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BILL ANALYSIS



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House Bill 4438 (Substitute H-1 as passed by the House)
Sponsor: Representative Lisa Posthumus Lyons
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 11-10-15

CONTENT

The bill would amend the Public Health Code to extend to any person or governmental entity that operates a business or activity at which anaphylaxis-causing allergens may be present, provisions applicable to a school board regarding the prescription and dispensing of auto-injectable epinephrine. The bill also would do the following with respect to such a person or governmental entity:

- Prescribe conditions for the storage, maintenance, and oversight of auto-injectable epinephrine, as well as training requirements for people who would provide or administer epinephrine.**
- Allow an employee or agent of the person or governmental entity or another individual who had completed the required training to administer epinephrine to a person who was experiencing anaphylaxis, or give it to the person for self-administration.**
- Allow the person or governmental entity to make epinephrine available to another individual to administer it, if it were stored in a locked, secure container and were made available only after consultation with a health care provider via electronic communication.**
- Provide for immunity from liability for injuries or damages resulting from the administration or self-administration of auto-injectable epinephrine, the failure to administer it, or any other related act or omission.**
- Require a report of each incident involving the administration of auto-injectable epinephrine to be submitted to the Department of Licensing and Regulatory Affairs (LARA).**
- Require LARA to publish an annual report that summarized and analyzed all of the incident reports.**

The bill would take effect 90 days after its enactment.

Prescription/Dispensing of Epinephrine

Under the Code, a prescriber may issue a prescription for, and a dispensing prescriber or pharmacist may dispense, auto-injectable epinephrine for the purpose of meeting the requirements of Section 1179a of the Revised School Code. When issuing the prescription or dispensing the epinephrine to a school board, the prescriber, dispensing prescriber, or pharmacist must insert the name of the school board as the name of the patient. A prescriber, dispensing prescriber, or pharmacist is not liable in a civil action for a properly stored and dispensed epinephrine auto-injector that was a proximate cause of injury or death to an individual due to the administration of or failure to administer the auto-injector.

The bill would refer to an "authorized entity" rather than a school board in these provisions. "Authorized entity" would mean any of the following:

- A school board for the purpose of meeting the requirements of Section 1179a of the Revised School Code.
- A person or governmental entity that operates or conducts a business or activity at which allergens capable of causing anaphylaxis may be present, including a recreation camp, youth sports league, amusement park, nonpublic school, religious institution, or sports arena.

(Section 1179a of the Revised School Code requires a school board to ensure that in each school it operates, there are a minimum number of employees who have been trained in the appropriate use and administration of an epinephrine auto-injector. A school board must develop and implement policies that are consistent with the medication administration guidelines of the Department of Education, and provide for the possession of at least two epinephrine auto-injectors in each school to be administered by a licensed registered professional nurse or a school employee trained in their use.)

Administration: Other People & Government Entities

The provisions described below would apply to an authorized entity that was a person or governmental entity that operates or conducts a business or activity at which anaphylaxis-causing allergens may be present.

An authorized entity would have to store auto-injectable epinephrine in a location readily accessible in an emergency and in accordance with the epinephrine's instructions for use and any additional requirements that were established by LARA. An authorized entity would have to designate an employee or agent who had completed the training required by the bill to be responsible for the storage, maintenance, and general oversight of the epinephrine acquired by the authorized entity.

An employee or agent of an authorized entity or another individual who had completed the training could use prescribed auto-injectable epinephrine on the premises of or in connection with the conduct of the authorized entity's business or activity to administer epinephrine to an individual whom the employee, agent, or other individual believed in good faith was experiencing anaphylaxis, or give the epinephrine to such an individual for self-administration, regardless of whether the individual had a prescription for auto-injectable epinephrine or had previously been diagnosed with an allergy.

Before providing or administering the epinephrine, the employee, agent, or other individual would have to complete an initial anaphylaxis training program, as well as a subsequent training program at least every two years following completion of the most recently completed training program that met all of the following requirements:

- Was 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.
- Was conducted online or in person.
- At a minimum, covered techniques on how to recognize symptoms of severe allergic reactions, including anaphylaxis; standards and procedures for the storage and administration of auto-injectable epinephrine; and emergency follow-up procedures.

An organization, person, entity, or class of individuals that conducted a training program would have to issue a certificate, on a form developed or approved by LARA, to each individual who successfully completed the program.

Except as otherwise provided, an authorized entity and its employees, agents, and other trained individuals that acted in accordance with the bill's requirements, an individual who used auto-injectable epinephrine obtained in accordance with and made available under the bill, or an organization, person, entity, or class of individuals that conducted a training program, would not be liable for any injuries or related damages that resulted from the administration or self-administration of auto-injectable epinephrine, the failure to administer it, or any other related act or omission. Immunity from liability would not apply to acts or omissions that constituted willful or wanton misconduct.

The bill provides that the administration of auto-injectable epinephrine would not be the practice of medicine. The bill would not eliminate, limit, or reduce any other immunity or defense that was available under Michigan law. An authorized entity located in Michigan would not be liable for any injuries or related damages that resulted from providing or administering auto-injectable epinephrine by its employees or agents outside of the State if either of the following requirements were met:

- The authorized entity or its employee or agent would not have been liable for the injuries or related damages had the provision or administration occurred in Michigan.
- The authorized entity or its employee or agent was not liable for the injuries or related damages under the law of the state in which it occurred.

An authorized entity would have to submit to LARA, on a form prescribed by the Department, a report of each incident on the premises of or in connection with the conduct of the entity's business or activity that involved the administration of auto-injectable epinephrine. The Department would have to publish an annual report that summarized and analyzed all of the reports submitted by authorized entities.

An authorized entity could make auto-injectable epinephrine available to an individual other than an employee, agent, or a person experiencing anaphylaxis, and the other individual could administer it to any person he or she believed in good faith to be experiencing anaphylaxis, if the epinephrine were stored in a locked, secure container and were made available only upon remote authorization by an authorized health care provider after consultation with the health care provider by audio, televideo, or other similar means of electronic communication. Under these circumstances, consultation with an authorized health care provider would not be the practice of telemedicine and would not violate any law or rule regulating the provider's scope of practice. "Authorized health care provider" would mean a prescriber as that term is defined in Section 17708 of the Code, other than a licensed dentist, optometrist, or veterinarian. (Under Section 17708, "prescriber" means a licensed dentist, doctor of medicine, osteopathic medicine and surgery, or podiatric medicine and surgery, optometrist certified to administer and prescribe therapeutic pharmaceutical agents, veterinarian, or other licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or osteopathic medicine and surgery.)

MCL 333.17744a et al.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bill would increase the cost of State government by a minimal amount, and would have an indeterminate fiscal impact on local governments that would depend on local decisions and circumstances. It would increase the costs of a local government or authority that determined to acquire and stock auto-injectable epinephrine for allergic emergencies, train one or more employees in the use of that medication, provide updated training at least every two years, and report incidents of use to the Department of Licensing and Regulatory Affairs (LARA). The local cost would vary depending on the number of doses acquired, the cost of the medication, the length of time before the medication expired, the number of people trained, and the cost of the training. The cost of two doses of epinephrine in auto-injectors is approximately \$555

at a retail pharmacy. The medication is available in different dosages for adults and children. The American Red Cross offers online training in signs and symptoms of anaphylaxis and the use of an epinephrine auto-injector for \$20; however, this course may not cover the material required by the bill or offer the certificate required. To the extent that the immunity provision would preclude potential liability, the bill could result in savings to local units. The bill would increase costs of LARA by a minimal amount due to the requirements to develop and make available forms for certificates to be awarded by trainers, receive reports of use of auto-injectable epinephrine pursuant to the bill, summarize and analyze the data, and publish an annual report.

Fiscal Analyst: Elizabeth Pratt
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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.