

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

10/24/2022 1:55 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Procedural and Universal Rules; Adopts new Division 102, repeals Division 001

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/22/2022 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.

CONTACT: Rachel Melvin
971-673-0001

800 NE Oregon St., Suite 150
Portland, OR 97232

pharmacy.rulemaking@bop.oregon.gov

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: 11/22/2022

TIME: 9:30 AM

OFFICER: Rachel Melvin

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 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.

Alternatively, you may dial

503-446-4951

Phone Conference ID:

146 611 440#

for audio only.

You must submit written comments before 4:30PM on November 22, 2022. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Creates new Division 102 and adopts existing procedural rules related to rulemaking, model rules of procedure, time for requesting a contested case hearing, filing exceptions to the board, petition for reconsideration or rehearing as condition for judicial review, duty to cooperate, inspections and records and document retention requirements. Repeals

Division 001.

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:

855-001-0000, 855-001-0005, 855-001-0012, 855-001-0016, 855-001-0017, 855-001-0035, 855-001-0040, 855-102-0005, 855-102-0010, 855-102-0015, 855-102-0020, 855-102-0025, 855-102-0035, 855-102-0040, 855-102-0050

REPEAL: 855-001-0000

RULE SUMMARY: Repeals Division 001. Relocates existing rules from Division 001 to newly created Division 102 Procedural and Universal Rules. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

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. Relocates existing rules from Division 001 to newly created Division 102 Procedural and Universal Rules. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

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. Relocates existing rules from Division 001 to newly created Division 102 Procedural and Universal Rules. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

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. Relocates existing rules from Division 001 to newly created Division 102 Procedural and Universal Rules. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

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. Relocates existing rules from Division 001 to newly created Division 102 Procedural and Universal Rules. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

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. Relocates existing rules from Division 001 to newly created Division 102 Procedural and Universal Rules. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

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. Relocates existing rules from Division 001 to newly created Division 102 Procedural and Universal Rules. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

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~~

ADOPT: 855-102-0005

RULE SUMMARY: Creates new Division 102 for procedural and universal rules. Proposed rules relocate existing procedural rules from Division 001 and adds rules related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public. Repeals Division 001.

CHANGES TO RULE:

855-102-0005

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

ADOPT: 855-102-0010

RULE SUMMARY: Creates new Division 102 for procedural and universal rules. Proposed rules relocate existing procedural rules from Division 001 and adds rules related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public. Repeals Division 001.

CHANGES TO RULE:

855-102-0010

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

ADOPT: 855-102-0015

RULE SUMMARY: Creates new Division 102 for procedural and universal rules. Proposed rules relocate existing procedural rules from Division 001 and adds rules related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public. Repeals Division 001.

CHANGES TO RULE:

855-102-0015

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

ADOPT: 855-102-0020

RULE SUMMARY: Creates new Division 102 for procedural and universal rules. Proposed rules relocate existing procedural rules from Division 001 and adds rules related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public. Repeals Division 001.

CHANGES TO RULE:

855-102-0020

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

ADOPT: 855-102-0025

RULE SUMMARY: Creates new Division 102 for procedural and universal rules. Proposed rules relocate existing procedural rules from Division 001 and adds rules related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public. Repeals Division 001.

CHANGES TO RULE:

855-102-0025

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

ADOPT: 855-102-0035

RULE SUMMARY: Creates new Division 102 for procedural and universal rules. Proposed rules relocate existing procedural rules from Division 001 and adds rules related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public. Repeals Division 001.

CHANGES TO RULE:

855-102-0035

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

ADOPT: 855-102-0040

RULE SUMMARY: Creates new Division 102 for procedural and universal rules. Proposed rules relocate existing procedural rules from Division 001 and adds rules related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public. Repeals Division 001.

CHANGES TO RULE:

855-102-0040

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 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

ADOPT: 855-102-0050

RULE SUMMARY: Creates new Division 102 for procedural and universal rules. Proposed rule adds a rule related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan to streamline rules and make rules easier to locate for licensees, registrants and the public.

CHANGES TO RULE:

855-102-0050

Record and Document Retention

(1) All records and documents required by ORS 475, ORS 689, and OAR 855:

(a) Must be retained for 3 years except that:

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

(B) Training records for patient care services, when required, must be retained for 3 years after ceasing participation in the activity requiring training;

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

(c) 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;

(d) May be in written or electronic format; and

(e) Made available to the board upon request.

(2) Records must be stored at the Drug Outlet for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days.

(3) Records generated under Independent Pharmacy Practice, must be stored at a health care organization, practitioner, pharmacy, or pharmacist office or in a secure location by the Pharmacist according to OAR 855-115-0100 for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days.

(4) Records must be written, electronic or a combination of the two.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508