Legislative Analysis

Mary Ann Cleary, Director
Phone: (517) 373-8080
http://www.house.mi.gov/hfa

STOCK EPINEPHRINE

House Bill 5668 (reported from committee as Substitute H-2)
Sponsor: Rep. Lisa Posthumus Lyons
Committee: Health Policy

First Analysis (12-8-14)

BRIEF SUMMARY: House Bill 5668 would allow certain entities to obtain stock epinephrine (auto-injectable epinephrine devices, such as EpiPens, intended for general usage) and allow trained individuals to administer the device to a person experiencing, or potentially experiencing, an episode of anaphylaxis. Briefly, the bill would:

- Allow a physician to prescribe, and a pharmacist to dispense, an auto-injectable epinephrine device to an authorized entity (which, in addition to schools, would include 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.

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.

THE APPARENT PROBLEM:

The standard treatment for the initial symptoms of a serious allergic reaction known as anaphylaxis is to immediately administer epinephrine to the individual. Anaphylactic reactions range from mild (hives, itchy skin or tongue) to life threatening (swelling of the tongue or throat cutting off the airway). Many adults and children who know they have a food allergy or allergy to medications or insect bites (such as bee stings) get a prescription from their doctors for an epinephrine auto-injector (EAI)—EpiPen being the most widely known. An EAI can be quickly and easily self-administered or administered by another person and can provide precious minutes to summon an ambulance or seek treatment at an emergency room.

However, people do not always have their EpiPens with them, some don't seek a new prescription when their EAIs expire and need replacement, and some never fill a prescription because of the cost (about $100-$200 depending on insurance coverage). By some estimates, more than half of adults and parents of children at risk of anaphylaxis do not carry EAIs with them at all times. Moreover, half of all allergic reactions leading to emergency treatment involved individuals who had no known allergies to food or other substances.

Recently enacted legislation now requires public schools in Michigan to have at least two "stock" epinephrine auto-injectors (meaning the prescription was not written for a particular individual) on site, as well as at least two individuals trained in recognizing symptoms of anaphylaxis and administration of EAIs. Recognizing the potential for saving the lives of people experiencing severe allergic reactions in other settings, such as restaurants, entertainment venues, and sports/recreational camps, legislation has been offered to expand the list of places where stock epinephrine could be available.

THE CONTENT OF THE BILL:

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:
  - o Techniques on how to recognize symptoms of severe allergic reactions, including anaphylaxis.
  - o Standards and procedures for the storage and administration of devices.
  - o 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 that have acted in accordance with the bill's requirements; an individual who obtains auto-injectable epinephrine from an authorized entity and administers it to another person as provided under the bill; or a person that conducts an anaphylaxis training program as specified in the bill 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 Proposed 333.17744b

ARGUMENTS:

For:

According to FARE (Food Allergy Research & Education), a food allergy reaction sends a person to the emergency room every three seconds. Up to 15 million Americans have an allergy to one or more foods, and the rates of new allergies are increasing; for instance, allergies in children reportedly increased about 50 percent between 1997 and 2011. Of life-threatening anaphylaxis events, apparently half or more happen to individuals with no known allergies, like the middle-school athlete who died from an allergic reaction to bites from fire ants during football practice. Multiple surveys in the US and Canada reveal that even most individuals who are aware of their allergies do not carry an EpiPen or other brand of epinephrine auto-injector (EAI) with them at all times. When anaphylaxis happens, a person can die within minutes if the reaction results in severe swelling of tissues in the throat, lung, or tongue. Immediate administration of epinephrine via an EAI can reduce the symptoms to allow time for emergency responders to arrive or to transport the person to an emergency room.

Here is how the bill can help: House Bill 5668 allows a physician to write an undesignated prescription for an EpiPen or other brand of EAI, meaning that no specific patient is identified. Currently, a physician must write a prescription for an EAI to a specific person known or suspected to have an allergy to a food, medication (e.g., penicillin), insect bite/sting, or substance (e.g., latex, certain chemicals) that puts them at risk of having an anaphylactic reaction. A doctor is unlikely to write a prescription for a

person who is not known to have such an allergy as administration of epinephrine does carry some risk of complications for persons having certain underlying medical conditions. Under House Bill 5668, an undesignated or "stock" prescription could only be issued to an entity listed in the bill. That list includes, in addition to schools, venues where allergens that may cause an anaphylactic reaction are likely to exist – restaurants, movie theaters, sports stadiums, sleep-a-way camps, sports camps, and amusement parks, day care centers, among others. The bill also allows a pharmacist to fill a prescription to an authorized entity.

Since over half of anaphylaxis happens to persons with no known allergy, many people experiencing this life-threatening reaction are unprepared. If a restaurant, camp, children's program, stadium, etc. had epinephrine auto-injectors available in such situations, fewer people may die or suffer serious complications from unforeseen allergic reactions. Though people at risk for anaphylaxis from a known allergy should carry an EAI at all times, research shows that most do not. People should not rely on a venue having EAIs available; however, the bill would help those who forgot to bring their EpiPens or who need a second dose.

The bill would require an entity obtaining a prescription for an EAI to train at least one employee in the safe storage and administration of the EAI. The training must include emergency follow-up procedures, because epinephrine can cause serious and even fatal reactions in some individuals, though that is rare. Moreover, some individuals need multiple doses of epinephrine to resolve the anaphylactic reaction or require other medical interventions. Similarly to providing CPR to a suspected heart attack victim 9-1-1 should always be called or the person transported to the nearest medical facility for additional assessment. Failure to comply with the bill's requirements pertaining to proper storage and training could nullify the immunity from lawsuits that the bill provides.

Most states have enacted legislation to increase the availability of EAIs in schools. Michigan now requires public schools to have at least two EAIs onsite for use by any individual – student or staff member – experiencing anaphylaxis. The bill merely expands that legislation to apply in other situations in which people are exposed to allergens that could cause anaphylaxis. In doing so, many deaths can be prevented.

Response:

The bill requires an authorized entity to include in its training component emergency follow-up procedures. However, the bill does not specifically require an entity to call 9-1-1 before or after an epinephrine auto-injector device is administered. As mentioned above, epinephrine carries some risks of complications, including fatal heart arrhythmias. The risk of complications increases with the use of certain medications and with certain underlying medical conditions such as high blood pressure and diabetes. With diabetes, obesity, and high blood pressure being so prevalent among adults, the impact of more persons with such underlying conditions being exposed to epinephrine via EIAs without prior assessment by a physician is not known. In addition, some individuals require multiple doses of epinephrine or other medical interventions. Even if use of an EpiPen appears to resolve symptoms, serious symptoms can recur later. Moreover, a person in distress may be suffering from a different medical event altogether.

Therefore, some feel that the bill should require calling 9-1-1 in order for the immunity to attach as delay in calling 9-1-1 can thus still result in a serious or fatal event.

Important Note: Anaphylaxis is a medical emergency. The potential for a rare, but serious, complication **is not a contraindication** to administering an EAI if the person appears to be having an anaphylactic reaction.

However, this underscores the importance of including a requirement that before or immediately after administering an EAI in a public venue under the bill, 9-1-1 should be called.

For:

The bill is similar to legislation that recently took effect in Florida. In response, the Walt Disney Parks and Resorts and Disney Cruise Lines announced that it will make stock epinephrine auto-injectors (namely, EpiPens and EpiPen Juniors) at its key U.S. properties, including Disneyland, Disney World, and cruise ships. Reportedly, Disney is working with the distributor of EpiPens to develop educational materials. In addition, pilot projects with public access to EAIs are being conducted in several cities in Canada. For example, the City of Hamilton, Ontario is experimenting with training security guards at a mall in the recognition of anaphylaxis and administration of EAIs after a young girl died from an anaphylactic reaction after eating an ice cream cone purchased at a mall in a different city. Such initiatives recognize the growing public health concern food allergies and allergies to other substances represent.

POSITIONS:

Entities testifying in or indicating support for the bill include:

The Office of Governor (9-30-14)
The Department of Community Health (9-30-14)
The Michigan Psychiatric Society (9-30-14)
The Michigan Association of Health Plans (9-30-14)
The Michigan Academy of Family Physicians (9-23-14)
The Michigan Pharmacists Association (9-23-14)
The Michigan Council for Maternal and Child Health (9-23-14)
HealthPlus of Michigan (9-23-14)

The Lenawee Substance Abuse Coalition indicated a neutral position on the bill. (9-23-14)

The Michigan Restaurant Association opposes the bill. (11-24-14)

Legislative Analyst: Susan Stutzky
Fiscal Analyst: Paul Holland

■ 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.