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
10/19/2023 5:02 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Changes a Pharmacist may make to a Schedule II Prescription

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/21/2023 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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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: 11/21/2023
TIME: 9:30 AM
OFFICER: Rachel Melvin

HEARING LOCATION
ADDRESS: Oregon Board of Pharmacy - Virtual Meeting , 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: 343868791
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 November 21, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposed amendments add items that a Pharmacist may change on a Schedule II prescription.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Drug Enforcement Administration (DEA) Frequently Asked Questions- What changes can be made to a schedule II paper prescription?
Current 9/6/2023 https://www.deadiversion.usdoj.gov/faq/prescriptions_faq.htm
Historical 8/19/2003
https://web.archive.org/web/20030819182549/http:/www.deadiversion.usdoj.gov/faq/general.htm#rx_change
7/30/2009 https://web.archive.org/web/20090730020033/http:/www.deadiversion.usdoj.gov/faq/general.htm#rx-7
10/3/2014
https://web.archive.org/web/20141003152536/http:/www.deadiversion.usdoj.gov/faq/prescriptions.htm#rx-7

Other state regulations: IA Rule 657-10.30 https://www.legis.iowa.gov/docs/iac/rule/12-30-2020.657.10.30.pdf
IL Rule 3100.400 https://www.ilga.gov/commission/jcar/admincode/077/077031000004000R.html

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

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

FISCAL AND ECONOMIC IMPACT:

The proposed rule amendments have no anticipated fiscal and economic impact

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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).

(1) The proposed rule amendments have no additional economic impact on state agencies, units of local government, or the public.
(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.
(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.
(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

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

The board did not direct staff to convene a Rules Advisory Committee or Workgroup to advise on the proposed rule amendments. Board members represent the interests of persons and communities likely to be affected by a proposed rule. Overall, board members are licensees of the Oregon Board of Pharmacy or public members who represent Oregon patients.

AMEND: 855-080-0085

RULE SUMMARY: Permits a Pharmacist to add the patient's address with appropriate verification to the schedule II prescription. Permits a Pharmacist to add the drug strength, dosage form, drug quantity, directions for use, prescriber's

address, and prescriber's DEA registration number and to amend or correct the date the prescription was issued and the date the prescription can be filled after consultation and agreement of the prescriber to a schedule II prescription. Requires documentation of amendments or additions. Prohibits changing the patient's name, controlled substance prescribed (except for generic substitution) and the name or signature of the prescriber.

CHANGES TO RULE:

855-080-0085
Prescription Requirements ¶

(1) Registrants, practitioners and Pharmacists as specified therein in the issuance, preparation, labeling, dispensing, recordkeeping and filing of prescriptions for controlled substances must comply with the provisions of 21 CFR 1306.01 (04/01/2022), 21 CFR 1306.02 (04/01/2022), 21 CFR 1306.03 (04/01/2022), 21 CFR 1306.04 (04/01/2022), 21 CFR 1306.05 (04/01/2022), 21 CFR 1306.06 (04/01/2022), 21 CFR 1306.07 (04/01/2022), 21 CFR 1306.08 (04/01/2022), 21 CFR 1306.09 (04/01/2022); 21 CFR 1306.11 (04/01/2022), 21 CFR 1306.12 (04/01/2022), 21 CFR 1306.13 (04/01/2022), 21 CFR 1306.14 (04/01/2022), 21 CFR 1306.15 (04/01/2022); 21 CFR 1306.21 (04/01/2022), 21 CFR 1306.22 (04/01/2022); 21 CFR 1306.23 (04/01/2022), 21 CFR 1306.24 (04/01/2022), 21 CFR 1306.25 (04/01/2022), 21 CFR 1306.27 (04/01/2022); and 21 CFR 1304.03(d) (04/01/2022).¶
(2) Controlled substances listed in 21 CFR 1308.15 (04/01/2022) as schedule V are prescription drugs.¶
(3) Pseudoephedrine and ephedrine may be:¶
(a) Provided to a patient without a prescription under ORS 475.230.¶
(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/2022), 21 CFR 1306.22 (04/01/2022); 21 CFR 1306.23 (04/01/2022), 21 CFR 1306.24 (04/01/2022), 21 CFR 1306.25 (04/01/2022), and 21 CFR 1306.27 (04/01/2022). ¶
(4) For a Schedule II controlled substance prescription, a Pharmacist may:¶
(a) Add the patient's address based on information provided by the patient or patient's agent with appropriate verification;¶
(b) Amend or add the following information after consultation with and agreement of the prescriber:¶
(A) Drug strength; ¶
(B) Dosage form;¶
(C) Drug quantity;¶
(D) Directions for use;¶
(E) Prescriber's address; and¶
(F) Prescriber's DEA registration number.¶
(c) Amend the following information after consultation with and agreement of the prescriber, the:¶
(A) Date the prescription was issued; and¶
(B) Date the prescription can be filled.¶
(d) For (b) and (c), the Pharmacist must document on the prescription the date and time of the prescriber's authorization, the amendment or addition authorized, and the Pharmacist's identity. ¶
(5) For a Schedule II controlled substance prescription, a Pharmacist must not change the patient's name, the controlled substance prescribed except for generic substitution, and the name or signature of the prescriber. ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.185, ORS 475.188