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ARCHIVES DIVISION

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TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 23-2022

CHAPTER 855

BOARD OF PHARMACY

FILED

04/22/2022 9:01 AM ARCHIVES DIVISION SECRETARY OF STATE & LEGISLATIVE COUNSEL

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

EFFECTIVE DATE: 04/22/2022 THROUGH 10/18/2022

AGENCY APPROVED DATE: 04/14/2022

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NEED FOR THE RULE(S):

Amends rule by adding "Intern" as required by 2022 HB 4034.

JUSTIFICATION OF TEMPORARY FILING:

2022 HB 4034 mandate, effective upon passage.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

2022 HB 4034 Engrossed

https://olis.oregonlegislature.gov/liz/2022R1/Downloads/MeasureDocument/HB4034/Enrolled

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 or pharmacy technician the person's valid government-issued photo identification.

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); and \P

- (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); ¶
- (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; \P
- (d) Ensure that only a Pharmacist, <u>Intern, Certified Oregon</u> 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 \P
- (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
- (6) Sections (4) and (5) do not apply to a pseudoephedrine or ephedrine when the drug is dispensed pursuant to a prescription.¶
- $\begin{array}{l} (7) \ \underline{\mathsf{PEach}} \ \underline{\mathsf{pharmaciesy}}, \ \mathsf{Pharmacists}, \ \mathsf{Certified} \ \mathsf{Oregon} \ \mathsf{Pharmacy} \ \mathsf{Technicians} \ \mathsf{and} \ \mathsf{Pharmacy} \ \mathsf{Technicians} \ \mathsf{involved} \\ \mathsf{in} \ \mathsf{the} \ \mathsf{provision} \ \mathsf{of} \ \mathsf{pseudoephedrine} \ \mathsf{or} \ \mathsf{ephedrine} \ \mathsf{to} \ \mathsf{a} \ \mathsf{purchaser} \ \mathsf{must} \ \mathsf{comply} \ \mathsf{with} \ \mathsf{the} \ \mathsf{provisions} \ \mathsf{of} \ \mathsf{21} \ \mathsf{CFR} \\ \mathsf{1314.01} \ (04/01/2020), \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.02} \ (04/01/2020), \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.03} \ (04/01/2020), \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.20} \ (04/01/2020), \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.25} \ (04/01/2020), \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.30} \ (04/01/2020), \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.35} \ (04/01/2020), \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.40} \ (04/01/2020), \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.42} \ (04/01/2020), \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.45} \ (04/01/2020); \ \mathsf{and} \ \mathsf{21} \ \mathsf{CFR} \ \mathsf{1314.50} \ (04/01/2020). \\ \mathsf{Statutory/Other} \ \mathsf{Authority:} \ \mathsf{ORS} \ \mathsf{689.205}, \ \mathsf{2021} \ \mathsf{HB} \ \mathsf{2648} \ \mathsf{ORS} \ \mathsf{475.230}, \ \mathsf{2022} \ \mathsf{HB} \ \mathsf{4034} \\ \end{aligned}$

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