

Department of Legislative Services
 Maryland General Assembly
 2020 Session

FISCAL AND POLICY NOTE
 Third Reader

Senate Bill 477

(Senator Carozza, *et al.*)

Finance

Health and Government Operations

Public Health - Emergency Use Auto-Injectable Epinephrine Program -
 Revisions

This bill renames the Emergency Use Auto-Injectable Epinephrine Program at Institutions of Higher Education to be the Emergency Use Auto-Injectable Epinephrine Program, and expands eligible participants to include *any* food service facility in the State that voluntarily participates in the program. The bill makes conforming changes throughout the relevant statutory provisions.

Fiscal Summary

State Effect: General fund expenditures increase by \$117,800 in FY 2021 for staff and computer programing costs; out-years reflect annualization, elimination of one-time costs, and ongoing costs. General fund revenues increase by an indeterminate amount from certification fees beginning in FY 2021.

(in dollars)	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
GF Revenue	-	-	-	-	-
GF Expenditure	\$117,800	\$49,100	\$50,100	\$51,900	\$53,700
Net Effect	(\$117,800)	(\$49,100)	(\$50,100)	(\$51,900)	(\$53,700)

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. Revenues are not affected.

Small Business Effect: Minimal.

Analysis

Bill Summary: Broadly, under current law, qualified individuals (through issuance of a certificate) who are employed by a food service facility or a recreation and wellness facility at an “eligible institution” are authorized to obtain, store, and administer auto-injectable epinephrine to individuals experiencing (or believed to be experiencing) anaphylaxis. An “eligible institution” is an institution of higher education that has a food service facility or a recreation and wellness facility on the premises and is authorized to obtain and store auto-injectable epinephrine.

The bill expands the current law program by authorizing individuals employed by a “participating facility” to obtain, store, and administer auto-injectable epinephrine under specified circumstances. A “participating facility” is a recreational wellness facility at an eligible institution or a food service facility (including a food service facility at an eligible institution). Thus, under the bill, employees of a stand-alone food service facility may obtain, store, and administer auto-injectable epinephrine pursuant to the State’s program rather than only individuals at a food service facility at an eligible institution.

The bill replaces references to “an eligible institution” with “each participating facility.” Under the bill, if a participating facility is a food service facility that is part of an eligible institution, either entity may pay the application fee on behalf of the applicant.

Current Law: Chapter 527 of 2018 established 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. There are legal immunities for certificate holders, prescribing physicians, and pharmacists acting in compliance with the program. There are also reporting requirements for certificate holders and MDH. MDH adopted implementing regulations (COMAR 10.13.04.01–.03) that went into effect May 20, 2019.

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 holder may appoint an agent to administer auto-injectable epinephrine. 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. MDH did not establish a certification fee under the regulations promulgated in 2019.

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.

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.

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. There is no duty to obtain a certificate.

State Expenditures: MDH general fund expenditures increase by \$117,846 in fiscal 2021, which accounts for the bill's October 1, 2020 effective date. This estimate reflects the cost of hiring one part-time (50%) nursing program consultant/administrator to review applications, issue certificates, and implement the broader program. It includes a salary,

fringe benefits, one-time start-up costs (including software development for a customer relationship management online platform), and ongoing operating expenses. The information and assumptions used in calculating the estimate are stated below:

- This analysis assumes that any enforcement is complaint-based.
- Although MDH already administers the Emergency Use Auto-Injectable Epinephrine Program at Institutions of Higher Education, the program is significantly expanded under the bill to include food service facilities.
- Expansion of the program under the bill could introduce thousands of additional participating facilities and individuals.
- MDH needs to develop online applications and program management capacity.
- MDH cannot implement the bill with current staff levels.

Position	0.5
Salary and Fringe Benefits	\$37,717
One-time Contractual Programming Costs	75,000
Other Operating Expenses	<u>5,129</u>
Total FY 2021 State Expenditures	\$117,846

Future year expenditures reflect a part-time salary (50%) with annual increases and employee turnover and ongoing operating expenses.

The Department of Legislative Services (DLS) notes that, although the fiscal and policy note for House Bill 1473 of 2018 (Chapter 527) estimated that MDH needed to hire one part-time medical services review nurse to implement the Emergency Use Auto-Injectable Epinephrine Program at Institutions of Higher Education, MDH did not hire this employee.

State Revenues: MDH is authorized to collect fees associated with certification. Although MDH does not collect fees for the current program, MDH anticipates charging a \$50 fee for the expanded program under the bill. Thus, general fund revenues increase beginning in fiscal 2021. However, since there is no reliable estimate of the number of individuals who will seek certification under the bill, DLS is unable to provide an accurate estimate of general fund revenues at this time. *For illustrative purposes only*, if 200 individuals seek certification, and MDH charges \$50 per application, general fund revenues for MDH increase by \$10,000 in that year.

Additional Information

Prior Introductions: None.

Designated Cross File: HB 1462 (Delegate Metzgar, *et al.*) - Health and Government Operations.

Information Source(s): Baltimore City Community College; University System of Maryland; Morgan State University; Maryland Department of Health; Department of Legislative Services

Fiscal Note History: First Reader - February 27, 2020
mr/jc Third Reader - March 10, 2020

Analysis by: Kathleen P. Kennedy

Direct Inquiries to:
(410) 946-5510
(301) 970-5510