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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

04/16/2021 3:30 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Removes limitation on epinephrine dispensed to an entity

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/26/2021 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@oregon.gov

800 NE Oregon St., Suite 150
Portland, OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/26/2021

TIME: 9:30 AM

OFFICER: Rachel Melvin

ADDRESS: Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held via telephonic conference call. To participate, call 1-877-873-8017, participant code 139360#. Email written comment to pharmacy.rulemaking@oregon.gov by 4:30PM on 5/26/2021. Oral comment can be offered at the hearing on the date and time listed above.

NEED FOR THE RULE(S):

Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a vaccine.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

CDC Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination
<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>

FISCAL AND ECONOMIC IMPACT:

None anticipated.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

There are no known economic impacts to the Oregon Board of Pharmacy, small businesses or members of the public.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved in the development of proposed revisions to these rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

The proposed rule is a result of the current ongoing public health emergency.

AMEND: 855-041-2320

RULE SUMMARY: This rule removes the limit of the number of epinephrine devices that may be dispensed to an entity. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a vaccine.

CHANGES TO RULE:

855-041-2320

Epinephrine ¶¶

- (1) A pharmacist may fill an order for epinephrine to be used by trainees to treat an anaphylactic reaction. Trainees must be 18 years of age or older and must have responsibility for or contact with at least one (1) other person as a result of the trainee's occupation or volunteer status, such as, but not limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide or chaperone.¶¶
- (2) Individuals must successfully complete a training program approved by the Oregon Health Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:¶¶
 - (a) Statement of Completion; and¶¶
 - (b) Authorization to Obtain Epinephrine.¶¶
- (3) Acquisition of epinephrine from a pharmacy to be used for the treatment of allergic emergencies may occur in the following manners:¶¶
 - (a) A pharmacist may dispense epinephrine to a trainee upon presentation of the Statement of Completion and Authorization to Obtain Epinephrine certificate to a pharmacy when:¶¶
 - (A) A pharmacist may generate a prescription for; and dispense an emergency supply of epinephrine for not more than one adult and one child dose package, as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Epinephrine certificate.¶¶
 - (B) The pharmacist who generates the hardcopy prescription for epinephrine in this manner shall reduce the prescription to writing; and file the prescription in a manner appropriate for a non-controlled substance.¶¶
 - (C) Once the pharmacist generates the epinephrine prescription, the pharmacist shall write in the appropriate space provided on the Authorization to Obtain Epinephrine certificate the date and the number of doses dispensed; and return the certificate to the trainee.¶¶
 - (D) The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used to obtain

epinephrine up to four (4) times within three (3) years from the date of the initial training.¶

(E) Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire three (3) years from the date of the trainee's last Oregon Health Authority approved allergy response training.¶

(F) Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.¶

(b) A pharmacist may dispense epinephrine to an entity when:¶

(A) The epinephrine is acquired by a valid prescription presented to the pharmacy;¶

(B) The prescription identifies the entity as the patient for the purpose of prescribing;¶

~~(i) The pharmacist shall use the name of the entity as the patient for the purpose of labeling the prescription.¶~~

~~(ii) The prescription shall be limited to one adult and one child dose package per trained employee per location.¶~~

(C) ~~For the purpose of this rule, an entity conducts business at a single physical loca and labeling the prescription.~~

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 433.825