

216-RICR-20-10-5

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 20 – COMMUNITY HEALTH

SUBCHAPTER 10 - SCREENING, MEDICAL SERVICES, AND REPORTING

PART 5 – Epinephrine Auto-Injectors for Emergency Administration

5.1 Authority

These regulations are established pursuant to the authority conferred under R.I. Gen. Laws Chapter [23-6.4](#), for the purpose of establishing the procedures for an authorized entity to acquire and maintain a supply of epinephrine auto-injectors for administration to an individual experiencing anaphylaxis.

5.2 Definitions

- A. Wherever used in this Part, the following terms shall be construed as follows:
1. "Act" means R.I. Gen Laws Chapter [23-6.4](#), entitled "Life-saving Allergy Medication - Stock Supply of Epinephrine Auto-Injectors - Emergency Administration."
 2. "Administer" means the direct application of an epinephrine auto-injector to the body of an individual.
 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 § 5.3.1 of this Part.
 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.
 5. "Department" means the Rhode Island Department of Health.
 6. "Director" means the Director of the Rhode Island Department of Health.
 7. "Epinephrine auto-injector" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.

8. “Provide” means the supplying of one or more epinephrine auto-injectors to an individual.

5.3 Applicability

This Part applies to authorized health care providers, pharmacists and authorized entities, as defined by the Act and this Part.

5.3.1 Authorized Entity

- A. Pursuant to R.I. Gen. Laws § [23-6.4-1\(2\)](#), the Director has determined that the following entities and organizations are considered authorized entities:
 1. A food business required to register with the Department on an annual basis pursuant to R.I. Gen. Laws § [21-27-10](#);
 2. 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 (Part 30-05-3 of this Title);
 3. A family day care home as defined in R.I. Gen. Laws § [23-28.1-5\(5\)](#);
 4. A place of assembly as specified in R.I. Gen. Laws Chapter [23-28.6](#);
 5. A state or local governmental agency or facility;
 6. An organized athletic team, league or association; and
 7. A place of employment which provides in-house employee health services.

5.4 Training for Use of Epinephrine Auto-injectors

- A. Anaphylaxis training must be completed in accordance with R.I. Gen. Laws § [23-6.4-6](#).
 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.

5.4.1 Operations Plan Required

- A. An authorized entity described in § 5.3.1 of this Part which chooses to acquire and stock a supply of epinephrine auto-injectors must maintain an Operations plan on the premises. The plan shall include at a minimum:
1. How the training described in R.I. Gen. Laws § [23-6.4-6](#) will be provided.
 2. How the epinephrine auto-injectors will be acquired.
 3. Name and contact information for the prescribing authorized health care provider.
 4. Where and how the epinephrine auto-injectors will be stored.
 5. Names of the designated employees and/or agents who have completed the training program and are authorized to administer the epinephrine auto-injectors.
 6. Description of the process to allow individuals, other than those trained per R.I. Gen. Laws § [23-6.4-6](#), 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 R.I. Gen. Laws § [23-6.4-5](#).
 7. How and when the epinephrine auto-injectors will be inspected for an expiration date that has not passed, and how that will be recorded.
 8. Description of the process to replace an epinephrine auto-injector that is nearing its expiration date or if one has been administered.
 9. Description of the process to report each incident to the Department pursuant to R.I. Gen. Laws § [23-6.4-8](#).

5.5 Reporting Requirements

Authorized entities must comply with the reporting requirements contained in R.I. Gen. Laws § 23-6.4-8. Such reporting must occur according to procedures and format required by the Department.

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