

Department of Legislative Services
 Maryland General Assembly
 2014 Session

FISCAL AND POLICY NOTE

House Bill 1333 (Delegate Pena-Melnyk, *et al.*)
 Health and Government Operations

Public Health - Emergency Use Auto-Injectable Epinephrine Program

This bill establishes an Emergency Use Auto-Injectable Epinephrine Program in the Department of Health and Mental Hygiene (DHMH), which authorizes certain individuals (through the issuance of a certificate) to administer epinephrine to an individual experiencing, or believed to be experiencing, anaphylaxis in an emergency situation when medical services are not immediately available. To qualify for a certificate, an individual must be (1) 18 or older; (2) have, or reasonably expect to have, responsibility for at least one other person in their line of work or due to their volunteer status; and (3) successfully complete an educational training program approved by the department.

Fiscal Summary

State Effect: General fund expenditures increase by \$59,200 in FY 2015 for DHMH’s Health Systems and Infrastructure Administration (HSIA) to hire one full-time employee to establish, implement, and operate the program. General fund revenues increase as a result of fees collected from certifications. Future years reflect annualization and inflation.

(in dollars)	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
GF Revenue	-	-	-	-	-
GF Expenditure	\$59,200	\$75,300	\$78,800	\$82,500	\$86,400
Net Effect	(\$59,200)	(\$75,300)	(\$78,800)	(\$82,500)	(\$86,400)

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

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: DHMH may adopt regulations for the administration of the program, collect fees, issue and renew certificates to eligible persons, and conduct and approve educational training programs by other State agencies or private entities.

Educational training programs must be conducted by a licensed physician or nurse practitioner, a nationally recognized organization with experience in training laypersons in emergency medical treatment, or any other DHMH-approved person. The training must include (1) the recognition of the symptoms of anaphylaxis; (2) procedures for emergency administration of auto-injectable epinephrine; (3) proper follow-up emergency procedures after administration of auto-injectable epinephrine; and (4) standards and procedures for obtaining, and the proper and secure storage of, auto-injectable epinephrine.

To obtain a certificate, a person must submit an application to DHMH and pay the application fee set by DHMH. Once granted, certificates are valid for two years. To renew a certificate, the holder must complete a DHMH-approved refresher training program or demonstrate proficiency to DHMH.

Physicians may prescribe, and a pharmacist may dispense, auto-injectable epinephrine to a certificate holder. A certificate holder may possess and store prescribed auto-injectable epinephrine. In an emergency situation, when physician or emergency medical services are not immediately available, a certificate holder may administer auto-injectable epinephrine to an individual who the certificate holder believes in good faith is experiencing anaphylaxis.

A cause of action may not arise against a certificate holder for acting in good faith while rendering emergency treatment to an individual who is experiencing or believed to be experiencing anaphylaxis unless the certificate holder's conduct amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct. A cause of action may not arise against a physician or pharmacist for acting in compliance with the bill and in good faith. The bill does not affect any other immunities or defenses to which a volunteer, 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 issued under the bill's provisions. The bill does not create a duty to obtain a certificate.

If a certificate holder administers auto-injectable epinephrine, he or she must submit an incident report form to DHMH. DHMH must publish a report summarizing the information obtained from these reports by January 31 of each year.

Current Law: Each local board of education must establish a policy for public schools within its jurisdiction to authorize the school nurse and other school personnel to administer auto-injectable epinephrine, if available, to a student who is determined to be or perceived to be in anaphylaxis. The policy must also include training for school personnel on how to recognize the symptoms of anaphylaxis, procedures for the emergency administration of auto-injectable epinephrine, proper follow-up emergency procedures, and a provision authorizing a school nurse to obtain and store at a public school auto-injectable epinephrine to be used in a an emergency situation.

Although DHMH is charged with administering the Insect Sting Emergency Treatment Program under Title 13, Subtitle 7 of the Health-General Article, the program is not funded and, thus, established. That program would provide certification to qualified individuals to possess epinephrine and administer epinephrine to a person suffering or believed to be suffering a severe adverse reaction to an insect sting. A certificate holder is immune from civil liability for any act or omission in the course of responding in good faith to the reaction, except where the conduct amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct.

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 breathing difficulty. 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 pre-dosed auto-injector that can be administered with minimal training.

State Fiscal Effect: General fund expenditures increase by \$59,237 in fiscal 2015, which accounts for the bill's October 1, 2014 effective date. The estimate reflects the cost of hiring one full time program administrator to establish, implement, and operate the program. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

HSIA advises that it needs two full-time employees to fully establish and implement the program. However, the Department of Legislative Services (DLS) disagrees and advises that one full-time program administrator can likely develop regulations, collect fees, issue

and renew certificates to eligible persons; approve educational training programs; and publish the report required by the bill. To the extent that a large number of individuals seek certification, HSIA may need additional employees to handle the load.

Position	1
Salaries and Fringe Benefits	\$54,432
Operating Expenses	<u>4,805</u>
Total FY 2015 State Expenditures	\$59,237

The bill authorizes DHMH to collect fees in order to defray costs of implementing the program. Thus, general fund revenues increase beginning in fiscal 2015. However, DLS is unable to provide an accurate estimate at this time because the fee amount has not been set, and DHMH was unable to provide an estimate of the number of individuals who may seek certification.

HSIA advises that a similar Overdose Response Program that authorizes individuals to administer naloxone to individuals believed to be experiencing a drug overdose does not require the collection of fees. Thus, HSIA implies that collection of fees is also unnecessary for the bill's program. DLS notes that the target populations for the program set forth in the bill and the Overdose Response Program are quite different and that it is feasible that fees can successfully be collected to defray the Emergency Use Auto-Injectable Epinephrine Program.

Additional Information

Prior Introductions: None.

Cross File: SB 915 (Senator Manno) - Finance and Judicial Proceedings.

Information Source(s): Department of Legislative Services

Fiscal Note History: First Reader - March 6, 2014
ncs/ljm

Analysis by: Kathleen P. Kennedy

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