

**Department of Legislative Services**  
 Maryland General Assembly  
 2016 Session

**FISCAL AND POLICY NOTE**  
**First Reader**

House Bill 1418 (Delegate Cullison)  
 Health and Government Operations

**Public Health - Emergency Use Auto-Injectable Epinephrine Program for Food Service Facilities**

This bill establishes an Emergency Use Auto-Injectable Epinephrine Program for Food Service Facilities in the Department of Health and Mental Hygiene (DHMH) to authorize individuals in a food service facility (through the issuance of a certificate) to obtain, store, and, when medical services are not immediately available, administer auto-injectable epinephrine to individuals experiencing anaphylaxis. To *qualify* for a certificate, an individual must (1) own or operate a food service facility and (2) successfully complete, at the individual’s expense, an educational training program approved by DHMH. The bill establishes legal immunities for certificate holders or their agents, prescribing physicians, and pharmacists acting in compliance with the program. The bill also establishes reporting requirements for certificate holders and DHMH.

**Fiscal Summary**

**State Effect:** General fund expenditures increase by \$47,300 in FY 2017 for DHMH’s Prevention and Health Promotion Administration to hire one full-time employee to establish the program and issue certificates. General fund revenues increase to the extent that DHMH collects fees for certification. Future years reflect annualization and inflation.

(in dollars)	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
GF Revenue	-	-	-	-	-
GF Expenditure	\$47,300	\$57,900	\$60,200	\$62,600	\$65,200
Net Effect	(\$47,300)	(\$57,900)	(\$60,200)	(\$62,600)	(\$65,200)

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

**Local Effect:** Local health departments can conduct any necessary inspections with existing resources during the course of current food service facility inspections.

**Small Business Effect:** Minimal.

---

## **Analysis**

**Bill Summary:** DHMH may adopt regulations for the administration of the program, collect fees, issue and renew certificates to eligible persons, and approve educational training programs (which may be online).

To *obtain* a certificate, an applicant must submit an application to DHMH and pay the application fee set by DHMH. Once granted, a certificate is valid for two years. To renew a certificate, the certificate holder must complete a DHMH-approved refresher training program. A replacement certificate may be issued if the certificate holder pays the 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 and successfully complete an educational training program approved by DHMH.

A physician 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 and the necessary paraphernalia. In an emergency situation when physician or emergency medical services are not immediately available, a certificate holder or their agent 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 or an agent for 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 unless the certificate holder or agent's conduct amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct. 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 an individual certified under the bill. 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.

If a certificate holder administers auto-injectable epinephrine, he or she must submit a report to DHMH for each incident that occurred on the certificate holder's premises that

involved the administration of auto-injectable epinephrine. DHMH must publish a report summarizing the information obtained from these reports by January 31 of each year.

**Current Law:** Chapter 342 of 2015 established the Emergency Allergy Treatment Program within DHMH, 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 DHMH-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 DHMH.

A certificate holder must submit a report to DHMH 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. DHMH 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.

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 DHMH or a suitable license from a local health department in order to operate a food establishment. A representative of DHMH may enter any food establishment at a reasonable time to conduct inspections. In general, local health departments conduct inspections of food establishments.

**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 Fiscal Effect:** General fund expenditures increase by \$47,256 in fiscal 2017, which accounts for the bill's October 1, 2016 effective date. This estimate reflects the cost of hiring one full-time grade 10 office secretary to issue and renew certificates. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Position	1.0
Salary and Fringe Benefits	\$40,791
Operating Expenses	<u>6,465</u>
<b>Total FY 2017 State Expenditures</b>	<b>\$47,256</b>

Future year expenditures reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

The bill authorizes DHMH to collect fees associated with certification. Thus, general fund revenues increase beginning in fiscal 2017. However, the Department of Legislative Services 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.

---

### **Additional Information**

**Prior Introductions:** None.

**Cross File:** SB 898 (Senator Klausmeier) - Finance.

**Information Source(s):** Department of Health and Mental Hygiene, Maryland Association of County Health Officers, Kidshealth.org, Department of Legislative Services

**Fiscal Note History:** First Reader - March 7, 2016  
md/ljm

---

Analysis by: Kathleen P. Kennedy

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