

HOUSE BILL 536

J1, J2, F5

5lr1960

By: **Delegates Guzzone, Boaf, Chisholm, Hill, Lopez, Martinez, and M. Morgan**

Introduced and read first time: January 22, 2025

Assigned to: Ways and Means and Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Education and Health – Emergency Use Epinephrine – Alterations**

3 FOR the purpose of altering the defined term “auto-injectable epinephrine” to be
4 “emergency use epinephrine” and to include certain drug delivery devices and
5 products; altering the name of the Emergency Use Auto-Injectable Epinephrine
6 Program to be the Emergency Use Epinephrine Program; and generally relating to
7 emergency use epinephrine.

8 BY repealing and reenacting, with amendments,

9 Article – Education

10 Section 7–426.2, 7–426.3, and 9.5–117(a)(3) and (f)

11 Annotated Code of Maryland

12 (2022 Replacement Volume and 2024 Supplement)

13 BY repealing and reenacting, without amendments,

14 Article – Education

15 Section 9.5–117(a)(1)

16 Annotated Code of Maryland

17 (2022 Replacement Volume and 2024 Supplement)

18 BY repealing and reenacting, with amendments,

19 Article – Health – General

20 Section 13–702, 13–704(e), 13–705, 13–706(a), 13–707(a) and (b), and 13–708(b); and

21 13–7A–01, 13–7A–02, 13–7A–03(a)(5), 13–7A–06, 13–7A–07(a) and (b),

22 13–7A–08(b), and 13–7A–09 to be under the amended subtitle “Subtitle 7A.

23 Emergency Use Epinephrine Program”

24 Annotated Code of Maryland

25 (2023 Replacement Volume and 2024 Supplement)

26 BY repealing and reenacting, without amendments,

27 Article – Health Occupations

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



Section 14–5F–01(a) and 14–5F–04.1(a)(1)
Annotated Code of Maryland
(2021 Replacement Volume and 2024 Supplement)

BY repealing

Article – Health Occupations
Section 14–5F–01(c)
Annotated Code of Maryland
(2021 Replacement Volume and 2024 Supplement)

BY repealing and reenacting, with amendments,

Article – Health Occupations
Section 14–5F–01(d) through (g), 14–5F–04.1(d)(1), and 14–5F–14(a)(5)
Annotated Code of Maryland
(2021 Replacement Volume and 2024 Supplement)

BY adding to

Article – Health Occupations
Section 14–5F–01(g)
Annotated Code of Maryland
(2021 Replacement Volume and 2024 Supplement)

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

Article – Education

7–426.2.

(a) (1) In this section the following words have the meanings indicated.

(2) “Anaphylaxis” means a sudden, severe, and potentially life–threatening allergic reaction that occurs when an individual is exposed to an allergen.

(3) [“Auto–injectable”] **“EMERGENCY USE** epinephrine” means a portable, disposable drug delivery device **OR PRODUCT APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation.

(b) Each county board shall establish a policy for public schools within its jurisdiction to authorize the school nurse and other school personnel to administer [auto–injectable] **EMERGENCY USE** epinephrine, if available, to a student who is determined to be or perceived to be in anaphylaxis, regardless of whether the student:

(1) Has been identified as having an anaphylactic allergy, as defined in § 7–426.1 of this subtitle; or

(2) Has a prescription for epinephrine as prescribed by an authorized licensed health care practitioner under the Health Occupations Article.

(c) The policy established under subsection (b) of this section shall include:

(1) Training for school personnel on how to recognize the symptoms of anaphylaxis;

(2) Procedures for the emergency administration of [auto-injectable] **EMERGENCY USE** epinephrine;

(3) The proper follow-up emergency procedures;

(4) A provision authorizing a school nurse to obtain and store at a public school [auto-injectable] **EMERGENCY USE** epinephrine to be used in an emergency situation; and

(5) A requirement that each public school develop and implement a method for notifying the parents or guardians of students of the school's policy under this section at the beginning of each school year.

(d) Except for any willful or grossly negligent act, a school nurse or other school personnel who respond in good faith to the anaphylactic reaction of a child in accordance with this section may not be held personally liable for any act or omission in the course of responding to the reaction.

(e) (1) Each public school shall submit, on the form that the Department requires, a report to the Department on each incident at the school or at a related school event that required the use of [auto-injectable] **EMERGENCY USE** epinephrine.

(2) The Department shall develop and disseminate a standard form to report each incident requiring the use of [auto-injectable] **EMERGENCY USE** epinephrine at a public school.

7-426.3.

(a) (1) In this section the following words have the meanings indicated.

(2) "Anaphylaxis" means a sudden, severe, and potentially life-threatening allergic reaction that occurs when an individual is exposed to an allergen.

(3) ["Auto-injectable"] "**EMERGENCY USE** epinephrine" means a portable, disposable drug delivery device **OR PRODUCT APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation.

(4) “School personnel” means individuals who are employed by a nonpublic school, including part-time employees, teachers and substitute teachers employed by the school for at least 7 days each school year, a school nurse, registered nurse case manager, delegating nurse, and administrative staff.

(b) Each nonpublic school in the State may establish a policy authorizing school personnel to administer [auto-injectable] **EMERGENCY USE** epinephrine, if available, to a student who is determined to be or perceived to be in anaphylaxis, regardless of whether the student:

(1) Has been identified as having an anaphylactic allergy, as defined in § 7-426.1 of this subtitle; or

(2) Has a prescription for epinephrine as prescribed by an authorized licensed health care practitioner under the Health Occupations Article.

(c) The policy established under subsection (b) of this section shall include:

(1) Training for school personnel on how to recognize the signs and symptoms of anaphylaxis by a licensed health care practitioner who is authorized to administer [auto-injectable] **EMERGENCY USE** epinephrine and who has been trained in an established protocol on how to recognize the signs and symptoms of anaphylaxis;

(2) Procedures for the emergency administration of [auto-injectable] **EMERGENCY USE** epinephrine;

(3) The proper follow-up emergency procedures;

(4) A provision authorizing a school nurse or other licensed health care practitioner to obtain, and[,] school personnel to store, at a nonpublic school [auto-injectable] **EMERGENCY USE** epinephrine to be used in an emergency situation;

(5) A requirement that the nonpublic school develop and implement a method for notifying the parents or guardians of students of the school’s policy under this section at the beginning of each school year; and

(6) An ongoing process for oversight and monitoring by a licensed health care practitioner of the implementation of the policy established under subsection (b) of this section.

(d) Except for any willful or grossly negligent act, school personnel who respond in good faith to the anaphylactic reaction of a child in accordance with this section may not be held personally liable for any act or omission in the course of responding to the reaction.

9.5-117.

(a) (1) In this section the following words have the meanings indicated.

(3) [“Auto–injectable”] **“EMERGENCY USE epinephrine”** has the meaning stated in § 7–426.2 of this article.

(f) Except for any willfully or grossly negligent act, a child care provider or an employee of a child care provider who responds in good faith to the anaphylactic reaction of a child in accordance with the guidelines implemented under this section or by use of [auto–injectable] **EMERGENCY USE epinephrine** is immune from civil liability for any act or omission in the course of responding to the reaction.

Article – Health – General

13–702.

(a) In this subtitle the following words have the meanings indicated.

(b) “Agent” means an individual who:

(1) Is at least 18 years of age;

(2) Has successfully completed, at the expense of an applicant, an educational training program approved by the Department; and

(3) Is appointed by a certificate holder to administer [auto–injectable] **EMERGENCY USE epinephrine** in accordance with the provisions of this subtitle.

(c) “Anaphylaxis” means a sudden, severe, and potentially life–threatening allergic reaction that occurs when an individual is exposed to an allergen.

[(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.]

[(e)] **(D)** “Certificate” means a certificate or an endorsement on the operating certificate of a youth camp issued by the Department to an individual who operates a youth camp under Title 14, Subtitle 4 of this article to obtain, store, and administer [auto–injectable] **EMERGENCY USE epinephrine**.

[(f)] **(E)** “Certificate holder” means an individual who is authorized by the Department to obtain, store, and administer [auto–injectable] **EMERGENCY USE epinephrine** to be used in an emergency situation.

(F) “EMERGENCY USE EPINEPHRINE” MEANS A PORTABLE, DISPOSABLE DRUG DELIVERY DEVICE OR PRODUCT APPROVED BY THE FEDERAL FOOD AND

1 DRUG ADMINISTRATION THAT CONTAINS A PREMEASURED SINGLE DOSE OF
2 EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.

3 (g) “Program” means the Emergency and Allergy Treatment Program.

4 (h) “Registered nurse practitioner” has the meaning stated in § 8–101 of the
5 Health Occupations Article.

6 (i) “Youth camp” has the meaning stated in § 14–401 of this article.

7 13–704.

8 (e) An applicant shall have a written policy that includes:

9 (1) Authorization for the certificate holder or agent to administer
10 [auto–injectable] **EMERGENCY USE** epinephrine, if available, to an individual who has
11 been determined to be or is believed to be experiencing anaphylaxis, whether or not the
12 individual:

13 (i) Has previously been known to have experienced anaphylaxis; or

14 (ii) Has a prescription for epinephrine prescribed by an authorized
15 health care practitioner licensed under the Health Occupations Article;

16 (2) A requirement that youth camp personnel complete training on how to
17 recognize the symptoms of anaphylaxis;

18 (3) Procedures for the emergency administration of [auto–injectable]
19 **EMERGENCY USE** epinephrine;

20 (4) Procedures for proper emergency follow–up;

21 (5) Authorization for a certificate holder to obtain and store
22 [auto–injectable] **EMERGENCY USE** epinephrine to be used in an emergency; and

23 (6) A requirement that each certificate holder implement a method for
24 notifying the parent or guardian of a camper of the youth camp’s policy under this section
25 before the camper’s attendance.

26 13–705.

27 (a) (1) A registered nurse practitioner or a physician licensed to practice
28 medicine in the State may prescribe [auto–injectable] **EMERGENCY USE** epinephrine in
29 the name of a certificate holder.

(2) A registered nurse practitioner, a pharmacist licensed to practice pharmacy in the State, or a physician may dispense [auto-injectable] **EMERGENCY USE** epinephrine under a prescription issued to a certificate holder.

(b) A certificate holder may:

(1) On presentment of a certificate, receive from any registered nurse practitioner or any physician licensed to practice medicine in the State a prescription for [auto-injectable] **EMERGENCY USE** epinephrine and the necessary paraphernalia for the administration of [auto-injectable] **EMERGENCY USE** epinephrine; and

(2) Possess and store prescribed [auto-injectable] **EMERGENCY USE** epinephrine and the necessary paraphernalia for the administration of [auto-injectable] **EMERGENCY USE** epinephrine.

(c) In an emergency situation when registered nurse practitioner, physician, or emergency medical services are not immediately available, a certificate holder or agent may administer [auto-injectable] **EMERGENCY USE** epinephrine to an individual who is experiencing or believed in good faith by the certificate holder or agent to be experiencing anaphylaxis.

13-706.

(a) A certificate holder shall submit to the Department, on a form required by the Department, a report of each incident that occurs while the youth camp is in session that required the administration of [auto-injectable] **EMERGENCY USE** epinephrine.

13-707.

(a) A cause of action may not arise against a certificate holder or agent authorized under this subtitle for any act or omission when the certificate holder or agent is acting in good faith while administering [auto-injectable] **EMERGENCY USE** epinephrine to an individual experiencing or believed by the certificate holder or agent to be experiencing anaphylaxis, except where the conduct of the certificate holder or agent amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct.

(b) (1) A cause of action may not arise against any physician for any act or omission when the physician in good faith prescribes or dispenses [auto-injectable] **EMERGENCY USE** epinephrine and the necessary paraphernalia for the administration of [auto-injectable] **EMERGENCY USE** epinephrine to a person certified by the Department under this subtitle.

(2) A cause of action may not arise against any pharmacist for any act or omission when the pharmacist in good faith dispenses [auto-injectable] **EMERGENCY USE** epinephrine and the necessary paraphernalia for the administration of [auto-injectable] **EMERGENCY USE** epinephrine to a person certified by the Department under this subtitle.

(3) A cause of action may not arise against any nurse practitioner for any act or omission when the nurse practitioner in good faith prescribes or dispenses [auto-injectable] **EMERGENCY USE** epinephrine and the necessary paraphernalia for the administration of [auto-injectable] **EMERGENCY USE** epinephrine to a person certified by the Department under this subtitle.

13–708.

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

Subtitle 7A. Emergency Use [Auto-Injectable] Epinephrine Program.

13–7A–01.

(a) In this subtitle the following words have the meanings indicated.

(b) “Agent” means an individual who:

(1) Is at least 18 years of age;

(2) Has successfully completed, at the expense of the participating facility, an educational training program approved by the Department under § 13–7A–03 of this subtitle; and

(3) Is designated by a certificate holder to administer [auto-injectable] **EMERGENCY USE** epinephrine in accordance with the provisions of this subtitle.

(c) “Anaphylaxis” means a sudden, severe, and potentially life-threatening allergic reaction that occurs when an individual is exposed to an allergen.

[(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.]

[(e)] **(D)** “Certificate” means a certificate issued by the Department to an individual to obtain, store, and administer [auto-injectable] **EMERGENCY USE** epinephrine.

[(f)] **(E)** “Certificate holder” means an individual who is authorized by the Department to obtain, store, and administer [auto-injectable] **EMERGENCY USE** epinephrine to be used in an emergency situation.

1 [(g)] (F) “Eligible institution” means an institution of higher education that has
2 a food service facility or a recreation and wellness facility on the premises and that is
3 authorized under this subtitle to obtain and store [auto-injectable] **EMERGENCY USE**
4 epinephrine.

5 (G) **“EMERGENCY USE EPINEPHRINE” MEANS A PORTABLE, DISPOSABLE**
6 **DRUG DELIVERY DEVICE OR PRODUCT APPROVED BY THE FEDERAL FOOD AND**
7 **DRUG ADMINISTRATION THAT CONTAINS A PREMEASURED SINGLE DOSE OF**
8 **EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.**

9 (h) “Food service facility” has the meaning indicated in § 21–301 of this article.

10 (i) “Participating facility” means a recreation or wellness facility at an eligible
11 institution or a food service facility, including a food service facility at an eligible
12 institution, in the State that voluntarily participates in the Program.

13 (j) “Program” means the Emergency Use [Auto-Injectable] Epinephrine
14 Program established under § 13–7A–02 of this subtitle.

15 13–7A–02.

16 (a) There is an Emergency Use [Auto-Injectable] Epinephrine Program.

17 (b) The purpose of the Program is to authorize individuals employed by a
18 participating facility to obtain and store [auto-injectable] **EMERGENCY USE** epinephrine
19 and administer [auto-injectable] **EMERGENCY USE** epinephrine to individuals who are
20 experiencing or are believed to be experiencing anaphylaxis when a physician or emergency
21 medical services are not immediately available.

22 (c) (1) Subject to paragraph (4) of this subsection, each participating facility
23 may obtain:

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

26 (ii) A supply of [auto-injectable] **EMERGENCY USE** epinephrine
27 from a licensed pharmacist or a licensed physician as provided in § 13–7A–06 of this
28 subtitle.

29 (2) Each participating facility shall store a supply of [auto-injectable]
30 **EMERGENCY USE** epinephrine obtained under paragraph (1)(ii) of this subsection:

31 (i) In accordance with the manufacturer’s instructions; and

32 (ii) In a location that is readily accessible to employees or affiliated
33 individuals in an emergency situation.

(3) Each participating facility shall designate the employees who are certificate holders or designated affiliated individuals who are certificate holders who will be responsible for the storage, maintenance, and control of the supply of [auto-injectable] **EMERGENCY USE** epinephrine.

(4) A participating facility may not obtain or store [auto-injectable] **EMERGENCY USE** epinephrine unless the participating facility has at least two employees or designated affiliated individuals who are certificate holders.

(5) 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.

13-7A-03.

(a) The Department shall:

(5) Develop a method by which certificate holders may submit a report to the Department about each incident that occurred on the premises of a participating facility that involved the administration of [auto-injectable] **EMERGENCY USE** epinephrine by a certificate holder or an agent; and

13-7A-06.

(a) (1) A physician licensed to practice medicine in the State may prescribe [auto-injectable] **EMERGENCY USE** epinephrine in the name of a certificate holder.

(2) A pharmacist licensed to practice pharmacy in the State or a physician may dispense [auto-injectable] **EMERGENCY USE** epinephrine under a prescription issued to a certificate holder.

(b) A certificate holder may:

(1) On presentment of a certificate, receive from any physician licensed to practice medicine in the State a prescription for [auto-injectable] **EMERGENCY USE** epinephrine and the necessary paraphernalia for the administration of [auto-injectable] **EMERGENCY USE** epinephrine; and

(2) Possess and store prescribed [auto-injectable] **EMERGENCY USE** epinephrine and the necessary paraphernalia for the administration of [auto-injectable] **EMERGENCY USE** epinephrine.

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

1 13-7A-07.

2 (a) (1) Except as provided in paragraph (2) of this subsection, a cause of action
3 may not arise against a certificate holder for any act or omission if the certificate holder or
4 agent is acting in good faith while administering [auto-injectable] **EMERGENCY USE**
5 epinephrine to an individual who is experiencing or believed by the certificate holder or
6 agent to be experiencing anaphylaxis except where the conduct of the certificate holder or
7 agent amounts to gross negligence, willful or wanton misconduct, or intentionally tortious
8 conduct.

9 (2) The provisions of paragraph (1) of this subsection do not apply if a
10 certificate holder or participating facility that makes available, or a certificate holder who
11 administers, [auto-injectable] **EMERGENCY USE** epinephrine to an individual who is
12 experiencing or is believed by the certificate holder or participating facility to be
13 experiencing anaphylaxis:

14 (i) Fails to follow standards and procedures for storage and
15 administration of [auto-injectable] **EMERGENCY USE** epinephrine; or

16 (ii) Administers [auto-injectable] **EMERGENCY USE** epinephrine
17 that is beyond the manufacturer's expiration date.

18 (b) (1) A cause of action may not arise against any physician for any act or
19 omission if the physician in good faith prescribes or dispenses [auto-injectable]
20 **EMERGENCY USE** epinephrine and the necessary paraphernalia for the administration of
21 [auto-injectable] **EMERGENCY USE** epinephrine to a certificate holder or participating
22 facility under this subtitle.

23 (2) A cause of action may not arise against any pharmacist for any act or
24 omission if the pharmacist in good faith dispenses [auto-injectable] **EMERGENCY USE**
25 epinephrine and the necessary paraphernalia for the administration of [auto-injectable]
26 **EMERGENCY USE** epinephrine to a certificate holder or a participating facility under this
27 subtitle.

28 13-7A-08.

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

33 13-7A-09.

34 A certificate holder shall submit to the Department, in the manner required under §
35 13-7A-03 of this subtitle, a report of each incident that occurred on the premises of a

participating facility that involved the administration of [auto-injectable] **EMERGENCY USE** epinephrine by a certificate holder or an agent.

Article – Health Occupations

14–5F–01.

(a) In this subtitle the following words have the meanings indicated.

[(c) “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.]

[(d)] (C) “Board” means the State Board of Physicians.

[(e)] (D) “Committee” means the Naturopathic Medicine Advisory Committee.

[(f)] (E) “Council” means the Naturopathic Doctors Formulary Council.

[(g)] (F) (1) “Device” means a device used in the diagnosis, treatment, or prevention of disease.

(2) “Device” does not include:

(i) Any surgical or dental instrument;

(ii) Any physical therapy equipment;

(iii) Any X-ray apparatus; or

(iv) Any component part or accessory of any of the items listed in items (i) through (iii) of this paragraph.

(G) “EMERGENCY USE EPINEPHRINE” MEANS A PORTABLE, DISPOSABLE DRUG DELIVERY DEVICE OR PRODUCT APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION THAT CONTAINS A PREMEASURED SINGLE DOSE OF EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.

14–5F–04.1.

(a) (1) There is a Naturopathic Doctors Formulary Council within the Board.

(d) (1) The formulary adopted by the Board shall include:

(i) Nonprescription drugs and devices;

1 (ii) Prescription oxygen and [auto-injectable] **EMERGENCY USE**
2 epinephrine; and

3 (iii) Prescription diaphragms and cervical caps for contraception.

4 14-5F-14.

5 (a) A license authorizes a licensee, consistent with naturopathic education and
6 training and competence demonstrated by passing the naturopathic physician licensing
7 examination, to:

8 (5) Administer [auto-injectable] **EMERGENCY USE** epinephrine;

9 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July
10 1, 2025.