

SENATE BILL 898

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6lr2757
CF HB 1418

By: **Senator Klausmeier**

Introduced and read first time: February 5, 2016

Assigned to: Finance

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 18, 2016

CHAPTER _____

1 AN ACT concerning

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

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 requirements for an authorized entity to obtain and store a supply of
7 auto-injectable epinephrine; prohibiting an authorized entity from obtaining and
8 storing auto-injectable epinephrine unless the authorized entity has a certain
9 number of certain employees or certain affiliated individuals; requiring an
10 authorized entity to maintain a copy of a certain certificate issued to certain
11 individuals; establishing qualifications for an individual to obtain a certificate to
12 obtain, store, and administer auto-injectable epinephrine to be used in an emergency
13 situation; establishing the term of a certain certificate; ~~establishing the purpose of~~
14 ~~the Program;~~ authorizing the Department to adopt certain regulations, ~~collect~~
15 ~~certain fees, issue and renew certain certificates, and;~~ requiring the Department to
16 approve certain training programs ~~relating to the Program;~~ establishing
17 qualifications for applicants for a certain certificate; ~~requiring the Department to~~
18 ~~issue certain certificates to certain applicants;~~ providing for the contents,
19 ~~replacement, term,~~ and renewal of certain certificates; authorizing certain
20 physicians to prescribe and certain pharmacists and physicians to dispense
21 auto-injectable epinephrine to certain certificate holders or authorized entities;
22 authorizing certain certificate holders or authorized entities to take certain actions;
23 authorizing a certificate holder ~~or an agent~~ to administer
24 auto-injectable epinephrine to a certain individual in a certain situation; providing
25 that a cause of action may not arise against certain certificate holders or authorized

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.



~~entities or certain agents~~ for certain acts or omissions under certain circumstances;

~~providing a certain exception to a certain immunity~~; 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 or authorized

~~entities~~ 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 or authorized entities under certain

 circumstances; providing for immunity from civil liability for certain individuals

 under certain circumstances; providing for the effect of certain provisions of this Act;

~~providing for the application of this Act~~; providing for the construction of this Act;

~~requiring certain certificate holders to submit to the Department a certain report~~;

~~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 for Food Service Facilities~~ certification for

obtaining, storing, and administering auto-injectable epinephrine.

BY adding to

Article – Health – General

Section 13-7A-01 through ~~13-7A-10~~ 13-7A-09 to be under the new subtitle

“Subtitle 7A. Emergency ~~Use~~ Administration of Auto-Injectable Epinephrine

~~Program for Food Service Facilities~~”

Annotated Code of Maryland

(2015 Replacement Volume)

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

That the Laws of Maryland read as follows:

Article – Health – General

SUBTITLE 7A. EMERGENCY ~~USE~~ ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE ~~PROGRAM FOR FOOD SERVICE FACILITIES.~~

13-7A-01.

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

(B) “~~AGENT~~ AFFILIATED INDIVIDUAL” MEANS AN INDIVIDUAL WHO:

(1) IS AT LEAST 18 YEARS OF AGE;

(2) HAS AN UNPAID AND CLOSE ASSOCIATION WITH AN AUTHORIZING
ENTITY;

1 ~~(2)~~ **(3)** HAS SUCCESSFULLY COMPLETED, AT THE EXPENSE OF THE
2 APPLICANT, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE
3 DEPARTMENT; AND

4 ~~(3)~~ **(4)** IS ~~APPOINTED BY A CERTIFICATE HOLDER TO~~ DESIGNATED
5 BY AN AUTHORIZED ENTITY TO OBTAIN, STORE, AND ADMINISTER
6 AUTO-INJECTABLE EPINEPHRINE IN ACCORDANCE WITH THE PROVISIONS OF THIS
7 SUBTITLE.

8 (C) “ANAPHYLAXIS” MEANS A SUDDEN, SEVERE, AND POTENTIALLY
9 LIFE-THREATENING ALLERGIC REACTION THAT OCCURS WHEN AN INDIVIDUAL IS
10 EXPOSED TO AN ALLERGEN.

11 (D) **(1)** “AUTHORIZED ENTITY” MEANS AN ENTITY:

12 **(I)** AT WHICH ALLERGENS CAPABLE OF CAUSING ANAPHYLAXIS
13 MAY BE PRESENT; AND

14 **(II)** THAT IS AUTHORIZED UNDER THIS SUBTITLE TO OBTAIN
15 AND STORE AUTO-INJECTABLE EPINEPHRINE.

16 **(2)** “AUTHORIZED ENTITY” INCLUDES:

17 **(I)** A COLLEGE OR UNIVERSITY;

18 **(II)** A DAY CARE FACILITY;

19 **(III)** A FOOD SERVICE FACILITY;

20 **(IV)** AN AMUSEMENT PARK; AND

21 **(V)** A YOUTH SPORTS LEAGUE.

22 **(3)** “AUTHORIZED ENTITY” DOES NOT INCLUDE A YOUTH CAMP AS
23 DEFINED IN § 14-401 OF THIS ARTICLE.

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

28 ~~(E)~~ **(F)** “CERTIFICATE” MEANS A CERTIFICATE ISSUED BY AN
29 EDUCATIONAL PROGRAM APPROVED BY THE DEPARTMENT TO AN INDIVIDUAL TO
30 OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE EPINEPHRINE.

1 ~~(F)~~ (G) "CERTIFICATE HOLDER" MEANS AN INDIVIDUAL WHO IS:

2 (1) IS AT LEAST 18 YEARS OLD; AND

3 (2) IS AUTHORIZED BY THE DEPARTMENT TO OBTAIN, STORE, AND
 4 ADMINISTER AUTO-INJECTABLE EPINEPHRINE TO BE USED IN AN EMERGENCY
 5 SITUATION.

6 ~~(C) "FOOD SERVICE FACILITY" HAS THE MEANING STATED IN § 21-301 OF~~
 7 ~~THIS ARTICLE.~~

8 ~~(H) "PROGRAM" MEANS THE EMERGENCY USE AUTO-INJECTABLE~~
 9 ~~EPINEPHRINE PROGRAM FOR FOOD SERVICE FACILITIES ESTABLISHED UNDER §~~
 10 ~~13-7A-02 OF THIS SUBTITLE.~~

11 13-7A-02.

12 THIS SUBTITLE DOES NOT APPLY TO:

13 (1) THE EMERGENCY AND ALLERGY TREATMENT PROGRAM UNDER
 14 SUBTITLE 7 OF THIS TITLE;

15 (2) PUBLIC ELEMENTARY AND SECONDARY SCHOOLS; OR

16 (3) NONPUBLIC ELEMENTARY AND SECONDARY SCHOOLS.

17 13-7A-03.

18 (A) SUBJECT TO SUBSECTION (C) OF THIS SECTION, AN AUTHORIZED
 19 ENTITY MAY OBTAIN:

20 (1) A PRESCRIPTION FOR A SUPPLY OF AUTO-INJECTABLE
 21 EPINEPHRINE FROM A LICENSED PHYSICIAN AS PROVIDED IN § 13-7A-07 OF THIS
 22 SUBTITLE; AND

23 (2) A SUPPLY OF AUTO-INJECTABLE EPINEPHRINE FROM A LICENSED
 24 PHARMACIST OR A LICENSED PHYSICIAN AS PROVIDED IN § 13-7A-07 OF THIS
 25 SUBTITLE.

26 (B) (1) AN AUTHORIZED ENTITY SHALL STORE A SUPPLY OF
 27 AUTO-INJECTABLE EPINEPHRINE OBTAINED UNDER SUBSECTION (A)(2) OF THIS
 28 SECTION:

1 **(I) IN ACCORDANCE WITH THE MANUFACTURER'S**
2 **INSTRUCTIONS; AND**

3 **(II) IN A LOCATION THAT IS READILY ACCESSIBLE TO**
4 **EMPLOYEES OR AFFILIATED INDIVIDUALS IN AN EMERGENCY SITUATION.**

5 **(2) AN AUTHORIZED ENTITY SHALL DESIGNATE THE EMPLOYEES WHO**
6 **ARE CERTIFICATE HOLDERS OR AFFILIATED INDIVIDUALS WHO ARE CERTIFICATE**
7 **HOLDERS WHO WILL BE RESPONSIBLE FOR THE STORAGE, MAINTENANCE, AND**
8 **CONTROL OF THE SUPPLY OF THE AUTO-INJECTABLE EPINEPHRINE.**

9 **(C) (1) AN AUTHORIZED ENTITY MAY NOT OBTAIN OR STORE**
10 **AUTO-INJECTABLE EPINEPHRINE UNLESS THE AUTHORIZED ENTITY HAS AT LEAST**
11 **TWO:**

12 **(I) EMPLOYEES WHO ARE CERTIFICATE HOLDERS; OR**

13 **(II) DESIGNATED AFFILIATED INDIVIDUALS WHO ARE**
14 **CERTIFICATE HOLDERS.**

15 **(2) AN OWNER OF AN AUTHORIZED ENTITY WHO IS A CERTIFICATE**
16 **HOLDER SHALL BE DEEMED TO BE AN EMPLOYEE FOR PURPOSES OF THE**
17 **REQUIREMENT UNDER PARAGRAPH (1) OF THIS SUBSECTION.**

18 **(D) AN AUTHORIZED ENTITY SHALL MAINTAIN A COPY OF THE CERTIFICATE**
19 **ISSUED TO AN EMPLOYEE OR AN AFFILIATED INDIVIDUAL UNDER § 13-7A-06 OF**
20 **THIS SUBTITLE.**

21 ~~**(A) THERE IS AN EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE**~~
22 ~~**PROGRAM FOR FOOD SERVICE FACILITIES IN THE DEPARTMENT.**~~

23 ~~**(B) THE PURPOSE OF THE PROGRAM IS TO PROVIDE A MEANS OF**~~
24 ~~**AUTHORIZING INDIVIDUALS IN A FOOD SERVICE FACILITY TO OBTAIN AND STORE**~~
25 ~~**AUTO-INJECTABLE EPINEPHRINE AND ADMINISTER AUTO-INJECTABLE**~~
26 ~~**EPINEPHRINE TO INDIVIDUALS WHO ARE EXPERIENCING ANAPHYLAXIS WHEN**~~
27 ~~**PHYSICIAN OR EMERGENCY MEDICAL SERVICES ARE NOT IMMEDIATELY AVAILABLE.**~~

28 ~~**13-7A-03. 13-7A-04.**~~

29 **THE DEPARTMENT MAY:**

30 **(1) ADOPT MAY ADOPT REGULATIONS FOR THE ADMINISTRATION OF**
31 **THE PROGRAM TO CARRY OUT THIS SUBTITLE; AND**

1 (2) ~~COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE~~
2 ~~PROGRAM;~~

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

5 (4) ~~APPROVE~~ SHALL APPROVE EDUCATIONAL TRAINING PROGRAMS,
6 INCLUDING PROGRAMS CONDUCTED BY OTHER STATE AGENCIES OR PRIVATE
7 ENTITIES.

8 ~~13-7A-04.~~ 13-7A-05.

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

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

12 ~~(C)~~ (B) (1) THE APPLICANT SHALL SUCCESSFULLY COMPLETE, AT THE
13 EXPENSE OF THE APPLICANT, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY
14 THE DEPARTMENT.

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

17 ~~13-7A-05.~~

18 ~~AN APPLICANT FOR A CERTIFICATE SHALL:~~

19 ~~(1) SUBMIT AN APPLICATION TO THE DEPARTMENT ON THE FORM~~
20 ~~THAT THE DEPARTMENT REQUIRES; AND~~

21 ~~(2) PAY TO THE DEPARTMENT THE APPLICATION FEE SET BY THE~~
22 ~~DEPARTMENT.~~

23 13-7A-06.

24 (A) ~~THE~~ AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE
25 DEPARTMENT SHALL ISSUE A CERTIFICATE TO ANY APPLICANT WHO MEETS THE
26 REQUIREMENTS OF THIS SUBTITLE.

27 (B) ~~EACH CERTIFICATE SHALL INCLUDE:~~

28 ~~(1) THE FULL NAME OF THE CERTIFICATE HOLDER; AND~~

29 ~~(2) A SERIAL NUMBER.~~

1 ~~(C) A REPLACEMENT CERTIFICATE MAY BE ISSUED TO REPLACE A LOST,~~
2 ~~DESTROYED, OR MUTILATED CERTIFICATE IF THE CERTIFICATE HOLDER PAYS THE~~
3 ~~CERTIFICATE REPLACEMENT FEE.~~

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

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

8 13-7A-07.

9 (A) (1) A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE
10 MAY PRESCRIBE AUTO-INJECTABLE EPINEPHRINE IN THE NAME OF A:

11 (I) A CERTIFICATE HOLDER; OR

12 (II) SUBJECT TO SUBSECTION (C) OF THIS SECTION, AN
13 AUTHORIZED ENTITY.

14 (2) A PHARMACIST LICENSED TO PRACTICE PHARMACY IN THE STATE
15 OR A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE MAY DISPENSE
16 AUTO-INJECTABLE EPINEPHRINE UNDER A PRESCRIPTION ISSUED TO A
17 CERTIFICATE HOLDER OR AN AUTHORIZED ENTITY.

18 (B) A CERTIFICATE HOLDER MAY:

19 (1) ON PRESENTMENT OF A CERTIFICATE, RECEIVE FROM ANY
20 PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE A PRESCRIPTION FOR
21 AUTO-INJECTABLE EPINEPHRINE ~~AND THE NECESSARY PARAPHERNALIA FOR THE~~
22 ~~ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; AND~~

23 (2) POSSESS AND STORE PRESCRIBED AUTO-INJECTABLE
24 EPINEPHRINE ~~AND THE NECESSARY PARAPHERNALIA FOR THE ADMINISTRATION OF~~
25 ~~AUTO-INJECTABLE EPINEPHRINE.~~

26 (C) AN AUTHORIZED ENTITY MAY:

27 (1) ON PRESENTMENT OF A CERTIFICATE OF AN EMPLOYEE OF THE
28 AUTHORIZED ENTITY OR AN AFFILIATED INDIVIDUAL, RECEIVE FROM ANY
29 PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE A PRESCRIPTION FOR
30 AUTO-INJECTABLE EPINEPHRINE; AND

1 **(2) POSSESS AND STORE THE PRESCRIBED AUTO-INJECTABLE**
 2 **EPINEPHRINE.**

3 ~~(c)~~ **(d)** IN AN EMERGENCY SITUATION WHEN A PHYSICIAN OR
 4 EMERGENCY MEDICAL SERVICES ARE NOT IMMEDIATELY AVAILABLE, A
 5 **CERTIFICATE HOLDER OR AN AUTHORIZED ENTITY MAY MAKE AVAILABLE AND A**
 6 **CERTIFICATE HOLDER ~~OR AN AGENT~~ MAY ADMINISTER AUTO-INJECTABLE**
 7 **EPINEPHRINE TO AN INDIVIDUAL WHO IS EXPERIENCING OR IS BELIEVED IN GOOD**
 8 **FAITH BY THE CERTIFICATE HOLDER ~~OR AGENT~~ TO BE EXPERIENCING**
 9 **ANAPHYLAXIS.**

10 **13-7A-08.**

11 **(A) (1)** A CAUSE OF ACTION MAY NOT ARISE AGAINST A CERTIFICATE
 12 **HOLDER OR AN AUTHORIZED ENTITY ~~OR AN AGENT~~ FOR ANY ACT OR OMISSION IF**
 13 **THE CERTIFICATE HOLDER ~~OR AGENT~~ OR AUTHORIZED ENTITY IS ACTING IN GOOD**
 14 **FAITH WHILE MAKING AVAILABLE OR ADMINISTERING AUTO-INJECTABLE**
 15 **EPINEPHRINE TO AN INDIVIDUAL WHO IS EXPERIENCING OR BELIEVED BY THE**
 16 **CERTIFICATE HOLDER ~~OR AGENT~~ OR AUTHORIZED ENTITY TO BE EXPERIENCING**
 17 **ANAPHYLAXIS EXCEPT WHERE THE CONDUCT OF THE CERTIFICATE HOLDER ~~OR~~**
 18 **~~AGENT~~ OR AUTHORIZED ENTITY AMOUNTS TO GROSS NEGLIGENCE, WILLFUL OR**
 19 **WANTON MISCONDUCT, OR INTENTIONALLY TORTIOUS CONDUCT.**

20 **(2)** **THE PROVISIONS OF PARAGRAPH (1) OF THIS SUBSECTION DO**
 21 **NOT APPLY IF A CERTIFICATE HOLDER OR AN AUTHORIZED ENTITY THAT MAKES**
 22 **AVAILABLE, OR A CERTIFICATE HOLDER WHO ADMINISTERS, AUTO-INJECTABLE**
 23 **EPINEPHRINE TO AN INDIVIDUAL WHO IS EXPERIENCING OR IS BELIEVED BY THE**
 24 **CERTIFICATE HOLDER OR AUTHORIZED ENTITY TO BE EXPERIENCING**
 25 **ANAPHYLAXIS:**

26 **(i)** **FAILS TO FOLLOW STANDARDS AND PROCEDURES FOR**
 27 **STORAGE AND ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; OR**

28 **(ii)** **ADMINISTERS AUTO-INJECTABLE EPINEPHRINE THAT IS**
 29 **BEYOND THE MANUFACTURER'S EXPIRATION DATE.**

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

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

11 ~~13-7A-09.~~

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

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

20 ~~13-7A-10.~~

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

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

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