3 are certificate holders who will be responsible for the storage, maintenance, and control of 4 the supply of auto-injectable epinephrine.

5 (4) [An eligible institution] A PARTICIPATING FACILITY may not obtain 6 or store auto-injectable epinephrine unless the [eligible institution] PARTICIPATING 7 FACILITY has at least two employees or designated affiliated individuals who are 8 certificate holders.

9 (5) [An eligible institution] EACH PARTICIPATING FACILITY shall 10 maintain a copy of the certificate issued to an employee or a designated affiliated individual 11 under § 13–7A–05 of this subtitle.

12 13–7A–03.

13 (a) The Department shall:

14 (1) Adopt regulations for the administration of the Program;

15 (2) Collect fees necessary for the administration of the Program;

16 (3) Issue a certificate to, or renew the certificate of, an individual meeting 17 the requirements of § 13–7A–04 of this subtitle;

18 (4) Approve educational training programs, including programs conducted
19 by other State agencies or private entities;

20 (5) Develop a method by which certificate holders may submit a report to 21 the Department about each incident that occurred on the premises of a [food service facility 22 or a recreation and wellness facility at an eligible institution] **PARTICIPATING FACILITY** 23 that involved the administration of auto-injectable epinephrine by a certificate holder or 24 an agent; and

(6) On or before January 31 each year, publish a report summarizing the
 information obtained from reports submitted to the Department under item (5) of this
 subsection.

- 28 (b) The Department may:
- 29 (1) Set an application fee for a certificate;

30 (2) Establish a fee for the renewal or replacement of a certificate; and

31 (3) Require applicants to apply to the Program in the manner the 32 Department chooses. 1 (c) An educational training program approved by the Department under 2 subsection (a)(4) of this section may be an online training program.

3 13–7A–04.

4 (a) To qualify for a certificate, an applicant shall:

5 (1) Be employed by a [food service facility or a recreation and wellness 6 facility at an eligible institution] **PARTICIPATING FACILITY**;

7 (2) Successfully complete, at the expense of the [eligible institution] 8 PARTICIPATING FACILITY, an educational training program approved by the Department 9 under § 13–7A–03 of this subtitle;

10 (3) Submit an application to the Department in a manner required by the 11 Department under § 13–7A–03 of this subtitle; and

12 (4) Subject to subsection (b) of this section, pay to the Department an 13 application fee required under § 13–7A–03 of this subtitle.

14 (b) (1) [An eligible institution] A PARTICIPATING FACILITY may pay the 15 application fee on behalf of the applicant.

16 (2) IF THE PARTICIPATING FACILITY IS A FOOD SERVICE FACILITY 17 THAT IS PART OF AN ELIGIBLE INSTITUTION, EITHER ENTITY MAY PAY THE 18 APPLICATION FEE ON BEHALF OF THE APPLICANT.

19 13–7A–05.

20 (a) The Department shall issue a certificate to any applicant who meets the 21 requirements of § 13–7A–04 of this subtitle.

- 22 (b) Each certificate shall include:
- 23 (1) The full name of the certificate holder; and
- 24 (2) A serial number.

(c) A replacement certificate may be issued to replace a lost, destroyed, or
 mutilated certificate if the certificate holder pays a certificate replacement fee set by the
 Department.

- 28 (d) (1) A certificate shall be valid for a term of 1 year.
- 29 (2) To renew a certificate for an additional 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.

3 13–7A–06.

4 (a) (1) A physician licensed to practice medicine in the State may prescribe 5 auto-injectable epinephrine in the name of a certificate holder.

6 (2) A pharmacist licensed to practice pharmacy in the State or a physician 7 may dispense auto-injectable epinephrine under a prescription issued to a certificate 8 holder.

9 (b) A certificate holder may:

10 (1) On presentment of a certificate, receive from any physician licensed to 11 practice medicine in the State a prescription for auto-injectable epinephrine and the 12 necessary paraphernalia for the administration of auto-injectable epinephrine; and

13 (2) Possess and store prescribed auto-injectable epinephrine and the 14 necessary paraphernalia for the administration of auto-injectable epinephrine.

15 (c) In an emergency situation when a physician or emergency medical services 16 are not immediately available, a certificate holder or an agent may administer 17 auto-injectable epinephrine to an individual who is experiencing or is believed in good faith 18 by the certificate holder or agent to be experiencing anaphylaxis.

19 13–7A–07.

20Except as provided in paragraph (2) of this subsection, a cause of action (a) (1)21may not arise against a certificate holder for any act or omission if the certificate holder or 22agent is acting in good faith while administering auto-injectable epinephrine to an 23individual who is experiencing or believed by the certificate holder or agent to be 24experiencing anaphylaxis except where the conduct of the certificate holder or agent 25amounts to gross negligence, willful or wanton misconduct, or intentionally tortious 26conduct.

27 (2) The provisions of paragraph (1) of this subsection do not apply if a 28 certificate holder or [an eligible institution] **PARTICIPATING FACILITY** that makes 29 available, or a certificate holder who administers, auto-injectable epinephrine to an 30 individual who is experiencing or is believed by the certificate holder or [authorized entity] 31 **PARTICIPATING FACILITY** to be experiencing anaphylaxis:

32 (i) Fails to follow standards and procedures for storage and 33 administration of auto-injectable epinephrine; or

34 (ii) Administers auto-injectable epinephrine that is beyond the 35 manufacturer's expiration date.

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1 (b) (1) A cause of action may not arise against any physician for any act or 2 omission if the physician in good faith prescribes or dispenses auto-injectable epinephrine 3 and the necessary paraphernalia for the administration of auto-injectable epinephrine to 4 a certificate holder or [an eligible institution] **PARTICIPATING FACILITY** under this 5 subtitle.

6 (2) A cause of action may not arise against any pharmacist for any act or 7 omission if the pharmacist in good faith dispenses auto-injectable epinephrine and the 8 necessary paraphernalia for the administration of auto-injectable epinephrine to a 9 certificate holder or [an eligible institution] A PARTICIPATING FACILITY under this 10 subtitle.

11 (c) This section does not affect and may not be construed as affecting any 12 immunities from civil liability or defenses established by any other provision of law or by 13 common law to which a physician or pharmacist may be entitled.

14 13–7A–08.

(a) This subtitle may not be construed to create a duty on any individual
EMPLOYED BY A RECREATION OR WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION
OR FOOD SERVICE FACILITY to obtain a certificate under this subtitle, and an individual
EMPLOYED BY A RECREATION OR WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION
OR FOOD SERVICE FACILITY may not be held civilly liable for failing to obtain a certificate
under this subtitle.

(b) An individual may not be held civilly liable in any action arising from or in connection with the administration of auto-injectable epinephrine by the individual solely because the individual did not possess a certificate issued under this subtitle.

24 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 or a recreation and wellness facility at an eligible institution] A **PARTICIPATING FACILITY** that involved the administration of auto-injectable epinephrine by a certificate holder or an agent.

30 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 31 October 1, 2020.