

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

08/17/2023 9:38 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Proactive procedural review; Pharmacists and Pharmacy Technicians

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/27/2023 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: 09/27/2023

TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Oregon Board of Pharmacy - Virtual Meeting , 800 NE Oregon St., Suite 150, Portland, OR 97232

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, email address and phone number 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 September 27, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

REMOTE MEETING DETAILS

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

PHONE NUMBER: 503-446-4951

CONFERENCE ID: 764448015

NEED FOR THE RULE(S)

Relocates and reorganizes existing Pharmacist rules from Division 019 related to applicability, definitions and counseling. Removes some prohibited practices for Certified Oregon Pharmacy Technicians and Pharmacy Technicians. Board staff are reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

OBOP 2022-2026 Strategic Plan https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

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

Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

FISCAL AND ECONOMIC IMPACT:

None anticipated

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).

There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

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

Small businesses were not involved in the development of proposed revisions to these rules.

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

Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

RULES PROPOSED:

855-115-0001, 855-115-0005, 855-115-0145, 855-125-0150

ADOPT: 855-115-0001

RULE SUMMARY: Proposed rule relocates and revises existing rule OAR 855-019-0100 to OAR 855-115-0001 related to applicability. Removes provision for Interns that is now included in OAR 855-120-0135 and removes board waiver of rule. Clarifies which pharmacists working for out-of-state pharmacies must be licensed by the board.

CHANGES TO RULE:

855-115-0001

Applicability

(1) This Division applies to any Pharmacist who engages in the practice of pharmacy.¶

(2) Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance with statutes and rules unless exempt under ORS 689.225. ¶

(3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a pharmacist located in another state who is working for an out-of-state licensed Drug Outlet

Pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification is not required to be licensed by the board unless they are the Pharmacist-in-charge (PIC).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.255

ADOPT: 855-115-0005

RULE SUMMARY: Proposed rule relocates and revises the existing definition of "Counseling" from OAR 855-019-0110 and adds revised definition of "Drug utilization review" or "DUR" from OAR 855-006-0005 to OAR 855-115-0005.

CHANGES TO RULE:

855-115-0005

Definitions

(1) "Counseling" or "Counsel" means an oral, electronic or written communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.¶

(2) "Drug utilization review" or "DUR" means evaluation of a prescription to identify and resolve potential problems through the review of information provided to the Pharmacist by the patient, patient's agent, prescriber and the patient's record.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155

RULE SUMMARY: Proposed rule relocates and revises existing rule from OAR 855-019-0230 to OAR 855-115-0145 related to counseling. Clarifies circumstances that require a Pharmacist to offer counseling, removes reference to Intern provided counseling that is now included in OAR 855-120-0135, introduces provisions for written counseling and supplemental information when required by federal law, permits any board licensee to accept declination of counseling and adds requirements for documentation of the licensee's identity for counseling, attempts to counsel or declination of counseling.

CHANGES TO RULE:

855-115-0145

Counseling

(1) For each prescription, the pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.¶

(2) The pharmacist must counsel the patient or patient's agent on the use of a drug or device upon request.¶

(3) The pharmacist must offer to counsel the patient or patient's agent on the use of a drug or device:¶

(a) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;¶

(b) When there has been a change in the dose, formulation, or directions;¶

(c) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or¶

(d) For any refill that the pharmacist deems counseling is necessary. ¶

(4) When communicating (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the pharmacist is proficient in the patient's preferred language.¶

(5) For a prescription where counseling has only been provided in writing, the pharmacist must provide drug information in a format accessible by the patient, including information on when the pharmacist is available and how the patient or patient's agent may contact the pharmacist.¶

(6) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused:¶

(a) Only a licensee can accept a patient's or patient's agent's request not to be counseled, when counseling is required.¶

(b) The pharmacist may choose not to release the prescription until counseling has been completed.¶

(7) Counseling must be provided under conditions that maintain patient privacy and confidentiality.¶

(8) Counseling, offers to counsel or declinations of counseling regarding prescriptions must be documented with the licensee's identity.¶

(9) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-125-0150

RULE SUMMARY: Proposed rule relocates and revises portions of existing rule in OAR 855-019-0200(3) to OAR 855-125-0150 related to prohibited practices for Certified Oregon Pharmacy Technicians and Pharmacy Technicians. Each Certified Oregon Pharmacy Technician and Pharmacy Technician must adhere to specific limitations and responsibilities, which include refraining from engaging in the practice of pharmacy, not performing tasks requiring judgment without pharmacist verification, not engaging in discriminatory behavior, and not refusing Pharmacist interactions requested by patients, patient agents, or practitioners.

CHANGES TO RULE:

855-125-0150

Prohibited Practices

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:

(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0105(4), including but not limited to the following tasks:

(a) Evaluate and interpret a prescription;

(b) Conduct a Drug Utilization Review or Drug Regimen Review;

(c) Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription that requires judgment;

(d) Counsel a patient or the patient's agent regarding a prescription;

(e) Advise on therapeutic values, content, hazards and use of drugs and devices;

(f) Interpret the clinical data in a patient record system or patient chart;

(g) Conduct Medication Therapy Management;

(h) Practice pursuant to a Clinical Pharmacy Agreement or Collaborative Drug Therapy Management;

(i) Practice pursuant to Statewide Drug Therapy Management Protocols;

(j) Prescribe a vaccine, drug or device;

(k) Administer a drug or device;

(l) Order, interpret or monitor a laboratory test;

(m) Supervise, direct, or control another licensee in the licensee practicing or assisting in the practice of pharmacy;

(n) Delegate tasks to healthcare providers; and

(o) Deny the patient or the patient's agent request to speak to the Pharmacist.

(2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.

(3) Perform any task while assisting in the practice of pharmacy that requires judgment unless it is verified by a Pharmacist.

(4) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace.

(5) Refuse a request from a patient, patient's agent, or practitioner to interact with a Pharmacist.

Statutory/Other Authority: ORS 689.205, ORS 689.225

Statutes/Other Implemented: ORS 689.155