# OFFICE OF THE SECRETARY OF STATE

CHERYL MYERS **ACTING SECRETARY OF STATE** & TRIBAL LIAISON



#### **ARCHIVES DIVISION**

STEPHANIE CLARK **DIRECTOR** 

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# NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855 **BOARD OF PHARMACY**  **FILED** 

06/15/2023 4:02 PM **ARCHIVES DIVISION** SECRETARY OF STATE

FILING CAPTION: Adopts new Division 104 for Universal Rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/26/2023 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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Filed By:

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Portland, OR 97232

Rachel Melvin

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Rules Coordinator

## HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 07/26/2023 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: 627978258** 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 July 26, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

# **NEED FOR THE RULE(S)**

Creates new Division 104. Relocates and amends existing procedural rules from Division 001 to new Division 104. Relocates OAR 855-041-1167 to OAR 855-104-0050. Relocates OAR 855-010-0130 to OAR 855-104-0150. After the board permanently adopts and publishes Division 104, repeals Division 001, OAR 855-041-1167 and OAR 855-010-0130 on the effective date of Division 104.

## DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

None available.

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

Proposed rules provide clarity for licensees, and registrants. It is anticipated that the proposed rules will not impact any group of people differently than others.

# 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 the proposed rule amendments.

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

Board staff recommends adopting the proposed rules for transparency and clarity for licensees and registrants.

# **RULES PROPOSED:**

855-104-0005, 855-104-0010, 855-104-0015, 855-104-0050, 855-104-0055, 855-104-0060, 855-104-0100, 855-104-0105, 855-104-0110, 855-104-0115, 855-104-0150

ADOPT: 855-104-0005

RULE SUMMARY: Proposed universal rule for applicants, licensees and registrants related to "Duty to Cooperate" requirements. Relocates and amends existing rule from OAR 855-001-0030 to OAR 855-104-0005.

**CHANGES TO RULE:** 

## 855-104-0005

Duty to Cooperate

(1) Applicants, licensees, and registrants must timely comply with all board requests, including responding accurately, fully and truthfully to inquiries and providing requested materials within the time allowed by the board and complying with a subpoena. ¶

(2) Applicants, licensees, and registrants must comply with the terms of board orders and agreements. Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 676.612

RULE SUMMARY: Proposed new universal rule for licensee responsibilities related to "Duty to Report".

**CHANGES TO RULE:** 

# 855-104-0010

Responsibilities: Duty to Report

(a) 10 days if they:¶

(A) Are convicted of a misdemeanor or a felony; or ¶

(B) Are arrested for a felony; or ¶

(C) Have reasonable cause to believe that any suspected violation of ORS 475, ORS 689 or OAR 855 has occurred.¶

(b) 10 working days if they have reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct to that licensee's board; or ¶

(c) 15 days, if any change in:¶

(A) Legal name;¶

(B) For Pharmacists and Interns, name used when engaging in the practice of pharmacy and for Certified Oregon Pharmacy Technicians and Pharmacy Technicians, name used when assisting in the practice of pharmacy.¶

(C) Preferred email address;¶

(D) Personal phone number;¶

(E) Personal physical address;¶

(F) Personal mailing address; and ¶

(G) Employer.¶

(2) A licensee who reports to a board in good faith as required by ORS 676.150 is immune from civil liability for making the report.¶

(3) A Pharmacist, Certified Oregon Pharmacy Technician or Pharmacy Technician who reports to a board in good faith as required by ORS 689.455 is not subject to an action for civil damages as a result thereof.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 676.150, ORS 689.155, ORS 689.455, ORS 689.486

RULE SUMMARY: Proposed new universal rule related to licensee and registrant responsibilities regarding

"Confidentiality".

**CHANGES TO RULE:** 

# 855-104-0015

Responsibilities: Confidentiality

(1) No licensee or registrant of the board who obtains any patient information may disclose that information to a third-party without the consent of the patient except as provided in (2)(a)-(e) of this rule.¶

(2) A licensee or registrant may disclose patient information:

(a) To the board;¶

(b) To a practitioner, Pharmacist, Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician or registrant, if disclosure is authorized by a Pharmacist and disclosure is necessary to protect the patient's health or well-being; or ¶

(c) To a third-party when disclosure is authorized or required by law; or ¶

(d) As permitted pursuant to federal and state patient confidentiality laws; or \[ \]

(e) To the patient or to persons as authorized by the patient.¶

(3) A licensee or registrant of the board may not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (2)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315

Statutes/Other Implemented: ORS 689.155

RULE SUMMARY: Proposed new universal rule relocates existing licensee and registrant requirements related to "Patients Access to Pharmacy Records" from OAR 855-041-1167 to newly created OAR 855-104-0050.

**CHANGES TO RULE:** 

#### 855-104-0050

Patients Access to Pharmacy Records

(1) Licensees and registrants of the board must make health information in the pharmacy record available to the patient or the patient's representative upon their request, to inspect and obtain a copy of health information about the individual, except as provided by law and this rule. The patient may request all or part of the record. A summary may substitute for the actual record only if the patient agrees to the substitution. Board licensees and registrants are encouraged to use the written authorization form provided by ORS 192.566.¶

(2) For the purpose of this rule, "health information in the pharmacy record" means any oral, written or electronic information in any form or medium that is created or received and relates to:¶

(a) The past, present, or future physical or mental health of the patient. ¶

(b) The provision of healthcare to the patient.¶

(c) The past, present, or future payment for the provision of healthcare to the patient. ¶

(3) Upon request, the entire health information record in the possession of the board licensee will be provided to the patient. This includes records from other healthcare providers. Information which may be withheld includes:¶ (a) Information which was obtained from someone other than a healthcare provider under a promise of confidentiality and access to the information would likely reveal the source of the information;¶

(b) Psychotherapy notes;¶

(c) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and ¶

(d) Other reasons specified by federal regulation.¶

(4) Registrants who have permanently closed must notify patients according to OAR 855-041-1092.¶

 $(5) A \, reasonable \, cost \, may \, be \, imposed \, for \, the \, costs \, incurred \, in \, complying \, with \, the \, patient's \, request \, for \, health \, information \, pursuant \, to \, ORS \, 192.563. \P$ 

(6) A patient may not be denied summaries or copies of pharmacy records because of inability to pay. ¶

(7) Requests for pharmacy records must be complied with within a reasonable amount of time not to exceed 30 days from the receipt of the request.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 192.553, ORS 192.556, ORS 192.558, ORS 192.563, ORS 192.566

RULE SUMMARY: Proposed new universal rule adds licensee and registrant requirements related to "Record and

Document Retention".

CHANGES TO RULE:

#### 855-104-0055

Record and Document Retention

(1) Each licensee and registrant must create documents and retain records required by ORS 475, ORS 689, and

OAR 855. Documents and records:¶

(a) May be in written or electronic format; ¶

(b) Must be stored securely;¶

(c) Must be made available to the board upon request; and \( \big| \)

(d) Must be retained for 3 years except that:¶

(A) Clinical pharmacy records must be retained for 7 years; and ¶

(B) Training records for immunization administration and protocol and formulary compendia prescribing, must be retained for 6 years or uploaded into the licensee's electronic licensing record with the board;¶

(2) Records generated by a registrant:¶

(a) Must be stored on-site by the registrant for at least 12 months and must be provided to the board immediately upon request at the time of inspection; ¶

(b) May be stored in a secured off-site location after 12 months of storage at the registrant and must be provided to the board upon request within 3 business days;¶

(3) Records generated in the practice of pharmacy that do not belong to a registrant must be stored by a

Pharmacist in a secure manner and provided to the board upon request within 3 business days;¶

(4) Records must be retained for longer periods of time than required under this rule if: ¶

(a) Federal law provides for a longer retention schedule; or ¶

(b) Licensee or registrant has received notice of a Board investigation to which the records would be relevant; ¶

(c) Licensee or registrant has received a Board request to retain the records for a longer period of time.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.508

RULE SUMMARY: Placeholder for future rules related to "Public Records Request to the Board".

**CHANGES TO RULE:** 

855-104-0060

Public Records Request to the Board

<u>Placeholder</u>

<u>Statutory/Other Authority: ORS 689.205</u> <u>Statutes/Other Implemented: ORS 192.440</u>

RULE SUMMARY: Proposed universal rule related to requirements for requesting a contested case hearing. Relocates existing rule from OAR 855-001-0012 to OAR 855-104-0100.

**CHANGES TO RULE:** 

# 855-104-0100

Time for Requesting a Contested Case Hearing

A request for a contested case hearing must be in writing and must be received by the board within 21 days from the date the contested case notice was served. When the board has issued a denial of a license, a request for a contested case hearing must be in writing and must be received by the board within 60 days from the date the licensure denial was served.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 183.435

RULE SUMMARY: Proposed universal rule related to requirements for filing exceptions and argument to the board. Relocates and amends existing rule from OAR 855-001-0016 to OAR 855-104-0105.

**CHANGES TO RULE:** 

# 855-104-0105

Filing Exceptions and Argument to the Board

After a proposed order has been served on a party, the party has 30 days to file written exceptions with the board from receipt of the proposed order.

<u>Statutory/Other Authority: ORS 689.205</u> <u>Statutes/Other Implemented: ORS 689.151</u>

RULE SUMMARY: Proposed universal rule related to requirements for petition for reconsideration or rehearing as condition for judicial review. Relocates exisiting rule from OAR 855-001-0017 to OAR 855-104-0110.

**CHANGES TO RULE:** 

# 855-104-0110

Petition for Reconsideration or Rehearing as Condition for Judicial Review

All parties, including limited parties, must file a petition for reconsideration or rehearing with the board as a condition for obtaining judicial review of any order of the board.

<u>Statutory/Other Authority: ORS 689.205</u> <u>Statutes/Other Implemented: ORS 689.151</u>

RULE SUMMARY: Proposed universal rule related to licensee and registrant requirements for "Inspections". Relocates existing rule from OAR 855-001-0040 to OAR 855-104-0115.

**CHANGES TO RULE:** 

#### 855-104-0115

<u>Inspections</u>

- (1) A Compliance Officer is a board authorized representative and must be permitted entry to any drug outlet to conduct inspections at all reasonable hours. ¶
- (2) The Compliance Officer is authorized and must be permitted to perform the following to determine compliance with ORS 475, ORS 689, and OAR 855 and board orders including but not limited to:¶
- (a) Inspecting conditions, structures, equipment, materials, and methods for compliance: ¶
- (b) Inspecting all drugs and devices;¶
- (c) Taking photographs, recording video and audio; and ¶
- (d) Reviewing, verifying and making copies of records and documents.¶
- (3) All licensees and employees must fully comply and cooperate with all questions and requests made by the

Compliance Officer at the time of inspection. ¶

(4) Refusal to allow inspection is grounds for discipline.

Statutory/Other Authority: ORS 475.125, ORS 689.205

Statutes/Other Implemented: ORS 689.155

RULE SUMMARY: Proposed universal rule related to licensure requirements and process regarding "Military Spouse or Domestic Partner". Relocates and amends existing rule from OAR 855-010-0130 to OAR 855-104-0150, adds "intern".

**CHANGES TO RULE:** 

#### 855-104-0150

Military Spouse or Domestic Partner Licensure Process

- (1) "Military spouse or domestic partner" means a spouse or domestic partner of an active member of the Armed Forces of the United States who is the subject of a military transfer to Oregon. ¶
- (2) To qualify for licensure under this rule, the military spouse or domestic partner must meet the following requirements: ¶
- (a) Meet the qualifications for licensure as stated in OAR 855-115, OAR 855-120 or OAR 855-125.¶
- (b) Be married to, or in a domestic partnership with, a member of the Armed Forces of the United States who is assigned to a duty station located in Oregon by official active duty military order;¶
- (c) Applicant must complete an application for licensure, provide the board with a valid email address, and complete and pass a national fingerprint-based criminal background check;¶
- (d) Provide evidence of current licensure as a pharmacist, intern or pharmacy technician issued by another state;¶ (e) Provide to the board, in a manner determined by the board, sufficient proof that the person is in good standing with the issuing out-of-state professional licensing board; and ¶
- (f) Demonstrate competency as a pharmacist, intern or pharmacy technician by having at least one year of active practice during the three years immediately preceding the application.¶
- (3) A temporary authorization under this section is valid until the earliest of the following: ¶
- (a) Two years after the date of issuance; ¶
- (b) The date the spouse or domestic partner of the person to whom the authorization was issued completes the spouse's term of service in this state; or ¶
- (c) The date the person's authorization issued by the other state expires. ¶
- (4) A temporary authorization issued under this section is not renewable.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.265, ORS 670.400, ORS 670.403