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SHEMIA FAGAN
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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
10/25/2021 5:12 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: 2021 HB 2648 allows transfer of pseudoephedrine or ephedrine without prescription. Procedural rule review

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/23/2021 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@bop.oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxilary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/23/2021
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 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.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 472 815 435# for audio only.

You may file written comments before 4:30PM on November 23, 2021 by emailing your comments to pharmacy.rulemaking@bop.oregon.

NEED FOR THE RULE(S)

Revisions to Division 080 are necessary to allow a pharmacist or pharmacy technician to transfer a drug containing pseudoephedrine or ephedrine without prescription to a person who is at least 18 years of age and presents person's valid government-issued photo identification pursuant to 2021 HB 2648 and effective 1/1/2022.
Procedural rules revisions to ensure clarity, transparency and promote patient safety.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2021 HB 2648 and related statutes
ORS 475.754 Affirmative defense to unlawfully possessing pseudoephedrine
ORS 475.950(2)(f) Failure to report precursor substances transaction.
ORS 475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records.
DEA Pharmacists Manual (v.2020) pg. 90-96
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
21 CFR 1306 (XX/XX/XXXX) Prescriptions
21 CFR 1307 (XX/XX/XXXX) Miscellaneous
21 CFR 1308 (XX/XX/XXXX) Schedules of Controlled Substances
21 CFR 1314 (XX/XX/XXXX) Retail Sale of Scheduled Listed Chemical Products
Table of Exempted Prescription Products (06/26/2021) per 21 CFR 1308.32

FISCAL AND ECONOMIC IMPACT:

No fiscal 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 proposed revisions to these rules.

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

Legislative directive of 2021 HB 2648

RULES PROPOSED:
855-041-1030, 855-080-0023, 855-080-0026, 855-080-0028, 855-080-0029, 855-080-0031, 855-080-0080, 855-080-0085

AMEND: 855-041-1030

RULE SUMMARY: Revisions to Division 080 are necessary to allow for the transfer of pseudoephedrine or ephedrine required by 2021 HB 2648. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-1030
Reporting Drug Loss ¶

(1) Disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices ~~shall~~must immediately be reported to the ~~B~~board.¶
(2) The outlet ~~shall notify the Board in the event of a~~must ensure that confirmed significant drug loss or ~~violation~~any loss related to suspected drug theft of a controlled substance is reported to the board within one ~~(1)~~

business day. ¶
(3) At the time a Report of Theft or Loss of Controlled Substances (D~~.E.A.~~EA Form 106) or Report of Theft or Loss of Listed Chemicals (DEA Form 107) is sent to the Drug Enforcement Administration, a copy i~~shall be~~ sent to the ~~B~~board.
Statutory/Other Authority: ORS 475.035, ORS 689.155, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

AMEND: 855-080-0023

RULE SUMMARY: Revisions to Division 080 are necessary to allow for the transfer of pseudoephedrine or ephedrine required by 2021 HB 2648. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-080-0023
Schedule III ¶

Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.13 (04/01/2020)~~; 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~~.
Statutory/Other Authority: ORS 689.205, ORS 475.973
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0026

RULE SUMMARY: Revisions to Division 080 are necessary to allow for the transfer of pseudoephedrine or ephedrine required by 2021 HB 2648. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

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¶
(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 ORS XXX.XXX [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; ¶
(d) Ensure that only a Pharmacist, 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, 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) Pharmacies, Pharmacists, 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), 21 CFR 1314.02 (04/01/2020), 21 CFR 1314.03 (04/01/2020), 21 CFR 1314.05 (04/01/2020), 21 CFR 1314.10 (04/01/2020), 21 CFR 1314.15 (04/01/2020), 21 CFR 1314.20 (04/01/2020), 21 CFR 1314.25, (04/01/2020); 21 CFR 1314.30 (04/01/2020), 21 CFR 1314.35 (04/01/2020), 21 CFR 1314.40 (04/01/2020), 21 CFR 1314.42 (04/01/2020), 21 CFR 1314.45 (04/01/2020); and 21 CFR 1314.50 (04/01/2020).
Statutory/Other Authority: ORS 689.205, 2021 HB 2648
Statutes/Other Implemented: ORS 475.035, 2021 HB 2648

AMEND: 855-080-0028

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

CHANGES TO RULE:

855-080-0028
Excluded or Exempted Substances ¶

~~Drugs and their generic equivalent~~(1) The board adopts the excluded substances liste found in 21 CFR 1308.22 (04/01/2020)~~ are excluded from the schedules in OAR 855-080-0021 through 855-080-0026~~.¶
(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/2020).¶
(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (06/26/2021) pursuant to 21 CFR 1308.32 (04/01/2020).
Statutory/Other Authority: ORS 689.205, ORS 689.155
Statutes/Other Implemented: ~~ORS 475.035~~

ADOPT: 855-080-0029

RULE SUMMARY: Revisions to Division 080 are necessary to allow for the transfer of pseudoephedrine or ephedrine required by 2021 HB 2648.

CHANGES TO RULE:

855-080-0029
Acceptable Subpoenas for Law Enforcement Agencies to Obtain Pseudoephedrine or Ephedrine Log Information
(1) "Law Enforcement Agency" includes the following:¶
(a) County sheriffs, municipal police departments, police departments established by a university under ORS 352.121 or 353.125 and state police;¶
(b) Other police officers of this state or another state, including humane special agents as defined in ORS 181A.345;¶
(c) The Oregon Department of Justice when conducting a criminal investigation;¶
(d) A tribal government as defined in ORS 181A.680 that employs authorized tribal police officers as defined in ORS 181A.680; and¶
(e) Law enforcement agencies of the federal government.¶
(2) Acceptable subpoenas for a law enforcement agency to obtain information in a pseudoephedrine or ephedrine log are subpoenas lawfully issued by:¶
(a) A grand jury under ORS 136.563;¶
(b) A district attorney under ORS 136.565;¶
(c) The Oregon Attorney General under ORS 183.073;¶
(d) A law enforcement agency of a tribal government under tribal subpoena authority; and¶
(e) A federal law enforcement agency under federal subpoena power.¶
(3) Subpoenas that meet the criteria in (2) are accepted by the board under ORS XXX.XXX [section 2, subsection 5 of HB 2648 (2021)]. The board does not act as a decisionmaker as to a subpoena issued for pseudoephedrine or ephedrine logs under this rule. The board is not a party to a subpoena for information contained in a pseudoephedrine or ephedrine log under this rule.
Statutory/Other Authority: ORS 689.205, 2021 HB 2648
Statutes/Other Implemented: 2021 HB 2648, ORS 475.035

AMEND: 855-080-0031

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

CHANGES TO RULE:

855-080-0031
Registration Requirements ¶

(1) Every person who manufactures, delivers or dispenses any controlled substance within this state or who proposes to engage in the manufacture, delivery or dispensing of any controlled substance within this state must obtain a controlled substance registration annually issued by the State Board of Pharmacy.¶
(2) The board adopts the exceptions to registration for distribution by dispenser to another practitioner pursuant to 21 CFR 1307.11 (04/01/2020).¶
(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/2020).
Statutory/Other Authority: ORS 689.155, ORS 689.205
Statutes/Other Implemented: ORS 475.125

REPEAL: 855-080-0080

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

CHANGES TO RULE:

~~855-080-0080~~
~~Special Exceptions ¶~~

~~The board adopts the exceptions to registration found in 21 CFR 1307.11 (04/01/2020) and 21 CFR 1307.13 (04/01/2020).~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 475.035~~

AMEND: 855-080-0085

RULE SUMMARY: Revisions to Division 080 are necessary to allow for the transfer of pseudoephedrine or ephedrine required by 2021 HB 2648. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

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 (04/01/2020), 21 CFR 1306.02 (04/01/2020), 21 CFR 1306.03 (04/01/2020), 21 CFR 1306.04 (04/01/2020), 21 CFR 1306.05 (04/01/2020), 21 CFR 1306.06 (04/01/2020), 21 CFR 1306.07 (04/01/2020), 21 CFR 1306.08 (04/01/2020), 21 CFR 1306.09 (04/01/2020); 21 CFR 1306.11 (04/01/2020), 21 CFR 1306.12 (04/01/2020), 21 CFR 1306.13 (04/01/2020), 21 CFR 1306.14 (04/01/2020), 21 CFR 1306.15 (04/01/2020); 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25 (04/01/2020), 21 CFR 1306.2~~6~~7 (04/01/2020); and 21 CFR 1304.03(d) (04/01/2020). ¶
(2) Controlled substances listed in 21 CFR 1308.15 (XX/XX/XXXX) as schedule V are prescription drugs. ¶
(3) Pseudoephedrine and ephedrine may be:¶
(a) Provided to a patient without a prescription under ORS XXX.XXX [section 2 of HB 2648 (2021)].¶
(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.2~~7~~2 (04/01/2020); ~~and 21 CFR 1304.03(d)~~21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25 (04/01/2020), and 21 CFR 1306.27 (04/01/2020).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.185, ORS 475.188