

# SENATE BILL 898

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CF 6lr2971

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By: **Senator Klausmeier**

Introduced and read first time: February 5, 2016

Assigned to: Finance

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

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.

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

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

6 (H) "PROGRAM" MEANS THE EMERGENCY USE AUTO-INJECTABLE  
7 EPINEPHRINE PROGRAM FOR FOOD SERVICE FACILITIES ESTABLISHED UNDER §  
8 13-7A-02 OF THIS SUBTITLE.

9 13-7A-02.

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

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

17 13-7A-03.

18 THE DEPARTMENT MAY:

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

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

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

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

27 13-7A-04.

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

30 (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.

1           **(A) (1) A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE**  
2 **MAY PRESCRIBE AUTO-INJECTABLE EPINEPHRINE IN THE NAME OF A CERTIFICATE**  
3 **HOLDER.**

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

7           **(B) A CERTIFICATE HOLDER MAY:**

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

12           **(2) POSSESS AND STORE PRESCRIBED AUTO-INJECTABLE**  
13 **EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE ADMINISTRATION OF**  
14 **AUTO-INJECTABLE EPINEPHRINE.**

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

20 **13-7A-08.**

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

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

1           **(2) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHARMACIST**  
2 **FOR ANY ACT OR OMISSION IF THE PHARMACIST IN GOOD FAITH DISPENSES**  
3 **AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE**  
4 **ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL**  
5 **CERTIFIED BY THE DEPARTMENT UNDER THIS SUBTITLE.**

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

10 **13-7A-09.**

11           **(A) THIS SUBTITLE MAY NOT BE CONSTRUED TO CREATE A DUTY ON ANY**  
12 **INDIVIDUAL TO OBTAIN A CERTIFICATE UNDER THIS SUBTITLE, AND AN INDIVIDUAL**  
13 **MAY NOT BE HELD CIVILLY LIABLE FOR FAILING TO OBTAIN A CERTIFICATE UNDER**  
14 **THIS SUBTITLE.**

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

19 **13-7A-10.**

20           **(A) A CERTIFICATE HOLDER SHALL SUBMIT TO THE DEPARTMENT, ON A**  
21 **FORM REQUIRED BY THE DEPARTMENT, A REPORT OF EACH INCIDENT THAT**  
22 **OCCURRED ON THE CERTIFICATE HOLDER'S PREMISES THAT INVOLVED THE**  
23 **ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE.**

24           **(B) ON OR BEFORE JANUARY 31 EACH YEAR, THE DEPARTMENT SHALL**  
25 **PUBLISH A REPORT SUMMARIZING THE INFORMATION OBTAINED FROM THE**  
26 **REPORTS SUBMITTED TO THE DEPARTMENT UNDER SUBSECTION (A) OF THIS**  
27 **SECTION.**

28           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
29 October 1, 2016.