OFFICE OF THE SECRETARY OF STATE
SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

PERMANENT ADMINISTRATIVE ORDER

BP 27-2022
CHAPTER 855
BOARD OF PHARMACY

FILED
06/15/2022 3:20 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Adds definitions and updates incorporated standards adopted by reference

EFFECTIVE DATE: 06/16/2022

AGENCY APPROVED DATE: 06/09/2022

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@bop.oregon.gov

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

Filed By:
Rachel Melvin
Rules Coordinator

RULES:
855-006-0005, 855-041-1046, 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, 855-080-0028, 855-080-0031, 855-080-0065, 855-080-0070, 855-080-0075, 855-080-0085, 855-139-0350, 855-139-0460

AMEND: 855-006-0005

REPEAL: Temporary 855-006-0005 from BP 25-2022

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: In alignment with the directives of 2021 HB 2359: Adds definitions for (7) “Certified health care interpreter”, (19) “Health care interpreter”, (20) “Health care interpreter registry” and (21) “Individual with limited English proficiency”. In alignment with the directives of 2022 HB 4034: (18) “Final Verification”.

Updates versions of 21 USC (3/15/2022) in (1), (5), (22), (25) and (44); Pharmacopeia <USP> and National Formulary <NF> (USP NF 2022, Issue 1), Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2022) in (31) that are adopted by reference. Removes language that is no longer relevant due to the end of the declared public health emergency in (50) “Supervision by a Pharmacist”. Proactive procedural rule review to add definitions for (15) “Custodian of pharmacy records” and (43) “Reasonable professional judgment”. Adds 'Certified Oregon Pharmacy Technician or' to (8), (47)(a)(b)(A)(B) and (53).

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. ~~12/09/2021~~3/15/2022)¶
(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) (~~12~~03/15/202~~1~~2).¶
(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 ~~p~~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 ~~p~~Pharmacist are not considered ~~p~~Certified Oregon Pharmacy Technicians or Pharmacy ~~t~~Technicians.¶
(~~8~~9) "Clinical Pharmacy Agreement" means an agreement between a ~~p~~Pharmacist or pharmacy and a health care organization or a physician that permits the ~~p~~Pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.¶
(~~9~~10) "Collaborative Drug Therapy Management" means the participation by a ~~p~~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 ~~p~~Pharmacist and one practitioner; or¶
(b) Is agreed to by one or more ~~p~~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.¶
(1~~0~~1) "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 ~~p~~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.¶
(1~~1~~2) "Confidential Information" means any patient information obtained by a ~~p~~Pharmacist or pharmacy.¶
(1~~2~~3) "Consulting Pharmacist" means a ~~p~~Pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.¶
(1~~3~~4) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.¶
(1~~4~~5) "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.¶
(1~~5~~7) "Entry system" enables control of access to a secured area.¶
(1~~6~~8) "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.¶
(19) "Health care interpreter" has the meaning given that term in ORS 413.550.¶
(20) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.¶
(21) "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.¶
(22) "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) (~~12/01~~03/15/202~~1~~2).¶
(~~17~~23) "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.¶
(~~18~~24) "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.¶
(~~19~~25) "Misbranded" has the same definition as set forth in 21 USC 352 (v. ~~12/09/2021~~03/15/2022).¶
(2~~0~~6) "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.¶
(2~~1~~7) "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.¶
(2~~2~~8) "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.¶
(2~~3~~9) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.¶
(~~24~~30) "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 ~~p~~Pharmacist, for pharmacy staff and for the general public;¶
(d) Maintaining confidentiality of patient information.¶
(~~25~~31) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP ~~43-NF 38 v. 202~~NF 2022, Issue 1), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 202~~1~~2), or any supplement to any of these.¶
(3~~2~~6) "Oral Counseling" means an oral communication process between a ~~p~~Pharmacist and a patient or a patient's agent in which the ~~p~~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.¶
(~~27~~33) 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 ~~p~~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.¶
(~~28~~34) "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.¶
(~~29~~35) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the

~~p~~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.¶
(3~~0~~6) "Practice of clinical pharmacy" means:¶
(a) The health science discipline in which, in conjunction with the patient's other practitioners, a ~~p~~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 ~~p~~Pharmacist pursuant to a clinical pharmacy agreement.¶
(3~~1~~7) "Practice of pharmacy" is as defined in ORS 689.005.¶
(3~~2~~8) "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.¶
(3~~3~~9) "Prescription released by the ~~p~~Pharmacist" means, a prescription which has been reviewed by the ~~p~~Pharmacist that does not require further ~~p~~Pharmacist intervention such as reconstitution or counseling.¶
(~~34~~0) "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.¶
(~~35~~41) "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 ~~p~~Pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.¶
(~~36~~42) "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.¶
(~~37~~43) "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.¶
(44) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (~~12/01~~03/15/202~~1~~2) 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.¶
(~~38~~45) "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.¶
(~~39~~46) "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.¶
(4~~0~~7) "Specialized Education Program" means;¶
(a) A program providing education for persons desiring licensure as ~~pharmacy t~~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 ~~pharmacy t~~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 ~~p~~Pharmacists~~ or p~~, Certified Oregon Pharmacy Technicians or Pharmacy ~~t~~Technicians;¶
(B) An employer recognized by the board as representing ~~p~~Pharmacists~~ or p~~, Certified Oregon Pharmacy Technicians or Pharmacy ~~t~~Technicians; or¶
(C) A trade association recognized by the board as representing pharmacies.¶
(4~~1~~8) "Still image capture" means a specific image captured electronically from a video or other image capture

device.¶
(4~~2~~9) "Store and forward" means a video or still image record which is saved electronically for future review.¶
(4~~3~~50) "Supervision by a ~~p~~Pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the ~~pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or c~~Intern, Certified Oregon ~~p~~Pharmacy ~~t~~Technician~~'s action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a p~~ or Pharmacy ~~t~~Technician ~~or intern~~ being supervised, coupled with the ability to control and be responsible for the ~~technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders. ¶~~
~~(44~~Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician's action.¶
(51) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.¶
(45~~2~~) "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.¶
(4~~6~~53) "Verification" means the confirmation by the ~~p~~Pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an ~~i~~Intern ~~or a p~~, a Certified Oregon Pharmacy ~~t~~Technician, or a ~~certified Oregon p~~Pharmacy ~~t~~Technician.
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

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference versions of 21 CFR (4/1/2021), 21 USC (3/15/2022) in compliance with ORS 183.337.

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 (04/01/202~~0~~1), 21 CFR 1317.35 (04/01/202~~0~~1), 21 CFR 1317.40 (04/01/202~~0~~1), 21 CFR 1317.55 (04/01/202~~0~~1), 21 CFR 1317.60 (04/01/202~~0~~1), 21 CFR 1317.65 (04/01/202~~0~~1), 21 CFR 1317.70 (04/01/202~~0~~1), 21 CFR 1317.75 (04/01/202~~0~~1), 21 CFR 1317.80 (04/01/202~~0~~1), and 21 CFR 1317.85 (04/01/202~~0~~1); and¶
(d) 21 USC 822 (04~~/01~~3/15/202~~1~~2), 21 USC 822a (04~~/01~~3/15/202~~1~~2).
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: 855-041-1145

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference versions of 16 CFR (1/1/2021) in compliance with ORS 183.337.

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 (041/01/2021), 16 CFR 1701 (041/01/2021), and 16 CFR 1702 (041/01/2021).¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-7050

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 21 CFR (4/1/2021) in compliance with ORS 183.337.

CHANGES TO RULE:

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

As used in OAR 855-041--7000 through 855-041--7080:¶
(1)~~(a)~~ "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.¶
(~~b~~2) For the purposes of Schedule II prescriptions in 21 CFR 1306.11~~-1306.13~~ (04/01/2021), 21 CFR 1306.12 (04/01/2021), 21 CFR 1306.13 (04/01/2021), 21 CFR 1306.14 (04/01/2021), and 21 CFR 1306.15 (04/01/2021), the DEA definition of "long term care facility" as defined in 21 CFR 1300.01~~(25~~ (04/01/2021) includes "community--based care facilities."¶
(~~2~~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.¶
(~~3~~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.
Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.~~0~~305

AMEND: 855-043-0545

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 16 CFR (1/1/2021) in compliance with ORS 183.337.

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 (04<u>1</u>/01/2021), 16 CFR 1701 (04<u>1</u>/01/2021) and 16 CFR 1702 (04<u>1</u>/01/2021).¶
(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.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0740

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference versions of 16 CFR (1/1/2021) in compliance with ORS 183.337.

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 (04<u>1</u>/01/2021), 16 CFR 1701 (04<u>1</u>/01/2021) and 16 CFR 1702 (04<u>1</u>/01/2021).¶
(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.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

AMEND: 855-045-0200

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of United States Pharmacopeia USP <1231> (12/1/2021) in compliance with OAR-010-0021.

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 (08/01/2016), 1231 (~~08~~12/01/202~~18~~), and 1821 (05/01/2017).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-080-0020

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference versions of 21 USC (3/15/2022). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

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 (04~~/01~~3/15/202~~1~~2), 21 USC 812 (04~~/01~~3/15/202~~1~~2) and as amended by the ~~B~~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

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 21 CFR (4/1/2021). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

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 (04/01/202~~0~~1), 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.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055, ORS 475.065, ~~ORS 475.005~~

AMEND: 855-080-0022

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 21 CFR (4/1/2021). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

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 (04/01/202~~0~~1) 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 475.005, ORS 475.035, ORS 475.055, ORS 475.065~~, ORS 475.005~~

AMEND: 855-080-0023

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 21 CFR (4/1/2021. Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

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 (04/01/202~~0~~1).
Statutory/Other Authority: ORS 689.205, ORS 475.973
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0024

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 21 CFR (4/1/2021). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

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 (04/01/202~~0~~1), unless specifically excepted or listed in another schedule.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0028

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 21 CFR (4/1/2021). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

CHANGES TO RULE:

855-080-0028
Excluded or Exempted Substances ¶

(1) The board adopts the excluded substances list found in 21 CFR 1308.22 (04/01/202~~0~~1).¶
(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/202~~0~~1).¶
(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (0~~6/26~~2/11/202~~1~~2) pursuant to 21 CFR 1308.32 (04/01/202~~0~~1).
Statutory/Other Authority: ORS 689.205, ORS 475.035
Statutes/Other Implemented: ORS 689.155, ORS 475.035

AMEND: 855-080-0031

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 21 CFR (4/1/2021). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

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 (04/01/202~~0~~1).¶
(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/202~~0~~1).
Statutory/Other Authority: ORS 689.155, ORS 689.205
Statutes/Other Implemented: ORS 475.125

AMEND: 855-080-0065

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 21 CFR (4/1/2021). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

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 (04/01/202~~0~~1), 21 CFR 1301.02 (04/01/202~~0~~1), 21 CFR 1301.71 (04/01/202~~0~~1), 21 CFR 1301.72 (04/01/202~~0~~1), 21 CFR 1301.73 (04/01/202~~0~~1), 21 CFR 1301.74 (04/01/202~~0~~1), 21 CFR 1301.75 (04/01/202~~0~~1), 21 CFR 1301.76 (04/01/202~~0~~1), 21 CFR 1301.77 (04/01/202~~0~~1), 21 CFR 1301.90 (04/01/202~~0~~1), 21 CFR 1301.91 (04/01/202~~0~~1), 21 CFR 1301.92 (04/01/202~~0~~1), and 21 CFR 1301.93 (04/01/202~~0~~1).¶
(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.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.135, ORS 475.125

AMEND: 855-080-0070

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference versions of 21 CFR (4/1/2021) and 21 USC (3/15/2022). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

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 (0~~4/01~~3/15/202~~1~~2); 21 CFR 1304.01 (04/01/202~~0~~1), 21 CFR 1304.02 (04/01/202~~0~~1), 21 CFR 1304.03 (04/01/202~~0~~1), 21 CFR 1304.04 (04/01/202~~0~~1), 21 CFR 1304.05 (04/01/202~~0~~1), 21 CFR 1304.06 (04/01/202~~0~~1); 21 CFR 1304.11 (04/01/202~~0~~1); 21 CFR 1304.21 (04/01/202~~0~~1), 21 CFR 1304.22 (04/01/202~~0~~1), 21 CFR 1304.23 (04/01/202~~0~~1), 21 CFR 1304.24 (04/01/202~~0~~1), 21 CFR 1304.25 (04/01/202~~0~~1), 21 CFR 1304.26 (04/01/202~~0~~1); 21 CFR 1304.31 (04/01/202~~0~~1), 21 CFR 1304.32 (04/01/202~~0~~1), 21 CFR 1304.33 (04/01/202~~0~~1).¶
(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.
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 475.165

AMEND: 855-080-0075

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference versions of 21 CFR (4/1/2021), 21 USC (3/15/2022). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337.

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 (0~~4/01~~3/15/202~~1~~2) and 21 CFR 1305.01 (04/01/202~~0~~1), 21 CFR 1305. 02 (04/01/202~~0~~1), 21 CFR 1305.03 (04/01/202~~0~~1), 21 CFR 1305.04 (04/01/202~~0~~1), 21 CFR 1305.05 (04/01/202~~0~~1), 21 CFR 1305.06 (04/01/202~~0~~1), 21 CFR 1305.07 (04/01/202~~0~~1); 21 CFR 1305.11 (04/01/202~~0~~1), 21 CFR 1305.12 (04/01/202~~0~~1), 21 CFR 1305.13 (04/01/202~~0~~1), 21 CFR 1305.14 (04/01/202~~0~~1), 21 CFR 1305.15 (04/01/202~~0~~1), 21 CFR 1305.16 (04/01/202~~0~~1), 21 CFR 1305.17 (04/01/202~~0~~1), 21 CFR 1305.18 (04/01/202~~0~~1), 21 CFR 1305.19 (04/01/202~~0~~1), 21 CFR 1305.20 (04/01/202~~0~~1); 21 CFR 1305.21 (04/01/202~~0~~1), 21 CFR 1305.22 (04/01/202~~0~~1), 21 CFR 1305.23 (04/01/202~~0~~1), 21 CFR 1305.24 (04/01/202~~0~~1), 21 CFR 1305.25 (04/01/202~~0~~1), 21 CFR 1305.26 (04/01/202~~0~~1), 21 CFR 1305.27 (04/01/202~~0~~1), 21 CFR 1305.28 (04/01/202~~0~~1), and 21 CFR 1305.29 (04/01/202~~0~~1).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.175

AMEND: 855-080-0085

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 21 CFR (4/1/2021). Revisions are necessary to comply with ORS 475.035, ORS 475.055, and ORS 183.337. Adds 'ORS 475.230' to (3)(a).

CHANGES TO RULE:

855-080-0085
Prescription Requirements ¶

(1) Registrants, practitioners and ~~p~~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 (04/01/202~~0~~1), 21 CFR 1306.02 (04/01/202~~0~~1), 21 CFR 1306.03 (04/01/202~~0~~1), 21 CFR 1306.04 (04/01/202~~0~~1), 21 CFR 1306.05 (04/01/202~~0~~1), 21 CFR 1306.06 (04/01/202~~0~~1), 21 CFR 1306.07 (04/01/202~~0~~1), 21 CFR 1306.08 (04/01/202~~0~~1), 21 CFR 1306.09 (04/01/202~~0~~1); 21 CFR 1306.11 (04/01/202~~0~~1), 21 CFR 1306.12 (04/01/202~~0~~1), 21 CFR 1306.13 (04/01/202~~0~~1), 21 CFR 1306.14 (04/01/202~~0~~1), 21 CFR 1306.15 (04/01/202~~0~~1); 21 CFR 1306.21 (04/01/202~~0~~1), 21 CFR 1306.22 (04/01/202~~0~~1); 21 CFR 1306.23 (04/01/202~~0~~1), 21 CFR 1306.24 (04/01/202~~0~~1), 21 CFR 1306.25 (04/01/202~~0~~1), 21 CFR 1306.27 (04/01/202~~0~~1); and 21 CFR 1304.03(d) (04/01/202~~0~~1).¶
(2) Controlled substances listed in 21 CFR 1308.15 (04/01/2021) as schedule V are prescription drugs.¶
(3) Pseudoephedrine and ephedrine may be:¶
(a) Provided to a patient without a prescription under ~~section 2 of HB 2648 (2021)~~ORS 475.230.¶
(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/202~~0~~1), 21 CFR 1306.22 (04/01/202~~0~~1); 21 CFR 1306.23 (04/01/202~~0~~1), 21 CFR 1306.24 (04/01/202~~0~~1), 21 CFR 1306.25 (04/01/202~~0~~1), and 21 CFR 1306.27 (04/01/202~~0~~1).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.185, ORS 475.188

AMEND: 855-139-0350

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference version of 16 CFR (1/1/2021). Revisions are necessary to comply with ORS 183.337.

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 (04<u>1</u>/01/2021), 16 CFR 1701 (04<u>1</u>/01/2021), and 16 CFR 1702 (04<u>1</u>/01/2021).-¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-139-0460

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Amendments include revised reference versions of 21 CFR (4/1/2021) and 21 USC (3/15/2022). Revisions are necessary to comply with ORS 183.337.

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 (04/01/202~~0~~1), 21 CFR 1317.35 (04/01/202~~0~~1), 21 CFR 1317.40 (04/01/202~~0~~1), 21 CFR 1317.55 (04/01/202~~0~~1), 21 CFR 1317.60 (04/01/202~~0~~1), 21 CFR 1317.65 (04/01/202~~0~~1), 21 CFR 1317.70 (04/01/202~~0~~1), 21 CFR 1317.75 (04/01/202~~0~~1), 21 CFR 1317.80 (04/01/202~~0~~1), and 21 CFR 1317.85 (04/01/202~~0~~1); and¶
(d) 21 USC 822 (0~~4/01~~3/15/202~~1~~2), 21 USC 822a (0~~4/01~~3/15/202~~1~~2).
Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218