Legislative Analysis

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EPiPENS: EXPAND ENTITIES HAVING PRESCRIPTIONS

House Bill 4438 (reported from committee as H-1)
Sponsor: Rep. Lisa Posthumus Lyons
Committee: Health Policy ***(Enacted as Public Act 221 of 2015)***
Complete to 7-15-15

BRIEF SUMMARY: The bill would allow a physician to prescribe an epinephrine injector (or EpiPen) for public and private schools, recreation camps, youth sports leagues, amusement parks, religious institutions, and sports arenas; and would limit liability for administering the device.

FISCAL IMPACT: House Bill 4438 would have a likely nominal and entirely voluntary fiscal impact on local units of government to the extent that local units purchase auto-injectable epinephrine as permitted by House Bill 4438 and then comply with the bill's storage, training, and reporting requirements.

THE APPARENT PROBLEM:

EpiPens are used by people with severe allergies to counter anaphylactic shock—customarily, to open the air passages when one is unable to breathe. The syringe (or pen) contains epinephrine, a drug that can rapidly reverse life-threatening effects of an allergic reaction, if administered into the thigh within minutes of the reaction.

What causes anaphylaxis? Allergens are ubiquitous, and cannot always be avoided. Thousands of people have known food allergies—including an estimated four- to five-percent of all school children, according to the U.S. Center for Disease Control. Other people react to bee or wasp stings. Yet others are allergic to the dander carried by pets—most especially cats. Those who suffer life-threatening allergic reactions know these events can occur any place and at any time. See ***Background Information*** below.

Public Act 186 of 2013 (effective in March of 2014) added a new section to the Public Health Code to allow school board officials to receive a prescription for auto-injectable epinephrine devices (more commonly known as EpiPens) from a physician. The new law also authorized a pharmacist to fill that prescription. Under the statute, either a school nurse or a trained school employee may administer the device.

In addition, a companion bill, now Public Act 187 of 2013, amended the Revised School Code to establish training and storage protocols for schools and to require each school to have at least two auto-injectable epinephrine devices on site.

Now legislation has been introduced to encourage additional organizations and businesses—including public and private schools, recreation camps, youth sports leagues, amusement parks, religious institutions, and sports arenas—to have prescription EpiPens

on site, and to train people who can administer them. The bill also would limit the liability of the businesses and organizations choosing to do so.

THE CONTENT OF THE BILL:

Overall, House Bill 4438 (H-1) would do the following:

- Allow a physician to prescribe, and a pharmacist to dispense, an auto-injectable epinephrine device to an authorized entity (a term that includes public and private schools, recreation camps, youth sports leagues, amusement parks, religious institutions, sports arenas and other places where allergens causing anaphylaxis may be present).
- Establish storage and training requirements for devices.
- Provide limited civil liability for administering a device.
- Establish certain reporting requirements if a device is administered.

The bill would go into effect 90 days after it was enacted into law.

A more detailed description of the bill follows.

House Bill 4438 (H-1) would amend the Public Health Code to expand the list of entities authorized to obtain an EpiPen or similar device (hereinafter "device") under a prescription. Under the bill, an ***authorized entity*** may obtain a prescription for a device from a prescriber and a pharmacist may fill that prescription. "Authorized entity" is defined to mean any of the following:

- A school board for the purpose of meeting the requirements of Section 1179a of the Revised School Code (as added by Public Act 187 of 2013).
- A person or governmental entity that operates or conducts a business or activity at which allergens capable of causing anaphylaxis may be present. The term includes, but is not limited to, a recreation camp, youth sports league, amusement park, nonpublic school, religious institution, or sports arena.

The bill also adds a new section regarding storage, training of employees, and civil immunity that pertains to entities other than schools and school boards that acquire and stock a supply of devices.

Storage requirements

The devices must be stored in a location readily accessible in an emergency and in accordance with the device's instructions for use and any additional requirements established by the Department of Licensing and Regulatory Affairs (LARA). The authorized entity must designate an employee or agent who has completed the required training to be responsible for the storage, maintenance, and general oversight of the device.

Use of the device

An employee or agent or other individual who has completed the required training may, either on the premises of, or in connection with the conduct of, the business or activity of the authorized entity, do any of the following:

- Provide a device to an individual believed in good faith to be experiencing anaphylaxis for immediate self-administration, regardless of whether that

individual has a prescription for a device or has previously been diagnosed with an allergy.

- Administer a device to an individual who the employee, agent, or other individual believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for a device or has previously been diagnosed with an allergy.

Training

Before an authorized entity provides or administers a device, its employee, agent, or other individual must complete an initial anaphylaxis training program, and a subsequent program at least every two years thereafter, that meets all of the following requirements:

- Is conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or by a person, entity, or class of individuals approved by LARA.
- Is conducted online or in person.
- At a minimum, covers all of the following:
  - Techniques on how to recognize symptoms of severe allergic reactions, including anaphylaxis.
  - Standards and procedures for the storage and administration of devices.
  - Emergency follow-up procedures.

Certificate

An organization, person, entity, or class of individuals that conducts an anaphylaxis training program would be required to issue a certificate, on a form developed or approved by LARA, to each individual who successfully completes the training program.

Civil immunity

An authorized entity and its employees, agents, and other trained individuals that have acted in accord with these requirements; an individual who self-injects auto-injectable epinephrine provided under the bill; or an organization, person, entity, or class of individuals that conducts an anaphylaxis training program would not be liable for any injuries or related damages resulting from the administration of a device, the failure to administer a device, or any other act or omission taken under this provision of the bill. However, the immunity provided by this provision would not apply to acts or omissions that constitute willful misconduct or wanton misconduct.

In addition, the bill stipulates that supplying or administering a device would not be the practice of medicine.

Further, the civil immunity would not eliminate, limit, or reduce any other immunity or defense that may be available under state laws. An authorized entity located in Michigan would not be liable for any injuries or related damages that result from the providing or administering of a device by its employees or agents when outside of Michigan if those persons would not have been liable for the injuries or related damages had the provision or administration of the device occurred in Michigan or, would not have been liable under the laws in the state in which the provision or administration occurred.

Report

A report of each incident involving the administration of a device on the premises of or in connection with the conduct of the business or activity of the authorized entity would have to be submitted by the authorized entity to LARA on a form prescribed by the department. LARA would be required to annually publish a report summarizing and analyzing all reports submitted to it under the bill.

Administration of a device by a third party

An authorized entity could make a device available to individuals other than their employees, etc., under certain conditions. If the device were stored in a locked, secure container and made available only upon remote authorization by an authorized health care provider, the other individual may administer the device to any person he or she believes in good faith to be experiencing anaphylaxis. The authorization could be done by audio, tele-video, or other similar means of electronic communication. Consultation with an authorized health care provider would not be considered the practice of telemedicine and would not violate any law or rule regulating the scope of practice of the health care provider. As used in the bill, "authorized health care provider" would mean a prescriber as that term is defined in Section 17708 of the Public Health Code, other than a licensed dentist, optometrist, or veterinarian.

MCL 333.17744a and 333.17744b, as proposed.

BACKGROUND INFORMATION:

According to the Michigan Allergy and Asthma Society, an estimated eight percent of American children—15 million youngsters—suffer from food allergies, about one in every 13 children. In addition, an estimated three percent of the population suffers from stinging insect allergy which can be potentially fatal to a child, as well.

The incidence of allergies in young people is on the rise. That increase is attributed to better detection as medical diagnostic tests improve and to an increasing imbalance in the human immune system.

There are nonlife threatening allergic reactions such as rashes and hives or swelling that can be relieved with antihistamines. However, sometimes when people experience an allergic reaction, they have difficulty breathing, as their airways close. Their allergic reactions, left unattended, can result in death.

All allergic reactions are called anaphylaxis—any sudden and severe allergic reaction that may affect the whole body. Symptoms can include hives; lip, tongue and throat swelling; nausea, vomiting diarrhea, cramping; shortness of breath, wheezing, coughing; drop in blood pressure; and loss of consciousness.

Epinephrine—a form of adrenaline from the adrenal gland—is the only chemical that can reverse the life threatening symptoms of severe allergic reactions, and protect vital organs. The average time to respiratory or cardiac arrest due to food allergy is 30 minutes, according to the Allergy and Asthma Network. The drug epinephrine is available in an auto-injector delivery system, such as Auvi-Qs, and EpiPens. These are prescription devices that contain a premeasured dose of epinephrine. The needles (designed to penetrate

clothing) are protected inside the devices until you push the injector against your thigh. The injected epinephrine can reverse life-threatening allergic symptoms in as little as five seconds.

For further information about severe allergic reactions, called anaphylaxis, as well as about prevention and treatment, visit the following websites:

- Allergy and Asthma Network, Mothers of Asthmatics at www.aanma.org
- American College of Allergy, Asthma & Immunology at www.acaai.org
- National Association of School Nurses at www.nasn.org

ARGUMENTS:

For:

Proponents say that this bill is needed to ensure the health and safety of those who suffer from severe allergic reactions (customarily to proteins found in the foods they eat, but also to insect venom). The bills will allow businesses and organizations to stock unassigned epinephrine auto-injectors and to administer the medication (without fear of liability) if their students, fans, customers, clients, or congregants experience life-threatening anaphylaxis.

The incidence of severe allergic reactions is said to be on the rise. Indeed, according to the CDC National Health Interview Survey (June 2009, updated 2011), throughout the United States, food allergies cause 30,000 cases of anaphylaxis and 150 deaths annually. If more people are trained to administer epinephrine auto-injectors, the adverse consequences from severe allergic reactions can be avoided

POSITIONS:

The Food Allergy & Anaphylaxis Michigan Association supports the bill. (6-9-15)

The Michigan Academy of Family Physicians supports the bill. (6-9-15)

The Michigan Council for Maternal and Child Health supports the bill. (6-9-15)

The Michigan Association of Non-Public Schools supports the bill. (6-9-15)

The Michigan Pharmacy Association supports the bill. (6-9-15)

The Michigan Catholic Conference supports the bill. (6-9-15)

Legislative Analyst: J. Hunault
Fiscal Analyst: Paul Holland

■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.