RULES AND REGULATIONS PERTAINING TO ACQUIRING AND STOCKING EPINEPRHINE AUTO-INJECTORS FOR EMERGENCY ADMINISTRATION

[R23-6.4-EPI]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

February 2015

INTRODUCTION

These *Rules and Regulations Pertaining to Acquiring and Stocking Epinephrine Auto-injectors for Emergency Administration* [R23-6.4-EPI] are promulgated pursuant to the authority set forth in RIGL Chapter 23-6.4, and establish the procedures for an authorized entity to acquire and maintain a supply of epinephrine auto-injectors for administration to an individual experiencing anaphylaxis.

Pursuant to the provisions of RIGL § 42-35-3(a)(3) and § 42-35.1-4, consideration was given to: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulation; and (3) significant economic impact on small business Based on the available information, no known alternative approach, duplication or overlap was identified.

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SECTION 1.0 *Definitions*

Wherever used in these Regulations, the following terms shall be construed as follows:

1.1 ***"Act"*** refers to Chapter 23-6.4 of the General Laws of Rhode Island, entitled "Life-saving Allergy Medication - Stock Supply of Epinephrine Auto-Injectors - Emergency Administration."

1.2 ***"Administer"*** means the direct application of an epinephrine auto-injector to the body of an individual.

1.3 ***"Authorized entity"*** means any entity or organization at, or in connection with, where allergens capable of causing anaphylaxis may be present, as specified in § 2.4 of these Regulations.

1.4 ***"Authorized health care provider"*** means a physician, nurse, or other person duly authorized by law, in the state in which they practice, to prescribe drugs.

1.5 ***"Department"*** means the Rhode Island Department of Health.

1.6 ***"Director"*** means the means the Director of the Rhode Island Department of Health.

1.7 ***"Epinephrine auto-injector***" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.

1.8 ***"Provide"*** means the supplying of one or more epinephrine auto-injectors to an individual.

1.9 ***"RIGL"*** means the General Laws of Rhode Island, as amended.

1.10 ***"These Regulations"*** mean all parts of Rhode Island *Rules and Regulations Pertaining to Acquiring and Stocking Epinephrine Auto-injectors for Emergency Administration* [*R23-6.4-EPI*]

SECTION 2.0 *Applicability*

2.1 These Regulations permit an authorized health care provider to prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with the Act and these Regulations.

2.2 These Regulations permit a pharmacist to dispense epinephrine auto-injectors pursuant to a prescription issued in the name of an authorized entity.

2.3 These Regulations permit an authorized entity to acquire and stock a supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with the Act and these Regulations.

2.4 **Authorized Entity.** Pursuant to § 23-6.4-1(2) of the Act, the Director has determined that the following entities and organizations are considered authorized entities:

(a) A food business required to register with the Department on an annual basis pursuant to RIGL § 21-27-10;

(b) A pre-school, school, college or university as defined in the Department's *Rules and Regulations Pertaining to Immunization and Communicable Disease Testing in Preschool, School, Colleges or Universities*;

(c) A family day care home as defined in RIGL § 23-28.1-5(5);

(d) A place of assembly as specified in RIGL § 23-28.6;

(e) A state or local governmental agency or facility;

(f) An organized athletic team, league or association; and

(g) A place of employment which provides in-house employee health services.

SECTION 3.0 *Training for Use of Epinephrine Auto-injectors*

3.1 An employee, agent, or other individual described in § 4.3 of these Regulations must complete an anaphylaxis training program[1] prior to providing or administering an epinephrine auto-injector made available by an authorized entity.

3.2 Training required by § 3.1 of these Regulations shall be conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment, or an entity or individual approved by the Department. Training may be conducted online or in person and, at a minimum, shall cover:

(a) Techniques on how to recognize symptoms of severe allergic reactions, including anaphylaxis;

(b) Standards and procedures for the storage and administration of an epinephrine auto-injector; and

(c) Emergency follow-up procedures.

3.3 The entity that conducts the training required by § 3.1 of these Regulations shall issue a certificate, on a form developed or approved by the Department, to each person who successfully completes the anaphylaxis training program.

SECTION 4.0 *Acquisition, Storage and Use of Epinephrine Auto-injectors*

4.1 Epinephrine auto-injectors acquired by an authorized entity pursuant to the Act and these Regulations shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use.

4.2 An authorized entity shall designate employees or agents who have completed the training required by § 3.1 of these Regulations to be responsible for the storage, maintenance, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

4.3 **Use of Epinephrine Auto-injectors.** An employee or agent of an authorized entity, or other individual, who has completed the training required by § 3.1 of these Regulations,

[1] A healthcare provider (e.g., physician, physician assistant, nurse, EMT, etc.) who is currently licensed by the Department, and who has received anaphylaxis training as part of their professional development, is not required to complete this additional training.

may, on the premises of or in connection with the authorized entity, use epinephrine auto-injectors prescribed pursuant to the Act and these Regulations to:

(a) Provide an epinephrine auto-injector to any individual who, the employee, agent, or other individual, believes in good faith is experiencing anaphylaxis, for immediate self-administration, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.

(b) Administer an epinephrine auto-injector to any individual who, the employee, agent, or other individual, believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.

4.4 **Expanded Availability**. An authorized entity that acquires a stock supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with the Act and these Regulations, may make such epinephrine auto-injectors available to individuals other than those trained individuals described in § 4.3 of these Regulations, and such individuals may administer such epinephrine auto-injector to any individual believed in good faith to be experiencing anaphylaxis, if the epinephrine auto-injectors are stored in a locked, secure container and are made available only upon remote authorization by an authorized health care provider after consultation with the authorized health care provider by audio, tele-video, or other similar means of electronic communication.

(a) Consultation with an authorized health care provider for this purpose shall not be considered the practice of telemedicine or otherwise be construed as violating any law or rule regulating the authorized health care provider's professional practice.

4.5 **Good Samaritan Protections**. An authorized entity that possesses and makes available epinephrine auto-injectors and its employees, agents, and other trained individuals; a person who uses an epinephrine auto-injector made available pursuant to § 4.4 of these Regulations; an authorized health care provider who prescribes epinephrine auto-injectors to an authorized entity; and an individual or entity that conducts the training described in § 3.2 of the Regulations, shall not be liable for any civil damages that result from the administration or self-administration of an epinephrine auto-injector; the failure to administer an epinephrine auto-injector; or any other act or omission taken pursuant to the Act and these Regulations; provided, however, this immunity does not apply to acts or omissions constituting gross negligence or willful or wanton conduct.

(a) The administration of an epinephrine auto-injector in accordance with the Act and these Regulations is not the practice of medicine.

(b) The provisions of § 4.5 of these Regulations do not eliminate, limit, or reduce any other immunity or defense that may be available under Rhode Island law.

(c) An entity located in Rhode Island shall not be liable for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector by its employees or agents outside of the State of Rhode Island if the entity or its employee or agent:

(1) Would not have been liable for such injuries or related damages had the provision or administration occurred within the State of Rhode Island; or

(2) Are not liable for such injuries or related damages under the law of the state in which such provision or administration occurred.

4.6 **Operations Plan Required.** An authorized entity described in § 2.4 of these Regulations must maintain an Operations plan on the premises and submit the plan to the Department. The plan shall include at a minimum:

(a) How the training described in § 3.0 of these Regulations will be provided.

(b) How the epinephrine auto-injectors will be acquired.

(c) Name and contact information for the prescribing authorized health care provider.

(d) Where and how the epinephrine auto-injectors will be stored.

(e) Names of the designated employees and/or agents who have completed the training program and are authorized to administer the epinephrine auto-injectors.

(f) Description of the process to allow individuals, other than those trained per § 4.3 of these Regulations, to be provided the epinephrine auto-injectors via remote authorization by an authorized health care provider, after consultation with the authorized health care provider by audio, tele-video, or other similar means of electronic communication, pursuant to § 4.4 of these Regulations.

(g) How and when the epinephrine auto-injectors will be inspected for an expiration date that has not passed, and how that will be recorded.

(h) Description of the process to replace an epinephrine auto-injector that is nearing its expiration date or if one has been administered.

(i) Description of the process to report each incident to the Department pursuant to § 5.0 of these Regulations

SECTION 5.0 *Reporting Requirements*

5.1 An authorized entity that possesses and makes available epinephrine auto-injectors shall report each incident on the authorized entity's premises that involves the administration of an epinephrine auto-injector to the Department within forty-eight (48) hours, using the reporting format approved by the Department.

SECTION 6.0 *Severability*

6.1 If any provisions of these Regulations or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.