

OFFICE OF THE SECRETARY OF STATE

LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON



ARCHIVES DIVISION

STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

06/20/2024 11:33 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Eliminates Remote Dispensing Site Pharmacy (RDSP) general requirement related to mileage limitation

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/23/2024 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.

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@bop.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: 07/23/2024

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: 836629590

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/

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

pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.

You must submit written comments before 4:30PM on July 23, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes amending general requirements by eliminating the mileage limitation between a Remote Dispensing Site Pharmacy and its Affiliated Pharmacy.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

April 2024 Board Meeting Agenda, mailing #F

https://www.oregon.gov/pharmacy/Documents/April_2024_Bd_Mtg_Agenda.pdf

June 2024 Board Meeting Agenda, mailing #C

https://www.oregon.gov/pharmacy/Documents/June_2024_Bd_Mtg_Agenda.pdf

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

Proposed amendments provide clarity, transparency for licensees/registrants and promotes patient safety, no effects on racial equity are anticipated.

FISCAL AND ECONOMIC IMPACT:

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

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 will have no additional economic impact on state agencies, units of local government, or the public. The proposed rule applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.

The proposed rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

The proposed rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

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

Licensees and registrants who identify as a small business 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.

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

The resources involved in convening a RAC were not necessary to amend this rule. Board members represent the interests of persons and communities likely to be affected by a proposed rule and were able to provide information necessary to draft the proposed rule.

AMEND: 855-139-0200

RULE SUMMARY: Proposes to repeal (2) in its entirety eliminating mileage requirements between the RDSP and RDSP Affiliated Pharmacy. The Board received public feedback related to mileage requirements between the RDSP and RDSP Affiliated Pharmacy during the April 2024 board meeting. The Board discussed repealing (2) during the June 2024 board meeting.

CHANGES TO RULE:

855-139-0200

Outlet: General Requirements

(1) A RDSP Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.¶

- (2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.¶
- (3) A RDSP and its RDSP Affiliated Pharmacy must:¶
- (a) Have the same owner; or¶
 - (b) Have a written contract that specifies:¶
 - (A) The services to be provided by each licensee and registrant;¶
 - (B) The responsibilities of each licensee and registrant; and¶
 - (C) The accountabilities of each licensee and registrant;¶
 - (c) Ensure each prescription is dispensed in compliance with OAR 855-019115, OAR 855-0125 and OAR 855-139;¶
 - (d) Comply with all applicable federal and state laws and rules;¶
 - (e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians or Pharmacy Technicians authorized to access the RDSP and operate the telepharmacy system;¶
 - (f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians or Pharmacy Technicians in the operation of the telepharmacy system and RDSP;¶
 - (g) Develop, implement and enforce a continuous quality improvement program for dispensing services from a RDSP designed to objectively and systematically:¶
 - (A) Monitor, evaluate, document the quality and appropriateness of patient care;¶
 - (B) Improve patient care; and¶
 - (C) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence;¶
 - (h) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy; and¶
 - (i) Develop, implement and enforce a process for an in person physical inspection of the RDSP by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy. The inspection must utilize the RDSP self-inspection form, be documented, and records retained.

Statutory/Other Authority: ORS 689.205, ORS 689.700, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, ORS 689.700, 2022 HB 4034