

Department of Legislative Services
Maryland General Assembly
2016 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 898

(Senator Klausmeier)

Finance

Health and Government Operations

Public Health - Auto-Injectable Epinephrine - Certification for Emergency Administration

This bill allows an “authorized entity” and a certificate holder that meets specified requirements to obtain and store auto-injectable epinephrine. Further, an authorized entity may make available, and a certificate holder may administer, auto-injectable epinephrine in a specified emergency situation. Certificates are to be issued by an educational program that is approved by the Department of Health and Mental Hygiene (DHMH). The bill establishes legal immunities for certificate holders, authorized entities, prescribing physicians, and pharmacists acting in compliance with the bill.

Fiscal Summary

State Effect: None. To the extent that any such program exists, DHMH can approve an educational training program with existing budgeted resources and staff.

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary: DHMH may adopt implementing regulations and must approve educational training programs (which may be online), including programs conducted by other State agencies or private entities.

An “authorized entity” is an entity at which allergens capable of causing anaphylaxis may be present and that is authorized to obtain and store auto-injectable epinephrine under the

bill. “Authorized entity” includes, but is not limited to, a college or university, a day care facility, a food service facility, an amusement park, and a youth sports league.

The bill specifically excludes from the definition of “authorized entity” a youth camp (which may participate in the Emergency and Allergy Treatment Program). Further, the bill’s provisions do not apply to the Emergency and Allergy Treatment Program or public and nonpublic elementary and secondary schools.

An “affiliated individual” is an individual who is (1) at least age 18; (2) has an unpaid and close association with an authorizing entity; (3) has successfully completed, at the expense of the applicant, a DHMH-approved educational training program; and (4) is designated by an authorized entity to obtain, store (in compliance with certain specifications), and administer auto-injectable epinephrine. An authorized entity may obtain, possess, and store auto-injectable epinephrine if the authorized entity has at least two employees or designated affiliated individuals who are certificate holders. An authorized entity must store its supply of auto-injectable epinephrine under specified conditions and retain a copy of its employee’s or designated affiliated individual’s certificates.

To qualify for a certificate, an individual must be at least age 18 and successfully complete, at the expense of the applicant, an educational training program (which may be an online training program). A DHMH-approved educational training program *must* issue a certificate to any applicant who meets the bill’s requirements; a certificate is valid for two years. A certificate holder is authorized to obtain, possess, store, and administer auto-injectable epinephrine to be used in a specified emergency situation.

A physician may prescribe, and a pharmacist may dispense, auto-injectable epinephrine to a certificate holder or, under specified circumstances, to an authorized entity. In an emergency situation when physician or emergency medical services are not immediately available, a certificate holder or an authorized entity may make available and 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 or authorized entity for acting in good faith while making available or administering auto-injectable epinephrine to an individual who is experiencing or believed by the certificate holder or authorized entity to be experiencing anaphylaxis unless the certificate holder or authorized entity (1) engages in conduct that amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct; (2) fails to follow standards and procedures for storage and administration of auto-injectable epinephrine; or (3) administers auto-injectable epinephrine that is beyond the manufacturer’s expiration date.

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 to a certificate holder or an authorized entity. 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: 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.

Background: DHMH advises that it is unaware of any qualifying educational programs in the State that offer training on the storage and administration of auto-injectable epinephrine and would be willing to administer certificates.

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.

Additional Information

Prior Introductions: None.

Cross File: HB 1418 (Delegate Cullison) - Health and Government Operations.

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

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