

Department of Legislative Services  
 Maryland General Assembly  
 2018 Session

FISCAL AND POLICY NOTE  
 Enrolled - Revised

House Bill 1473

(Delegate Pena-Melnyk, *et al.*)

Health and Government Operations

Finance

Public Health - Emergency Use Auto-Injectable Epinephrine Program at  
 Institutions of Higher Education

This bill establishes the Emergency Use Auto-Injectable Epinephrine Program at Institutions of Higher Education within the Maryland Department of Health (MDH) to authorize qualified individuals (through issuance of a certificate) employed by a food service facility or a recreation and wellness facility at an “eligible institution” to obtain, store, and administer auto-injectable epinephrine to individuals experiencing (or believed to be experiencing) anaphylaxis. Eligible institutions can also obtain and store auto-injectable epinephrine under specified circumstances. The bill establishes legal immunities for certificate holders, prescribing physicians, and pharmacists acting in compliance with the program. The bill also establishes reporting requirements for certificate holders and MDH.

Fiscal Summary

**State Effect:** General fund expenditures increase by \$26,500 in FY 2019 for staff to establish the program and begin reviewing and approving applications for certification. Future years reflect annualization and ongoing costs. General fund revenues increase beginning in FY 2019 from certification fees. No material impact on public four-year institutions of higher education or Baltimore City Community College.

(in dollars)	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
GF Revenue	-	-	-	-	-
GF Expenditure	\$26,500	\$29,500	\$30,200	\$31,400	\$32,700
Net Effect	(\$26,500)	(\$29,500)	(\$30,200)	(\$31,400)	(\$32,700)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

**Local Effect:** Local health departments can conduct any necessary inspections with existing resources during the course of current food service facility inspections. No material impact on local community colleges. Revenues are not affected.

**Small Business Effect:** Minimal.

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## Analysis

**Bill Summary:** MDH must adopt regulations to administer the program, collect fees, issue and renew certificates to eligible persons, and approve educational training programs (which may be online). MDH may set various fees and require applicants to apply in a manner chosen by MDH. If a certificate holder administers auto-injectable epinephrine, he or she must submit a report to MDH for each incident that occurred on the certificate holder's premises that involved the administration of auto-injectable epinephrine, in a format required by MDH. MDH must publish a report summarizing the information obtained from these reports by January 31 of each year.

To qualify for a certificate, an individual must (1) be employed at a food service facility or a recreation and wellness facility at an eligible institution; (2) successfully complete, at the expense of the eligible institution, an MDH-approved educational training program; (3) submit an application; and (4) pay any required application fee (an eligible institution *may* pay the application fee on behalf of the applicant). MDH must issue a certificate to any qualified applicant. A certificate is valid for one year and may be renewed upon the applicant successfully completing an MDH-approved refresher training program. A replacement certificate may be issued after paying a replacement fee. A certificate holder may appoint an agent to administer auto-injectable epinephrine in accordance with the bill. An agent must be age 18 or older, have successfully completed an educational training program approved by MDH, and be designated by a certificate holder to administer auto-injectable epinephrine.

A physician may prescribe, and a pharmacist may dispense, auto-injectable epinephrine to a certificate holder. A certificate holder or an eligible institution may possess and store prescribed auto-injectable epinephrine and the necessary paraphernalia. An eligible institution must store auto-injectable epinephrine in accordance with manufacturer's instructions in a location that is readily accessible to employees or affiliated individuals in an emergency situation. An eligible institution must also (1) designate the employees (or designated affiliated individuals) who are certificate holders and will be responsible for storing, maintaining, and controlling the supply of auto-injectable epinephrine and (2) maintain a copy of the certificate issued to an employee or a designated affiliated individual. Further, an eligible institution may not obtain or store auto-injectable epinephrine unless it has at least two employees or designated affiliated individuals who are certificate holders.

In an emergency situation when 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 to be experiencing anaphylaxis.

A cause of action may not arise against a *certificate holder* for acting in good faith while the certificate holder or an agent administers auto-injectable epinephrine to an individual who is experiencing or believed to be experiencing anaphylaxis unless (1) the certificate holder's or agent's conduct amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct or (2) the certificate holder or an eligible institution fails to follow standards and procedures for storage and administration of auto-injectable epinephrine or administers expired auto-injectable epinephrine. Similar immunity is not extended under the bill to an agent designated by a certificate holder or an eligible institution.

A cause of action may not arise against a physician if the physician in good faith prescribes or dispenses, or against a pharmacist if the pharmacist in good faith dispenses, auto-injectable epinephrine and the necessary paraphernalia to a certificate holder or an eligible institution. The bill does not affect any other immunities from civil liability or defenses to which a physician or pharmacist may be entitled.

An individual may not be held civilly liable in any action arising from the administration of auto-injectable epinephrine by the individual solely because the individual did not possess a certificate. The bill does not create a duty to obtain a certificate.

### **Current Law:**

#### *Emergency Allergy Treatment Program*

Chapter 342 of 2015 established the Emergency Allergy Treatment Program within MDH, which is a program for certificate holders or their agents to administer auto-injectable epinephrine to an individual determined to be, or believed in good faith to be, experiencing anaphylaxis within the context of youth camps.

An applicant for a certificate must operate a youth camp, be age 18 or older, and complete a MDH-approved educational training program, at the applicant's expense. A certificate is valid for up to one year. An applicant must have a written policy for their youth camp that includes specified information. An "agent" is an individual who is appointed by a certificate holder to administer auto-injectable epinephrine in accordance with statutory provisions. An agent must be age 18 or older and complete an educational training program, at the applicant's expense, that is approved by MDH.

A certificate holder must submit a report to MDH of each incident that occurs while the youth camp is in session that required the administration of auto-injectable epinephrine.

There is no time period within which the incident report must be submitted. MDH must publish a report that summarizes the information obtained from these required reports by January 31 annually.

A licensed physician may prescribe and dispense, and a licensed pharmacist may dispense, auto-injectable epinephrine to a certificate holder. A certificate holder may receive, possess, and store auto-injectable epinephrine. There are legal immunities for certificate holders or their agents, prescribing physicians, and pharmacists acting in compliance with the program.

### *Food Service Facilities*

Generally, a “food service facility” is a place where food or drink is prepared for sale or service on the premises or elsewhere or any operation where food is served or provided to the public, regardless of whether there is a charge. Food service facilities are a type of “food establishment” regulated under the Health-General Article. A person must have a license from MDH or a suitable license from a local health department in order to operate a food establishment. A representative of MDH may enter any food establishment at a reasonable time to conduct inspections. In general, local health departments conduct inspections of food establishments.

### *Institutions of Higher Education*

An “institution of higher education” is an institution of postsecondary education that generally limits enrollment to graduates of secondary schools and that awards degrees at either the associate, baccalaureate, or graduate level. Public, private nonprofit, and for-profit institutions of higher education are all included in the definition. There are 57 institutions of higher education in the State.

**Background:** Allergens such as insect stings or bites, foods, latex, and medications are common causes of anaphylaxis; however, it may also be induced through exercise. According to the National Institutes of Health, the prevalence of food allergies is approximately 5% in children and 4% in adults. Kidshealth.org attributes most food allergies to eight common foods: milk, eggs, peanuts, soy, wheat, tree nuts, fish, and shellfish. Allergic reactions can range from mild skin rashes to gastrointestinal discomfort to severe anaphylaxis, which causes swelling of the airways and difficulty breathing. In severe cases, it can lead to loss of consciousness or death. The most common treatment for anaphylaxis is epinephrine, which often comes in the form of a predosed auto-injector that can be administered with minimal training.

**State Revenues:** The bill authorizes MDH to collect fees associated with certification. Thus, general fund revenues increase beginning in fiscal 2019. MDH anticipates charging

\$250 for application and renewal fees. However, since there is no reliable estimate of the number of individuals who will seek certification under the bill, the Department of Legislative Services is unable to provide an accurate estimate of general fund revenues. There are 57 institutions of higher education in the State, but the number that have food service facilities and recreation and wellness facilities is unknown. Some institutions have multiple campuses and multiple food service facility vendors. Similarly, institutions may have multiple recreation and wellness facilities. Since the program is elective, no one is required to obtain a certificate under the bill; however, there must be at least two certificate holders at each participating eligible institution (employees or designated affiliated individuals). As an *illustrative example* only, if 200 individuals seek certification, and MDH charges \$250 per application, general fund revenues for MDH increase by \$50,000 in that year.

**State Expenditures:** General fund expenditures for MDH increase by \$26,479 in fiscal 2019, which accounts for the bill’s October 1, 2018 effective date. This estimate reflects the cost of hiring one part-time (25%) medical services review nurse to review applications, issue certificates, and implement the program. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses. It is assumed that any enforcement at recreation and wellness facilities is complaint-based.

Position	0.25
Salary and Fringe Benefits	\$21,472
One-time Start-up Costs	4,890
Ongoing Operating Expenses	<u>115</u>
<b>Total FY 2019 State Expenditures</b>	<b>\$26,479</b>

Future year expenditures reflect a full part-time salary (25%) with annual increases and employee turnover and ongoing operating expenses.

**Additional Comments:** The bill applies to private nonprofit and for-profit institutions of higher education in the same manner as to public institutions of higher education. Should any participate, they can do so without any material impact on their operations or finances.

### Additional Information

**Prior Introductions:** None.

**Cross File:** None.

**Information Source(s):** Maryland Association of County Health Officers; Baltimore City Community College; University System of Maryland; St. Mary’s College of Maryland;

Maryland Independent College and University Association; Maryland Department of Health; Department of Legislative Services

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