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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/16/2021 3:10 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Proactive rule review incorporating standards by reference

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.

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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: 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):

The proposed revisions are to clarify the date of incorporated standards of reference, as discussed in with the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019) and to amend and repeal outdated regulations. The revision 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:

21 CFR (04/01/2020) https://www.govinfo.gov/content/pkg/CFR-2020-title21-vol9/pdf/CFR-2020-title21-vol9-chapII.pdf, 21 USC (04/01/2021) https://uscode.house.gov/download/download.shtml, ORS 475.035 and ORS 475.055 https://www.oregonlegislature.gov/bills_laws/ors/ors475.html, ORS 183.337 https://www.oregonlegislature.gov/bills_laws/ors/ors183.html

FISCAL AND ECONOMIC IMPACT:

None 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?

A RAC was not necessary to clarify dates of incorporated standards of reference.

RULES PROPOSED:

855-080-0015, 855-080-0020, 855-080-0021, 855-080-0022, 855-080-0023, 855-080-0024, 855-080-0026, 855-080-0028, 855-080-0031, 855-080-0041, 855-080-0050, 855-080-0055, 855-080-0065, 855-080-0070, 855-080-0075, 855-080-0080, 855-080-0085, 855-080-0095, 855-080-0105

AMEND: 855-080-0015

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

CHANGES TO RULE:

855-080-0015
Definitions ¶

As used in these rules:¶
(1) "Act" means the Uniform Controlled Substances Act, ORS Chapter 475, and rules thereunder;¶
(2) "CFR" means Code of Federal Regulations;¶
(3) ~~The term "registr~~"USC" means United States Code;¶
(4) "Emergency Situations" ~~or varimeants thereof means the annual registration required of manufacturers, distributors and dispensers~~ose situations in which the prescribing practitioner who authorizes an oral prescription of a controlled substance~~s under ORS 475.125, and the term "registrants" or variants thereof refers to persons so registered; provided that wher~~ listed in schedule II of the Federal Controlled Substances Act determines that:¶
(a) Immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and¶
(b) No appropriate alternative tr~~eferences of this nature are used in CFR sections referred to in these rules,~~atment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, and¶

(c) It is not reasonably possible for the pre~~ference is to the registratio~~scribing practitioner to provide a written pre~~quirements and registrants under the Federal Controlled Substances Act, and Title 21, CFR.¶~~
~~(4) "USC" means United States Code;~~scription to be presented to the person dispensing the substance, prior to the dispensing.¶
(5) Terms not defined in this rule have the definitions set forth in ORS 475.005.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035, ORS 475.940, ORS 475.185

AMEND: 855-080-0020

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

CHANGES TO RULE:

855-080-0020
Schedules ¶

Pursuant to ORS 475.005(6) those drugs and their immediate precursors classified in Schedules I through V under the Federal Controlled Substances Act, 21 U~~.S.C. Sections 811 to 812~~SC 811 (04/01/2021), 21 USC 812 (04/01/2021) and as amended by the Board pursuant to ORS 475.035 are the controlled substances for purposes of regulation and control under the Act. Those schedules are set out in OAR 855-080-0021 through 855-080-0026.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0021

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

CHANGES TO RULE:

855-080-0021
Schedule I ¶

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR ~~part~~ 1308.11 (04/01/2020), and unless specifically ex~~cepted~~empt or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:¶
(a) 1,4-butanediol;¶
(b) Gamma-butyrolactone¶
(c) Methamphetamine, except as listed in OAR 855-080-0022;¶
(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)¶
(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.¶
(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,¶
(A) Methylmethcathinone (Mephedrone);¶
(B) Methylenedioxypyrovalerone (MDPV);¶
(C) Methylenedioxymethylcathinone (Methylone);¶
(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);¶
(E) Fluoromethcathinone (Flephedrone);¶
(F) 4-Methoxymethcathinone (Methedrone).¶
(2) Schedule I also includes any compounds in the following structural classes (2a-2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:¶
(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;¶
(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;¶
(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;¶
(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this

structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);¶
(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;¶
(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;¶
(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;¶
(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;¶
(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;¶
(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and¶
(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.¶
(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or is not an FDA approved drug.¶
(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.¶
(5) Schedule I also includes any compounds in the following structural classes (a - b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:¶
(a) Benzodiazepine class: A fused 1,4-diazepine and benzene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Clonazolam, Flualprazolam¶
(b) Thienodiazepine class: A fused 1,4-diazepine and thiophene ring structure with a phenyl connected to the 1,-4-diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Etizolam¶
(6) Exceptions. The following are exceptions to subsection (1) of this rule:¶
(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;¶

(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;¶
(c) Marijuana and delta-9-tetrahydrocannabinol (THC).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035, ORS 475.059,65, ORS 475.065

AMEND: 855-080-0022

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

CHANGES TO RULE:

855-080-0022
Schedule II ¶

Schedule II consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR ~~part~~ 1308.12 (04/01/2020) and any quantity of methamphetamine, when in the form of a FDA approved product containing methamphetamine, its salts, isomers and salts of its isomers as an active ingredient for the purposes of currently accepted medical use.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035, ORS 475.059, ORS 475.065~~, 2017 OL Ch. 021~~

AMEND: 855-080-0023

RULE SUMMARY: 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 ~~part~~ 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: 855-080-0024

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

CHANGES TO RULE:

855-080-0024
Schedule IV ¶

Schedule IV consists of:~~¶~~
~~(1)~~ The drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR ~~part~~ 1308.14 (04/01/2020), unless specifically excepted or listed in another schedule~~: and¶~~
~~(2) Products containing carisoprodol or the salts of carisoprodol as an active ingredient~~.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0026

RULE SUMMARY: 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 ~~part~~ 1308.15 (04/01/2020).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0028

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

CHANGES TO RULE:

855-080-0028
Excluded Substances ¶

~~The following d~~Drugs and their generic equivalents listed in 21 CFR 1308.22 (04/01/2020) are exc~~ept~~luded from the schedules in OAR 855-080-0021 through 855-080-0026~~:¶~~
~~(1) Benzedrex inhaler (Propylhexedrine).¶~~
~~(2) Vicks - Vapor inhaler (Levmetamfetamine)~~.
Statutory/Other Authority: ORS 689.205, ORS 689.155
Statutes/Other Implemented: ORS ~~689.15~~475.035

AMEND: 855-080-0031

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

CHANGES TO RULE:

855-080-0031
Registration Requirements ¶

~~M~~Every person who manufacture~~r~~s, d~~istributors, and pharmacies or other drug outlets are required to register~~ elivers or dispenses any controlled substance within this state or who proposes to engage in the manufacture, delivery or dispensing of any controlled substance within the~~ Board under the Uniform C~~is state, must obtain a controlled ~~S~~substance~~s Act~~ registration annually issued by the State Board of Pharmacy.
Statutory/Other Authority: ORS 689.155, ORS 689.205
Statutes/Other Implemented: ORS 475.125

ADOPT: 855-080-0041

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

CHANGES TO RULE:

855-080-0041
Exemption to Registration
The following persons are not required to register to manufacture, dispense or deliver controlled substances and may lawfully possess controlled substances under ORS 475.005 to ORS 475.285 and ORS 475.752 to ORS 475.980:¶
(1) An agent or employee of any registered manufacturer, distributor or dispenser of any controlled substance if the agent or employee is acting in the usual course of business or employment.¶
(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment.¶
(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance, unless otherwise prohibited.¶
(4) A practitioner otherwise licensed under the laws of this state and authorized to dispense or administer a controlled substance by the licensing authority.¶
(5) A person providing proof of a valid DEA registration certificate pursuant to ORS 475.135(3) conducting research with controlled substances in Sections I through V within this state.
Statutory/Other Authority: ORS 689.155, ORS 689.205
Statutes/Other Implemented: ORS 475.125, ORS 475.135

REPEAL: 855-080-0050

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

CHANGES TO RULE:

~~855-080-0050~~
~~Separate Registration for Places of Business~~
~~A separate registration is required for each principal place of business where controlled substances are manufactured or from which controlled substances are distributed or dispensed.~~
~~Statutory/Other Authority: ORS 475, 689~~
~~Statutes/Other Implemented:~~

REPEAL: 855-080-0055

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

CHANGES TO RULE:

~~855-080-0055~~
~~Separate Registration for Independent Activities~~
~~The manufacturing and distributing of controlled substances are deemed activities independent of each other. A separate registration is required for each activity; however, a person registered to manufacture may distribute or dispense any controlled substance which they are registered to manufacture, provided that, unless specifically exempted, they comply with all requirements and duties prescribed by statute and rules for persons registered to distribute or dispense as applicable.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 475.125, 689.155~~

AMEND: 855-080-0065

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

CHANGES TO RULE:

855-080-0065
Security ¶

(1) All applicants ~~for~~and registra~~tion and registrants~~nts as applicable to the registration classification must comply with the security requirements of 21 CFR 1301.0~~2, 1301.71 through 1301.76 and 1301.90 through~~1301.93~~, which apply to their registration classification. The requirements of 21 CFR 1301.75 and 1301.76 relating to "practitioners" are applicable to applicants and registrants who are drug dispensers.~~1 (04/01/2020), 21 CFR 1301.02 (04/01/2020), 21 CFR 1301.71 (04/01/2020), 21 CFR 1301.72 (04/01/2020), 21 CFR 1301.73 (04/01/2020), 21 CFR 1301.74 (04/01/2020), 21 CFR 1301.75 (04/01/2020), 21 CFR 1301.76 (04/01/2020), 21 CFR 1301.77 (04/01/2020), 21 CFR 1301.90 (04/01/2020), 21 CFR 1301.91 (04/01/2020), 21 CFR 1301.92 (04/01/2020), and 21 CFR 1301.93 (04/01/2020). ¶
(2) The security requirements of ~~subsection one~~(1) of this rule apply to all "~~"~~controlled substances,"~~"~~ as defined in these rules, ~~except~~including ephedrine, pseudoephedrine and phenylpropanolamine.¶
(3) Applicants and registrants must guard against theft and diversion of ephedrine, pseudoephedrine and phenylpropanolamine.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.135, ORS 475.125

AMEND: 855-080-0070

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

CHANGES TO RULE:

855-080-0070
Records and Inventory ¶

(1) All registered persons shallrants must, as applicable to the registration classification, keep records and maintain inventories in conformmpliance with 21 U.S.C. Section 827SC 827 (04/01/2021); 21 CFR 1304.01 (04/01/2020), 21 CFR 1304.02 (04/01/2020), 21 CFR 1304. 03 (04/01/2020), 21 CFR 1304.04 (04/01/2020), 21 CFR 1304.05 (04/01/2020), 21 CFR 1304.06 (04/01/2020); 21 CFR 1304.02 through 1304.11; 1304.21 through 1304.26; 1304.31 through 1304.33; except that a11 (04/01/2020); 21 CFR 1304.21 (04/01/2020), 21 CFR 1304.22 (04/01/2020), 21 CFR 1304.23 (04/01/2020), 21 CFR 1304.24 (04/01/2020), 21 CFR 1304.25 (04/01/2020), 21 CFR 1304.26 (04/01/2020); 21 CFR 1304.31 (04/01/2020), 21 CFR 1304.32 (04/01/2020), 21 CFR 1304.33 (04/01/2020). ¶
(2) A written inventory of all controlled substances shallmust be taken by registrants annually within 365 7 days of the last written inventory. ¶
(3) All such records shallmust be maintained for a period of three years.
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 475.165

AMEND: 855-080-0075

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

CHANGES TO RULE:

855-080-0075
Order ~~Form~~s for Schedule I and II Controlled Substance~~s~~ ¶

Controlled substances in Schedules I and II ~~shall~~must be distributed by a registrant to another registrant only pursuant to an order form ~~in conformance with 21 U.S.C. Section 828 and 21 CFR 1305.01 through 1305.29~~or electronic order in compliance with 21 USC 828 (04/01/2021) and 21 CFR 1305.01 (04/01/2020), 21 CFR 1305.02 (04/01/2020), 21 CFR 1305.03 (04/01/2020), 21 CFR 1305.04 (04/01/2020), 21 CFR 1305.05 (04/01/2020), 21 CFR 1305.06 (04/01/2020), 21 CFR 1305.07 (04/01/2020); 21 CFR 1305.11 (04/01/2020), 21 CFR 1305.12 (04/01/2020), 21 CFR 1305.13 (04/01/2020), 21 CFR 1305.14 (04/01/2020), 21 CFR 1305.15 (04/01/2020), 21 CFR 1305.16 (04/01/2020), 21 CFR 1305.17 (04/01/2020), 21 CFR 1305.18 (04/01/2020), 21 CFR 1305.19 (04/01/2020), 21 CFR 1305.20 (04/01/2020); 21 CFR 1305.21 (04/01/2020), 21 CFR 1305.22 (04/01/2020), 21 CFR 1305.23 (04/01/2020), 21 CFR 1305.24 (04/01/2020), 21 CFR 1305.25 (04/01/2020), 21 CFR 1305.26 (04/01/2020), 21 CFR 1305.27 (04/01/2020), 21 CFR 1305.28 (04/01/2020), and 21 CFR 1305.29 (04/01/2020).
Statutory/Other Authority: ORS ~~475, 689~~689.205
Statutes/Other Implemented: ORS 475.175

AMEND: 855-080-0080

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

CHANGES TO RULE:

855-080-0080
Special Exceptions ¶

The ~~provisions of 21 CFR 1307.11 through 1307.13 are applicable under the Act~~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: Rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-080-0085
Prescription Requirements ¶

~~(1) Except as provided in sections (2) and (3) of this rule, the provisions of 21 CFR 1306.01 through 1306.27 and 1304.03(d) shall be complied with by the r~~Registrants, practitioners and pharmacists as specified therein in the issuance, preparation, labeling dispensing, recordkeeping and filing of prescriptions for controlled substances~~. An electronic prescription is permitted for any substance listed in OAR 855-080-0022 through 855-080-0026 when so permitted by federal regulations.¶~~

~~(2) The provisions of 21 CFR 1306.11(a) under section (1) of this rule are amended by deleting "which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act."¶~~

~~(3) The provisions of 21 CFR 1306.21 through~~ 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.~~2~~07 ~~under section (1) of this rule shall be deemed to apply also to controlled substances listed in Schedule V.¶~~

~~(4) Controlled substances in Schedules III, IV, and V which are prescription drugs determined by the Board pursuant to ORS 475.185(3) are those prescription drugs as determined under the Federal Food, Drug, and Cosmetic Act. Such drugs are "Legend Drugs" and bear the legend "Caution: Federal law prohibits dispensing without a prescription", or an equivalent legend. In addition, any preparation containing any amount of codeine or its salts, opium, or paregoric in Schedules III, IV, or V is a prescription drug as determined by the Board pursuant to ORS 475.185(3).¶~~

~~(5) "Emergency Situations" as referred to in ORS 475.185(2) mean the same as specified in 21 CFR 290.10~~ (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 1306.26 (04/01/2020), 21 CFR 1306.27 (04/01/2020); and 21 CFR 1304.03(d) (04/01/2020).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.185, ORS 475.188

REPEAL: 855-080-0095

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

CHANGES TO RULE:

~~855-080-0095~~
~~Verification of Research Registration~~
~~Persons conducting research with controlled substances in Sections I through V within this state who are not otherwise exempt from registration pursuant to ORS 475.125(3), may, upon furnishing the Board a copy of a current federal registration certificate issued for such a purpose, pursuant to ORS 475.135, receive written verification of such submission from the Board's Executive Director.~~
~~Statutory/Other Authority: ORS 475~~
~~Statutes/Other Implemented:~~

REPEAL: 855-080-0105

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

CHANGES TO RULE:

~~855-080-0105~~
~~Disposal of Drugs~~
~~(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.¶~~
~~(2) Controlled substances which are expired, deteriorated or unwanted shall be disposed of in conformance with 21 CFR 1317.¶~~
~~(3) Expired, deteriorated, discontinued, or unwanted controlled substances in a long-term care facility shall be destroyed and the destruction jointly witnessed on the premises by any two of the following:¶~~
~~(a) The consultant pharmacist or registered nurse designee.¶~~
~~(b) The Director of Nursing Services or supervising nurse designee¶~~
~~(c) The administrator of the facility or an administrative designee¶~~
~~(d) A Registered Nurse employed by the facility¶~~
~~(4) The destruction shall be documented and signed by the witnesses and the document retained at the facility for a period of at least three years. Copies of the document shall be sent to the consultant pharmacist. Any destruction of controlled substances deviating from this procedure must be approved by the Board prior to implementation.¶~~
~~(5) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.305~~