

OFFICE OF THE SECRETARY OF STATE

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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

12/22/2023 8:13 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Repeals Division 001; Procedural Rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 01/24/2024 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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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: 01/24/2024

TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Oregon Board of Pharmacy - Virtual Hearing, 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: 618712182

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 January 24, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Repeals Division 001 Procedural Rules in its entirety, effective at 11:59PM on 2/29/2024.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

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

The proposed rule repeal is not expected to affect racial equity in this state.

FISCAL AND ECONOMIC IMPACT:

The proposed rule repeal has no anticipated fiscal and economic impact.

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 repeal 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):

Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

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

The board adopted new Division 104 Universal rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

RULES PROPOSED:

855-001-0000, 855-001-0005, 855-001-0012, 855-001-0016, 855-001-0017, 855-001-0035, 855-001-0040

REPEAL: 855-001-0000

RULE SUMMARY: Repeals Division 001 Procedural Rules in its entirety. The board adopted Division 104 Universal Rules in August 2023, which replaces Division 001. Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

~~855-001-0000~~

~~Notice of Proposed Rule ¶¶~~

~~Prior to the permanent adoption, amendment, or repeal of any rule, the State Board of Pharmacy must give notice of its intended action as required in ORS 183.335:¶¶~~

~~(1) In a manner established by rule adopted by the board under ORS 183.341(4), which provides a reasonable opportunity for interested persons to be notified of the agency's proposed action;¶¶~~

~~(2) In the bulletin referred to in ORS 183.360 at least 21 days prior to the effective date;¶¶~~

~~(3) To persons who have requested notice pursuant to ORS 183.335(8) at least 28 days before the effective date; and¶¶~~

~~(4) To persons specified in ORS 183.335(15) at least 49 days before the effective date; and¶¶~~

~~(5) To persons or organizations the Board's Executive Director determines, pursuant to ORS 183.335, are interested persons in the subject matter of the proposed rule, or would be likely to notify interested persons of~~

the proposal; and¶¶

(a) Oregon State Pharmacy Association;¶¶

(b) Oregon Society of Health System Pharmacists;¶¶

(6) To the Associated Press and the Capitol Press Room.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 183.335

REPEAL: 855-001-0005

RULE SUMMARY: Repeals Division 001 Procedural Rules in its entirety. The board adopted Division 104 Universal Rules in August 2023, which replaces Division 001. Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

~~855-001-0005~~

~~Model Rules of Procedure ¶¶~~

~~Pursuant to the provisions of ORS 183.341, the Board of Pharmacy adopts the Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act effective 07/2019. These rules must be controlling except as otherwise required by statute or rule. ¶¶~~

~~[ED. NOTE: The full text of the Attorney General's Model Rules of Procedure is available from the office of the Attorney General or Board of Pharmacy.]~~

~~Statutory/Other Authority: ORS 183.341, ORS 689.205~~

~~Statutes/Other Implemented: ORS 183.341~~

REPEAL: 855-001-0012

RULE SUMMARY: Repeals Division 001 Procedural Rules in its entirety. The board adopted Division 104 Universal Rules in August 2023, which replaces Division 001. Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

~~855-001-0012~~

~~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~~

REPEAL: 855-001-0016

RULE SUMMARY: Repeals Division 001 Procedural Rules in its entirety. The board adopted Division 104 Universal Rules in August 2023, which replaces Division 001. Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

~~855-001-0016~~

~~Filing Exceptions and Argument to the Board ¶~~

~~After a proposed order has been served on a party, the board must notify the party when written exceptions must be filed to be considered by the board.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.151~~

REPEAL: 855-001-0017

RULE SUMMARY: Repeals Division 001 Procedural Rules in its entirety. The board adopted Division 104 Universal Rules in August 2023, which replaces Division 001. Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

~~855-001-0017~~

~~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.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.151~~

REPEAL: 855-001-0035

RULE SUMMARY: Repeals Division 001 Procedural Rules in its entirety. The board adopted Division 104 Universal Rules in August 2023, which replaces Division 001. Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

~~855-001-0035~~

~~Duty to Cooperate ¶~~

~~(1) Applicants, licensees, and registrants must comply with all board requests, including responding 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~~

REPEAL: 855-001-0040

RULE SUMMARY: Repeals Division 001 Procedural Rules in its entirety. The board adopted Division 104 Universal Rules in August 2023, which replaces Division 001. Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.

CHANGES TO RULE:

~~855-001-0040~~

~~Inspections ¶¶~~

~~(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 records and documents required by ORS 475, ORS 689, and OAR 855: ¶¶~~

~~(a) Must be stored on-site for 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 on-site storage and must be provided to the board upon request within three business days; and ¶¶~~

~~(c) May be in written or electronic format. ¶¶~~

~~(4) All licensees and employees must fully comply and cooperate with all questions and requests made by the Compliance Officer at the time of inspection. ¶¶~~

~~(5) Refusal to allow inspection is grounds for discipline.~~

~~Statutory/Other Authority: ORS 475.125, ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~