

# SENATE BILL 1159

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SB 898/16 – FIN

8lr3566

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By: **Senator Klausmeier**

Introduced and read first time: February 19, 2018

Assigned to: Rules

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## A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Emergency Use Auto–Injectable Epinephrine Program for Food**  
3 **Service Facilities**

4 FOR the purpose of establishing the Emergency Use Auto–Injectable Epinephrine Program  
5 for Food Service Facilities in the Maryland Department of Health; establishing the  
6 purpose of the Program; authorizing the Department to adopt certain regulations,  
7 collect certain fees, issue and renew certain certificates, and approve certain training  
8 programs relating to the Program; establishing qualifications for applicants for a  
9 certain certificate; requiring the Department to issue certain certificates to certain  
10 applicants; providing for the contents, replacement, term, and renewal of certain  
11 certificates; authorizing certain physicians to prescribe and certain pharmacists to  
12 dispense auto–injectable epinephrine to certain certificate holders; authorizing  
13 certain certificate holders to take certain actions; authorizing a certificate holder or  
14 an agent to administer auto–injectable epinephrine to a certain individual in a  
15 certain situation; providing that a cause of action may not arise against certain  
16 certificate holders or certain agents for certain acts or omissions under certain  
17 circumstances; providing that a cause of action may not arise against certain  
18 physicians who prescribe or dispense auto–injectable epinephrine and certain  
19 paraphernalia to certain certificate holders under certain circumstances; providing  
20 that a cause of action may not arise against certain pharmacists who dispense  
21 auto–injectable epinephrine and certain paraphernalia to certain certificate holders  
22 under certain circumstances; providing for immunity from civil liability for certain  
23 individuals under certain circumstances; providing for the effect of certain provisions  
24 of this Act; providing for the construction of this Act; requiring certain certificate  
25 holders to submit to the Department a certain report; requiring the Department to  
26 publish a certain report on or before a certain date each year; defining certain terms;  
27 and generally relating to the Emergency Use Auto–Injectable Epinephrine Program  
28 for Food Service Facilities.

29 BY adding to  
30 Article – Health – General

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Section 13-7A-01 through 13-7A-10 to be under the new subtitle "Subtitle 7A.  
2 Emergency Use Auto-Injectable Epinephrine Program for Food Service  
3 Facilities"

4 Annotated Code of Maryland  
5 (2015 Replacement Volume and 2017 Supplement)

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

8 **Article – Health – General**

9 **SUBTITLE 7A. EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE PROGRAM FOR**  
10 **FOOD SERVICE FACILITIES.**

11 **13-7A-01.**

12 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS  
13 INDICATED.

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

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

16 (2) HAS SUCCESSFULLY COMPLETED, AT THE EXPENSE OF THE  
17 APPLICANT, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE  
18 DEPARTMENT; AND

19 (3) IS APPOINTED BY A CERTIFICATE HOLDER TO ADMINISTER  
20 AUTO-INJECTABLE EPINEPHRINE IN ACCORDANCE WITH THE PROVISIONS OF THIS  
21 SUBTITLE.

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

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

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

31 (F) "CERTIFICATE HOLDER" MEANS AN INDIVIDUAL WHO IS AUTHORIZED

1 BY THE DEPARTMENT TO OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE  
2 EPINEPHRINE TO BE USED IN AN EMERGENCY SITUATION.

3 (G) "FOOD SERVICE FACILITY" HAS THE MEANING STATED IN § 21-301 OF  
4 THIS ARTICLE.

5 (H) "PROGRAM" MEANS THE EMERGENCY USE AUTO-INJECTABLE  
6 EPINEPHRINE PROGRAM FOR FOOD SERVICE FACILITIES ESTABLISHED UNDER §  
7 13-7A-02 OF THIS SUBTITLE.

8 13-7A-02.

9 (A) THERE IS AN EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE  
10 PROGRAM FOR FOOD SERVICE FACILITIES IN THE DEPARTMENT.

11 (B) THE PURPOSE OF THE PROGRAM IS TO PROVIDE A MEANS OF  
12 AUTHORIZING INDIVIDUALS IN A FOOD SERVICE FACILITY TO OBTAIN AND STORE  
13 AUTO-INJECTABLE EPINEPHRINE AND ADMINISTER AUTO-INJECTABLE  
14 EPINEPHRINE TO INDIVIDUALS WHO ARE EXPERIENCING ANAPHYLAXIS WHEN A  
15 PHYSICIAN OR EMERGENCY MEDICAL SERVICES ARE NOT IMMEDIATELY AVAILABLE.

16 13-7A-03.

17 THE DEPARTMENT MAY:

18 (1) ADOPT REGULATIONS FOR THE ADMINISTRATION OF THE  
19 PROGRAM;

20 (2) COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE  
21 PROGRAM;

22 (3) ISSUE A CERTIFICATE TO AND RENEW A CERTIFICATE OF AN  
23 INDIVIDUAL MEETING THE REQUIREMENTS OF THIS SUBTITLE; AND

24 (4) APPROVE EDUCATIONAL TRAINING PROGRAMS, INCLUDING  
25 PROGRAMS CONDUCTED BY OTHER STATE AGENCIES OR PRIVATE ENTITIES.

26 13-7A-04.

27 (A) TO QUALIFY FOR A CERTIFICATE, AN INDIVIDUAL SHALL MEET THE  
28 REQUIREMENTS OF THIS SECTION.

29 (B) THE APPLICANT SHALL OWN OR OPERATE A FOOD SERVICE FACILITY.

1 (C) (1) THE APPLICANT SHALL SUCCESSFULLY COMPLETE, AT THE  
2 EXPENSE OF THE APPLICANT, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY  
3 THE DEPARTMENT.

4 (2) THE EDUCATIONAL TRAINING PROGRAM REQUIRED UNDER  
5 PARAGRAPH (1) OF THIS SUBSECTION MAY BE AN ONLINE TRAINING PROGRAM.

6 13-7A-05.

7 AN APPLICANT FOR A CERTIFICATE SHALL:

8 (1) SUBMIT AN APPLICATION TO THE DEPARTMENT ON THE FORM  
9 THAT THE DEPARTMENT REQUIRES; AND

10 (2) PAY TO THE DEPARTMENT THE APPLICATION FEE SET BY THE  
11 DEPARTMENT.

12 13-7A-06.

13 (A) THE DEPARTMENT SHALL ISSUE A CERTIFICATE TO ANY APPLICANT  
14 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 (C) A REPLACEMENT CERTIFICATE MAY BE ISSUED TO REPLACE A LOST,  
19 DESTROYED, OR MUTILATED CERTIFICATE IF THE CERTIFICATE HOLDER PAYS THE  
20 CERTIFICATE REPLACEMENT FEE.

21 (D) (1) THE CERTIFICATE SHALL BE VALID FOR 2 YEARS.

22 (2) TO RENEW THE CERTIFICATE FOR AN ADDITIONAL 2-YEAR TERM,  
23 THE APPLICANT SHALL SUCCESSFULLY COMPLETE A REFRESHER EDUCATIONAL  
24 TRAINING PROGRAM APPROVED BY THE DEPARTMENT.

25 13-7A-07.

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-08.**

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

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

31           **(2) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHARMACIST**  
32 **FOR ANY ACT OR OMISSION IF THE PHARMACIST IN GOOD FAITH DISPENSES**  
33 **AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE**  
34 **ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL**

1 CERTIFIED BY THE DEPARTMENT UNDER THIS SUBTITLE.

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

6 13-7A-09.

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

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

15 13-7A-10.

16 (A) A CERTIFICATE HOLDER SHALL SUBMIT TO THE DEPARTMENT, ON A  
17 FORM REQUIRED BY THE DEPARTMENT, A REPORT OF EACH INCIDENT THAT  
18 OCCURRED ON THE CERTIFICATE HOLDER'S PREMISES THAT INVOLVED THE  
19 ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE.

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

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