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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 6-2021
CHAPTER 855
BOARD OF PHARMACY

FILED
03/24/2021 9:34 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Removes limitation on epinephrine dispensed to an entity

EFFECTIVE DATE: 03/24/2021 THROUGH 09/19/2021

AGENCY APPROVED DATE: 03/24/2021

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NEED FOR THE RULE(S):

For COVID-19 vaccines, appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.

JUSTIFICATION OF TEMPORARY FILING:

COVID-19 vaccination locations should have at least 3 doses of epinephrine available at all times, and the ability to quickly obtain additional doses to replace supplies after epinephrine is administered to a patient. If an entity providing COVID-19 vaccinations does not have enough epinephrine available on site while administering the vaccine, Oregonians that experience a reaction to the vaccine may be inadequately treated, possibly resulting in death. Failure to adopt this temporary rule could result in a decrease in access to COVID-19 vaccines.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>

AMEND: 855-041-2320

RULE SUMMARY: This temporary rule removes the limit of the number of epinephrine devices that may be dispensed to a entity. For COVID-19 vaccines, appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 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