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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

12/21/2022 9:27 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Incorporates rules to address safe pharmacy practice conditions

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 01/26/2023 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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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: 01/26/2023

TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Oregon Board of Pharmacy, 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 contact information to pharmacy.rulemaking@bop.oregon.gov to receive the link to join the virtual meeting. Please indicate which rule(s) you would like to comment on.

You must submit written comments before 4:30PM on January 26, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

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REMOTE MEETING DETAILS

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

PHONE NUMBER: 503-446-4951

SPECIAL INSTRUCTIONS:

Phone Conference ID = 294 493 511#

NEED FOR THE RULE(S)

Amends general responsibilities for Pharmacist. Amends outlet personnel and grounds for discipline.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Safe Pharmacy Practice Conditions Workgroup meeting minutes:

January 2022 https://www.oregon.gov/pharmacy/Documents/January_2022_SPPC_WKGP_Mtg_Minutes.pdf

March 2022 https://www.oregon.gov/pharmacy/Documents/March_2022_SPPC_WKGP_Mtg_Minutes.pdf

May 2022 https://www.oregon.gov/pharmacy/Documents/May_2022_SPPC_WKGP_Mtg_Minutes.pdf

July 2022 https://www.oregon.gov/pharmacy/Documents/July_2022_SPPC_WKGP_Mtg_Minutes.pdf

September 2022

https://www.oregon.gov/pharmacy/Documents/September_2022_SPPC_WKGP_Mtg_Minutes.pdf

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

Adopting the proposed amendments may increase patient safety for all Oregonians in every community by ensuring that licensees have a properly staffed working environment to ensure safe pharmacy practice conditions. A properly staffed working environment may create fewer opportunities for medication errors and increase the availability of the Pharmacist to provide necessary patient care services such as dispensing prescriptions, medication counseling and immunizations. Adds incentivizing or inducing a new prescription or the transfer of a prescription, which introduces additional clerical workload for pharmacy staff, to Drug Outlet Grounds for Discipline.

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).

None anticipated. The rulemaking imposes no additional mandatory reporting, recordkeeping, or other administrative requirements on small businesses.

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

Small businesses were not involved with the development of the proposed rules.

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

A Workgroup was convened per the board's direction.

RULES PROPOSED:

855-019-0200, 855-041-1010, 855-041-1170

AMEND: 855-019-0200

RULE SUMMARY: Proposed amendments in Division 019 clarify that the Pharmacist-on-duty has autonomy to control each aspect of the practice of pharmacy, which includes temporarily shutting down services if understaffed, responsibility for the conduct, operation, management and control of the pharmacy and conducting themselves in a professional manner.

CHANGES TO RULE:

Pharmacist: General Responsibilities ¶¶

ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A Pharmacist licensed to practice pharmacy by the board has the duty to use that degree of care, skill, diligence and reasonable professional judgment that is exercised by an ordinarily careful Pharmacist in the same or similar circumstances.¶¶

(1) A Pharmacist is responsible for their own actions; however, this does not absolve the pharmacy from responsibility for the Pharmacist's actions.¶¶

(2) A Pharmacist and pharmacy are responsible for the actions of Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians.¶¶

(3) Only a Pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require reasonable professional judgment of a Pharmacist include but are not limited to:¶¶

(a) Drug Utilization Review;¶¶

(b) Counseling;¶¶

(c) Drug Regimen Review;¶¶

(d) Medication Therapy Management;¶¶

(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;¶¶

(f) Practice pursuant to State Drug Therapy Management Protocols;¶¶

(g) Prescribing a drug or device, as authorized by statute;¶¶

(h) Ordering, interpreting and monitoring of a laboratory test;¶¶

(i) Oral receipt or transfer of a prescription; and¶¶

(j) Verification of the work performed by those under their supervision.¶¶

(4) A Pharmacist must:¶¶

(a) Comply with all state and federal laws and rules governing the practice of pharmacy;¶¶

(b) Control each aspect of the practice of pharmacy;¶¶

(c) Ensure each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;¶¶

(d) Ensure non-Pharmacist personnel only perform duties they are licensed and trained to perform.¶¶

(e) Know the identity of each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction and control at all times;¶¶

(f) Ensure that their supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, determine how many licensed individuals the Pharmacist is capable of supervision of non-Pharmacist personnel does not exceed their capacity to supervise based on the workload and services being provided.¶¶

(g) Ensure there is sufficient staff to provide services in a safe manner. The Pharmacist on duty may temporarily shut down a service or services if the Pharmacist determines, in their reasonable professional judgment, that there is insufficient staff to practice in a safe manner.¶¶

(h) Conduct the services being provided in a professional manner at all times and not engage in any form of discrimination, harassment, intimidation, or assault in the workplace.¶¶

(i) Ensure and enforce the drug outlet written procedures for use of Certified Oregon Pharmacy Technicians and Pharmacy Technicians as required by OAR 855-025-0035;¶¶

(j) Ensure the security of the pharmacy area including:¶¶

(A) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;¶¶

(B) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;¶¶

(C) Ensuring that only a Pharmacist has access to the pharmacy when the pharmacy is closed.¶¶

(5) A Pharmacist may delegate final verification of drug and 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.¶¶

(6) A Pharmacist may permit an Intern under their direction and supervision to perform any task listed in OAR 855-019-0200(3), except that an Intern ~~may~~must not:

(a) Perform the duties of a Pharmacist until after the Intern has successfully completed their first academic year, and only after successful completion of coursework corresponding to those duties;

(b) Prescribe a drug or device; or

(c) Perform final verification or verification as defined in OAR 855-006-0005.

(7) Each Pharmacist on duty and the PIC is responsible for the conduct, operation, management and control of the pharmacy:

Statutory/Other Authority: ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.025, ORS 689.151, ORS 689.155, ORS 689.645, ORS 689.682, ORS 689.689, 2022 HB 4034

AMEND: 855-041-1010

RULE SUMMARY: Proposed amendments in Division 041 add requirements for each Drug Outlet to provide a working environment that protects the health, safety and welfare of a patient which includes sufficient personnel, rest periods, meal breaks, time to complete professional duties and responsibilities, to abide by the Pharmacist-on-duty's decision to shut down services and to respond substantively to a Pharmacist concern of insufficient staffing.

CHANGES TO RULE:

855-041-1010

~~Personnel (Both Retail and Institutional Drug Outlets) Outlet (RP & IP): Personnel~~

~~(1) Each Drug Outlet Pharmacy must:~~

~~(1) Have one Pharmacist-in-charge employed on a regular basis at that location who shall be responsible for the daily operation of the pharmacy. The Pharmacist-in-charge shall be indicated on the application for a new or relocated pharmacy and for pharmacy renewal registration.~~

~~(2) A resident pharmacy that reports terminating or allowing a Board licensee to resign in lieu of termination must report the termination or resignation to the board within 10 working days.~~

~~(3) Ensure that it is in compliance with all state and federal laws and rules governing the practice of pharmacy.~~

~~(4) Provide a working environment that protects the health, safety and welfare of a patient which includes but not limited to:~~

~~(a) Sufficient personnel to prevent fatigue, distraction to the Board within 10 working day or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.~~

~~(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.~~

~~(3c) A pharmacy must ensure that it is in compliance with all state and federal laws and rules governing the practice of pharmacy adequate time for a Pharmacist to complete professional duties and responsibilities as specified in OAR 855-019;~~

~~(d) Ensure there is sufficient staff to provide services in a safe manner. The outlet must abide by the Pharmacist-on-duty's decision to temporarily shut down a service or services and must respond substantively to a Pharmacist who has identified staffing concerns.~~

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305

AMEND: 855-041-1170

RULE SUMMARY: Proposed amendments in Division 041 amends grounds for discipline to include failing to provide a working environment that protects the health, safety and welfare of a patient, overriding or interfering with the Pharmacist-on-duty's control of all aspects of the practice of pharmacy, and incentivizing or inducing a new prescription or the transfer of a prescription.

CHANGES TO RULE:

855-041-1170

Outlet (RP & IP): Grounds for Discipline ¶¶

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:¶¶

(1) Unprofessional conduct as defined in OAR 855-006-00205;¶¶

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:¶¶

(a) Is false, fraudulent, deceptive, or misleading; or¶¶

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.¶¶

(3) ~~Failure~~reing to provide a working environment that protects the health, safety and welfare of a patient ~~which includes but is not limited to: as required in OAR 855-041-1010.~~¶¶

~~(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.¶¶~~

~~(b) Appropriate opportunities for uninterrupted rest periods and meal breaks. Incentivizing or inducing a new prescription or the transfer of a prescription. ¶¶~~

~~(c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:¶¶~~

~~(A) Drug Utilization Review;¶¶~~

~~(B) Immunization;¶¶~~

~~(C) Counseling;¶¶~~

~~(D) Verification of the accuracy of a prescription; and¶¶~~

~~(E) All other duties and responsibilities of a pharmacist as specified in Division 19 of this chapter of rules.¶¶~~

~~(4) Introducing external factors such as productivity or production quotas or o~~Overriding or interfering with the Pharmacist-on-duty's control of all aspects of their programs to the extent that they interfere with the ability to provide appropriate professional services to the public~~actice of pharmacy. ¶¶~~

~~(5) Incenting or inducing the transfer of a prescription absent professional rationale~~Any other grounds found in ORS 689.405 or ORS 689.490.

Statutory/Other Authority: ORS 689.151, ORS 689.155(2), ORS 689.205, ORS 689.225(4)

Statutes/Other Implemented: ORS 689.155