OFFICE OF THE SECRETARY OF STATE

TOBIAS READ SECRETARY OF STATE

MICHAEL KAPLAN
DEPUTY SECRETARY OF STATE



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

06/26/2025 9:24 AM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Updates incorporated standards adopted by reference

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/22/2025 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: 07/22/2025 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: 429564160 SPECIAL INSTRUCTIONS:

This hearing 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. Please indicate which

rule(s) you would like to comment on.

You must submit written comments before 4:30PM on July 22, 2025. Email written comments to

pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposed amendments incorporate updated standards adopted by reference as required by the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (OAR 855-102-0045).

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Adopted Standards by Reference:

Part 1301 – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances - 21 CFR (04/01/2024)

Accreditation Council on Pharmaceutical Education (ACPE) Accredited Providers of Continuing Pharmacy Education (05/27/2025)

ACCME List of Recognized State Medical Society Accreditors (05/27/2025)

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.

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.

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.

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

Registrants who identify as a small business and who have signed up to receive 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.

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

No. Amendments are required per ORS 183.337 pursuant to ORS 475.035 and ORS 475.055.

RULES PROPOSED:

855-115-0130, 855-135-0001

AMEND: 855-115-0130

RULE SUMMARY: Proposes to revise referenced versions of the Code of Federal Regulations (CFR) in (1)(g)(C)(D).

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; \P
- (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; \P
- (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. 04/01/20234); and ¶
- (D) Listed chemicals per 21 CFR 1310.05 (v. 04/01/20234); and ¶
- (2) A Pharmacist who utilizes licensees remotely, must comply with OAR 855-041-3200 through OAR 855-041-3250. \P
- (3) When engaging in the practice of pharmacy per ORS 689, each Pharmacist may delegate final verification of drug and drug dosage, 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

AMEND: 855-135-0001

RULE SUMMARY: Proposes revising reference versions of ACPE and ACCME in (1)(a)(b).

CHANGES TO RULE:

855-135-0001

Continuing Pharmacy Education: Definitions

- (1) "Accredited program" means a structured continuing pharmacy education (CPE) program which has been reviewed and approved by a provider of: ¶
- (a) Continuing pharmacy education that is accredited by the Accreditation Council on Pharmaceutical Education (ACPE) (v. 06/015/27/20225);¶
- (b) Continuing medical education (CME) accredited by the Accreditation Council for Continuing Medical Education (ACCME) or an ACCME-recognized State Medical Society (v. 065/27/20225) as an American Medical Association (AMA) Category 1 CME program; or ¶
- (c) Continuing veterinary medical education (CVME) approved by the American Association of Veterinary State Boards Registry of Approved Continuing Education (AAVSB-RACE) as a medical program.¶
- (2) "Board-approved program" means a structured continuing pharmacy education program which has been reviewed and approved by the board.¶
- (3) "Certificate of completion" means a certificate or other official document issued to a participant certifying the successful completion of a continuing pharmacy education program.¶
- (4) "Continuing Pharmacy Education" or "CPE" means an accredited or board-approved program designed to support the continuing development of Pharmacists, Interns, Certified Oregon Pharmacy Technicians or Pharmacy Technicians to maintain and enhance their competence applicable to the practice of pharmacy or the assistance of the practice of pharmacy. ¶
- (5) "Contact hour" means sixty minutes of continuing pharmacy education. ¶
- (6) "CPE Monitor" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy (NABP) for monitoring continuing pharmacy education that Pharmacists, Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians receive from participating providers;¶
- (7) "Cultural competence" means the lifelong process of examining the values and beliefs and developing and applying an inclusive approach to health care practice in a manner that recognizes the content and complexities of provider-patient communication and interaction and preserves the dignity of individuals, families, and communities.¶
- (a) Cultural competence applies to all patients.¶
- (b) Culturally competent providers do not make assumptions on the basis of an individual's actual or perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital status, socio-economic status, veteran's status, sexual orientation, gender identity, gender expression, gender transition status, level of formal education, physical or mental disability, medical condition or any consideration recognized under federal, state and local law.¶
- (8) "Medication error prevention" means the prevention of events that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer. ¶
- (9) "Patient safety" means the prevention of healthcare related errors or the elimination or mitigation of patient injury caused by healthcare related errors. ¶
- (10) "Pain management education program" means a specific one-hour web-based program developed by the Pain Management Commission of the Oregon Health Authority.¶
- (11) "Pharmacy law" means the body of laws relating to pharmacy practice.¶
- (12) "Structured continuing pharmacy education" or "Structured CPE" means education that includes defined learning objectives, qualified instructors, learning assessment, and a program evaluation.

Statutory/Other Authority: ORS 689.205, ORS 676.850

Statutes/Other Implemented: ORS 413.450, ORS 413.590, ORS 689.255, ORS 689.285, ORS 689.486, ORS 689.490