

OFFICE OF THE SECRETARY OF STATE

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ARCHIVES DIVISION

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**NOTICE OF PROPOSED RULEMAKING**  
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855  
BOARD OF PHARMACY

**FILED**

10/15/2024 8:55 AM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Provides exemption to registration requirement

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2024 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.*

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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: 11/26/2024

TIME: 9:30 AM

OFFICER: Rachel Melvin

REMOTE HEARING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 503-446-4951

CONFERENCE ID: 705344933

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony virtually during this hearing, sign up on our website at

[www.oregon.gov/pharmacy/pages/](http://www.oregon.gov/pharmacy/pages/)

rulemaking-information or email your first and last name and email address to

pharmacy.rulemaking@bop.oregon.gov. Please indicate which

rule(s) you would like to comment on.

You must submit written comments before 4:30PM on November 26, 2024. Email written comments to

pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Adds exemption to registration requirements for businesses or other establishments only distributing over-the-counter short-acting opioid antagonist drugs at no cost.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2023 HB 2395 <https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/HB2395/Enrolled>

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The proposed rule amendments are not expected to affect racial equity in this state.

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FISCAL AND ECONOMIC IMPACT:

No fiscal anticipated. Licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

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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).*

The proposed rule amendments will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

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

Registrants who identify as a small business and have signed up to receive rulemaking notices will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

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

No. The resources involved in convening an RAC were not necessary to amend this rule.

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AMEND: 855-035-0005

RULE SUMMARY: Proposes to amend rule by adding that a business or other establishment who only distribute over-the-counter short-acting opioid antagonist drugs at no cost are not required to register with the board as a nonprescription drug outlet.

CHANGES TO RULE:

855-035-0005  
Applications ¶¶

- (1) All applications for registration of a new or relocated proprietary drug outlet shall be accompanied by the required fees as set forth in 855-110-0007.¶¶
- (2) Application shall specify the location of the proprietary drug outlet. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant's affiliation with the owner:¶¶
  - (a) If the owner is a partnership or other multiple owner, the names of the partners or persons holding the five largest interests shall be indicated on the application.¶¶
  - (b) If the owner is a corporation, the name filed shall be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.¶¶
  - (c) Upon request by the Board, the applicant shall furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.¶¶
- (3) All registration renewal applications shall be accompanied by the annual fee and contain the same information required in subsections (2)(a), (b) and (c) of this rule.¶¶
- (4) If the annual registration fee referred to in section (1) of this rule is not paid by January 31 of the current year, a delinquent fee as set forth in OAR 855-110-0007 shall be included with the application for registration renewal.¶¶
- (5) A change of ownership or location requires a new application, fee and registration within 15 days of the change

.¶

(6) The registration certificate is issued to a person or firm and is non-transferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.¶

(7) The registration fee cannot be prorated.¶

(8) No nonprescription drug or medical gas authorized to be sold at retail under this registration shall be sold, given away, or otherwise disposed of until application has been approved and a certificate of registration issued. There shall be four types of drug outlet registrations:¶

(a) Class A shall be for all outlets except those that own more than one vending machine distributing more than six nonprescription drugs.¶

(b) Class B shall be for all outlets except those that own more than one vending machine distributing six or less nonprescription drugs.¶

(c) Class C shall be for all outlets distributing medicinal gases.¶

(d) Class D shall be for all outlets with more than one vending machine distributing nonprescription drugs.¶

(e) Class E shall be for any nonprofit, tax exempt, food distribution facility that distributes food products and nonprescription drugs at no cost, other than nominal delivery charges, to charitable organizations including regional food banks, for distribution at no cost to individuals. This registration, which shall be issued at no cost to the registrant, expires on January 31st annually.¶

Explanation:(f) The intention of this section is that an owner of a single vending machine that contains over-the-counter medications can register as either a Class A or Class B outlet based on the number of medications in the machine. The owner of more than one vending machine that contains over-the-counter medications shall register as a Class D outlet and inform the Board of their locations. Class E registration is intended for the Oregon Food Bank and other regional food banks located in Oregon.¶

(9) If there is more than one drug outlet under the same roof and each outlet is independently operated by different owners, a separate registration shall be obtained for each outlet.¶

(10) In case of loss of the certificate of registration, the Board may require a sworn statement before a notary public to be filed in the Board office before duplicate certificates of registration can be issued.¶

(11) Each vending machine that contains nonprescription drugs must have an obvious and legible statement on the machine that identifies the owner of the machine, advises the customer to check the expiration date of the product before using, and lists the phone number for the Board of Pharmacy.¶

(12) A Class D nonprescription drug outlet shall keep the Board informed in writing of the current location of all of its vending machines.¶

(13) Notwithstanding the requirements of this rule and the other rules in this Division, upon written request the Board may waive any of the requirements of this rule or the other rules in this Division if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing. ¶

(14) A business or other establishment that is only distributing over-the-counter short-acting opioid antagonist drugs at no cost is not required to register with the board as a nonprescription drug outlet.

Statutory/Other Authority: ORS 689.155, ORS 689.205

Statutes/Other Implemented: ORS 475.035, ORS 689.135, ORS 689.305