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> **ARCHIVES DIVISION**

SECRETARY OF STATE & LEGISLATIVE COUNSEL

PERMANENT ADMINISTRATIVE ORDER

BP 13-2024 CHAPTER 855 **BOARD OF PHARMACY**

FILING CAPTION: Repeals Division 001; Procedural Rules

EFFECTIVE DATE: 02/29/2024

AGENCY APPROVED DATE: 02/09/2024

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RULES:

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

NOTICE FILED DATE: 12/22/2023

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 Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.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 ORS183.341(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 ORS183.335(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 f

(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



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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 Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.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

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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

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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

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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

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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

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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