

Secretary of State
NOTICE OF PROPOSED RULEMAKING*
A Statement of Need and Fiscal Impact accompanies this form

FILED
6-14-16 3:05 PM
ARCHIVES DIVISION
SECRETARY OF STATE

Board of Pharmacy	855
Agency and Division	Administrative Rules Chapter Number
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Rules Coordinator	Telephone
Board of Pharmacy, 800 NE Oregon St., # 150, Portland, OR 97232	
Address	

RULE CAPTION

Amends Division 041 rules for acquisition of epinephrine by an entity, pursuant to a prescription.

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION

Secure approval of rule numbers with the Administrative Rules Unit prior to filing

ADOPT:

AMEND:

855-041-2320

REPEAL:

RENUMBER: Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.

AMEND AND RENUMBER: Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.

Statutory Authority:

689.205

Other Authority:

Statutes Implemented:

689.155, 433.825

RULE SUMMARY

Division 041 Epinephrine rules are updated to incorporate 2013 legislative authority for an entity to acquire epinephrine for emergency use. These rules were previously noticed in May 2016 and are being re-noticed due to changes recommended by the Oregon Health Authority and staff clarifications.

Updated proposed rules are posted on the Board's website at: www.pharmacy.state.or.us.

A public rulemaking hearing may be requested in writing by 10 or more people, or by an association with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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.

<u>07-25-2016 4:30 p.m.</u>	<u>Karen MacLean</u>	<u>Karen.S.MacLean@state.or.us</u>
Last Day (m/d/yyyy) and Time for public comment	Rules Coordinator Name	Email Address

*The Oregon Bulletin is published on the 1st of each month and updates the rule text found in the Oregon Administrative Rules Compilation.

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855
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Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of:

Amends Division 041 rules for acquisition of epinephrine by an entity, pursuant to a prescription.

Statutory Authority:

689.205

Other Authority:

Statutes Implemented:

689.155, 433.825

Need for the Rule(s):

Rules are needed to incorporate a 2013 statute implemented in ORS 433.825 that specifically allows an entity to acquire epinephrine with a valid prescription when they employ someone who has completed an Oregon Health Authority approved training program for the treatment of allergic emergencies.

Documents Relied Upon, and where they are available:

ORS Chapter 433

Fiscal and Economic Impact:

None.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

None.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small business and types of businesses and industries with small businesses subject to the rule:

Approximately 50-100 pharmacy outlets registered with the Board are classified as small businesses. These rules allow a pharmacist to dispense epinephrine to a trainee upon presentation of a Statement of Completion and Authorization to Obtain Epinephrine certificate. These rules also allow a pharmacist to dispense epinephrine to an entity that employees a trained individual upon presentation of a prescription. This should not result in an increased cost of compliance.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

None.

c. Equipment, supplies, labor and increased administration required for compliance:

None.

How were small businesses involved in the development of this rule?

Small businesses were not involved in the development of this rule.

Administrative Rule Advisory Committee consulted?:No

If not, why?:

These rules were mandated by 2013 legislation. The Board consulted the Oregon Health Authority in the development of these rules.

07-25-2016 4:30 p.m.
Last Day (m/d/yyyy) and Time

Karen MacLean
Printed Name

Karen.S.MacLean@state.or.us
Email Address

for public comment

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310.

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