

**SMALL BUSINESS IMPACT STATEMENT**

In order to accurately predict the impact the adoption, amendment, or repeal of a regulation will have on small businesses, the promulgating authority must conduct a thorough analysis that not only considers the potential effects of the action but also quantifies the costs, if any, associated with each. The questions below are designed to aid promulgating authorities in conducting their analysis.

**Agency submitting regulation:**

RI Department of Health

**Subject matter of regulation:**

Rules and Regulations Pertaining to Acquiring and Stocking Epinephrine Auto-injectors for Emergency Administration [R23-6.4-EPI]

**ERLID No:**

7985

**Statutory authority:**

RIGL Chapter 23-6.4

**Other agencies affected:**

None

**Other regulations that may duplicate or conflict with the regulation:**

None

**Describe the scope and objectives of the regulation:**

Establish the procedures for an authorized entity to acquire and maintain a supply of epinephrine auto-injectors for administration to an individual experiencing anaphylaxis.

**What was the rationale for establishing this regulation?**

See previous response

**Does the rationale still exist?**

The enabling legislation was passed during the 2014 legislative session.

**Is the rationale still relevant?**

N/A

**Business industry (s) affected by the regulation:**

The following entities and organizations can qualify as an "authorized entity":  
(a) A food business required to register with the Department of Health on an annual basis pursuant to RIGL § 21-27-10;  
(b) A pre-school, school, college or university as defined in the Department of Health's Rules and Regulations Pertaining to

**Types of businesses included in the industry (s):**

See previous response

**Total number of small businesses included in the regulated industry (s) (Please see the attached guidance documents for assistance determining the total number of small businesses)**

Insufficient information at this point because this is a new program and no authorized entities have been approved. In addition, this is an optional program and it is uncertain how many of the potential qualified entities will actually participate in this program.

**Number of small businesses potentially subject to the proposed regulation:**

See previous response

**How often do small businesses contact your agency for assistance with clarification of the regulation and/or receive assistance with compliance issues?**

N/A - new program

**What is the cost to your agency of establishing and enforcing this regulation?**

< \$5,000 (< 0.05 FTE) per year.

**What would the consequences be if the regulation did not exist?**

Could increase numbers of communicable and foodborne illnesses, lack of uniformity in the way recreational facilities operate

**Effective date used in cost estimate:**

FY-2015 HEALTH Budget Data - Average cost per FTE

**For each question below, please answer “yes” or “no” and offer a brief explanation. Please describe any facts, data, views, arguments, or other input from small businesses, organizations or any other sources that were used to quantify the impacts outlined below.**

1.	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p><b>Do small businesses have to create, file, or issue additional reports?</b></p> <p>The regulations establish several required reports. However, none are unique to small businesses</p>
2.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	<p><b>Do small businesses have to implement additional recordkeeping procedures?</b></p> <p>The regulations establish several recordkeeping requirements for epi-pens and training of individuals authorized to administer the epi-pens. However, none are unique to small businesses</p>
3.	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	<p><b>Do small businesses have to provide additional administrative oversight?</b></p> <p>Yes, as noted in responses to Questions 1 &amp; 2</p>
4.	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p><b>Do small businesses have to hire additional employees in order to comply with the proposed regulation?</b></p>

5.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Does compliance with the regulation require small businesses to hire other professionals (e.g. a lawyer, accountant, engineer, etc.)?</b></p> <div style="border: 1px solid black; height: 50px; width: 100%;"></div>
6.	Yes  <input checked="" type="checkbox"/>	No  <input type="checkbox"/>	<p><b>Does the regulation require small businesses to purchase a product or make any other capital investments in order to comply with the regulation?</b></p> <div style="border: 1px solid black; padding: 5px;">Epi-pens</div>
7.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Are performance standards more appropriate than design standards?</b></p> <div style="border: 1px solid black; padding: 5px;"> <p>The enabling legislation directs the Department of Health to establish requirements for “authorized entities “ to acquire and maintain a supply of epinephrine auto-injectors for administration to an individual experiencing anaphylaxis. Because of the public health</p> </div>
8.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Does the regulation require small businesses to cooperate with audits, inspections, or other regulatory enforcement activities?</b></p> <div style="border: 1px solid black; padding: 5px;">No specific requirements</div>
9.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Does the regulation have the effect of creating additional taxes and/or fees for small businesses?</b></p> <div style="border: 1px solid black; height: 50px; width: 100%;"></div>
10.	Yes  <input checked="" type="checkbox"/>	No  <input type="checkbox"/>	<p><b>Does the regulation require small businesses to provide educational services to keep up to date with regulatory requirements?</b></p> <div style="border: 1px solid black; padding: 5px;">Only to the extent of training required if an additional individual needs to be authorized to administer an epi-pen.</div>

11.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Is the regulation likely to <i>deter</i> the formation of small businesses in RI?</b></p> <div style="border: 1px solid black; height: 80px; width: 100%;"></div>
12.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Is the regulation likely to <i>encourage</i> the formation of small businesses in RI?</b></p> <div style="border: 1px solid black; height: 60px; width: 100%;"></div>
13.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Can the regulation provide for less stringent compliance or reporting requirements for small businesses?</b></p> <div style="border: 1px solid black; padding: 5px;">See response to Question 7</div>
14.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Can the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses?</b></p> <div style="border: 1px solid black; padding: 5px;">See previous response.</div>
15.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Can the compliance or reporting requirements be consolidated or simplified for small businesses?</b></p> <div style="border: 1px solid black; padding: 5px;">See previous response.</div>
16.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Can performance standards for small businesses replace design or operational standards?</b></p> <div style="border: 1px solid black; padding: 5px;">See previous response</div>

17.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Are there alternative regulatory methods that would minimize the adverse impact on small businesses?</b></p> <div data-bbox="440 281 1528 407" style="border: 1px solid black; padding: 5px;"> <p>See previous response</p> </div>
18.	Yes  <input type="checkbox"/>	No  <input checked="" type="checkbox"/>	<p><b>Have any small businesses or small business organizations been contacted during the preparation of this document? If so, please describe.</b></p> <div data-bbox="440 520 1528 646" style="border: 1px solid black; height: 60px;"></div>