Legislative Analysis

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EPI PENS: EXPAND ENTITIES WHICH MAY OBTAIN A PRESCRIPTION

House Bill 5668
Sponsor: Rep. Lisa Posthumus Lyons
Committee: Health Policy

Complete to 9-22-14

A SUMMARY OF HOUSE BILL 5668 AS INTRODUCED 6-12-14

The bill would:

- Allow a physician to prescribe, and a pharmacist to dispense, an auto-injectable epinephrine device to an authorized entity (which includes schools, restaurants, camps, and other places where certain allergens may be present);

- Establish storage and training requirements for devices;

- Provide limited civil liability for administering a device; and

- Establish certain reporting requirements if a device is administered.

Public Act 186 of 2013, which took effect in March of 2014, added a new section to the Public Health Code to allow school boards to receive a prescription for auto-injectable epinephrine devices (commonly known as EpiPens) from a physician and for a pharmacy to fill the prescription. Either a school nurse or a trained school employee may administer the device. A companion bill, Public Act 187, amended the Revised School Code to establish training and storage protocols for schools and to require each school to have at least two devices.

House Bill 5668 amends 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 restaurant, recreation camp, youth sports league, amusement park, 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 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 or person 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; an individual who self-injects auto-injectable epinephrine provided under the bill; or a person 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 provision or administration 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 believed in good faith to be experiencing anaphylaxis. The authorization could be done by audio, televideo, 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 professional 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.

FISCAL IMPACT:

House Bill 5668 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 HB 5668 and, if so, comply with the bill's storage, training, and reporting requirements.

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