Significant Legislative Rule Analysis

Chapter 246-570 WAC
a Rule Concerning
Epinephrine autoinjectors and anaphylaxis training and reporting for authorized entities.

July 17, 2017
SECTON 1:
Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

An epinephrine autoinjector is a medical device used to deliver a single dose of epinephrine or adrenaline. Most epinephrine autoinjectors are spring-loaded syringes used for the treatment of acute allergic reactions to avoid or treat the onset of anaphylactic shock. Anaphylactic shock is a serious allergic reaction with rapid onset and may cause death.

The 2016 legislature passed Substitute Senate Bill (SSB) 6421 (chapter 10, Laws of 2016), codified as RCW 70.54.440 regarding epinephrine autoinjectors, *Epinephrine Autoinjectors—Prescribing to certain entities—Training—Liability—Incident reporting*. The statute does not apply to credentialed health care practitioners who may by law prescribe, dispense or administer epinephrine autoinjectors as part of their professional duties.

The statute applies to authorized entities choosing to obtain epinephrine autoinjectors. An authorized entity is defined as “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.” Before an authorized entity may obtain epinephrine autoinjectors, employees or representatives connected with the entity must complete an anaphylaxis and epinephrine autoinjector training.

RCW 70.54.440 requires the department to write rules to provide standards for authorized entities and training programs. Rules will define the process for reporting incidents of epinephrine autoinjector use to the department. In addition, rules will establish standards for trainings, so that training participants do not receive inaccurate information about anaphylaxis which could cause incorrect administration of epinephrine and increase risks to public safety.
SECTION 2:
Is a Significant Analysis required for this rule?

Yes, a significant analysis is required. RCW 34.05.328 requires a significant analysis for rules that adopts a new, or makes significant amendments to, a policy or regulatory program. However, the department has determined that no significant analysis is required for the following sections of rule:

<table>
<thead>
<tr>
<th>WAC Section</th>
<th>Reason</th>
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<tbody>
<tr>
<td>WAC 246-570-001 - Purpose of WAC 246-570-010 through 246-570-060</td>
<td>Does not meet the definition of significant legislative rule under RCW 34.05.328(5)(c).</td>
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<tr>
<td>WAC 246-570-010 Definitions.</td>
<td>Does not meet the definition of significant legislative rule under RCW 34.05.328(5)(c).</td>
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<tr>
<td>WAC 246-570-030 Epinephrine autoinjector and anaphylaxis training certification.</td>
<td>Does not meet the definition of significant legislative rule under RCW 34.05.328(5)(b)(v).</td>
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SECTION 3:
Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The goals and objectives of chapter 70.54 RCW are to improve injury and illness prevention and health promotion. RCW 70.54.440 meets those goals and objectives by providing the option for authorized entities to obtain epinephrine autoinjectors when individuals connected with the entity complete an approved training in epinephrine autoinjector and anaphylaxis. Authorized entities who obtain the epinephrine autoinjectors will be prepared to assist in the treatment of persons experience anaphylaxis in a timely manner consistent with the need for a quick response. Training will promote public safety by providing information to properly assess allergic reactions and administer epinephrine autoinjectors.

The proposed rules meet the specific objectives of RCW 70.54.440 by establishing standards for the following:

- Training providers,
- Training content,
- Certificates,
SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The goals and objectives of RCW 70.54.440 are met by providing clear and appropriate rules to set the standards for training providers and training content. Rulemaking is appropriate to promote clear and consistent standards so training participants receive accurate information about anaphylaxis leading to the correct administration of epinephrine, which will reduce patient risks and increase public safety.

The department determined that there are no feasible alternatives to rulemaking to require training providers to meet certain standards, and for training participants to acquire specific content relating to epinephrine autoinjectors and anaphylaxis.

SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

A. Proposed New Section - WAC 246-570-020 Proof of autoinjector and anaphylaxis training to obtain epinephrine autoinjector for an authorized entity.

Description

Previously, authorized entities did not have a route to obtain epinephrine autoinjectors, and prescriptions were provided to individuals with known allergies. The proposed rule provides the authority for a prescriber or dispenser to request proof of epinephrine autoinjector and anaphylaxis training from an employee or representative of the authorized entity.
Cost/Benefit Analysis

RCW 74.54.440 requires a certificate of completion of epinephrine autoinjector and anaphylaxis training in order to obtain an epinephrine autoinjector for an authorized entity. The rule imposes minimal or no costs in providing proof to a prescriber or dispenser. The benefit of providing proof demonstrates the authorized entity meets the training requirements of the statute and rules.

B. Proposed New Section - WAC 246-570-040 Approved epinephrine autoinjector and anaphylaxis training provider.

Description

This rule sets standards for training providers to be approved to provide epinephrine autoinjector and anaphylaxis training.

Cost/Benefit Analysis

- Subsections (1) (b) (ii) and (iii) of this proposed rule require training providers to have knowledge and experience in delivering training in epinephrine autoinjectors and anaphylaxis. The department determined through research and a survey that most training providers already have experience and knowledge with first aid many of which already have existing content about allergic reactions, anaphylaxis, and epinephrine. The addition of these elements to the training will add minimal costs to those training providers who do not already include these elements. These training providers will benefit from these additional requirements with the opportunity to train more individuals with the potential of increased revenue.

- RCW 70.54.440 requires training providers to provide certificates to persons who successfully complete the training. The training certificate acts as documentation for an authorized entity to obtain epinephrine autoinjector. Most training providers already provide a certificate of completion.

Subsections (2) (i) through (v) of this proposed rule requires a training provider to include specific information on training certificates. If a training provider needs to update the training certificates to meet the rule requirements, the training provider will incur any associated costs. Certificates may need to be updated to include the training providers contact information and specific information about the content of the training, “Name of the training or other information indicating that the training was in anaphylaxis and epinephrine autoinjector storage,
In response to a survey, one potential training provider reported that the cost to update their certificate to adhere to the proposed rule requirements would be approximately five dollars. This cost is administrative and has minimal impact to these businesses, while the benefit is clear documentation for authorized entities to obtain epinephrine autoinjectors. The benefits outweigh the costs of this rule subsection.

C. Proposed New Section - WAC 246-570-050 Epinephrine autoinjector and anaphylaxis training content.

Most of the proposed rule does not fit the definition for a significant analysis of the rule, by adopting or incorporating by reference without material change Washington state statute, RCW 34.05.328(5)(b)(iii).

Description

RCW 70.54.440 requires an epinephrine autoinjector training to include the following content: recognizing symptoms, requirements for storage, administration, and emergency procedures. The rule sets the standard to include content about difference of administration of epinephrine between adults and children. The rule sets the requirement for trainings to include a competency assessment.

Cost/Benefit Analysis

The following are portions of this rule section which require a significant analysis:

- Subsection (1) (d) The use and administration of an epinephrine autoinjector with adults and children.

This requirement of the proposed rule may cause minimal costs to update training in accordance with the rule. A training may only include general content on the use and administration of an epinephrine autoinjector and not specifically include content for both adults and children. However, training providers more than likely have the first aid and medical knowledge and experience to update materials or training content to meet this requirement without spending a great deal of time and effort. In response to a survey, one training provider reported that this content is already in their training and would not lead to additional costs. The benefit of providing content for the use and administration of an epinephrine autoinjector for both adults and children is to prevent incorrect epinephrine dosages from being administered. This will increase public safety with minimal costs for training providers.
• Subsection (1) (e) A mechanism to assess competency of the participant.

This requirement of the proposed rule may cause minimal costs to a training provider as they may need to add a mechanism to assess competency of trainees. Many training providers already have a mechanism to assess the competency of training participants. The competency assessment may be determined by the training provider such as a hands on demonstration or verbal or written examinations. The benefit of assessing competency of training participants is to identify areas where additional knowledge is needed to correctly administer epinephrine autoinjectors and recognize symptoms of anaphylaxis or severe allergic reaction. The benefit of these proposed rules outweighs the costs by increasing the likelihood of the correct use of epinephrine autoinjectors.

D. Proposed New Section - WAC 246-570-060 Epinephrine autoinjector incident reporting.

Most of the proposed rule does not fit the definition for a significant analysis of the rule, by adopting or incorporating by reference without material change Washington state statute, RCW 34.05.328(5)(b)(iii).

Description

RCW 70.54.440 requires authorized entities to report incidents of administering or providing an epinephrine autoinjector to a person believed to be suffering from anaphylaxis. The rule sets the standard to report the incident within five days of the incident.

Cost/Benefit Analysis

Subsection (2) requires authorized entities to report an incident within five days of the incident. The cost associated with this requirement is considered minimal and consists of the time to complete the incident report. Five days was selected to impress upon the authorized entities the importance of reporting the incident in a timely manner as well as to increase the likelihood the reported information is accurate. The department has already developed an online tool to reduce the time and effort to report incidents. The benefit of timely reporting outweighs the costs by improving the quality of the data shared with the department and the public on the use of epinephrine autoinjectors.

E. Propose New Section – WAC 246-570-070 Training approval process.

Description
RCW 70.54.440 allows the department of health to approve epinephrine autoinjector and anaphylaxis training providers. The proposed rule sets the standards for the approval process and references the adjudicative process for training providers that are denied or revoked.

Cost/Benefit Analysis

Training providers are required to submit documentation to demonstrate how they meet the requirements of the proposed chapter. Training providers will already meet or will need to adjust their training to meet the requirements. The cost for training providers will depend on the areas which are deemed deficient. Potential areas of deficiency have been addressed in B through D of this section of the significant analysis.

Costs for the actual submittal of documentation to the department will be minimal. The costs will consist of time spent completing the form. The benefit of submitting documentation for approval will be the opportunity to provide training to representatives of authorized entities.

SECTION 6:
Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

The department held two internal meetings with professions that are directly impacted by the statute which included prescribers and dispensers of medications. Representatives from the Medical Quality Assurance Commission, Nursing Care Quality Assurance Commission, Pharmacy Quality Assurance Commission, and Board of Osteopathic Physicians and Surgeons reviewed and provided input to the rule language.
In addition to seeking input from these professions, draft rule language was sent to training providers and authorized entities impacted by these rules. The department evaluated all input and incorporated some of the comments.

The department considered other requirements for entities and training programs; however, the statute gives the department limited authority to set requirements. The proposed rules are the least burdensome requirements while ensuring public health and safety.

The alternate version of this rule section included:

**WAC 246-570-070 Training approval process.**

The proposed rule sets the standards for the approval process and references the adjudicative process for training providers that are denied or revoked. Since the department is responsible for approving trainings under RCW 70.54.440 (4)(a) the department is required to following adjudicative proceedings under chapter WAC 246-10.

The department discussed an alternative of accepting trainings after training providers determined for themselves if they met the training requirements. The training providers would have been required to maintain documentation on how they met the training requirements. The alternative language was disregarded due to the department’s obligation to approve and provide training providers an opportunity to seek an adjudicative resolution when the department denies or revokes their training.

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**SECTION 7:**

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The proposed rules do not require those to whom it applies to take an action that violates requirements of another federal or state law.

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**SECTION 8:**
Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The proposed rules do not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:
Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

There are no federal regulations or statutes applicable to the same activity or subject matter.

SECTION 10:
Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There were no other identified federal, state or local laws applicable to the same activity or subject matter.