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By: Senators Carozza, Klausmeier, Beidle, and Hershey Introduced and read first time: January 29, 2020 Assigned to: Finance

A BILL ENTITLED

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 $\mathbf{5}$ Program at Institutions of Higher Education to be the Emergency Use 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 12manner; requiring participating food service facilities to designate certain employees 13 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 16entity may pay a certain application fee if a food service facility is part of an eligible 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 19circumstances; 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,

23 Article – Health – General

- 24 Section 13–7A–01 through 13–7A–04 and 13–7A–07 through 13–7A–09 to be under 25 the amended subtitle "Subtitle 7A. Emergency Use Auto–Injectable 26 Epinephrine Program"
- 27 Annotated Code of Maryland
- 28 (2019 Replacement Volume)
- 29 BY repealing and reenacting, without amendments,

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



2 SENATE BILL 477		
$ \begin{array}{c} 1 \\ 2 \\ 3 \\ 4 \end{array} $	Article – Health – General Section 13–7A–05 and 13–7A–06 Annotated Code of Maryland (2019 Replacement Volume)	
$5 \\ 6$	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:	
7	Article – Health – General	
8 9	Subtitle 7A. Emergency Use Auto–Injectable Epinephrine Program [at Institutions of Higher Education].	
10	13–7A–01.	
11	(a)	In this subtitle the following words have the meanings indicated.
12	(b)	"Agent" means an individual who:
13		(1) Is at least 18 years of age;
$\begin{array}{c} 14\\ 15\\ 16\end{array}$		(2) Has successfully completed, at the expense of the [eligible institution] TING FACILITY, an educational training program approved by the Department -7A-03 of this subtitle; and
17 18	epinephrine	(3) Is designated by a certificate holder to administer auto-injectable in accordance with the provisions of this subtitle.
19 20	(c) allergic read	"Anaphylaxis" means a sudden, severe, and potentially life–threatening ction that occurs when an individual is exposed to an allergen.
$21 \\ 22 \\ 23$		"Auto-injectable epinephrine" means a portable, disposable drug delivery contains a premeasured single dose of epinephrine that is used to treat s in an emergency situation.
$\begin{array}{c} 24 \\ 25 \end{array}$	(e) obtain, store	"Certificate" means a certificate issued by the Department to an individual to e, and administer auto–injectable epinephrine.
26 27 28	(f) to obtain, s situation.	"Certificate holder" means an individual who is authorized by the Department tore, and administer auto–injectable epinephrine to be used in an emergency
29 30 31		"Eligible institution" means an institution of higher education that has a food ity or a recreation and wellness facility on the premises and that is authorized subtitle to obtain and store auto—injectable epinephrine.
32	(h)	"Food service facility" has the meaning indicated in § 21–301 of this article.

1 (i) "PARTICIPATING FACILITY" MEANS A RECREATION OR WELLNESS 2 FACILITY AT AN ELIGIBLE INSTITUTION OR A FOOD SERVICE FACILITY, INCLUDING 3 A FOOD SERVICE FACILITY AT AN ELIGIBLE INSTITUTION, IN THE STATE THAT 4 VOLUNTARILY PARTICIPATES IN THE PROGRAM.

5 (J) "Program" means the Emergency Use Auto–Injectable Epinephrine Program 6 [at Institutions of Higher Education] established under § 13–7A–02 of this subtitle.

7 13–7A–02.

8 (a) There is an Emergency Use Auto-Injectable Epinephrine Program [at 9 Institutions of Higher Education].

10 (b) The purpose of the Program is to authorize individuals employed by a [food 11 service facility or a recreation and wellness facility at an eligible institution] 12 **PARTICIPATING FACILITY** to obtain and store auto-injectable epinephrine and 13 administer auto-injectable epinephrine to individuals who are experiencing or are believed 14 to be experiencing anaphylaxis when a physician or emergency medical services are not 15 immediately available.

16 (c) (1) Subject to paragraph (4) of this subsection, [an eligible institution]
 17 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

20 (ii) A supply of auto-injectable epinephrine from a licensed 21 pharmacist or a licensed physician as provided in § 13-7A-06 of this subtitle.

22 (2) [An eligible institution] **EACH PARTICIPATING FACILITY** shall store 23 a supply of auto–injectable epinephrine obtained under paragraph (1)(ii) of this subsection:

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(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.

27 (3) [An eligible institution] EACH PARTICIPATING FACILITY shall 28 designate the employees who are certificate holders or designated affiliated individuals who 29 are certificate holders who will be responsible for the storage, maintenance, and control of 30 the supply of auto-injectable epinephrine.

31 (4) [An eligible institution] A PARTICIPATING FACILITY may not obtain 32 or store auto-injectable epinephrine unless the [eligible institution] PARTICIPATING

$\frac{1}{2}$	FACILITY has at least two employees or designated affiliated individuals who are certificate holders.		
$egin{array}{c} 3 \ 4 \ 5 \end{array}$	(5) [An eligible institution] EACH PARTICIPATING FACILITY shall maintain a copy of the certificate issued to an employee or a designated affiliated individual under § 13–7A–05 of this subtitle.		
6	13–7A–03.		
7	(a) The Department shall:		
8	(1) Adopt regulations for the administration of the Program;		
9	(2) Collect fees necessary for the administration of the Program;		
10 11	(3) Issue a certificate to, or renew the certificate of, an individual meeting the requirements of § 13–7A–04 of this subtitle;		
$\begin{array}{c} 12 \\ 13 \end{array}$			
$14 \\ 15 \\ 16 \\ 17 \\ 18$	the Department about each incident that occurred on the premises of a [food service facility or a recreation and wellness facility at an eligible institution] PARTICIPATING FACILITY that involved the administration of auto-injectable epinephrine by a certificate holder or		
19 20 21	(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.		
22	(b) The Department may:		
23	(1) Set an application fee for a certificate;		
24	(2) Establish a fee for the renewal or replacement of a certificate; and		
$\begin{array}{c} 25\\ 26 \end{array}$	(3) Require applicants to apply to the Program in the manner the Department chooses.		
$\begin{array}{c} 27\\ 28 \end{array}$	(c) An educational training program approved by the Department under subsection (a)(4) of this section may be an online training program.		
29	13–7A–04.		
30	(a) To qualify for a certificate, an applicant shall:		

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1 (1) Be employed by a [food service facility or a recreation and wellness 2 facility at an eligible institution] **PARTICIPATING FACILITY**;

3 (2) Successfully complete, at the expense of the [eligible institution] 4 **PARTICIPATING FACILITY**, an educational training program approved by the Department 5 under § 13–7A–03 of this subtitle;

- 6 (3) Submit an application to the Department in a manner required by the 7 Department under § 13–7A–03 of this subtitle; and
- 8 (4) Subject to subsection (b) of this section, pay to the Department an 9 application fee required under § 13–7A–03 of this subtitle.

10 (b) (1) [An eligible institution] A PARTICIPATING FACILITY may pay the 11 application fee on behalf of the applicant.

12 (2) IF THE PARTICIPATING FACILITY IS A FOOD SERVICE FACILITY 13 THAT IS PART OF AN ELIGIBLE INSTITUTION, EITHER ENTITY MAY PAY THE 14 APPLICATION FEE ON BEHALF OF THE APPLICANT.

15 13–7A–05.

16 (a) The Department shall issue a certificate to any applicant who meets the 17 requirements of § 13–7A–04 of this subtitle.

- 18 (b) Each certificate shall include:
- 19 (1) The full name of the certificate holder; and
- 20 (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.

24 (d) (1) A certificate shall be valid for a term of 1 year.

25 (2) To renew a certificate for an additional 1-year term, the renewal 26 applicant shall successfully complete a refresher educational training program approved 27 by the Department under § 13-7A-03 of this subtitle.

28 13–7A–06.

29 (a) (1) A physician licensed to practice medicine in the State may prescribe 30 auto-injectable epinephrine in the name of a certificate holder.

1 (2) A pharmacist licensed to practice pharmacy in the State or a physician 2 may dispense auto-injectable epinephrine under a prescription issued to a certificate 3 holder.

4 (b) A certificate holder may:

5 (1) On presentment of a certificate, receive from any physician licensed to 6 practice medicine in the State a prescription for auto-injectable epinephrine and the 7 necessary paraphernalia for the administration of auto-injectable epinephrine; and

8 (2) Possess and store prescribed auto-injectable epinephrine and the 9 necessary paraphernalia for the administration of auto-injectable epinephrine.

10 (c) In an emergency situation when a physician or emergency medical services 11 are not immediately available, a certificate holder or an agent may administer 12 auto-injectable epinephrine to an individual who is experiencing or is believed in good faith 13 by the certificate holder or agent to be experiencing anaphylaxis.

14 13–7A–07.

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Except as provided in paragraph (2) of this subsection, a cause of action 15(a) (1)may not arise against a certificate holder for any act or omission if the certificate holder or 16agent is acting in good faith while administering auto-injectable epinephrine to an 1718 individual who is experiencing or believed by the certificate holder or agent to be 19experiencing anaphylaxis except where the conduct of the certificate holder or agent amounts to gross negligence, willful or wanton misconduct, or intentionally tortious 2021conduct.

22 (2) The provisions of paragraph (1) of this subsection do not apply if a 23 certificate holder or [an eligible institution] **PARTICIPATING FACILITY** that makes 24 available, or a certificate holder who administers, auto-injectable epinephrine to an 25 individual who is experiencing or is believed by the certificate holder or [authorized entity] 26 **PARTICIPATING FACILITY** to be experiencing anaphylaxis:

27 (i) Fails to follow standards and procedures for storage and 28 administration of auto-injectable epinephrine; or

29 (ii) Administers auto-injectable epinephrine that is beyond the 30 manufacturer's expiration date.

31 (b) (1) A cause of action may not arise against any physician for any act or 32 omission if the physician in good faith prescribes or dispenses auto-injectable epinephrine 33 and the necessary paraphernalia for the administration of auto-injectable epinephrine to 34 a certificate holder or [an eligible institution] **PARTICIPATING FACILITY** under this 35 subtitle.

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(2) A cause of action may not arise against any pharmacist for any act or

1 omission if the pharmacist in good faith dispenses auto-injectable epinephrine and the 2 necessary paraphernalia for the administration of auto-injectable epinephrine to a 3 certificate holder or [an eligible institution] A PARTICIPATING FACILITY under this 4 subtitle.

5 (c) This section does not affect and may not be construed as affecting any 6 immunities from civil liability or defenses established by any other provision of law or by 7 common law to which a physician or pharmacist may be entitled.

8 13–7A–08.

9 (a) This subtitle may not be construed to create a duty on any individual 10 EMPLOYED BY A RECREATION OR WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION 11 OR FOOD SERVICE FACILITY to obtain a certificate under this subtitle, and an individual 12 EMPLOYED BY A RECREATION OR WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION 13 OR FOOD SERVICE FACILITY may not be held civilly liable for failing to obtain a certificate 14 under this subtitle.

15 (b) An individual may not be held civilly liable in any action arising from or in 16 connection with the administration of auto-injectable epinephrine by the individual solely 17 because the individual did not possess a certificate issued under this subtitle.

18 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.

24 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 25 October 1, 2020.