AN ACT CONCERNING EPINEPHRINE AUTO INJECTORS

SUMMARY: This act allows an authorized entity (e.g., for-profit or nonprofit entity) to acquire and maintain a supply of epinephrine auto-injectors (e.g., EpiPens) from a wholesaler and provide or administer them to a person experiencing an anaphylactic reaction. To do this, the authorized entity must (1) establish a medical protocol with a prescribing practitioner and (2) have at least one employee or agent trained in recognizing the signs and symptoms of anaphylaxis, administering the medication, and following emergency protocol.

The act establishes related training, storage, and medication administration requirements.

The act also generally grants immunity from civil and criminal liability to (1) prescribing practitioners who establish medical protocols with authorized entities and (2) authorized entities, the state or its political subdivisions, or their trained employees who provide or administer epinephrine auto-injectors to someone experiencing anaphylaxis.

Additionally, the act authorizes the commissioners of consumer protection or public health to adopt regulations to implement the act’s provisions.

The act also makes technical and conforming changes. (PA 19-118, § 63, also makes a technical change to the act.)

EFFECTIVE DATE: Upon passage

§ 1 — MEDICAL PROTOCOLS FOR EPINEPHRINE AUTO-INJECTORS

The act allows a prescribing practitioner authorized to prescribe an epinephrine auto-injector to establish a medical protocol with an authorized entity for the entity’s trained employee or agent to administer the medication to provide emergency care to a person experiencing an allergic reaction.

The medical protocol must include:
1. any training requirements for an employee or agent in addition to those described below,
2. record-keeping requirements,
3. proper storage and maintenance of the epinephrine auto injectors, and
4. procedures for handling emergency medical situations involving anaphylactic reactions at the entity’s place of business.

Under the act, the medical protocol is deemed established for a legitimate medical purpose and in the usual course of the prescribing practitioner’s professional practice. The authorized entity must maintain a copy of the medical protocol at its place of business and review it at least annually with its trained
employees and agents and prescribing practitioner.

§§ 1 & 2 — AUTHORIZED ENTITY EPINEPHRINE STOCK

The act allows an authorized entity that has a medical protocol with a prescribing practitioner to acquire and maintain a supply of epinephrine auto-injectors from a wholesaler. It establishes related training, storage, and medication administration requirements.

Under the act, an “authorized entity” is a for-profit or nonprofit entity or organization with at least one trained employee. The act excludes from the definition (1) the state or any political subdivision authorized to purchase epinephrine from a prescription drug manufacturer under existing law or (2) local or regional boards of education and licensed or certified ambulances required to maintain or carry epinephrine auto-injectors under existing law.

Training

In order for an authorized entity’s employee or agent to administer an epinephrine auto-injector, the employee or agent must be:
1. certified as having completed a first aid course offered by the American Red Cross, American Heart Association, National Ski Patrol, Department of Public Health, or a local health director or
2. trained by a licensed physician, physician assistant, advanced practice registered nurse, or emergency medical services (EMS) personnel and have written acknowledgement of the training.

Under the act, the first aid course or health provider training must include training in how to (1) recognize the signs and symptoms of anaphylaxis, (2) administer the medication, and (3) follow emergency protocol. The authorized entity must maintain documentation of the employees’ or agents’ training.

Storage

The authorized entity must designate trained employees or agents to be responsible for the epinephrine auto-injectors’ storage, maintenance, and control.

Under the act, an authorized entity’s trained employee or agent must store the epinephrine auto-injectors in a location readily accessible in an emergency and in accordance with the medication instructions and the established medical protocol.

Medication Administration

The act allows an authorized entity’s trained employee or agent to administer an epinephrine auto-injector to someone he or she believes in good faith is experiencing an allergic reaction, even if the individual does not have a prescription for the medication or a prior diagnosis of an allergic condition. It also allows the employee or agent to provide the medication to the individual or the individual’s parent, guardian, or caregiver so that they may immediately
administer it.

Under the act, the employee or agent must promptly notify a local EMS organization after an epinephrine auto-injector from the authorized entity’s supply is administered. The authorized entity must also report to the prescribing practitioner who established the medical protocol within 30 days after the medication was administered and maintain a record of the administration.

§§ 1 & 3 — IMMUNITY FROM LIABILITY

Prescribing Practitioners

Under the act, a licensed health care provider authorized to prescribe an epinephrine auto-injector is immune from civil and criminal liability for (1) establishing a medical protocol with an authorized entity and (2) any subsequent use of the epinephrine auto-injector acquired or maintained by the authorized entity.

A prescribing practitioner who establishes a medical protocol with an authorized entity according to the act’s provisions is deemed not to have violated his or her professional standard of care.

Authorized Entities and Trained Employees

The act grants immunity from civil and criminal liability to an authorized entity, or the entity’s trained employee or agent, for providing or administering an epinephrine auto-injector to a person the agent or employee believes in good faith is experiencing anaphylaxis. Specifically, the act grants such immunity for any personal injuries resulting from ordinary negligence during the provision or administration of the medication.

The immunity does not extend to acts or omissions that constitute gross, willful, or wanton negligence.

The State and Its Employees

The act extends to the state and its employees the same immunity from civil and criminal liability as described above for authorized entities and trained employees. The immunity applies only if the state employee meets the act’s training requirements for authorized entities’ trained employees (i.e., completion of a first aid course or health provider training).