J1, F2 8lr2209

By: Delegates Pena-Melnyk, Angel, B. Barnes, Barron, Bromwell, Cullison, Frush, Hayes, Kelly, Kipke, McDonough, Morgan, Saab, Sample-Hughes, Szeliga, Tarlau, Valentino-Smith, West, and K. Young

Introduced and read first time: February 9, 2018 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

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Public Health – Emergency Use Auto–Injectable Epinephrine Program for Food Service Facilities at Institutions of Higher Education

FOR the purpose of establishing the Emergency Use Auto-Injectable Epinephrine Program for food service facilities at eligible institutions of higher education; providing for the purpose of the Program; requiring the Maryland Department of Health to adopt certain regulations, collect certain fees, issue and renew certain certificates, approve certain training programs relating to the Program, develop a method by which certain reports may be made, and publish a certain report on or before a certain date each year; authorizing the Department to set certain fees and to establish procedures to apply to the Program; establishing qualifications for applicants for a certain certificate; authorizing certain certificate holders and agents to take certain actions; requiring the Department to issue certain certificates to certain applicants; providing for the contents, replacement, term, and renewal of certain certificates; authorizing certain physicians to prescribe and certain pharmacists and physicians to dispense auto-injectable epinephrine to certain certificate holders; authorizing a certificate holder or an agent to administer auto-injectable epinephrine to a certain individual in certain circumstances; providing that a cause of action may not arise against certain certificate holders or certain agents for certain acts or omissions under certain circumstances; 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 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 under certain circumstances; providing that certain individuals may not be liable for not taking certain actions; providing immunity from civil liability for certain individuals under certain circumstances; requiring certain certificate holders to submit to the Department certain reports; providing for the construction of this Act; requiring the Department to publish a certain report on or



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1	before a certain date each year; defining certain terms; and generally relating to the
2	Emergency Use Auto-Injectable Epinephrine Program.

- 3 BY adding to
- 4 Article Health General
- 5 Section 13–7A–01 through 13–7A–09 to be under the new subtitle "Subtitle 7A.
 - Emergency Use Auto-Injectable Epinephrine Program for Food Service
- 7 Facilities at Institutions of Higher Education"
- 8 Annotated Code of Maryland
- 9 (2015 Replacement Volume and 2017 Supplement)
- 10 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
- 11 That the Laws of Maryland read as follows:
- 12 Article Health General
- 13 SUBTITLE 7A, EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE PROGRAM FOR
- 14 FOOD SERVICE FACILITIES AT INSTITUTIONS OF HIGHER EDUCATION.
- 15 **13–7A–01.**
- 16 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
- 17 INDICATED.
- 18 **(B) "AGENT" MEANS AN INDIVIDUAL WHO:**
- 19 (1) IS AT LEAST 18 YEARS OF AGE;
- 20 (2) HAS SUCCESSFULLY COMPLETED, AT THE EXPENSE OF THE
- 21 APPLICANT, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE
- 22 DEPARTMENT UNDER § 13–7A–03 OF THIS SUBTITLE; AND
- 23 (3) Is designated by a certificate holder to administer
- 24 AUTO-INJECTABLE EPINEPHRINE IN ACCORDANCE WITH THE PROVISIONS OF THIS
- 25 SUBTITLE.

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- 26 (C) "ANAPHYLAXIS" MEANS A SUDDEN, SEVERE, AND POTENTIALLY
- 27 LIFE-THREATENING ALLERGIC REACTION THAT OCCURS WHEN AN INDIVIDUAL IS
- 28 EXPOSED TO AN ALLERGEN.
- 29 (D) "AUTO-INJECTABLE EPINEPHRINE" MEANS A PORTABLE, DISPOSABLE
- 30 DRUG DELIVERY DEVICE THAT CONTAINS A PREMEASURED SINGLE DOSE OF
- 31 EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.
 - (E) "CERTIFICATE" MEANS A CERTIFICATE ISSUED BY THE DEPARTMENT

- 1 TO AN INDIVIDUAL TO OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE 2
- EPINEPHRINE.
- (F) "CERTIFICATE HOLDER" MEANS AN INDIVIDUAL WHO IS AUTHORIZED 3
- 4 BY THE DEPARTMENT TO OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE
- EPINEPHRINE TO BE USED IN AN EMERGENCY SITUATION. 5
- 6 "ELIGIBLE INSTITUTION" MEANS AN INSTITUTION OF HIGHER 7 EDUCATION THAT HAS A FOOD SERVICE FACILITY ON THE PREMISES.
- 8 "FOOD SERVICE FACILITY" HAS THE MEANING INDICATED IN § 21–301 9 OF THIS ARTICLE.
- "PROGRAM" MEANS THE EMERGENCY USE AUTO-INJECTABLE 10 **(I)**
- 11 EPINEPHRINE PROGRAM FOR FOOD SERVICE FACILITIES AT INSTITUTIONS OF
- 12HIGHER EDUCATION ESTABLISHED UNDER § 13–7A–02 OF THIS SUBTITLE.
- 13-7A-02. 13
- THERE IS AN EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE 14
- 15 PROGRAM FOR FOOD SERVICE FACILITIES AT INSTITUTIONS OF HIGHER
- 16 EDUCATION.
- 17 THE PURPOSE OF THE PROGRAM IS TO AUTHORIZE INDIVIDUALS
- EMPLOYED BY A FOOD SERVICE FACILITY AT AN ELIGIBLE INSTITUTION TO OBTAIN 18
- 19 AND STORE AUTO-INJECTABLE EPINEPHRINE AND ADMINISTER AUTO-INJECTABLE
- 20 EPINEPHRINE TO INDIVIDUALS WHO ARE EXPERIENCING OR ARE BELIEVED TO BE
- 21EXPERIENCING ANAPHYLAXIS WHEN A PHYSICIAN OR EMERGENCY MEDICAL
- 22SERVICES ARE NOT IMMEDIATELY AVAILABLE.
- 13-7A-03.23
- 24(A) THE DEPARTMENT SHALL:
- 25**(1)** ADOPT REGULATIONS FOR THE ADMINISTRATION OF THE
- PROGRAM; 26
- 27 **(2)** COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE
- 28PROGRAM:
- 29 ISSUE A CERTIFICATE TO, OR RENEW THE CERTIFICATE OF, AN
- INDIVIDUAL MEETING THE REQUIREMENTS OF § 13–7A–04 OF THIS SUBTITLE; 30

- 1 (4) APPROVE EDUCATIONAL TRAINING PROGRAMS, INCLUDING 2 PROGRAMS CONDUCTED BY OTHER STATE AGENCIES OR PRIVATE ENTITIES;
- 3 (5) DEVELOP A METHOD BY WHICH CERTIFICATE HOLDERS MAY
- 4 SUBMIT A REPORT TO THE DEPARTMENT ABOUT EACH INCIDENT THAT OCCURRED
- 5 ON THE PREMISES OF A FOOD SERVICE FACILITY AT AN ELIGIBLE INSTITUTION THAT
- 6 INVOLVED THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE BY A
- 7 CERTIFICATE HOLDER OR AN AGENT; AND
- 8 (6) ON OR BEFORE JANUARY 31 EACH YEAR, PUBLISH A REPORT
- 9 SUMMARIZING THE INFORMATION OBTAINED FROM REPORTS SUBMITTED TO THE
- 10 DEPARTMENT UNDER ITEM (5) OF THIS SUBSECTION.
- 11 **(B)** THE DEPARTMENT MAY:
- 12 (1) SET AN APPLICATION FEE FOR A CERTIFICATE;
- 13 (2) ESTABLISH A FEE FOR THE RENEWAL OR REPLACEMENT OF A
 14 CERTIFICATE; AND
- ,
 - 15 (3) REQUIRE APPLICANTS TO APPLY TO THE PROGRAM IN THE
 - 16 MANNER THE DEPARTMENT CHOOSES.
 - 17 (C) AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE
 - 18 DEPARTMENT UNDER SUBSECTION (A)(4) OF THIS SECTION MAY BE AN ONLINE
 - 19 TRAINING PROGRAM.
 - 20 **13-7A-04.**
 - 21 TO QUALIFY FOR A CERTIFICATE, AN APPLICANT SHALL:
 - 22 (1) BE EMPLOYED BY A FOOD SERVICE FACILITY AT AN ELIGIBLE
 - 23 INSTITUTION:
 - 24 (2) SUCCESSFULLY COMPLETE, AT THE EXPENSE OF THE APPLICANT,
 - 25 AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE DEPARTMENT UNDER §
 - 26 **13–7A–03** OF THIS SUBTITLE;
 - 27 (3) SUBMIT AN APPLICATION TO THE DEPARTMENT IN A MANNER
 - 28 REQUIRED BY THE DEPARTMENT UNDER § 13–7A–03 OF THIS SUBTITLE; AND
 - 29 (4) PAY TO THE DEPARTMENT AN APPLICATION FEE REQUIRED
 - 30 UNDER § 13–7A–03 OF THIS SUBTITLE.

- 1 13-7A-05.
- 2 (A) THE DEPARTMENT SHALL ISSUE A CERTIFICATE TO ANY APPLICANT
- 3 WHO MEETS THE REQUIREMENTS OF § 13–7A–04 OF THIS SUBTITLE.
- 4 (B) EACH CERTIFICATE SHALL INCLUDE:
- 5 (1) THE FULL NAME OF THE CERTIFICATE HOLDER; AND
- 6 (2) A SERIAL NUMBER.
- 7 (C) A REPLACEMENT CERTIFICATE MAY BE ISSUED TO REPLACE A LOST,
- 8 DESTROYED, OR MUTILATED CERTIFICATE IF THE CERTIFICATE HOLDER PAYS A
- 9 CERTIFICATE REPLACEMENT FEE SET BY THE DEPARTMENT.
- 10 (D) (1) A CERTIFICATE SHALL BE VALID FOR A TERM OF 2 YEARS.
- 11 (2) TO RENEW A CERTIFICATE FOR AN ADDITIONAL 2-YEAR TERM,
- 12 THE RENEWAL APPLICANT SHALL SUCCESSFULLY COMPLETE A REFRESHER
- 13 EDUCATIONAL TRAINING PROGRAM APPROVED BY THE DEPARTMENT UNDER §
- 14 **13–7A–03** OF THIS SUBTITLE.
- 15 **13–7A–06.**
- 16 (A) (1) A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE
- 17 MAY PRESCRIBE AUTO-INJECTABLE EPINEPHRINE IN THE NAME OF A CERTIFICATE
- 18 HOLDER.
- 19 (2) A PHARMACIST LICENSED TO PRACTICE PHARMACY IN THE STATE
- 20 OR A PHYSICIAN MAY DISPENSE AUTO-INJECTABLE EPINEPHRINE UNDER A
- 21 PRESCRIPTION ISSUED TO A CERTIFICATE HOLDER.
- 22 (B) A CERTIFICATE HOLDER MAY:
- 23 (1) ON PRESENTMENT OF A CERTIFICATE, RECEIVE FROM ANY
- 24 PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE A PRESCRIPTION FOR
- 25 AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE
- 26 ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; AND
- 27 (2) Possess and Store Prescribed Auto-injectable
- 28 EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE ADMINISTRATION OF
- 29 AUTO-INJECTABLE EPINEPHRINE.

- 1 (C) IN AN EMERGENCY SITUATION WHEN A PHYSICIAN OR EMERGENCY
- 2 MEDICAL SERVICES ARE NOT IMMEDIATELY AVAILABLE, A CERTIFICATE HOLDER OR
- 3 AN AGENT MAY ADMINISTER AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL
- 4 WHO IS EXPERIENCING OR IS BELIEVED IN GOOD FAITH BY THE CERTIFICATE
- 5 HOLDER OR AGENT TO BE EXPERIENCING ANAPHYLAXIS.
- 6 **13-7A-07.**
- 7 (A) A CAUSE OF ACTION MAY NOT ARISE AGAINST A CERTIFICATE HOLDER
- 8 OR AN AGENT FOR ANY ACT OR OMISSION IF THE CERTIFICATE HOLDER OR AGENT
- 9 IS ACTING IN GOOD FAITH WHILE ADMINISTERING AUTO-INJECTABLE EPINEPHRINE
- 10 TO AN INDIVIDUAL WHO IS EXPERIENCING OR BELIEVED BY THE CERTIFICATE
- 11 HOLDER OR AGENT TO BE EXPERIENCING ANAPHYLAXIS EXCEPT WHERE THE
- 12 CONDUCT OF THE CERTIFICATE HOLDER OR AGENT AMOUNTS TO GROSS
- 13 NEGLIGENCE, WILLFUL OR WANTON MISCONDUCT, OR INTENTIONALLY TORTIOUS
- 14 CONDUCT.
- 15 (B) (1) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHYSICIAN FOR
- 16 ANY ACT OR OMISSION IF THE PHYSICIAN IN GOOD FAITH PRESCRIBES OR
- 17 DISPENSES AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY
- 18 PARAPHERNALIA FOR THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE
- 19 TO AN INDIVIDUAL CERTIFIED BY THE DEPARTMENT UNDER § 13–7A–05 OF THIS
- 20 SUBTITLE.
- 21 (2) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHARMACIST
- 22 FOR ANY ACT OR OMISSION IF THE PHARMACIST IN GOOD FAITH DISPENSES
- 23 AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE
- 24 ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL
- 25 CERTIFIED BY THE DEPARTMENT UNDER § 13–7A–05 OF THIS SUBTITLE.
- 26 (C) This section does not affect and may not be construed as
- 27 AFFECTING ANY IMMUNITIES FROM CIVIL LIABILITY OR DEFENSES ESTABLISHED BY
- 28 ANY OTHER PROVISION OF LAW OR BY COMMON LAW TO WHICH A PHYSICIAN OR
- 29 PHARMACIST MAY BE ENTITLED.
- 30 **13–7A–08.**
- 31 (A) THIS SUBTITLE MAY NOT BE CONSTRUED TO CREATE A DUTY ON ANY
- 32 INDIVIDUAL TO OBTAIN A CERTIFICATE UNDER THIS SUBTITLE, AND AN INDIVIDUAL
- 33 MAY NOT BE HELD CIVILLY LIABLE FOR FAILING TO OBTAIN A CERTIFICATE UNDER
- 34 THIS SUBTITLE.

- 1 (B) AN INDIVIDUAL MAY NOT BE HELD CIVILLY LIABLE IN ANY ACTION
- 2 ARISING FROM OR IN CONNECTION WITH THE ADMINISTRATION OF
- 3 AUTO-INJECTABLE EPINEPHRINE BY THE INDIVIDUAL SOLELY BECAUSE THE
- 4 INDIVIDUAL DID NOT POSSESS A CERTIFICATE ISSUED UNDER THIS SUBTITLE.
- 5 13-7A-09.
- 6 A CERTIFICATE HOLDER SHALL SUBMIT TO THE DEPARTMENT, IN THE
- 7 MANNER REQUIRED UNDER § 13-7A-03 OF THIS SUBTITLE, A REPORT OF EACH
- 8 INCIDENT THAT OCCURRED ON THE PREMISES OF A FOOD SERVICE FACILITY AT AN
- 9 ELIGIBLE INSTITUTION THAT INVOLVED THE ADMINISTRATION OF
- 10 AUTO-INJECTABLE EPINEPHRINE BY A CERTIFICATE HOLDER OR AN AGENT.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
- 12 October 1, 2018.