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BILL ANALYSIS

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Senate Bill 417 and 418 (as enacted)  
Sponsor: Senator Peter J. Lucido (S.B. 417)  
Senator Michael D. MacDonald (S.B. 418)  
Senate Committee: Health Policy and Human Services  
House Committee: Health Policy  
Ways and Means

**PUBLIC ACTS 311 & 312 of 2020**

Date Completed: 2-23-21

**RATIONALE**

According to the American College of Allergy, Asthma, and Immunology, allergies and allergic reactions are common among adults and children within the United States, with more than 50 million Americans suffering from allergies each year. Epinephrine, commonly referred to as adrenaline, is a hormone that narrows blood vessels and opens airways in the lungs, which can reverse symptoms of an allergic reaction caused by mild to severe allergies. However, in the case of anaphylaxis, a severe and potentially fatal allergic reaction, a synthetic epinephrine injection is necessary as soon as possible since the reaction often occurs within seconds or minutes after exposure to the allergen.

Reportedly, anaphylaxis is common in the United States, and its causes include food allergens, such as peanuts, milk, eggs, soy, fish and shellfish, or allergies related to bee stings, medications, latex, or exercise. People with a history of anaphylaxis can receive a physician's prescription for synthetic, auto-injectable epinephrine, which may be kept on hand for self-injection in case of an emergency. If necessary, a person experiencing anaphylaxis can inject him or herself, or receive the injection from a bystander, on the outside of the thigh, and then immediately seek professional medical treatment. Auto-injectable epinephrine can be crucial for the preservation of life between the time anaphylaxis begins and when a patient receives formal medical attention. Considering the prevalence of allergies that could lead to anaphylaxis and the necessity of administering an auto-injectable epinephrine injection in a timely manner, some people believe that auto-injectable epinephrine should be prescribed and distributed broadly. Accordingly, it was suggested that legislation be enacted allowing law enforcement agencies and fire departments, and their personnel, to purchase, possess, and administer auto-injectable epinephrine.

**CONTENT**

**Senate Bill 418 enacted the "Law Enforcement and Firefighter Access to Epinephrine Act" to do the following:**

- **Allow a law enforcement agency or organized fire department to purchase or possess auto-injectable epinephrine and allow the entity to distribute it to law enforcement officers or firefighters in its employ.**
- **Require an individual to complete training on the proper administration of auto-injectable epinephrine before administering auto-injectable epinephrine.**
- **Specify that an eligible entity that purchases, stores, or provides to a law enforcement officer or firefighter auto-injectable epinephrine for use under the bill is immune from civil liability for injuries, death, or damages arising out of the**

**administration of that auto-injectable epinephrine to any individual, if the conduct does not amount to gross negligence.**

- Specify that any law enforcement officer or firefighter who possessed, administered, or failed to administer auto-injectable epinephrine under the bill would be immune from civil liability for injuries, death, or damages arising out of the administration or failure to administer auto-injectable epinephrine to any individual, if the conduct does not constitute willful or wanton misconduct.**
- Specify that an eligible entity that purchased, possessed, or distributed auto-injectable epinephrine under the bill and any law enforcement officer or firefighter who possessed, administered, or failed to administer auto-injectable epinephrine under the bill is not subject to criminal prosecution.**
- Specify that the bill does not eliminate, limit, or reduce any other immunity or defense that may be available under the laws of the State.**

**Senate Bill 417 amended the Public Health Code to do the following:**

- Allow a prescriber to issue a prescription for and a dispensing prescriber or pharmacist to dispense auto-injectable epinephrine to an eligible entity authorized to purchase, possess, and distribute auto-injectable epinephrine under the Law Enforcement and Firefighter Access to Epinephrine Act.**
- Modify exemptions from liability related to the administration or self-administration of auto injectable epinephrine, the failure to administer auto-injectable epinephrine, or any other act or omission related to epinephrine under the Code.**

The bills took effect on December 29, 2020.

### **Senate Bill 418**

#### Definitions

"Eligible entity" means a law enforcement agency or organized fire department that is prescribed auto-injectable epinephrine.

"Law enforcement agency" means that term as defined in Section 2 of the Michigan Commission on Law Enforcement Standards Act: an entity that is established and maintained in accordance with the laws of the State and is authorized by the laws of the State to appoint or employ law enforcement officers.

"Organized fire department" means that term as defined in Section 1 of the Fire Prevention Code: a department, authority, or other governmental entity that safeguards life and property from damage from explosion, fire, or disaster and that provides fire suppression and other related services in the State. The term includes any lawfully organized firefighting force in Michigan.

"Law enforcement officer" means that term as defined in the Michigan Commission on Law Enforcement Standards Act.

"Firefighter" means that term as defined in Section 1 of the Fire Prevention Code: a member of an organized fire department, including a volunteer member or a member paid on call, who is responsible for, or is in a capacity that includes responsibility for, the extinguishment of fires, the directing of the extinguishment of fires, the prevention and detection of fires, and the enforcement of the general fire laws of this state. Firefighter does not include a person whose job description, duties, or responsibilities do not include direct involvement in fire suppression.

#### Purchase and Possession of Epinephrine

Under the bill, an eligible entity may purchase and possess auto-injectable epinephrine for purposes of the Act and may distribute auto-injectable epinephrine to law enforcement officers or

firefighters in its employ who have been trained in the administration of auto-injectable epinephrine as described below.

An individual must complete training on the proper administration of auto-injectable epinephrine before administering auto-injectable epinephrine under the Act. If a law enforcement officer or firefighter has completed the training, he or she may administer auto-injectable epinephrine to an individual who the law enforcement officer or firefighter has reason to believe is experiencing anaphylaxis, regardless of whether the individual has a prescription for epinephrine or has been diagnosed previously with an allergy.

#### Civil and Criminal Liability

An eligible entity that purchases, stores, or provides to a law enforcement officer or firefighter auto-injectable epinephrine for use under the bill is immune from civil liability for injuries, death, or damages arising out of the administration of that auto-injectable epinephrine to any individual, if the conduct does not amount to gross negligence that is the proximate cause of injury, death, or damage. Any law enforcement officer or firefighter who possesses, administers, or fails to administer auto-injectable epinephrine under the Act is immune from civil liability for injuries, death, or damages arising out of the administration or failure to administer auto-injectable epinephrine to any individual, if the conduct does not constitute willful or wanton misconduct that is the proximate cause of injury, death, or damage.

("Gross negligence" means that term as defined in Section 7 of Public Act 170 of 1964: conduct so reckless as to demonstrate a substantial lack of concern for whether an injury results.)

An eligible entity that purchases, possesses, or distributes auto-injectable epinephrine under the Act and any law enforcement officer or firefighter who possesses, administers, or fails to administer auto-injectable epinephrine under the Act is not subject to criminal prosecution for purchasing, possessing, or distributing auto-injectable epinephrine, or administering or failing to administer auto-injectable epinephrine to any individual under the Act.

The Act also does not eliminate, limit, or reduce any other immunity or defense that may be available under the laws of the State.

### **Senate Bill 417**

#### Auto-Injectable Epinephrine

Under the Code, notwithstanding any provision of the Code to the contrary, a prescriber may issue a prescription for and a dispensing prescriber or pharmacist may dispense auto-injectable epinephrine to an authorized entity. "Authorized entity" means any of the following:

- A school board for the purpose of meeting certain requirements 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.

Under the bill, "authorized entity" also means an eligible entity authorized to purchase, possess, and distribute auto-injectable epinephrine under the proposed Law Enforcement and Firefighter Access to Epinephrine Act.

The bill also specifies that a law enforcement officer or firefighter of an authorized entity, subject to the proposed training requirements in Senate Bill 418, and reasonable belief that a person was experiencing anaphylaxis, could possess and administer auto-injectable epinephrine dispensed to the entity under the Code.

The Public Health Code allowed an authorized entity that was not a school board to acquire and stock a supply of auto-injectable epinephrine under a prescription as authorized by the Code and was subject to the Code's requirements related to the storage, employee training, and administration of auto-injectable epinephrine. Under the bill, this provision applies only to 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.

Under the Code, a person or governmental entity that operates or conducts 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 (hereunder "authorized entity"), that acquires and stocks a supply of auto-injectable epinephrine must store auto-injectable epinephrine in a location readily accessible in an emergency and in accordance with the auto-injectable epinephrine's instructions for use and any additional requirements that are established by the Department of Licensing and Regulatory Affairs (LARA). The authorized entity described above must designate an employee or agent who has completed training required by the Code to be responsible for the storage, maintenance, and general oversight of the auto-injectable epinephrine acquired by the authorized entity. The Code allows the employee or agent, on the premises of or in connection with the conduct of the business or activity of the authorized entity described above, to use auto-injectable epinephrine for certain purposes prescribed by the Code.

Before providing or administering auto-injectable epinephrine made available by the authorized entity, an employee, agent, or other individual must complete an initial anaphylaxis training program and a subsequent anaphylaxis training program at least every two years. The training must meet certain requirements prescribed by the Code. An organization, person, entity, or class of individuals that conducts an anaphylaxis training program must issue a certificate, on a form developed or approved by LARA, to each individual who successfully completes the anaphylaxis training program.

The Code previously exempted the following from liability for any injuries or related damages that resulted from the administration or self-administration of auto-injectable epinephrine, the failure to administer auto-injectable epinephrine, or any other act or omission taken pursuant to the Code:

- An authorized entity and its employees, agents, and other trained individuals that had acted in accordance with the requirements described above.
- An individual who used auto-injectable epinephrine obtained in accordance with the requirements described above and made available in a manner prescribed by the Code.
- An organization, person, entity, or class of individuals that conducted an anaphylaxis training program described in and conducted in accordance with the requirements described above.

Instead, under the bill, the entities described above are not subject to any of the following:

- For an authorized entity or person other than an individual described above, civil liability for injury, death, or damages that result from the administration or self-administration of auto-injectable epinephrine, the failure to administer auto-injectable epinephrine, or any other act or omission taken pursuant to the Code if the conduct does not constitute gross negligence as that term is defined in Section 7 of Public Act 170 of 1964, that is proximate cause of the injury, death, or damages.
- For an individual described above, civil liability for injury, death, or damages that result from the administration or self-administration of auto-injectable epinephrine, the failure to administer auto-injectable epinephrine, or any other act or omission taken pursuant to the Code, if the conduct does not constitute willful or wanton misconduct that was the proximate cause of the injury, death, or damages.
- For an authorized entity or person including an individual described above, criminal prosecution for purchasing, possessing, or distributing auto-injectable epinephrine, the administration or

self-administration of auto-injectable epinephrine, the failure to administer auto-injectable epinephrine, or any other act or omission taken pursuant to the Code.

(Section 7 of Public Act 170 of 1964 defines "gross negligence" as conduct so reckless as to demonstrate a substantial lack of concern for whether an injury results.)

The Code also exempts from liability an authorized entity described above located in the State for any injuries or related damages that result from providing or administering auto-injectable epinephrine by its employees or agents outside of the State if either of the following requirements are met:

- The authorized entity or its employee or agent would not have been liable for the injuries or related damages and the provision or administration occurred in the State.
- The authorized entity or its employee or agent is not liable for the injuries or related damages under the law of the State in which the provision or administration occurred.

The bill specifies that these exemptions are for civil liability.

### Nursing Homes

The Public Health Code requires the Department of Health and Human Services (DHHS), in consultation with Department of Licensing and Regulatory Affairs, to implement, among other thing, a process for the creation of care and recovery centers within nursing homes for the purpose of providing care to individuals who have tested positive for coronavirus who have not met the criteria for the discontinuation of transmission-based precautions from the Centers for Disease Control and Prevention. The Department must require a nursing home seeking to operate a care and recovery center to apply to the DHHS and meet certain requirements.

Previously, those requirements included that the nursing home had to demonstrate to the DHHS that it had at least a three-star rating based on the Five Star Quality Rating System established by the Centers for Medicare and Medicaid Services (CMS). Instead, under the bill, the nursing home must demonstrate to the DHHS that it has at least an overall rating of three stars or a three-star rating in the staffing category, based on the Five-Star Rating System established by the CMS.

MCL 333.5145 et al. (S.B. 417)

### **ARGUMENTS**

*(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)*

#### **Supporting Argument**

From 2007 to 2017, the price of an EpiPen®, the only auto-injectable epinephrine device available for purchase until 2016, increased from \$94 to \$609. According to a study released by *JAMA*, an international, peer-reviewed medical journal, patients' out-of-pocket spending to acquire the device increased by 123.6%, from an average of \$33.8 to \$75.5 in that time. The out-of-pocket costs increased by 500% for some patients whose insurance plans required higher deductibles. In addition, patients must pay the high costs of the auto-injectable epinephrine devices annually because the devices expire every 12 to 18 months. The increases in price and out-of-pocket spending also coincided with a nearly 250% increase in the amount of annual prescriptions written for EpiPen. However, the study found that the annual rate of prescription fills during this time increased by only 1.6%.

The statistics on epinephrine's costs and adherence rates suggest that patients and parents of patients do not fill their prescriptions for auto-injectable epinephrine devices because they cannot afford to pay for them. As a result, these costs increase the risk of an individual's anaphylaxis's becoming fatal in a situation in which he or she encounters an allergen. If an emergency occurs,

and the patient does not have an auto-injectable epinephrine device, any responder to the call should have the means to administer promptly the synthetic epinephrine since a quick response can mean the difference between life and death. Law enforcement and firefighters should possess and have the training and capacity to administer the auto-injectable epinephrine device during a situation in which they are first to the scene of an anaphylactic emergency.

**Response:** The cost of an auto-injectable epinephrine device is significantly higher than the cost of an equivalent amount of epinephrine in a vial and the cost of a syringe, which can perform the safe lifesaving function when used properly. Instead of allowing only for the purchase, possession, and administration of auto-injectable epinephrine, the bill should allow law enforcement and firefighters with proper training to use generic epinephrine and a syringe to reduce the costs placed on law enforcement agencies and fire departments.

### **Supporting Argument**

In recent years, Michigan has expanded policies that allow certain nonmedically trained individuals who receive training in the administration of lifesaving medications to respond in the crucial moments of potentially fatal emergencies. In 2014, legislation took effect that allows school boards to purchase and possess auto-injectable epinephrine devices, and to train staff in the administration of the device to combat anaphylaxis in schools. Similarly, the Administration of Opioid Antagonists Act, which took effect in 2019, allows governmental agencies to purchase and possess an opioid antagonist, and to distribute the antagonist to employees with proper training to combat against opioid overdoses in the State. These are only a few of the many examples of preventative policies in the State situated to save lives by distributing medicine that is crucial at the immediate outset of a life-threatening emergency. The Law Enforcement and Firefighter Access to Epinephrine Act will continue this positive trend.

Legislative Analyst: Stephen Jackson  
Tyler VanHuyse

### **FISCAL IMPACT**

#### **Senate Bill 417**

The bill will have no fiscal impact on State or local government.

#### **Senate Bill 418**

The bill will have an indeterminate fiscal impact on fire departments and law enforcement agencies, as they will have the choice under the bill whether to possess auto-injectable epinephrine and train staff in its proper use. The purchases and training will involve costs that cannot be determined at this time.

Fiscal Analyst: Bruce Baker

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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.