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**
04/19/2023 11:52 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Updates incorporated standards adopted by reference; Amends Schedule III

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/23/2023 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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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: 05/23/2023
TIME: 9:30 AM
OFFICER: Rachel Melvin

HEARING LOCATION
ADDRESS: Virtual Hearing , 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 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 May 23, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

REMOTE MEETING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 518898073

NEED FOR THE RULE(S)

Proposed amendments incorporate updated standards adopted by reference as required the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019). Amends Schedule III rule by scheduling xylazine as a Schedule III.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Adopted Standards by Reference- 16 CFR (1/1/2022), 21 CFR (4/1/2022), 21 USC 352 (12/28/2022), 21 USC 353 (12/28/2022) 21 USC 351 (3/20/2023), 21 USC 811 (3/20/2023), 21 USC 812 (3/20/2023), 21 USC 822 (3/20/2023), 21 USC 822a (3/20/2023), 21 USC 827 (3/20/2023), 21 USC 828 (3/20/2023), 42 USC 262 (12/28/2022), United States Pharmacopeia <USP> and National Formulary <NF> (USP NF 2023, Issue 1 38 v. 2023), Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2023), USP 1229.5 (08/01/2022), and DEA Table of Exempted Prescription Products (08/22/2022)

Scheduling Xylazine-
Federal Bill: Combating Illicit Xylazine Act – Discussion Draft
https://www.cortezmasto.senate.gov/imo/media/doc/Combating Illicit Xylazine Act2.pdf
DEA Public Safety Alert 3/21/2023 https://www.dea.gov/alert/dea-reports-widespread-threat-fentanyl-mixed-xylazine#:~:text=United%20States%20Drug%20Enforcement%20Administration,-Search&text=
National Institute on Drug Abuse- Xylazine https://nida.nih.gov/research-topics/xylazine#Reference
OAR 875-015-0040 Minimum Standards for Veterinary Drugs
https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=280560

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

Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

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FISCAL AND ECONOMIC IMPACT:

None anticipated related to adoption of standards by reference. Regarding scheduling xylazine as a Schedule III, all veterinary facilities are required to have a controlled substance safe, or securely locked cabinet for storage of controlled substances; thus, it is not anticipated that there will be a fiscal impact on veterinary facilities.

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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).*

There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

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

Small businesses were not involved with the development of proposed amendments.

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

Amendments are required per ORS 183.337 pursuant to ORS 475.035 and ORS 475.055.

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RULES PROPOSED:
855-006-0005, 855-041-1046, 855-041-1092, 855-041-1145, 855-041-7050, 855-043-0545, 855-043-0740, 855-045-0200, 855-080-0020, 855-080-0021, 855-080-0022, 855-080-0023, 855-080-0024, 855-080-0026, 855-080-0028, 855-080-0031, 855-080-0065, 855-080-0070, 855-080-0075, 855-080-0085, 855-139-0145, 855-139-0350, 855-139-0460, 855-141-0350

AMEND: 855-006-0005

RULE SUMMARY: Proposed amendments include revised reference versions of 21 USC 351 v. 03/21/2023, 42 USC 262(k)(3)(A)(i) v. 12/28/2022, 21 USC 352 v. 12/28/2022, United States Pharmacopeia <USP>, official National Formulary <NF> v. USP NF 2023, official Homeopathic Pharmacopoeia of the United States <HPUS> v. 2023, 42 USC 262(a) v. 12/28/2022 and adds " [Publications: Publications referenced are available for review at the agency or from United States Pharmacopoeia.]".

CHANGES TO RULE:

855-006-0005
Definitions ¶

As used in OAR Chapter 855:¶
(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. 3/15/202~~2~~3).¶
(2) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.¶
(3) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.¶
(4) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.¶
(5) "Biosimilar" product means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (v. ~~03/15~~12/28/2022).¶
(6) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.¶
(7) "Certified health care interpreter" has the meaning given that term in ORS 413.550.¶
(8) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the Pharmacist are not considered Certified Oregon Pharmacy Technicians or Pharmacy Technicians.¶
(9) "Clinical Pharmacy Agreement" means an agreement between a Pharmacist or pharmacy and a health care organization, or a physician as defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010 that permits the Pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization, or physician or naturopathic physician.¶
(10) "Collaborative Drug Therapy Management" means the participation by a Pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration, and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:¶
(a) Is agreed to by one Pharmacist and one practitioner; or¶
(b) Is agreed to by one or more Pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic, or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.¶
(11) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:¶
(a) As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the Pharmacist and the patient, in the course of professional practice; or¶
(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or¶
(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.¶
(12) "Confidential Information" means any patient information obtained by a Pharmacist or pharmacy.¶
(13) "Consulting Pharmacist" means a Pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.¶
(14) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.¶
(15) "Custodian of pharmacy records" means a board licensee or registrant who is responsible for the maintenance, care or keeping of pharmacy records based on the services provided by the pharmacy, regardless of

whether the records are in that person's actual physical custody and control.¶
(16) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.¶
(17) "Drug Regimen Review" or "DRR" means the process conducted by a Pharmacist who is consulting for a long-term-care facility or other institution, either prior to dispensing or at a later time, with the goal of ensuring that optimal patient outcomes are achieved from the drug therapy.¶
(18) "Entry system" enables control of access to a secured area.¶
(19) "Final verification" means after prescription information is entered into a pharmacy's electronic system and reviewed by a Pharmacist for accuracy, a physical verification that the drug and drug dosage, device or product selected from a pharmacy's inventory pursuant to the electronic system entry is the prescribed drug and drug dosage, device, or product.¶
(20) "Good standing" means a license or registration that is not suspended, revoked, or otherwise restricted from the practice of pharmacy or subject to a current disciplinary order.¶
(21) "Health care interpreter" has the meaning given that term in ORS 413.550.¶
(22) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.¶
(23) "Individual with limited English proficiency" means a person who, by reason of place of birth or culture, communicates in a language other than English and does not communicate in English with adequate ability to communicate effectively with a health care provider.¶
(24) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 USC 262(k)(4) (v. ~~03/15~~12/28/2022).¶
(25) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.¶
(26) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.¶
(27) "Misbranded" has the same definition as set forth in 21 USC 352 (v. ~~03/15~~12/28/2022).¶
(28) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.¶
(29) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.¶
(30) "Nationally Certified Exam" means an exam that is approved by the board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible, and valid.¶
(31) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.¶
(32) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:¶
(a) The creation and retention of accurate and complete patient records;¶
(b) Assuming authority and responsibility for product selection of drugs and devices;¶
(c) Developing and maintaining a safe practice setting for the Pharmacist, for pharmacy staff and for the general public;¶
(d) Maintaining confidentiality of patient information.¶
(33) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (v. USP NF 202~~2~~3, Issue 1), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 202~~2~~3), or any supplement to any of these.¶
(34) "Oral Counseling" means an oral communication process between a Pharmacist and a patient or a patient's agent in which the Pharmacist obtains information from the patient (or agent) and the patient's pharmacy records,

assesses that information, and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.¶
(35) Participation in Drug Selection and Drug Utilization Review:¶
(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.¶
(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the Pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review include, but are not limited to:¶
(A) Over-utilization or under-utilization;¶
(B) Therapeutic duplication;¶
(C) Drug-disease contraindications;¶
(D) Drug-drug interactions;¶
(E) Incorrect drug dosage;¶
(F) Incorrect duration of treatment;¶
(G) Drug-allergy interactions; and¶
(H) Clinical drug abuse or misuse.¶
(36) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:¶
(a) Cure of a disease;¶
(b) Elimination or reduction of a patient's symptomatology;¶
(c) Arrest or slowing of a disease process; or¶
(d) Prevention of a disease or symptomatology.¶
(37) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.¶
(38) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board but has not completed the specialized education program pursuant to OAR 855-025-0012.¶
(39) "Practice of clinical pharmacy" means:¶
(a) The health science discipline in which, in conjunction with the patient's other practitioners, a Pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;¶
(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and¶
(c) The practice of pharmacy by a Pharmacist pursuant to a clinical pharmacy agreement.¶
(40) "Practice of pharmacy" is as defined in ORS 689.005.¶
(41) "Prescription drug" or "legend drug" is as defined in ORS 689.005 and:¶
(a) Required by federal law, prior to being dispensed or delivered, to be labeled with "Rx only"; or¶
(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.¶
(42) "Prescription released by the Pharmacist" means, a prescription which has been reviewed by the Pharmacist that does not require further Pharmacist intervention such as reconstitution or counseling.¶
(43) "Prohibited conduct" means conduct by a licensee that:¶
(a) Constitutes a criminal act against a patient or client; or¶
(b) Constitutes a criminal act that creates a risk of harm to a patient or client.¶
(44) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:¶
(a) Assure retention of their purity and potency;¶
(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;¶
(c) Assure security and minimize the risk of their loss through accident or theft;¶
(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;¶
(e) Protect the health, safety and welfare of the Pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.¶
(45) "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.¶
(46) "Reasonable professional judgment" means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities,

qualifications, and competencies, after careful review, analysis and consideration of the relevant subject matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion, or conclusion.¶
(47) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (v. ~~03/15~~12/28/2022) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.¶
(48) "Repackage" means the act of taking a drug from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug.¶
(49) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication, the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.¶
(50) "Specialized Education Program" means;¶
(a) A program providing education for persons desiring licensure as Certified Oregon Pharmacy Technicians or Pharmacy Technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or¶
(b) A structured program approved by the board and designed to educate Certified Oregon Pharmacy Technicians or Pharmacy Technicians in one or more specific issues of patient health and safety that is offered by:¶
(A) An organization recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians;¶
(B) An employer recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians; or¶
(C) A trade association recognized by the board as representing pharmacies.¶
(51) "Still image capture" means a specific image captured electronically from a video or other image capture device.¶
(52) "Store and forward" means a video or still image record which is saved electronically for future review.¶
(53) "Supervision by a Pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician being supervised, coupled with the ability to control and be responsible for the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician's action.¶
(54) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.¶
(55) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.¶
(56) "Verification" means the confirmation by the Pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an Intern, a Certified Oregon Pharmacy Technician, or a Pharmacy Technician. ¶
[Publications: Publications referenced are available for review at the agency or from United States Pharmacopoeia.]
Statutory/Other Authority: ORS 689.205, 2022 HB 4034
Statutes/Other Implemented: ORS 689.151, ORS 689.155, 2022 HB 4034

AMEND: 855-041-1046

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1317 (04/01/2022), 21 USC 822 (03/20/2023), 21 USC 822a (03/20/2023) and adds "[Publications: Publications referenced are available for review at the agency.]"

CHANGES TO RULE:

855-041-1046
Secure and Responsible Drug Disposal ¶

(1) A pharmacy that operates a drug take back collection program or that participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered with the DEA as an authorized collector to collect controlled and non-controlled drugs for destruction.¶
(2) A pharmacy that operates as a Drug Enforcement Agency (DEA) authorized collector must notify the board within 30 days of initiating or terminating the program and must establish and enforce policies and procedures, including but not limited to:¶
(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is accessible to the public, within view of the pharmacy counter and must not be located behind the pharmacy counter; and¶
(b) Provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation, and key accountability; and¶
(c) Personnel training and accountability.¶
(3) A pharmacy must inform consumers to directly deposit drugs into the collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected.¶
(4) A pharmacy must not dispose of drugs from pharmacy stock in a collection receptacle.¶
(5) The liner must be inserted and removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel.¶
(6) Liners that have been removed from a collection receptacle and immediately sealed must be directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution agent (such as registered UPS, FedEx, or USPS) or a reverse wholesaler registered with the DEA and the board.¶
(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to the board in writing within one day of discovery.¶
(8) A pharmacy must maintain all drug disposal records for a minimum of 3 years.¶
(9) Authorized collectors are required to comply with the following federal and state laws:¶
(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236, ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;¶
(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370, and OAR 340-098-0390;¶
(c) 21 CFR 1317.30 (04/01/2021~~2~~), 21 CFR 1317.35 (04/01/2021~~2~~), 21 CFR 1317.40 (04/01/2021~~2~~), 21 CFR 1317.55 (04/01/2021~~2~~), 21 CFR 1317.60 (04/01/2021~~2~~), 21 CFR 1317.65 (04/01/2021~~2~~), 21 CFR 1317.70 (04/01/2021~~2~~), 21 CFR 1317.75 (04/01/2021~~2~~), 21 CFR 1317.80 (04/01/2021~~2~~), and 21 CFR 1317.85 (04/01/2021~~2~~); and¶
(d) 21 USC 822 (03/~~15~~20/2022~~3~~), 21 USC 822a (03/~~15~~20/2022~~3~~).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218

AMEND: 855-041-1092

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1317 (04/01/2022), 21 USC 822 (03/20/2023), 21 USC 822a (03/20/2023) and adds "[Publications: Publications referenced are available for review at the agency.]"

CHANGES TO RULE:

855-041-1092
Retail Drug Outlet Pharmacy Closures: Temporary, Permanent or Emergency
(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a Retail Drug Outlet pharmacy is temporarily closed to the public the pharmacy must:¶
(a) Post notification of closure on each pharmacy entrance as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must include:¶
(A) Estimated period of time the pharmacy will be closed; and¶
(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).¶
(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:¶
(A) Estimated period of time the pharmacy will be closed; and¶
(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).¶
(c) If the pharmacy is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.¶
(d) Federal and state holidays are exempt from the requirements of (1).¶
(2) Permanent Closing. If a Retail Drug Outlet pharmacy is permanently closing to the public, the pharmacy must:¶
(a) Prior to closing, the pharmacy must comply with the following:¶
(A) Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:¶
(i) The last day the pharmacy will be open;¶
(ii) Name, address and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records;¶
(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and¶
(iv) The last day a transfer may be initiated.¶
(B) The notification must be made via:¶
(i) Distribution by direct mail or written notice with each prescription dispensed;¶
(ii) Public notice in a newspaper of general circulation, if available, in the area served by the pharmacy; and¶
(iii) Posting a closing notice on each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).¶
(iv) In addition to (i), (ii) and (iii), the pharmacy may also provide notification via email or text.¶
(C) Provide any new patients filling prescriptions during the 15 calendar day period prior to the pharmacy closing with written notification that includes:¶
(i) The last day the pharmacy will be open;¶
(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records;¶
(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and¶
(iv) The last day a transfer may be initiated.¶
(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/2021~~1~~2).¶
(b) On the date of closing or up to 24 hours after the permanent closure begins, the Pharmacist-in-charge must comply with the following:¶
(A) Complete and document an inventory of all controlled substances.¶
(B) If the pharmacy dispenses prescriptions:¶
(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed Pharmacist who will serve as the custodian of records;¶
(ii) Update the pharmacy operating status with each electronic prescribing vendor; and¶

(iii) Remove all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications).¶
(c) After closing. Within 30 calendar days after the closing of the pharmacy, the Pharmacist-in-charge must:¶
(A) Complete and document an inventory of all non-controlled drugs and devices.¶
(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the pharmacy by one or a combination of the following methods:¶
(i) Return to manufacturer or supplier (credit or disposal);¶
(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or¶
(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (04/1/2021~~1~~2), 21 CFR 1304.22 (04/1/2021~~1~~2), 21 CFR 1317.05 (04/1/2021~~1~~2), 21 CFR 1317.90 (04/1/2021~~1~~2) and 21 CFR 1317.95 (04/1/2021~~1~~2).¶
(C) Provide the board a written notice of the closing on a board prescribed form which includes the following information:¶
(i) Date of closing to the public and discontinuance of the business;¶
(ii) Date and time the inventory of all prescription drugs and devices was conducted;¶
(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the pharmacy were transferred or disposed;¶
(iv) If drugs were destroyed, name and license numbers of individuals that who witnessed the destruction;¶
(v) If the pharmacy is registered to possess controlled substances, confirmation that the pharmacy complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2021~~1~~2) for discontinuing operation as a pharmacy that dispenses controlled substances.¶
(vi) The name, address and phone number of the pharmacy that took possession of the pharmacy records or the Oregon licensed Pharmacist who is serve as the custodian of pharmacy records which must be maintained according to OAR 855-041-1160;¶
(vii) Confirmation all pharmacy labels and blank prescriptions were destroyed;¶
(viii) Confirmation all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and¶
(ix) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.¶
(D) Once the pharmacy has notified the board that the pharmacy is permanently closed, the license may not be renewed. The pharmacy may apply for a new license as specified in OAR 855-041-1080.¶
(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.¶
(3) Emergency closing. If a Retail Drug Outlet pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, or other emergency circumstances and the Pharmacist-in-charge cannot provide notification as required in (1), the Pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.¶
(4) Non-resident Retail Drug Outlet pharmacies are exempt from (1)-(3) and must follow laws and rules in the pharmacy's state of residence pertaining to temporary, permanent and emergency closures. The non-resident pharmacy must provide the board a written notice of the closing within 30 calendar days on a form prescribed by the board which includes the following information:¶
(a) Date of closing to the public and discontinuance of the business;¶
(b) If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or Oregon licensed Pharmacist who will serve as the custodian of records for Oregon patients to which the prescriptions, including refill information, and patient medication records were transferred; and¶
(c) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.¶
(5) The board may conduct an inspection to verify all requirements in subsection (1), (2), (3) and (4) of this section have been completed.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 475.035
Statutes/Other Implemented: ORS 689.205

AMEND: 855-041-1145

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1317 (04/01/2022), 21 USC 822 (03/20/2023), 21 USC 822a (03/20/2023) and adds "[Publications: Publications referenced are available for review at the agency.]"

CHANGES TO RULE:

855-041-1145
New Containers ¶

Each pharmacy must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/202~~1~~2), 16 CFR 1701 (01/01/202~~1~~2), and 16 CFR 1702 (01/01/202~~1~~2).¶
[Publications: Publications referenced are available f~~rom~~or review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-7050

RULE SUMMARY: Proposed amendments include revised reference versions of 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 1300.01 (04/01/2022) and adds " [Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-041-7050
Definitions - Long Term Care Pharmacy ¶

As used in OAR 855-041-7000 through 855-041-7080:¶
(1) "Long term care facility" means a facility with permanent facilities that include inpatient beds, providing medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the director, to provide treatment for two or more unrelated patients. "Long Term Care facility" includes skilled nursing facilities and intermediate care facilities but may not be construed to include facilities licensed and operated pursuant to ORS 443.400 to 443.455.¶
(2) For the purposes of Schedule II prescriptions in 21 CFR 1306.11 (04/01/2021~~1~~2), 21 CFR 1306.12 (04/01/2021~~1~~2), 21 CFR 1306.13 (04/01/2021~~1~~2), 21 CFR 1306.14 (04/01/2021~~1~~2), and 21 CFR 1306.15 (04/01/2021~~1~~2), the DEA definition of "long term care facility" as defined in 21 CFR 1300.01 (04/01/2021~~1~~2) includes "community-based care facilities."¶
(3) "Community Based Care Facility" means a home, facility or supervised living environment licensed or certified or otherwise recognized by an agency of the state of Oregon which provides 24-hour care, supervision, and assistance with medication administration. These include but are not limited to Adult Foster Homes, Residential Care Facilities (RCF), Assisted Living Facilities (ALF), Group Homes for the Developmentally Disabled and Mentally Retarded and Inpatient Hospice.¶
(4) "Pharmaceutical Care" means the responsible provision of any or all of the following services by the pharmacist:¶
(a) Develop and maintain policies and procedures for pharmaceutical services;¶
(b) Provide direction and oversight regarding all aspects of the acquisition, disposition, handling, storage, and administration of drugs including but not limited to the following:¶
(A) Receipt and interpretation of physician's orders;¶
(B) Ordering and receiving of medications;¶
(C) Handling of emergency drugs and supplies;¶
(D) Labeling of all drugs;¶
(E) Selection of drug delivery systems;¶
(F) Development of systems to provide timely delivery of drugs and supplies;¶
(G) Monitoring of drug storage conditions and expiration dates;¶
(H) Monitoring accuracy and efficiency of medication administration and compliance with physician's orders;¶
(I) Establishing and monitoring of appropriate record keeping;¶
(J) Accountability of controlled substances;¶
(K) Return, release, and/or destruction of discontinued or outdated drugs; and¶
(L) Compliance with state and federal laws and regulations related to pharmaceutical services and medication management.¶
(c) Provide training and in-service education to facility staff;¶
(d) Perform drug regimen review for each resident on a regularly scheduled basis for the purpose of promoting therapeutic appropriateness and achieving the desired drug therapy outcomes by identifying issues such as:¶
(A) Over-utilization or underutilization;¶
(B) Therapeutic duplication;¶
(C) Drug-disease contraindications;¶
(D) Drug-drug interactions;¶
(E) Incorrect drug, drug dosage or duration of drug treatment;¶
(F) Drug-allergy interaction;¶
(G) Clinical abuse/misuse;¶
(H) Untreated indication;¶
(I) Monitoring and assessing of drug therapy outcomes;¶
(e) Communicate effectively with residents' physicians and facility staff; and¶

(f) Participate in resident care planning. ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

AMEND: 855-043-0545

RULE SUMMARY: Proposed amendments include revised reference versions of 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022), 16 CFR 1702 (01/01/2022) and adds "[Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-043-0545
Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery
(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by the practitioner's licensing board.¶
(2) Drugs dispensed from the DPDO must be dispensed in compliance with the requirements of the practitioner's licensing board.¶
(3) A DPDO must comply with all requirements of State or federal law.¶
(4) A DPDO must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/202~~1~~2), 16 CFR 1701 (01/01/202~~1~~2) and 16 CFR 1702 (01/01/202~~1~~2).¶
(5) Dispensed drugs must be packaged by the DPDO, a pharmacy, or a manufacturer registered with the board.¶
(6) A DPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.¶
(7) A DPDO may deliver or mail prescription to the patient if:¶
(a) Proper drug storage conditions are maintained; and¶
(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:¶
(A) Drug name, class and indications;¶
(B) Proper use and storage;¶
(C) Common side effects;¶
(D) Precautions and contraindications; and¶
(E) Significant drug interactions.¶
(8) The DPDO must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.¶
(9) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0740

RULE SUMMARY: Proposed amendments include revised reference versions of 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022), 16 CFR 1702 (01/01/2022) and adds " [Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-043-0740
Community Health Clinic (CHC) - Dispensing and Drug Delivery ¶

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.¶
(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.¶
(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.¶
(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.¶
(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.¶
(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2021~~1~~2), 16 CFR 1701 (01/01/2021~~1~~2) and 16 CFR 1702 (01/01/2021~~1~~2).¶
(7) Dispensed drugs must be packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the board.¶
(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.¶
(9) A CHC must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.¶
(10) A CHC may deliver or mail prescription to the patient if:¶
(a) Proper drug storage conditions are maintained; and¶
(b) The CHC offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:¶
(A) Drug name, class and indications;¶
(B) Proper use and storage;¶
(C) Common side effects;¶
(D) Precautions and contraindications; and¶
(E) Significant drug interactions.¶
(11) The CHC must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.¶
(12) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

AMEND: 855-045-0200

RULE SUMMARY: Proposed amendments include revised reference versions of USP and USP-NF Chapter 1229.5 (08/01/2022) and adds " [Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]".

CHANGES TO RULE:

855-045-0200
Application ¶

(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for use or distribution in Oregon must register with the board as a drug outlet and comply with board regulations.¶
(2) These rules apply to sterile and non-sterile compounding of a drug.¶
(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:¶
(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (05/01/2020 v. 2014);¶
(b) USP <797> Pharmaceutical Compounding-Sterile Preparations (05/01/2020 v. 2008);¶
(c) USP <800> Hazardous Drugs-Handling in Healthcare Settings (07/01/2020 v. 2020);¶
(d) USP <825> Radiopharmaceuticals-Preparation, Compounding, Dispensing, and Repackaging (12/01/2020 v. 2020); and¶
(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/20~~16~~22), 1231 (12/01/2021), and 1821 (05/01/2017).¶
[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-080-0020

RULE SUMMARY: Proposed amendments include revised reference versions of Federal Controlled Substances Act, 21 USC 811 (03/20/2023), 21 USC 812 (03/20/2023) and adds " [Publications: Publications referenced are available for review at the agency.]".

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 USC 811 (03/~~15~~20/202~~2~~3), 21 USC 812 (03/~~15~~20/202~~2~~3) 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.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0021

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1308.11 (04/01/2022) and adds " [Publications: Publications referenced are available for review at the agency.]".

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 1308.11 (04/01/2021~~1~~2), and unless specifically exempt 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) is not an FDA approved drug or is exempted from the definition of controlled substance in ORS 475.005(6)(b)(A)-(E).¶
(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) The following substances per ORS 475.005(6)(b):¶
(A) The plant Cannabis family Cannabaceae;¶
(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;¶
(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;¶
(D) The seeds of the plant Cannabis family Cannabaceae; or¶
(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055, ORS 475.065

AMEND: 855-080-0022

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1308.12 (04/01/2022) and adds " [Publications: Publications referenced are available for review at the agency.]".

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 1308.12 (04/01/2021~~1~~2) 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.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055, ORS 475.065

AMEND: 855-080-0023

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1308.13 (04/01/2022), and adds "products containing xylazine including its salts, isomers, and salts of isomers of xylazine as an active ingredient." to Schedule III. Adds "[Publications: Publications referenced are available for review at the agency.]".

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 (04/01/2021~~).~~.2); and products containing xylazine including its salts, isomers, and salts of isomers of xylazine as an active ingredient. ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 475.973
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0024

RULE SUMMARY: Proposed amendments include revised reference versions of CFR 1308.14 (04/01/2022) and adds "[Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-080-0024
Schedule IV ¶

Schedule IV consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.14 (04/01/2021~~1~~2), unless specifically excepted or listed in another schedule.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0026

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1308.15 (04/01/2022), 21 CFR 1314.01 (04/01/2022), 21 CFR 1314.02 (04/01/2022), 21 CFR 1314.03 (04/01/2022), 21 CFR 1314.05 (04/01/2022), 21 CFR 1314.10 (04/01/2022), 21 CFR 1314.15 (04/01/2022), 21 CFR 1314.20 (04/01/2022), 21 CFR 1314.25, (04/01/2022); 21 CFR 1314.30 (04/01/2022), 21 CFR 1314.35 (04/01/2022), 21 CFR 1314.40 (04/01/2022), 21 CFR 1314.42 (04/01/2022), 21 CFR 1314.45 (04/01/2022); and 21 CFR 1314.50 (04/01/2022). Adds "[Publications: Publications referenced are available for review at the agency.]".

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 (04/01/202~~1~~2); 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 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 ORS 475.230;¶
(d) Ensure that only a Pharmacist, Intern, Certified Oregon Pharmacy Technician or 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, Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/202~~1~~2), 21 CFR 1314.02 (04/01/202~~1~~2), 21 CFR 1314.03 (04/01/202~~1~~2), 21 CFR 1314.05 (04/01/202~~1~~2), 21 CFR 1314.10 (04/01/202~~1~~2), 21 CFR 1314.15 (04/01/202~~1~~2), 21 CFR 1314.20 (04/01/202~~1~~2), 21 CFR 1314.25, (04/01/202~~1~~2); 21 CFR 1314.30 (04/01/202~~1~~2), 21 CFR 1314.35 (04/01/202~~1~~2), 21 CFR 1314.40 (04/01/202~~1~~2), 21 CFR 1314.42 (04/01/202~~1~~2), 21 CFR 1314.45

(04/01/2021~~1~~2); and 21 CFR 1314.50 (04/01/2021~~1~~2). ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 475.230, 2022 HB 4034
Statutes/Other Implemented: ORS 475.035, ORS 475.230, 2022 HB 4034

AMEND: 855-080-0028

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1308.22 (04/01/2022, 21 CFR 1308.24 (04/01/2022), the Table of Exempted Prescription Products (08/22/2022), 21 CFR 1308.32 (04/01/2022) and adds " [Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-080-0028
Excluded or Exempted Substances ¶

(1) The board adopts the excluded substances list found in 21 CFR 1308.22 (04/01/2021~~1~~2).¶
(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/2021~~1~~2).¶
(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (0~~2/11~~8/22/2022) pursuant to 21 CFR 1308.32 (04/01/2021~~1~~2).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 475.035
Statutes/Other Implemented: ORS 689.155, ORS 475.035

AMEND: 855-080-0031

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1307.11 (04/01/2022), 21 CFR 1307.13 (04/01/2022), and adds " [Publications: Publications referenced are available for review at the agency.]".

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 (04/01/2021~~1~~2).¶
(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/2021~~1~~2). ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.155, ORS 689.205
Statutes/Other Implemented: ORS 475.125

AMEND: 855-080-0065

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1301.01 (04/01/2022), 21 CFR 1301.02 (04/01/2022), 21 CFR 1301.71 (04/01/2022), 21 CFR 1301.72 (04/01/2022), 21 CFR 1301.73 (04/01/2022), 21 CFR 1301.74 (04/01/2022), 21 CFR 1301.75 (04/01/2022), 21 CFR 1301.76 (04/01/2022), 21 CFR 1301.77 (04/01/2022), 21 CFR 1301.90 (04/01/2022), 21 CFR 1301.91 (04/01/2022), 21 CFR 1301.92 (04/01/2022), and 21 CFR 1301.93 (04/01/2022). Adds "[Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-080-0065
Security ¶

(1) All applicants and registrants as applicable to the registration classification must comply with the security requirements of 21 CFR 1301.01 (04/01/2021~~1~~2), 21 CFR 1301.02 (04/01/2021~~1~~2), 21 CFR 1301.71 (04/01/2021~~1~~2), 21 CFR 1301.72 (04/01/2021~~1~~2), 21 CFR 1301.73 (04/01/2021~~1~~2), 21 CFR 1301.74 (04/01/2021~~1~~2), 21 CFR 1301.75 (04/01/2021~~1~~2), 21 CFR 1301.76 (04/01/2021~~1~~2), 21 CFR 1301.77 (04/01/2021~~1~~2), 21 CFR 1301.90 (04/01/2021~~1~~2), 21 CFR 1301.91 (04/01/2021~~1~~2), 21 CFR 1301.92 (04/01/2021~~1~~2), and 21 CFR 1301.93 (04/01/2021~~1~~2).¶
(2) The security requirements of (1) of this rule apply to all controlled substances, as defined in these rules, including ephedrine, pseudoephedrine, and phenylpropanolamine.¶
(3) Applicants and registrants must guard against theft and diversion of ephedrine, pseudoephedrine, and phenylpropanolamine.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.135, ORS 475.125

AMEND: 855-080-0070

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1304.01 (04/01/2021), 21 CFR 1304.02 (04/01/2022), 21 CFR 1304.03 (04/01/2022), 21 CFR 1304.04 (04/01/2022), 21 CFR 1304.05 (04/01/2022), 21 CFR 1304.06 (04/01/2022); 21 CFR 1304.11 (04/01/2022); 21 CFR 1304.21 (04/01/2022), 21 CFR 1304.22 (04/01/2022), 21 CFR 1304.23 (04/01/2022), 21 CFR 1304.24 (04/01/2022), 21 CFR 1304.25 (04/01/2022), 21 CFR 1304.26 (04/01/2022); 21 CFR 1304.31 (04/01/2022), 21 CFR 1304.32 (04/01/2022), 21 CFR 1304.33 (04/01/2022). Adds "[Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-080-0070
Records and Inventory ¶

(1) All registrants must, as applicable to the registration classification, keep records and maintain inventories in compliance with 21 USC 827 (03/15/2022); 21 CFR 1304.01 (04/01/2021), 21 CFR 1304.02 (04/01/202~~1~~2), 21 CFR 1304.03 (04/01/202~~1~~2), 21 CFR 1304.04 (04/01/202~~1~~2), 21 CFR 1304.05 (04/01/202~~1~~2), 21 CFR 1304.06 (04/01/202~~1~~2); 21 CFR 1304.11 (04/01/202~~1~~2); 21 CFR 1304.21 (04/01/202~~1~~2), 21 CFR 1304.22 (04/01/202~~1~~2), 21 CFR 1304.23 (04/01/202~~1~~2), 21 CFR 1304.24 (04/01/202~~1~~2), 21 CFR 1304.25 (04/01/202~~1~~2), 21 CFR 1304.26 (04/01/202~~1~~2); 21 CFR 1304.31 (04/01/202~~1~~2), 21 CFR 1304.32 (04/01/202~~1~~2), 21 CFR 1304.33 (04/01/202~~1~~2).¶
(2) A written inventory of all controlled substances must be taken by registrants annually within 367 days of the last written inventory.¶
(3) All such records must be maintained for a period of three years.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 475.165

AMEND: 855-080-0075

RULE SUMMARY: Proposed amendments include revised reference versions of 21 USC 828 (03/20/2023) and 21 CFR 1305.01 (04/01/2022), 21 CFR 1305. 02 (04/01/20212, 21 CFR 1305.03 (04/01/2022), 21 CFR 1305.04 (04/01/2022), 21 CFR 1305.05 (04/01/2022), 21 CFR 1305.06 (04/01/2022), 21 CFR 1305.07 (04/01/2022); 21 CFR 1305.11 (04/01/2022), 21 CFR 1305.12 (04/01/2022), 21 CFR 1305.13 (04/01/2022), 21 CFR 1305.14 (04/01/2022), 21 CFR 1305.15 (04/01/2022), 21 CFR 1305.16 (04/01/2022), 21 CFR 1305.17 (04/01/2022), 21 CFR 1305.18 (04/01/2022), 21 CFR 1305.19 (04/01/2022), 21 CFR 1305.20 (04/01/2022); 21 CFR 1305.21 (04/01/2022), 21 CFR 1305.22 (04/01/2022), 21 CFR 1305.23 (04/01/2022), 21 CFR 1305.24 (04/01/2022), 21 CFR 1305.25 (04/01/2022), 21 CFR 1305.26 (04/01/2022), 21 CFR 1305.27 (04/01/2022), 21 CFR 1305.28 (04/01/2022), and 21 CFR 1305.29 (04/01/2022). Adds "[Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-080-0075
Orders for Schedule I and II Controlled Substances
Controlled substances in Schedules I and II must be distributed by a registrant to another registrant only pursuant to an order form or electronic order in compliance with 21 USC 828 (03/~~15~~20/202~~2~~3) and 21 CFR 1305.01 (04/01/202~~1~~2), 21 CFR 1305. 02 (04/01/2021~~}~~2, 21 CFR 1305.03 (04/01/202~~1~~2), 21 CFR 1305.04 (04/01/202~~1~~2), 21 CFR 1305.05 (04/01/202~~1~~2), 21 CFR 1305.06 (04/01/202~~1~~2), 21 CFR 1305.07 (04/01/202~~1~~2); 21 CFR 1305.11 (04/01/202~~1~~2), 21 CFR 1305.12 (04/01/202~~1~~2), 21 CFR 1305.13 (04/01/202~~1~~2), 21 CFR 1305.14 (04/01/202~~1~~2), 21 CFR 1305.15 (04/01/202~~1~~2), 21 CFR 1305.16 (04/01/202~~1~~2), 21 CFR 1305.17 (04/01/202~~1~~2), 21 CFR 1305.18 (04/01/202~~1~~2), 21 CFR 1305.19 (04/01/202~~1~~2), 21 CFR 1305.20 (04/01/202~~1~~2); 21 CFR 1305.21 (04/01/202~~1~~2), 21 CFR 1305.22 (04/01/202~~1~~2), 21 CFR 1305.23 (04/01/202~~1~~2), 21 CFR 1305.24 (04/01/202~~1~~2), 21 CFR 1305.25 (04/01/202~~1~~2), 21 CFR 1305.26 (04/01/202~~1~~2), 21 CFR 1305.27 (04/01/202~~1~~2), 21 CFR 1305.28 (04/01/202~~1~~2), and 21 CFR 1305.29 (04/01/202~~1~~2).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.175

AMEND: 855-080-0085

RULE SUMMARY: Proposed amendments include revised reference versions 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), 21 CFR 1304.03(d) (04/01/2022), 21 CFR 1308.15 (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), and 21 CFR 1306.27 (04/01/2022). Adds "[Publications: Publications referenced are available for review at the agency.]".

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 (04/01/2021~~1~~2), 21 CFR 1306.02 (04/01/2021~~1~~2), 21 CFR 1306.03 (04/01/2021~~1~~2), 21 CFR 1306.04 (04/01/2021~~1~~2), 21 CFR 1306.05 (04/01/2021~~1~~2), 21 CFR 1306.06 (04/01/2021~~1~~2), 21 CFR 1306.07 (04/01/2021~~1~~2), 21 CFR 1306.08 (04/01/2021~~1~~2), 21 CFR 1306.09 (04/01/2021~~1~~2); 21 CFR 1306.11 (04/01/2021~~1~~2), 21 CFR 1306.12 (04/01/2021~~1~~2), 21 CFR 1306.13 (04/01/2021~~1~~2), 21 CFR 1306.14 (04/01/2021~~1~~2), 21 CFR 1306.15 (04/01/2021~~1~~2); 21 CFR 1306.21 (04/01/2021~~1~~2), 21 CFR 1306.22 (04/01/2021~~1~~2); 21 CFR 1306.23 (04/01/2021~~1~~2), 21 CFR 1306.24 (04/01/2021~~1~~2), 21 CFR 1306.25 (04/01/2021~~1~~2), 21 CFR 1306.27 (04/01/2021~~1~~2); and 21 CFR 1304.03(d) (04/01/2021~~1~~2).¶
(2) Controlled substances listed in 21 CFR 1308.15 (04/01/2021~~1~~2) 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 (04/01/2021~~1~~2), 21 CFR 1306.22 (04/01/2021~~1~~2); 21 CFR 1306.23 (04/01/2021~~1~~2), 21 CFR 1306.24 (04/01/2021~~1~~2), 21 CFR 1306.25 (04/01/2021~~1~~2), and 21 CFR 1306.27 (04/01/2021~~1~~2). ¶
[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

AMEND: 855-139-0145

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1301.52 (04/01/2022), 21 CFR 1304.21 (4/1/2022), 21 1304.22 (4/1/2022), 21 CFR 1317.05 (4/1/2022), 21 CFR 1317.90 (4/1/2022), 21 CFR 1317.95 (4/1/2022), and 21 CFR 1301.52 (04/01/2022). Adds "[Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-139-0145
Outlet: Closure- Temporary, Permanent and Emergency
(1) Temporary Closing. Unless subject to an exemption in OAR 855-~~041-1092~~139-0145(3), when a RDSP is temporarily closed to the public the RDSP must:¶
(a) Post notification of closure on each RDSP entrance as soon as the need to deviate from the posted hours is known by the RDSP, but no later than 2 hours after the temporary closure begins. The posting must include:¶
(A) Estimated period of time the RDSP will be closed; and¶
(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).¶
(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:¶
(A) Estimated period of time the RDSP will be closed; and¶
(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).¶
(c) If the RDSP is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.¶
(d) Federal and state holidays are exempt from the requirements of (1).¶
(2) Permanent Closing. If a RDSP is permanently closing to the public, the RDSP must:¶
(a) Prior to closing, the RDSP must comply with the following:¶
(A) Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:¶
(i) The last day the RDSP will be open;¶
(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;¶
(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and¶
(iv) The last day a transfer may be initiated.¶
(B) The notification must be made via:¶
(i) Distribution by direct mail or written notification with each prescription dispensed;¶
(ii) Public notice in a newspaper of general circulation, if available, in the area served by the RDSP; and¶
(iii) Posting a closing notice at each building and each RDSP entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).¶
(iv) In addition to (i), (ii) and (iii), the RDSP may also provide notification via email or text.¶
(C) Provide any new patients filling prescriptions during the 15-calendar day period prior to the RDSP closing with written notification that includes:¶
(i) The last day the RDSP will be open;¶
(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;¶
(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and¶
(iv) The last day a transfer may be initiated.¶
(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/202~~1~~2).¶
(b) On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:¶
(A) Complete and document an inventory of all controlled substances.¶
(B) If the RDSP dispenses prescriptions:¶
(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed Pharmacist who will serve as the custodian of records;¶

(ii) Update the RDSP operating status with each electronic prescribing vendor; and¶
(iii) Remove all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications).¶
(c) After closing. Within 30 calendar days after the closing of the RDSP, the pharmacist-in-charge must:¶
(A) Complete and document an inventory of all non-controlled drugs and devices.¶
(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the RDSP by one or a combination of the following methods:¶
(i) Return to manufacturer or supplier (credit or disposal);¶
(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or¶
(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (4/1/2021~~1~~2), 21 1304.22 (4/1/2021~~1~~2), 21 CFR 1317.05 (4/1/2021~~1~~2), 21 CFR 1317.90 (4/1/2021~~1~~2) and 21 CFR 1317.95 (4/1/2021~~1~~2).¶
(C) Provide the board a written notice of the closing on a board prescribed form which includes the following information:¶
(i) Date of closing to the public and discontinuance of the business;¶
(ii) Date and time the inventory of all prescription drugs and devices was conducted;¶
(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the RDSP were transferred or disposed;¶
(iv) If drugs were destroyed, name and license numbers of individuals who witnessed the destruction;¶
(v) If the RDSP is registered to possess controlled substances, confirmation that the RDSP complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2021~~1~~2) for discontinuing operation as a RDSP that dispenses controlled substances.¶
(vi) If the RDSP dispenses prescriptions, the name, address and phone number of the RDSP or Oregon licensed Pharmacist who will serve as the custodian of records to which the prescriptions, including refill information, and patient medication records were transferred;¶
(vii) Confirmation all RDSP labels and blank prescriptions were destroyed;¶
(viii) Confirmation all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and¶
(ix) Confirmation that each registration certificate issued to the RDSP by the board has been mailed to the board office.¶
(D) Once the RDSP has notified the board that the RDSP is permanently closed, the license may not be renewed. The RDSP may apply for a new license as specified in OAR 855-139-0015.¶
(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.¶
(3) Emergency closing. If the RDSP is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the Pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.¶
(4) The board may conduct an inspection to verify all requirements in subsection (1), (2), and (3) of this section have been completed.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.700
Statutes/Other Implemented: ORS 689.155, ORS 689.700

AMEND: 855-139-0350

RULE SUMMARY: Proposed amendments include revised reference versions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022), and 16 CFR 1702 (01/01/2022). Adds that publications are available "for review at" the agency.

CHANGES TO RULE:

855-139-0350
Dispensing: Containers
Each pharmacy must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/202~~1~~2), 16 CFR 1701 (01/01/202~~1~~2), and 16 CFR 1702 (01/01/202~~1~~2).¶
[Publications: Publications referenced are available f~~rom~~or review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-139-0460

RULE SUMMARY: Proposed amendments include revised reference versions of 21 CFR 1317.30 (04/01/2022), 21 CFR 1317.35 (04/01/2022), 21 CFR 1317.40 (04/01/2022), 21 CFR 1317.55 (04/01/2022), 21 CFR 1317.60 (04/01/2022), 21 CFR 1317.65 (04/01/2022), 21 CFR 1317.70 (04/01/2022), 21 CFR 1317.75 (04/01/2022), 21 CFR 1317.80 (04/01/2022), and 21 CFR 1317.85 (04/01/2022), 21 USC 822 (03/20/2023), and 21 USC 822a (03/20/2023). Adds "[Publications: Publications referenced are available for review at the agency.]".

CHANGES TO RULE:

855-139-0460
Drugs and Devices: Take-back Program
(1) A RDSP that operates a drug take-back collection program or that participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered with the DEA as an authorized collector to collect controlled and non-controlled drugs for destruction.¶
(2) A RDSP that operates as a Drug Enforcement Agency (DEA) authorized collector must notify the board within 30 days of initiating or terminating the program and must establish and enforce policies and procedures, including but not limited to:¶
(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is accessible to the public, within view of the pharmacy counter and must not be located behind the pharmacy counter; and¶
(b) Provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation, and key accountability; and¶
(c) Personnel training and accountability.¶
(3) A RDSP must inform consumers to directly deposit drugs into the collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected.¶
(4) A RDSP must not dispose of drugs from pharmacy stock in a collection receptacle.¶
(5) The liner must be inserted and removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel.¶
(6) Liners that have been removed from a collection receptacle and immediately sealed must be directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution agent (such as registered UPS, FedEx, or USPS) or a reverse wholesaler registered with the DEA and the board.¶
(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to the board in writing within one day of discovery.¶
(8) A RDSP must maintain all drug disposal records for a minimum of 3 years.¶
(9) Authorized collectors are required to comply with the following federal and state laws:¶
(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236, ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;¶
(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370, and OAR 340-098-0390;¶
(c) 21 CFR 1317.30 (04/01/2021~~1~~2), 21 CFR 1317.35 (04/01/2021~~1~~2), 21 CFR 1317.40 (04/01/2021~~1~~2), 21 CFR 1317.55 (04/01/2021~~1~~2), 21 CFR 1317.60 (04/01/2021~~1~~2), 21 CFR 1317.65 (04/01/2021~~1~~2), 21 CFR 1317.70 (04/01/2021~~1~~2), 21 CFR 1317.75 (04/01/2021~~1~~2), 21 CFR 1317.80 (04/01/2021~~1~~2), and 21 CFR 1317.85 (04/01/2021~~1~~2); and¶
(d) 21 USC 822 (03/~~15~~20/202~~2~~3), 21 USC 822a (03/~~15~~20/202~~2~~3).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218

AMEND: 855-141-0350

RULE SUMMARY: Proposed amendments include revised reference versions of 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022), and 16 CFR 1702 (01/01/2022). Adds that publications referenced are available "for review at" the agency.

CHANGES TO RULE:

855-141-0350
Dispensing: Containers
Each PPK must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/202~~1~~2), 16 CFR 1701 (01/01/202~~1~~2), and 16 CFR 1702 (01/01/202~~1~~2).¶
[Publications: Publications referenced are available f~~rom~~or review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155