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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

10/19/2023 5:00 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Pharmacists; Applicability, Definitions, Supervision, Counseling, PIC Qualifications & Limitations, CPA & CDTM

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/21/2023 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.

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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: 11/21/2023

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

REMOTE MEETING DETAILS

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

PHONE NUMBER: 503-446-4951

CONFERENCE ID: 343868791

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 November 21, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

855-115-0001 Applicability - Proposed rule adds new language related to applicability. Relocates and revises OAR 855-019-0001 related to applicability. Removes waiver authority and reference to Interns.

855-115-0005 Definitions - Relocates and reorganizes existing rules from Division 006 and 019 related to definitions of CPA, CDTM, Counseling and DUR. Board staff are reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

855-115-0122 - Adds proposed new rule to clarify required ratios for supervision of Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians. For direct patient care activities, rule allows a pharmacist to supervise up to 4 interns regardless of learning setting (e.g., school rotation or paid experience). For non-direct patient care activities, rule allows a pharmacist to supervise as many Interns they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare.

855-115-0145 Counseling - Relocates and reorganizes existing pharmacist rules from Division 019 related to counseling. Board staff are reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

855-115-0205 PIC: Qualifications and Limitations - In August 2023, the board adopted OAR 855-115-0200 effective 3/1/2024. The new rule that was adopted in August 2023 does not currently include requirements for a PIC between the effective date of the rule, 3/1/2024, and 7/1/2025. The current rule adopted also does not include limitations for a PIC. Proposed rule amendments add PIC qualification and limitation requirements. Having these requirements for a PIC will ensure public protection.

855-115-0315 Services: Clinical Pharmacy Agreement & Collaborative Drug Therapy Management - Relocates and revises existing CDTM rules from Division 019 into Division 115. Adds rules for CPA to Division 115.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

855-115-0001 Applicability- OBOP 2022-2026 Strategic Plan

https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

855-115-0005 Definitions - OBOP 2022-2026 Strategic Plan

https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

855-115-0122 Responsibilities: Supervision - OAR 855-120-1122 Responsibilities: Supervision - Preceptor, effective 3/1/2024 https://www.oregon.gov/pharmacy/Documents/Div_115_Pharmacists_BP_16-2023TrackedChanges.pdf

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

855-115-0145 Counseling - OBOP 2022-2026 Strategic Plan

https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

855-115-0205 PIC: Qualifications and Limitations - OAR 855-115-0200, effective 3/1/2024 (pg. 21)

https://www.oregon.gov/pharmacy/Documents/Div_115_Pharmacists_BP_16-2023TrackedChanges.pdf

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

855-115-0315 Services: CPA & CDTM – 5/4/2023 CDTM - CPA Workgroup Meeting Minutes

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

855-115-0001 Applicability, 855-115-0005 Definitions, 855-115-0122 Responsibilities: Supervision, 855-115-0145

Counseling, 855-115-0205 PIC: Qualifications and Limitations and 855-115-0315 Services: CPA & CDTM - The proposed rules are not expected to affect racial equity in this state.

FISCAL AND ECONOMIC IMPACT:

855-115-0001 Applicability – Pharmacists who are not working for a drug outlet and not included in the exemption would be required to obtain licensure in Oregon which depending on the method of licensure (e.g., reciprocity, score transfer, examination) costs between \$346.25 – \$396.25 (including fees) initially. In addition, pharmacists may need to pay an application fee to apply to transfer the North American Pharmacist Licensure Examination (\$85-\$185 per exam) score and/or pay an application fee (\$100 per exam) and take the Oregon Multistate Pharmacy Jurisprudence Examination (\$200). If the pharmacist chooses to renew their license, the biannual fee costs between \$324-374.

855-115-0005 Definitions - No anticipated fiscal and economic impact.

855-115-0122 Responsibilities: Supervision - Rule clarifies number of pharmacy Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians that can safely be supervised by a pharmacist. These licensees may increase the efficiency of a pharmacist by allowing them to direct their efforts to professional activities, therefore may positively impact an organizations bottom line.

855-115-0145 Counseling – An offer for the pharmacist to counsel must be made by a licensee. Pharmacies that utilize non-licensed personnel (i.e., clerks) may experience an increase in labor costs to ensure compliance with the rule. Per indeed.com, on average an Oregon Pharmacy clerk base salary is \$18.39/hr, Pharmacy Technician \$24.97/hr and Certified Pharmacy Technician \$29.96/hr. Acceptance of declination of counseling by a non-Pharmacist licensee may result in a decrease in labor costs. Per indeed.com, on average an Oregon Pharmacist base salary is \$63.07/hr.

855-115-0205 PIC: Qualifications and Limitations – Rule requires PIC to be an employee of the Drug Outlet. There may be an additional cost or savings to the Drug Outlet when employing a PIC instead of contracting with a PIC who is not an employee. These costs or savings are uncertain as this information is not currently available.

855-115-0315 Services: CPA & CDTM - No anticipated fiscal and economic impact.

Licensees, registrants and stakeholders may 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).

855-115-0001 Applicability, 855-115-0005 Definitions, 855-115-0122 Responsibilities, 855-115-0145 Counseling, 855-115-0205 PIC: Qualifications and Limitations, and 855-115-0315 Services: CPA and CDTM:

(1) The proposed new rule has no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule amendments 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.

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

(c) 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?

855-115-0001 Applicability, 855-115-0005 Definitions, 855-115-0122 Responsibilities: Supervision, 855-115-0145 Counseling, and 855-115-0205 PIC:Qualifications and Limitations - No. The board did not direct staff to convene a RAC or Workgroup to advise on the proposed rules. Board members represent the interests of persons and communities likely to be affected by the proposed rules and were able to provide expertise when drafting the proposed rules.

855-115-0315 Services: CPA & CDTM - No. The board directed staff to convene a CDTM – CPA Workgroup consisting of Subject Matter Experts with expertise related to CDTMs/CPAs to assist with the development of proposed rules/amendments. The CDTM/CPA workgroup held a meeting on 5/4/2023 and reviewed and provided input on all proposed rules/amendments related to CDTM and CPAs. The board reviewed and discussed the proposed rules at the October 2023 board meeting. Board members represent the interests of persons and communities likely to be affected by a proposed rule. Overall, board members are licensees of the Oregon Board of Pharmacy or public members who represent Oregon.

RULES PROPOSED:

855-115-0001, 855-115-0005, 855-115-0122, 855-115-0145, 855-115-0205, 855-115-0315

ADOPT: 855-115-0001

RULE SUMMARY: Proposed new rule relocates and revises existing rule language from 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 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 registered 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). This exception applies only when a pharmacist is dispensing, delivering or distributing drugs into Oregon from a registered drug outlet. A pharmacist who is providing other pharmacy services into Oregon must be licensed in Oregon.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.255

ADOPT: 855-115-0005

RULE SUMMARY: Rule relocates and revises existing definitions from OAR 855-006-0005, OAR 855-019-0110, OAR 855-019-0260 to OAR 855-115-0005 related to definitions.

CHANGES TO RULE:

855-115-0005

Definitions

(1) "Clinical Pharmacy Agreement" means an agreement between a Pharmacist or pharmacy and a health care organization, or a Physician as defined in ORS 677.010 or a Naturopathic Physician as defined in ORS 685.010 that permits the Pharmacist to engage in the practice of clinical pharmacy as defined in ORS 689.005 for the benefit of the patients of the health care organization, or Physician or Naturopathic Physician.¶

(2) "Collaborative Drug Therapy Management" means the process in which a Pharmacist or pharmacy and a health care provider or group of health care providers agree to a pre-specified drug therapy management protocol that is initiated for an individual patient on the prescription or prescription drug order of a participating provider.¶

(3) "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.¶

(4) "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

ADOPT: 855-115-0122

RULE SUMMARY: New rule that applies to all Pharmacists and aligns with previously adopted rule in OAR 855-120-1122 Responsibilities: Supervision- Preceptor. Permits a Pharmacist to supervise up to four Interns for direct patient care activities and supervise a suitable number for non-direct care activities. Clarifies in rule that the limit for supervision, direction and control of a COPT/PT is as determined by Pharmacist.

CHANGES TO RULE:

855-115-0122

Responsibilities: Supervision

(1) When supervising a Certified Oregon Pharmacy Technician or Pharmacy Technician, each Pharmacist may supervise as many Certified Oregon Pharmacy Technicians or Pharmacy Technicians as they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare.¶

(2) When supervising an Intern, each Pharmacist may supervise:¶

(a) No more than four Interns participating in direct patient care activities.¶

(b) As many Interns as they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare for Interns participating in non-direct patient care activities such as informational health fairs that provide general information, but not patient-specific information.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: 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 provide counseling, removes reference to Intern provided counseling that is now included in OAR 855-120-0135, introduces provisions for written counseling, requires supplemental information when required by federal law, permits any board licensee to offer for a pharmacist to provide counseling or accept declination of offer for pharmacist 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) Counseling must be provided or offered to be provided to 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. ¶

(3) An offer for the pharmacist to counsel under (1) and (2) must be made by a licensee.¶

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

(5) 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.¶

(6) 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.¶

(7) 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.¶

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

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

(10) 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: 855-115-0205

RULE SUMMARY: Proposed new rule adds PIC qualifications and limitations currently in rule from OAR 855-019-0300 to be effective 3/1/2024 to 6/30/2025. Utilizes PIC qualifications adopted by the board in OAR 855-115-0200 and adds limitations currently in rule from OAR 855-019-0300 effective 7/1/2025. Adds additional requirement that PIC must be employed by the outlet.

CHANGES TO RULE:

855-115-0205

Pharmacist-in-Charge: Qualifications and Limitations

(1) Effective March 1, 2024, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must have:

(a) Completed at least one year of pharmacy practice; or

(b) Completed a board provided PIC training course either before the appointment or within 90 days after the appointment; and

(c) Be employed by the outlet.

¶

(2) A Pharmacist must not be designated PIC of more than three pharmacies. The following drug outlet types do not count towards this limit:

(a) Pharmacy Prescription Kiosks in OAR 855-141; and

(b) Pharmacy Prescription Lockers in OAR 855-143.

(3) Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:

(a) Complete a board-provided PIC training course as described below:

(A) A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90 days after appointment.

(B) A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to the appointment.

(b) Complete a board provided PIC training course at least every five years.

(c) Be employed by the outlet.

(d) Not be designated PIC of more than three pharmacies. The following drug outlet types do not count towards this limit:

(A) Pharmacy Prescription Kiosk in OAR 855-141; and

(B) Pharmacy Prescription Locker in OAR 855-143.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-115-0315

RULE SUMMARY: Adds requirements for Pharmacists who provide Clinical Pharmacy Agreement services under a written protocol and modifies requirements from OAR 855-019-0260 for Pharmacists who provide Collaborative Drug Therapy Management services under a written protocol; relocates and revises existing language from OAR 855-019-0260. Requires protocol version to be documented.

CHANGES TO RULE:

855-115-0315

Services: Clinical Pharmacy Agreement & Collaborative Drug Therapy Management

- (1) A Pharmacist or pharmacy may engage in the practice of clinical pharmacy under a written Clinical Pharmacy Agreement with health care organization, Physician or Naturopathic Physician.¶
- (2) If the agreement in (1) is made with a health care organization, the organization is responsible for ensuring that each protocol utilized by a Pharmacist or pharmacy to provide clinical pharmacy services:¶
 - (a) Is developed and overseen by a Physician or Naturopathic Physician acting within their scope.¶
 - (b) Is reviewed by each participating health care provider.¶
 - (c) Does not allow any act that is prohibited by ORS 475, ORS 689 and OAR 855.¶
- (3) Each protocol developed under the agreement in (1) must include:¶
 - (a) The name of the principal Pharmacist and principal Physician or Naturopathic Physician who is responsible for:¶
 - (A) Initial training and ongoing competency assessment for participating Pharmacists; if necessary:¶
 - (B) Development, quality assurance and updating or discontinuing each protocol;¶
 - (b) The identification, either by name or by description, of each participating Pharmacist:¶
 - (c) The identification, either by name or description, of each participating Physician, Naturopathic Physician or health care provider within a health care organization. These persons must have scope to independently treat patients.¶
 - (d) The disease state or patient panel for which the Pharmacist may provide clinical pharmacy services:¶
 - (e) Types of clinical pharmacy services provided:¶
 - (f) Circumstances that require communication from the participating Pharmacist to the patient's Physician, Naturopathic Physician or health care provider within the health care organization such as:¶
 - (A) Information collected:¶
 - (B) Patient assessment:¶
 - (C) Plan of care including follow-up:¶
 - (D) Services provided; and¶
 - (E) Circumstances requiring urgent communication with the patient's health care provider; and¶
 - (g) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary.¶
- (4) A Pharmacist may engage in Collaborative Drug Therapy Management under a written protocol with a health care provider who is acting within their scope. ¶
- (5) Each protocol developed under the agreement in (4) must include:¶
 - (a) The name of the principal Pharmacist and health care provider who are responsible for:¶
 - (A) Initial training and ongoing competency assessment for participating Pharmacists, if necessary; and¶
 - (B) Development, quality assurance and updating or discontinuance of each protocol; ¶
 - (b) The identification, either by name or by description, of each participating Pharmacist:¶
 - (c) The identification, by name or description, of each participating health care provider or group of health care providers:¶
 - (d) A detailed description of the: ¶
 - (A) Indications:¶
 - (B) Drugs including dosage, frequency, duration and route of administration:¶
 - (C) Methods; ¶
 - (D) Procedures:¶
 - (E) Decision criteria; and ¶
 - (F) Plan the Pharmacist is to follow:¶
 - (e) Documentation the Pharmacist is to complete concerning actions taken and a plan or appropriate mechanism for communication, feedback, and reporting to the health care provider concerning specific actions taken.¶
 - (f) Circumstances which will cause the Pharmacist to initiate communication with the health care provider:¶
 - (g) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary:¶
- (6) Each protocol developed in (1) and (4) must be reviewed and updated, or discontinued at least every two years:¶

(7) The Pharmacist must document the protocol version and all clinical pharmacy activities in the prescription record, patient profile, electronic health record or in some other appropriate system.¶

(8) Records and documents must be retained according to OAR 855-104-0055.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155