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SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/16/2021 12:42 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Proactive procedural rule review

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/26/2021 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: 05/26/2021

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 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 5/26/2021. Oral comment can be offered at the hearing on the date and time listed above.

NEED FOR THE RULE(S):

Revisions 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:

None

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?

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

RULES PROPOSED:

855-001-0040, 855-041-1160, 855-041-6220

AMEND: 855-001-0040

RULE SUMMARY: Procedural rules revisions 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. ¶~~

~~(a2) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept under the Uniform Controlled Substances Act, the Oregon Pharmacy Act and these rule 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, ship: ¶~~

~~(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; ¶~~

~~(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; conditions, structures, equipment, materials, and methods for compliance; ¶~~

~~(b) Inspecting 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 ingredi Reviewing, verifying and making copies of records and documents; ¶~~

~~(e3) 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~~ 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 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 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. ¶~~

~~(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

AMEND: 855-041-1160

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

CHANGES TO RULE:

855-041-1160

~~Prescription Records and Retention Records~~ ¶

(1) Definitions. The following definitions apply to this rule:¶

(a) An "original prescription" is a prescription maintained in the same physical manner in which a pharmacy first receives the prescription. For example, for a prescription received by the pharmacy in writing on a prescription form, the original prescription consists of the original writing on the prescription form. For a prescription received by the pharmacy orally over the telephone, the original consists of the writing or electronic record that reflects receipt of the oral prescription.¶

(b) "Filing" and "file" mean the storage of the original prescription in such a manner that the original prescription is safeguarded and readily retrievable.¶

(2) Every pharmacy and pharmacist-in-charge of a pharmacy must ensure that original prescriptions are properly filed in compliance with this rule.¶

~~(3) All original prescriptions shall be filed for a minimum of three years from the date of first dispensing and shall at all times be open for inspection by the prescriber, and the Board of Pharmacy or its duly authorized agent.¶~~

~~(4) After 120 days, the paper prescription may be destroyed and filed in an electronic form if:¶~~

~~(a) The electronic form shows the exact and legible image of the original prescription;¶~~

~~(b) Notes of clarifications of and changes to the prescription are directly associated with the electronic form of the prescriptions; and¶~~

~~(c) The prescription is not for a controlled substance.¶~~

~~(5) This rule is not intended to alter or supersede the recordkeeping requirements of any other federal or Oregon statute or rule, including but not limited to ORS 689.508, OAR 855-041-1120, and rules related to records for prescriptions for controlled substances.¶~~

~~(6) Unless specified otherwise, all records and documentations required by OAR 855 division 041 must be retained for three years and made available RS 475, ORS 689, and OAR 855:¶~~

~~(a) Must be stored on-site for 12 months and must be provided to the Board for inspection upon request. Records must be stored immediately upon request.¶~~

~~(b) May be stored in a secured off-site for at least one year and may be stored in a secured off-site location if retrievable location after 12 months of on-site storage and must be provided to the board upon request within three business days. Records and documentation m; and¶~~

~~(c) May be in written, or electronic for a combination of the two mat.~~

Statutory/Other Authority: ORS 689.205

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

AMEND: 855-041-6220

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

CHANGES TO RULE:

855-041-6220

Records ¶

~~(1) Unless specified otherwise, a~~ All records and documentations ~~required by these rules, OAR 855-041-6000 through 855-041-6999 must be retained for three years and made available~~ ORS 475, ORS 689, and OAR 855:¶
~~(a) Must be stored on-site for 12 months and must be provided to the Bboard for inspection immediately upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable.¶~~

~~(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. Records and documentation m; and ¶~~

~~(c) May be written; or electronic for a combination of the two mat. ¶~~

(2) The PIC must ensure maintenance of written or electronic records and ~~report~~ documents as necessary to ensure patient health, safety and welfare. Records must include:¶

(a) Patient profiles and drug administration records;¶

(b) Reports of suspected adverse drug reactions;¶

(c) Inspections of drug storage areas;¶

(d) Annual controlled substance inventories;¶

(e) Controlled drug accountability reports;¶

(f) Collaborative Drug Therapy agreements;¶

(g) Current hospital drug formulary;¶

(h) Any other records and reports required by state and federal laws and regulations.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.508