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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

04/25/2022 12:02 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: 2022 HB 4034 allows an Intern to transfer pseudoephedrine or ephedrine without prescription

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/24/2022 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.

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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: 05/24/2022

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: 114 068 944# for audio only.

You may file written comments before 4:30PM on May 24, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

NEED FOR THE RULE(S)

Amends rule by adding "Intern" as required by 2022 HB 4034. Updates version dates of adopted standards by reference.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2022 HB 4034 <https://olis.oregonlegislature.gov/liz/2022R1/Downloads/MeasureDocument/HB4034/Enrolled>

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

Adopting proposed rule amendments will increase patient access to drugs containing pseudoephedrine or ephedrine by reducing barriers for pharmacy staff and the patient.

FISCAL AND ECONOMIC IMPACT:

No fiscal impact 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 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 the proposed amendments to the rule.

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

Legislative directive of 2022 HB 4034.

AMEND: 855-080-0026

RULE SUMMARY: OAR 855-080-0026 proposed amendments include adding "Intern" as mandated in 2022 HB 4034, which allows an Intern to transfer a drug containing pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine without a prescription from a practitioner to a person who is 18 years of age or older and who provides to the Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician the person's valid government-issued photo identification. Updates version dates of adopted standards by reference.

CHANGES TO RULE:

855-080-0026
Schedule V ¶¶

Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.15 (04/01/2020~~1~~); and¶¶

- (1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.¶¶
- (2) Products containing ephedrine or the salts of ephedrine as an active ingredient.¶¶
- (3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active ingredient.¶¶
- (4) In order to provide non-prescription pseudoephedrine or ephedrine to a purchaser, a pharmacy must:¶¶
 - (a) Store all pseudoephedrine and ephedrine behind the pharmacy counter in an area that is inaccessible to the public;¶¶
 - (b) Utilize an electronic system meeting the requirements under ~~section 2 of HB 2648 (2021)~~ORS 475.230;¶¶
 - (c) Train individuals who are responsible for providing pseudoephedrine or ephedrine to purchasers on the requirements of the Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177), the Combat Methamphetamine Enhancement Act of 2010, P.L. 111-268, and use of the electronic system as described in ~~2021 HB 2648~~ORS 475.230; ¶¶
 - (d) Ensure that only a Pharmacist, ~~Intern, Certified Oregon~~ Pharmacy Technician or ~~Certified Oregon~~ Pharmacy Technician provides pseudoephedrine or ephedrine to the purchaser after:¶¶
 - (A) Verifying that the purchaser is 18 years of age or older;¶¶
 - (B) Verifying the identity of the purchaser with valid government-issued photo identification; and¶¶
 - (C) Confirming the purchase is allowed via the electronic system; and¶¶

(e) Maintain an electronic log for at least three years from the date of the transaction that documents the following elements: ¶

(A) Date and time of the purchase; ¶

(B) Name, address and date of birth of the purchaser; ¶

(C) Form of government-issued photo identification and the identification number used to verify the identity of the purchaser; ¶

(D) Name of the government agency that issued the photo identification in (C); ¶

(E) Name of product purchased; ¶

(F) Quantity in grams of product purchased; ¶

(G) Name or initials of Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician who provides the drug; and ¶

(H) Signature of the purchaser. The signature of the purchaser may be recorded on a written log that also contains the transaction ID generated by the electronic system. ¶

(5) All sales of pseudoephedrine or ephedrine are subject to the following quantity limits and restrictions: ¶

(a) No more than 3.6 grams in a 24-hour period, no more than 9 grams in a 30-day period without regard to the number of transactions; and ¶

(b) For non-liquids, product packaging is limited to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches. ¶

(6) Sections (4) and (5) do not apply to a pseudoephedrine or ephedrine when the drug is dispensed pursuant to a prescription. ¶

(7) ~~Each pharmacy~~, Pharmacists, Intern, Certified Oregon Pharmacy Technicians and Pharmacy Technicians involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/2020~~1~~), 21 CFR 1314.02 (04/01/2020~~1~~), 21 CFR 1314.03 (04/01/2020~~1~~), 21 CFR 1314.05 (04/01/2020~~1~~), 21 CFR 1314.10 (04/01/2020~~1~~), 21 CFR 1314.15 (04/01/2020~~1~~), 21 CFR 1314.20 (04/01/2020~~1~~), 21 CFR 1314.25, (04/01/2020~~1~~); 21 CFR 1314.30 (04/01/2020~~1~~), 21 CFR 1314.35 (04/01/2020~~1~~), 21 CFR 1314.40 (04/01/2020~~1~~), 21 CFR 1314.42 (04/01/2020~~1~~), 21 CFR 1314.45 (04/01/2020~~1~~); and 21 CFR 1314.50 (04/01/2020~~1~~).

Statutory/Other Authority: ORS 689.205, ~~2021 HB 2648~~ ORS 475.230, 2022 HB 4034

Statutes/Other Implemented: ORS 475.035, ~~2021 HB 2648~~ ORS 475.230, 2022 HB 4034