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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

04/17/2024 2:35 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amends rule regarding delegation of final verification

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 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: 05/22/2024

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: 392711816

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 May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes adding "drug" and removing "form" in (3).

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

ORS 689.703 Final verification; delegation; rules https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

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. When the board sends the proposed rule to a rulemaking hearing, 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 rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

The 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: 855-115-0130

RULE SUMMARY: Proposed amendment adds "drug" and removes "form" from OAR 855-115-0130(3). The current rule permits a pharmacist to delegate final verification of a drug dosage "form" to a technician. ORS 689.703 does not permit final verification of the drug dosage "form" by a technician.

CHANGES TO RULE:

855-115-0130

Responsibilities: Practicing Pharmacy for a Drug Outlet

- (1) When practicing pharmacy per ORS 689 for a Drug Outlet, each Pharmacist must:
 - (a) Be responsible for the daily conduct, operation, management and control of the Drug Outlet pharmacy;
 - (b) Ensure that only a Pharmacist has access to the Drug Outlet pharmacy when the pharmacy is closed, except as permitted in OAR 855-041-6310;
 - (c) Ensure each prescription contains all the elements required in OAR 855-041 or OAR 855-139;
 - (d) Ensure the patient record contains the elements required in OAR 855-041 or OAR 855-139;
 - (e) Ensure prescriptions, prescription refills, and drug orders are dispensed:
 - (A) Accurately;

- (B) To the correct party;¶
- (C) Pursuant to a valid prescription; ¶
- (D) Pursuant to a valid patient-practitioner relationship; and ¶
- (E) For a legitimate medical purpose;¶
- (f) Ensure the Drug Outlet pharmacy is operated in a professional manner at all times; ¶
- (g) Ensure the drug outlet reports data as required by federal and state regulations, including but not limited to:¶
- (A) Prescription Drug Monitoring Program (PDMP) per ORS 413A.890, ORS 413A.895, ORS 413A.896, ORS 413A.898, and OAR 333-023;¶
- (B) Death with Dignity per ORS 127.800, ORS 127.805, ORS 127.810, ORS 127.815, ORS 127.820, ORS 127.825, ORS 127.830, ORS 127.835, ORS 127.840, ORS 127.845, ORS 127.850, ORS 127.855, ORS 127.860, ORS 127.865, ORS 127.870, ORS 127.875, ORS 127.880, ORS 127.885, ORS 127.890, ORS 127.892, ORS 127.895, ORS 127.897, and OAR 333-009;¶
- (C) Controlled substances per 21 CFR 1301.74 (v. 04/01/2022~~3~~); and¶
- (D) Listed chemicals per 21 CFR 1310.05 (v. 04/01/2022~~3~~); and¶
- (2) A Pharmacist who utilizes licensees remotely, must comply with OAR 855-041-3200 through OAR 855-041-3250.¶
- (3) When engaging in the practice of pharmacy per ORS 689, each Pharmacist may delegate final verification of drug and ~~drug dosage form~~, device, or product to a Certified Oregon Pharmacy Technician or Pharmacy Technician per ORS 689.005 when the following conditions are met:¶
- (a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;¶
- (b) The Certified Oregon Pharmacy Technician or Pharmacy Technician does not use discretion in conducting final verification;¶
- (c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and¶
- (d) Ensure the Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.¶

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.703