### PROPOSED RULE MAKING

**CR-102 (August 2017)**
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

**Agency:** Department of Health

- [x] Original Notice
- [ ] Supplemental Notice to WSR
- [ ] Continuance of WSR

- [x] Preproposal Statement of Inquiry was filed as WSR 16-20-069 ; or
- [ ] Expedited Rule Making--Proposed notice was filed as WSR ; or
- [ ] Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).
- [ ] Proposal is exempt under RCW .

**Title of rule and other identifying information:** (describe subject) Chapter 246-570 WAC, The Department of Health (department) is proposing epinephrine autoinjectors and anaphylaxis training and reporting for authorized entities.

**Hearing location(s):**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Location: (be specific)</th>
<th>Comment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 12, 2017</td>
<td>10:30AM</td>
<td>Department of Health Town Center 2, Rm 145 111 Israel Road SE Tumwater, WA 98501</td>
<td></td>
</tr>
</tbody>
</table>

**Date of intended adoption:** 10/24/2017 (Note: This is **NOT** the effective date)

**Submit written comments to:**

Name: Brett Lorentson
Address: Washington State Department of Health PO Box 47852 Olympia, WA 98504-7852
Email: https://fortress.wa.gov/doh/policyreview
Fax: 360-236-2901
Other: 
By (date) 10/12/2017

**Assistance for persons with disabilities:**

Contact Brett Lorentson
Phone: 360-236-4611
Fax: 360-236-2901
TTY: (360) 833-6388 or 711
Email: Brett.Lorentson@doh.wa.gov
Other: 
By (date) 10/06/2017

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** The proposed rules will implement RCW 70.54.440 and will establish new rules and standards for epinephrine autoinjectors and anaphylaxis training and reporting for authorized entities. The proposed rules set standards for training providers, training content, and providing proof of training.
**Reasons supporting proposal:** Prescribing health care practitioners may prescribe epinephrine autoinjectors to authorized entities as defined in the statute. These entities or organizations may acquire, stock and administer epinephrine autoinjectors. The statute requires the department to establish standards for training of employees and other certification requirements to implement this law.

**Statutory authority for adoption:** RCW 70.54.440 and RCW 43.70.040

**Statute being implemented:** RCW 70.54.440

<table>
<thead>
<tr>
<th>Is rule necessary because of a:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal Law?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal Court Decision?</td>
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<tr>
<td>State Court Decision?</td>
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</tbody>
</table>

If yes, CITATION:

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:** None

**Name of proponent:** (person or organization) Department of Health

<table>
<thead>
<tr>
<th>Private</th>
<th>Public</th>
<th>Governmental</th>
</tr>
</thead>
</table>

**Name of agency personnel responsible for:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Office Location</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brett Lorentson</td>
<td>111 Israel Rd SE, Tumwater, WA 98504-7852</td>
<td>360-236-4611</td>
</tr>
</tbody>
</table>

**Is a school district fiscal impact statement required under RCW 28A.305.135?**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

**Is a cost-benefit analysis required under RCW 34.05.328?**

**Yes:** A preliminary cost-benefit analysis may be obtained by contacting:

Name: Brett Lorentson
Address: Department of Health
PO Box 7852
Olympia, WA 98504-7852
Phone: 360-236-4611
Fax: 360-236-2901
TTY: (360) 833-6388 or 711
Email: Brett.Lorentson@doh.wa.gov
Other:

<table>
<thead>
<tr>
<th>No</th>
<th>Please explain:</th>
</tr>
</thead>
</table>
Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

- [ ] This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

- [ ] This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

- [ ] This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

- [ ] This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:
  - [ ] RCW 34.05.310(4)(b)
    (Internal government operations)
  - [ ] RCW 34.05.310(4)(c)
    (Incorporation by reference)
  - [ ] RCW 34.05.310(4)(d)
    (Correct or clarify language)
  - [ ] RCW 34.05.310(4)(e)
    (Dictated by statute)
  - [ ] RCW 34.05.310(4)(f)
    (Set or adjust fees)
  - [ ] RCW 34.05.310(4)(g)
    ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

- [ ] This rule proposal, or portions of the proposal, is exempt under RCW .

Explanation of exemptions, if necessary:

**COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES**

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

- [x] No  Briefly summarize the agency’s analysis showing how costs were calculated. The probably costs of the proposed rules are minimal administrative costs. The minor cost threshold is calculated below. The department estimates that the proposed rule does not impose more than minor costs on businesses. NAICS code/description: 611430, Professional and Management Development Training Total Establishments: 202Paid Employees: 1,297Annual Payroll ($1,000): 73,580Threshold calculation: (73,580*1,000/202)*(0.01) = 3,642NAICS code/description: 611699, All other Miscellaneous Schools and Instruction Total Establishments: 250Paid Employees: 1,598Annual Payroll ($1,000): 53,279Threshold calculation: (53,279*1,000/250)*(0.01) = 2,131

- [ ] Yes  Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

- Name:
- Address:
- Phone:
- Fax:
- TTY:
- Email:
- Other:

**Date:** 08/22/2017

**Name:** John Wiesman, DrPH, MPH

**Title:** Secretary of Health

**Signature:** [Signature]

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NEW SECTION

WAC 246-570-001 Purpose. The purpose of this chapter is to establish the requirements for epinephrine autoinjectors and anaphylaxis training for employees and representatives of authorized entities under RCW 70.54.440.

NEW SECTION

WAC 246-570-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly indicates otherwise.

(1) "Administer" or "administration" means the direct application of an epinephrine autoinjector to the body of an individual.

(2) "Authorized entity" means any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present including, but not limited to, restaurants, recreation camps, youth sports leagues, amusement parks, colleges, universities, and sports arenas.

(3) "Department" means the Washington state department of health.

(4) "Dispenser" means a health care provider who may dispense epinephrine autoinjectors pursuant to a prescription issued in the name of an authorized entity.

(5) "Epinephrine autoinjector" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.

(6) "Prescriber" means an authorized health care provider allowed by law to prescribe an epinephrine autoinjector in the course of professional practice.

(7) "Training provider" means an organization, entity, business, or individual who provides epinephrine autoinjector and anaphylaxis training.

(8) "Self-administration" means a person's discretionary use of an epinephrine autoinjector on themselves.

NEW SECTION

WAC 246-570-020 Proof of epinephrine autoinjector and anaphylaxis training to obtain an epinephrine autoinjector for an authorized entity. Prior to prescribing or dispensing an epinephrine autoinjector to an authorized entity, a prescriber or dispenser may require proof of epinephrine autoinjector and anaphylaxis training.
NEW SECTION

WAC 246-570-030 Epinephrine autoinjector and anaphylaxis training certification. An employee or representative of an authorized entity must complete an epinephrine autoinjector and anaphylaxis training program prior to providing or administering an epinephrine autoinjector made available by an authorized entity.

NEW SECTION

WAC 246-570-040 Approved epinephrine autoinjector and anaphylaxis training provider. (1) Epinephrine autoinjector and anaphylaxis training must be conducted by:
(a) A nationally recognized organization experienced in training laypersons in emergency health treatment. For the purposes of this section, the American Red Cross anaphylaxis and epinephrine autoinjector training course is an approved training provider; or
(b) A training provider approved by the department must meet the following requirements:
   (i) Training content must meet the requirements in WAC 246-570-050;
   (ii) Each individual providing training must have:
       (A) Knowledge of epinephrine autoinjector and anaphylaxis; and
       (B) Experience delivering training in epinephrine autoinjector administration, and anaphylaxis causes and symptoms.
(2) A training provider shall issue a certificate to each person who successfully completes training. The certificate must include:
   (a) The training provider's name, address and other contact information;
   (b) Name of the training participant;
   (c) Date the training was completed;
   (d) Expiration date, if any; and
   (e) The name of the training or other information indicating that the training was in anaphylaxis and epinephrine autoinjector storage, maintenance, and administration.

NEW SECTION

WAC 246-570-050 Epinephrine autoinjector and anaphylaxis training content. (1) Epinephrine autoinjector and anaphylaxis training may be conducted online or in person and at a minimum, must include:
(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 autoinjector;
(c) Emergency follow-up procedures;
(d) The use and administration of an epinephrine autoinjector with adults and children; and
(e) An assessment to ensure the participant gained competency in anaphylaxis and epinephrine autoinjector administration.
(2) Training must be based on current best practices.

NEW SECTION

WAC 246-570-060 Epinephrine autoinjector incident reporting. (1) Each authorized entity must report to the department each incident when an employee or representative who holds a training certificate under WAC 246-570-030 administers or provides an epinephrine autoinjector to a person believed to be suffering from anaphylaxis. (2) The incident report must be reported within five days of the incident. (3) The incident report must be on a form or format provided by the department.

NEW SECTION

WAC 246-570-070 Training approval process. The secretary will consider for approval any training program which meets the requirements as outlined in this chapter. (1) An authorized representative of the training program shall request approval on a form provided by the department. (2) The training program must submit documentation that its training content meets the requirements of WAC 246-570-050. (3) Upon the evaluation of a complete application, the secretary will grant or deny approval. (4) If the department notifies a training provider of the department's intent to deny or revoke approval, the training provider may request an adjudicative proceeding under chapter 246-10 WAC. A request for an adjudicative proceeding must be in writing, state the basis for contesting the adverse action, include a copy of the adverse notice and be served on and received by the department within twenty-eight days of the date the department mailed the adverse notice.