

Chapter 527

(House Bill 1473)

AN ACT concerning

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~~ at Institutions of Higher Education; providing for the purpose of the Program; authorizing certain eligible institutions of higher education to obtain and store auto-injectable epinephrine under certain circumstances; requiring certain eligible institutions of higher education to designate certain individuals for certain purposes; prohibiting certain eligible institutions of higher education from obtaining or storing auto-injectable epinephrine unless certain employees or individuals hold certain certificates; requiring certain institutions of higher education to maintain a certain copy of a certain certificate; 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 an eligible institution to pay the application fee on behalf of the applicant; 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 for a certain exception 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 and certain eligible institutions 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 and certain eligible institutions 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 before a certain date each year; defining certain terms; and generally relating to the Emergency Use Auto-Injectable Epinephrine Program at Institutions of Higher Education.

BY adding to

Article – Health – General

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 Facilities~~ at Institutions of Higher Education”

Annotated Code of Maryland

(2015 Replacement Volume and 2017 Supplement)

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 AUTO–INJECTABLE EPINEPHRINE PROGRAM ~~FOR FOOD–SERVICE FACILITIES~~ AT INSTITUTIONS OF HIGHER EDUCATION.

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 ~~APPLICANT~~ ELIGIBLE INSTITUTION, 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 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) “CERTIFICATE” MEANS A CERTIFICATE ISSUED BY THE DEPARTMENT TO AN INDIVIDUAL TO OBTAIN, STORE, AND ADMINISTER AUTO-INJECTABLE EPINEPHRINE.

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

(G) “ELIGIBLE INSTITUTION” MEANS AN INSTITUTION OF HIGHER EDUCATION THAT HAS A FOOD SERVICE FACILITY OR A RECREATION AND WELLNESS FACILITY ON THE PREMISES AND THAT IS AUTHORIZED UNDER THIS SUBTITLE TO OBTAIN AND STORE AUTO-INJECTABLE EPINEPHRINE.

(H) “FOOD SERVICE FACILITY” HAS THE MEANING INDICATED IN § 21-301 OF THIS ARTICLE.

(I) “PROGRAM” MEANS THE EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE PROGRAM ~~FOR FOOD SERVICE FACILITIES AT INSTITUTIONS OF HIGHER EDUCATION~~ AT INSTITUTIONS OF HIGHER EDUCATION ESTABLISHED UNDER § 13-7A-02 OF THIS SUBTITLE.

13-7A-02.

(A) THERE IS AN EMERGENCY USE AUTO-INJECTABLE EPINEPHRINE PROGRAM ~~FOR FOOD SERVICE FACILITIES AT INSTITUTIONS OF HIGHER EDUCATION~~ AT INSTITUTIONS OF HIGHER EDUCATION.

(B) THE PURPOSE OF THE PROGRAM IS TO AUTHORIZE INDIVIDUALS EMPLOYED BY A FOOD SERVICE FACILITY OR A RECREATION AND WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION TO OBTAIN AND STORE AUTO-INJECTABLE EPINEPHRINE AND ADMINISTER AUTO-INJECTABLE EPINEPHRINE TO INDIVIDUALS WHO ARE EXPERIENCING OR ARE BELIEVED TO BE EXPERIENCING ANAPHYLAXIS WHEN A PHYSICIAN OR EMERGENCY MEDICAL SERVICES ARE NOT IMMEDIATELY AVAILABLE.

(C) (1) SUBJECT TO PARAGRAPH (4) OF THIS SUBSECTION, AN ELIGIBLE INSTITUTION MAY OBTAIN:

(1) A PRESCRIPTION FOR A SUPPLY OF AUTO-INJECTABLE EPINEPHRINE FROM A LICENSED PHYSICIAN AS PROVIDED IN § 13-7A-06 OF THIS SUBTITLE; AND

(II) A SUPPLY OF AUTO-INJECTABLE EPINEPHRINE FROM A LICENSED PHARMACIST OR A LICENSED PHYSICIAN AS PROVIDED IN § 13-7A-06 OF THIS SUBTITLE.

(2) AN ELIGIBLE INSTITUTION SHALL STORE A SUPPLY OF AUTO-INJECTABLE EPINEPHRINE OBTAINED UNDER PARAGRAPH (1)(II) OF THIS SUBSECTION:

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

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

(3) AN ELIGIBLE INSTITUTION 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 EPINEPHRINE.

(4) AN ELIGIBLE INSTITUTION MAY NOT OBTAIN OR STORE AUTO-INJECTABLE EPINEPHRINE UNLESS THE ELIGIBLE INSTITUTION HAS AT LEAST TWO EMPLOYEES OR DESIGNATED AFFILIATED INDIVIDUALS WHO ARE CERTIFICATE HOLDERS.

(5) AN ELIGIBLE INSTITUTION 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:

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

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

(3) ISSUE A CERTIFICATE TO, OR RENEW THE CERTIFICATE OF, AN INDIVIDUAL MEETING THE REQUIREMENTS OF § 13-7A-04 OF THIS SUBTITLE;

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

(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 FOOD SERVICE FACILITY OR A RECREATION AND WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION THAT INVOLVED THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE BY A CERTIFICATE HOLDER OR AN AGENT; AND

(6) ON OR BEFORE JANUARY 31 EACH YEAR, PUBLISH A REPORT SUMMARIZING THE INFORMATION OBTAINED FROM REPORTS SUBMITTED TO THE DEPARTMENT UNDER ITEM (5) OF THIS SUBSECTION.

(B) THE DEPARTMENT MAY:

(1) SET AN APPLICATION FEE FOR A CERTIFICATE;

(2) ESTABLISH A FEE FOR THE RENEWAL OR REPLACEMENT OF A CERTIFICATE; AND

(3) REQUIRE APPLICANTS TO APPLY TO THE PROGRAM IN THE MANNER THE DEPARTMENT CHOOSES.

(C) AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE DEPARTMENT UNDER SUBSECTION (A)(4) OF THIS SECTION MAY BE AN ONLINE TRAINING PROGRAM.

13-7A-04.

(A) TO QUALIFY FOR A CERTIFICATE, AN APPLICANT SHALL:

(1) BE EMPLOYED BY A FOOD SERVICE FACILITY OR A RECREATION AND WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION;

(2) SUCCESSFULLY COMPLETE, AT THE EXPENSE OF THE ~~APPLICANT~~ ELIGIBLE INSTITUTION, AN EDUCATIONAL TRAINING PROGRAM APPROVED BY THE DEPARTMENT UNDER § 13-7A-03 OF THIS SUBTITLE;

(3) SUBMIT AN APPLICATION TO THE DEPARTMENT IN A MANNER REQUIRED BY THE DEPARTMENT UNDER § 13-7A-03 OF THIS SUBTITLE; AND

(4) ~~PAY~~ SUBJECT TO SUBSECTION (B) OF THIS SECTION, PAY TO THE DEPARTMENT AN APPLICATION FEE REQUIRED UNDER § 13-7A-03 OF THIS SUBTITLE.

(B) AN ELIGIBLE INSTITUTION MAY PAY THE APPLICATION FEE ON BEHALF OF THE APPLICANT.

13-7A-05.

(A) THE DEPARTMENT SHALL ISSUE A CERTIFICATE TO ANY APPLICANT WHO MEETS THE REQUIREMENTS OF § 13-7A-04 OF THIS SUBTITLE.

(B) EACH CERTIFICATE SHALL INCLUDE:

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

(2) A SERIAL NUMBER.

(C) A REPLACEMENT CERTIFICATE MAY BE ISSUED TO REPLACE A LOST, DESTROYED, OR MUTILATED CERTIFICATE IF THE CERTIFICATE HOLDER PAYS A CERTIFICATE REPLACEMENT FEE SET BY THE DEPARTMENT.

(D) (1) A CERTIFICATE SHALL BE VALID FOR A TERM OF ~~2-YEARS~~ 1 YEAR.

(2) TO RENEW A CERTIFICATE FOR AN ADDITIONAL ~~2-YEAR~~ 1-YEAR TERM, THE RENEWAL APPLICANT SHALL SUCCESSFULLY COMPLETE A REFRESHER EDUCATIONAL TRAINING PROGRAM APPROVED BY THE DEPARTMENT UNDER § 13-7A-03 OF THIS SUBTITLE.

13-7A-06.

(A) (1) A PHYSICIAN LICENSED TO PRACTICE MEDICINE IN THE STATE MAY PRESCRIBE AUTO-INJECTABLE 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 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 EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; AND

(2) POSSESS AND STORE PRESCRIBED AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE ADMINISTRATION OF AUTO-INJECTABLE 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 EPINEPHRINE TO AN INDIVIDUAL WHO IS EXPERIENCING OR IS BELIEVED IN GOOD FAITH BY THE CERTIFICATE HOLDER OR AGENT TO BE EXPERIENCING ANAPHYLAXIS.

13-7A-07.

(A) (1) ~~A~~ EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, A CAUSE OF ACTION MAY NOT ARISE AGAINST A CERTIFICATE HOLDER ~~OR AN AGENT~~ FOR ANY ACT OR OMISSION IF THE CERTIFICATE HOLDER OR AGENT IS ACTING IN GOOD FAITH WHILE ADMINISTERING AUTO-INJECTABLE EPINEPHRINE TO AN INDIVIDUAL WHO IS 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.

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

(I) FAILS TO FOLLOW STANDARDS AND PROCEDURES FOR STORAGE AND ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE; OR

(II) ADMINISTERS AUTO-INJECTABLE EPINEPHRINE THAT IS BEYOND THE MANUFACTURER'S EXPIRATION DATE.

(B) (1) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHYSICIAN FOR ANY ACT OR OMISSION IF THE PHYSICIAN IN GOOD FAITH PRESCRIBES OR DISPENSES AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE ~~TO AN INDIVIDUAL CERTIFIED BY THE DEPARTMENT UNDER § 13-7A-05 OF A~~ CERTIFICATE HOLDER OR AN ELIGIBLE INSTITUTION UNDER THIS SUBTITLE.

(2) A CAUSE OF ACTION MAY NOT ARISE AGAINST ANY PHARMACIST FOR ANY ACT OR OMISSION IF THE PHARMACIST IN GOOD FAITH DISPENSES AUTO-INJECTABLE EPINEPHRINE AND THE NECESSARY PARAPHERNALIA FOR THE

ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE TO ~~AN INDIVIDUAL CERTIFIED BY THE DEPARTMENT UNDER § 13-7A-05~~ OF A CERTIFICATE HOLDER OR AN ELIGIBLE INSTITUTION UNDER THIS SUBTITLE.

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

13-7A-08.

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

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

13-7A-09.

A CERTIFICATE HOLDER SHALL SUBMIT TO THE DEPARTMENT, IN THE MANNER REQUIRED UNDER § 13-7A-03 OF THIS SUBTITLE, A REPORT OF EACH INCIDENT THAT OCCURRED ON THE PREMISES OF A FOOD SERVICE FACILITY OR A RECREATION AND WELLNESS FACILITY AT AN ELIGIBLE INSTITUTION THAT INVOLVED THE ADMINISTRATION OF AUTO-INJECTABLE EPINEPHRINE BY A CERTIFICATE HOLDER OR AN AGENT.

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

Approved by the Governor, May 8, 2018.