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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

10/22/2020 3:39 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Proactive procedural rule review

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/24/2020 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
pharmacy.rulemaking@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: 11/24/2020

TIME: 8:30 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 via telephonic conference call. To participate, call 1-877-873-8017, participant code 139360#. Email written comment to pharmacy.rulemaking@oregon.gov by 4:30PM on 11/24/2020. Oral comment can be offered at the hearing on the date and time listed above.

NEED FOR THE RULE(S):

The revision to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the

Administrative Procedures Act 07/2019, ORS 689, ORS 676 and ORS 183. 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.

FISCAL AND ECONOMIC IMPACT:

There is no fiscal impact as a result of proposed rule changes.

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 Oregon Board of Pharmacy, 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 proposed revisions to these rules.

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

Changes made to rules were to align them with the latest edition of Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act and with the board's 2020-2024 Strategic Plan. There is no fiscal impact as a result of proposed rule changes.

RULES PROPOSED:

855-001-0000, 855-001-0005, 855-001-0010, 855-001-0012, 855-001-0015, 855-001-0016, 855-001-0035, 855-001-0040

AMEND: 855-001-0000

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

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 ~~shall~~must give notice of its intended action as required in ORS 183.335~~(4)~~:~~¶~~

(1) In a manner established by rule adopted by the ~~B~~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~~¶~~

(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 Pharmacists 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

AMEND: 855-001-0005

RULE SUMMARY: The revision to the proposed rule is to ensure clarity, transparency and promote patient safety.

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 ~~July 1, 07/2019~~. These rules ~~shall~~ 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: 855-001-0010

RULE SUMMARY: This rule is no longer relevant in order to be in compliance with current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act.

CHANGES TO RULE:

~~855-001-0010~~

~~Requiring an Answer to Charges as Part of Notices to Parties in Contested Cases~~

~~In addition to the requirements stated in rule 137-003-0505 of the Attorney General's Model Rules of Procedure adopted under OAR 855-001-0005, the notice to parties in contested cases may include a statement that an answer to the assertions or charges will be required, and if so, the consequences of failure to answer may be by enclosing a copy of rule 855-001-0015 with the notice.~~

~~Statutory/Other Authority: ORS 183~~

~~Statutes/Other Implemented: ORS 689~~

AMEND: 855-001-0012

RULE SUMMARY: The proposed revisions are necessary in order to be in compliance with current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act 07/2019 as is stated in OAR 855-001-0016.

CHANGES TO RULE:

855-001-0012

Time ~~F~~or Requesting a Contested Case Hearing ~~I~~

A request for a contested case hearing must be in writing and must be received by the ~~B~~board within ~~twenty-one~~ 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: 855-001-0015

RULE SUMMARY: This rule is no longer relevant in order to be in compliance with current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act.

CHANGES TO RULE:

~~855-001-0015~~

~~Hearing Request and Answers: Consequences of Failure to Answer~~

~~(1) A hearing request, and answer when required, shall be made in writing to the Board by the party or his attorney and an answer shall include the following:¶¶~~

~~(a) An admission or denial of each factual matter alleged in the notice;¶¶~~

~~(b) A short and plain statement of each relevant affirmative defense the party may have.¶¶~~

~~(2) Except for good cause:¶¶~~

~~(a) Factual matters alleged in the notice and not denied in the answer shall be presumed admitted;¶¶~~

~~(b) Failure to raise a particular defense in the answer will be considered a waiver of such defense;¶¶~~

~~(c) New matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and¶¶~~

~~(d) Evidence shall not be taken on any issue not raised in the notice and the answer.~~

~~Statutory/Other Authority: ORS 183~~

~~Statutes/Other Implemented:~~

AMEND: 855-001-0016

RULE SUMMARY: The proposed revisions are necessary in order to be in compliance with current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act.

CHANGES TO RULE:

855-001-0016

Filing Exceptions and Argument to the Board ¶

After a proposed order has been served on a party, the ~~B~~board ~~shall~~must notify the party when written exceptions must be filed to be considered by the Board and the Board shall notify the party when the party may appear before the Board to present argument regarding the proposed order board.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151

AMEND: 855-001-0035

RULE SUMMARY: The revision to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-001-0035

Duty to Cooperate ¶

~~Every~~ (1) Applicants, licensees, and registrant of the Board shall cooperate with the Board and shalls must comply with all board requests, including responding fully and truthfully to inquiries from and providing requested materials within the time allowed by the board and complying with any requests from the Board, subject only to the exercise of any applicable right or privilege 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 ~~689~~76.612

AMEND: 855-001-0040

RULE SUMMARY: The revision to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-001-0040

Inspections ¶

~~(1) The Board or a Compliance Officer its a board authorized representative may enter and shall be allowed entry to any drug outlet where drugs are stored, and the premises where the records associated with those drugs are stored, and must be permitted entry to any drug outlet to conduct inspections at reasonable times in a reasonable manner for the purpose of: all reasonable hours. ¶~~

~~(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept under the Uniform Controlled Substances Act, The Compliance Officer is authorized to perform and must be permitted to perform the following to determine compliance with the Oregon Pharmacy Act and these rule RS 475, ORS 689, and OAR 855 and board orders including; but not limited to, shipping: ¶~~

~~(a) inspecting records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each conditions, structures, equipment, materials, and methods for compliance; ¶~~

~~(b) inspecting within reasonable limits and a reasonable manner all pertinent equipment, finished and unfinished drugs and other substances or materials, containers, and labeling found at the drug outlet; all drugs and devices; ¶~~

~~(c) taking photographs, recording video and audio; and ¶~~

~~(ed) Making a physical inventory of all drugs on hand at the premises; ¶~~

~~(d) Collecting samples of drugs or ingredients; reviewing, verifying and making copies of records and documentation. ¶~~

~~(e) Checking of All records and information on distribution of drugs by the registrants as they relate to total distribution of the registrant; ¶~~

~~(f) All other things appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Uniform Controlled Substances Act, the Oregon Pharmacy Act and these rules. ¶~~

~~(2) The inspections hereunder may be conducted in connection with applications for initial or renewal registration or modification or amendment thereof and at such other times where the Board or its authorized representative determines that there is reasonable basis for concluding that inspection is necessitated in order to ensure that there is compliance with the Uniform Controlled Substances Act, the Oregon Pharmacy Act and these rules documentation required by ORS 475, ORS 689, and OAR 855 must be retained for three years, unless specified for longer, and made available for review to the Compliance Officer at the time of inspection. Records and documentation may be stored in a written or electronic format. Copies must be provided to the Compliance Officer at the time of inspection upon request. ¶~~

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

~~(35) Refusal to allow inspection is grounds for denial, suspension, or revocation of a registration discipline.~~

Statutory/Other Authority: ORS 475.125, ORS 689.205

Statutes/Other Implemented: ORS 689.155