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PERMANENT ADMINISTRATIVE ORDER

BP 8-2026

CHAPTER 855
BOARD OF PHARMACY

FILED: 06/17/2026 11:40 AM
ARCHIVES DIVISION SECRETARY OF STATE & LEGISLATIVE COUNSEL

FILING CAPTION: Creates new Division 183 for Drug Compounding; Repeals Division 45

EFFECTIVE DATE: 06/17/2026

AGENCY APPROVED DATE: 06/11/2026

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RULES:
855-006-0005, 855-041-1018, 855-043-0545, 855-043-0630, 855-043-0740, 855-045-0200, 855-045-0205, 855-045-0210, 855-045-0220, 855-045-0240, 855-045-0270, 855-183-0001, 855-183-0005, 855-183-0010, 855-183-0015, 855-183-0020, 855-183-0030

AMEND: 855-006-0005

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Amends definition of compounding by adding currently required components and revises referenced versions of the United States Code (USC), United States Pharmacopeia (USP), and Homeopathic Pharmacopoeia of the United States (HPUS).

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. 0~~3~~2/2~~5~~6/202~~5~~6).¶
(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. 0~~3~~2/2~~5~~6/202~~5~~6).¶
(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 who has taken and passed a national pharmacy technician certification examination offered by the Pharmacy Technician Certification Board (PTCB) or National Healthcareer Association (NHA) and is licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board.¶
(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 pr~~eparation,~~ocess of combining, admixing, ~~assembl~~dilut~~ing, p~~ackaging, or~~ooling, reconstituting other than as provided in the manufacturer's labeling, o~~f a drug or device:¶~~
~~(a) As the result of a~~r otherwise altering a drug product or bulk drug substance in accordance with a licensed practitioner's prescription drug order~~,~~ for ~~initiative based on the relationship between the practitioner, the Pharmacist and the patient, in the course of professional practice; or~~a patient specific prescription. Compounding includes the following:¶
(~~b~~a) ~~For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or~~Preparation of drug dosage forms for both human and animal patients;¶
(~~c~~b) ~~The p~~Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing ~~patterns~~or ordering patterns;¶
(c) For sterile preparations, compounding includes repackaging; and ¶
(d) Manipulation of commercial products for patient-specific needs beyond FDA-approved labeling.¶
(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) "Counseling" or "Counsel" means communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device. ¶
(15) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.¶
(16) "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.¶
(17) "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.¶
(18) "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.¶
(19) "Drug utilization review" or "DUR" means evaluation of a prescription to identify and resolve potential problems through the review of information provided to the Pharmacist by the patient, patient's agent, prescriber

and the patient's record.¶
(20) "Entry system" enables control of access to a secured area.¶
(21) "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.¶
(22) "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.¶
(23) "Health care interpreter" has the meaning given that term in ORS 413.550.¶
(24) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.¶
(25) "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.¶
(26) "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. 0~~3~~2/2~~5~~6/202~~5~~6).¶
(27) "Intern" means a person who is enrolled in or has completed a course of study at a board approved college or school of pharmacy and who is licensed with the board as an Intern.¶
(28) "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.¶
(29) "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.¶
(30) "Misbranded" has the same definition as set forth in 21 USC 352 (v. 0~~3~~2/2~~5~~6/202~~5~~6).¶
(31) "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.¶
(32) "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.¶
(33) "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.¶
(34) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.¶
(35) "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.¶
(36) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (v. USP NF 202~~3~~6, Issue ~~3~~1), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 202~~4~~6), or any supplement to any of these.¶
(37) "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.¶

(38) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.¶
(39) "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.¶
(40) "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.¶
(41) "Practice of pharmacy" is as defined in ORS 689.005.¶
(42) "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.¶
(43) "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.¶
(44) "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.¶
(45) "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.¶
(46) "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.¶
(47) "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.¶
(48) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (v. 0~~3~~2/2~~5~~6/202~~5~~6) 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.¶
(49) "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.¶
(50) "Still image capture" means a specific image captured electronically from a video or other image capture device.¶
(51) "Store and forward" means a video or still image record which is saved electronically for future review.¶
(52) "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.¶
(53) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.¶
(54) "Tamper-resistant Prescription" means a form for the purpose of issuing a handwritten or typed prescription, intended to be manually delivered to a pharmacy, which has been developed, and formatted to ensure security, integrity and authenticity using currently accepted technologies. Formatted features may include but are not limited to characteristics such as:¶
(a) The word "void" appears when photocopies are attempted;¶
(b) Background ink which reveals attempted alterations;¶
(c) Heat sensitive ink that changes colors;¶

(d) Penetrating ink to prevent chemical alterations;¶
(e) A watermark which cannot be photocopied;¶
(f) Coin reactive ink that reveals word when rubbed with a coin;¶
(g) Sequential numbering.¶
(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
Statutes/Other Implemented: ORS 689.005, ORS 689.151, ORS 689.155, ORS 689.703

AMEND: 855-041-1018

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Amends (1)(c) by removing Div 045 and adding Div 183. The Board voted to repeal Division 045 upon adoption of new Division 183 Drug Compounding rules.

CHANGES TO RULE:

855-041-1018
Outlet: General Requirements
A Drug Outlet Pharmacy must:¶
(1) Ensure each:¶
(a) Prescription is dispensed in compliance with OAR 855-041, OAR 855-115, OAR 855-120, OAR 855-125, OAR 855-139, OAR 855-141 and OAR 855-143;¶
(b) Controlled substance is dispensed in compliance with OAR 855-080; ¶
(c) Compounded preparation is dispensed in compliance with OAR 855-~~045~~183; and¶
(d) Radiopharmaceutical is dispensed in compliance with OAR 855-042.¶
(2) Comply with all applicable federal and state laws and rules;¶
(3) Ensure all licensees are trained to appropriately perform their duties prior to engaging or assisting in the practice of pharmacy.¶
(4) Ensure each licensed and non-licensed individual only perform duties they are licensed and trained to perform.¶
(5) Be responsible for the actions of each licensed and non-licensed individual.¶
(6) Establish, maintain and enforce the drug outlet written procedures required in OAR 855-041-1040.¶
(7) Comply with the Pharmacist's determination in OAR 855-115-0120(1)(k);¶
(8) Develop, implement and enforce a continuous quality improvement program for dispensing services from a Drug Outlet Pharmacy designed to objectively and systematically:¶
(a) Monitor, evaluate, document the quality and appropriateness of patient care;¶
(b) Improve patient care; and¶
(c) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

AMEND: 855-043-0545

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Amends rule by adding compliance requirements for a Dispensing Practitioner Drug Outlet (DPDO) who dispenses compounded preparations, adds a citation to OAR 855-183 and revises referenced versions of the Code of Federal Regulations (CFR).

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 (v. 01/01/2024~~4~~5), 16 CFR 1701 (v. 01/01/2024~~4~~5) and 16 CFR 1702 (v. 01/01/2024~~4~~5).¶
(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) ~~E~~Unless an exemption applies, 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 exemp~~.¶
(10) The DPDO must ensure that compounded preparations a~~pplies~~re dispensed in compliance with OAR 855-183.¶
[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: 855-043-0630

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Amends rule by adding that a Correctional Facility must ensure that compounded preparations are dispensed in compliance with OAR 855-183, adds citation to OAR 855-043-0610, removes prior reference to 2023 SB 450 and replaces it with ORS 689.813 statute implemented.

CHANGES TO RULE:

855-043-0630
Correctional Facility (CF) - Drug Delivery and Control ¶

(1) Policies and Procedures: The Pharmacist and the practitioner representing the facility are responsible for establishing written policies and procedures for medication management including, but not limited to, drug procurement, dispensing, administration, labeling, medication counseling, drug utilization review, medication records, parenterals, emergency and nonroutine dispensing procedures, stop orders, over-the-counter drugs, security, storage and disposal of drugs within the facility. Policies and procedures must be reviewed and updated annually by the Pharmacist and the practitioner, maintained in the facility; and be made available to the board for inspection. The facility must submit to the board for approval, the name of any employee Pharmacist or a written agreement between the Pharmacist and the facility regarding drug policies and procedures. The facility must notify the board of any change of Pharmacist within 15 days of the change.¶
(2) Dispensing: Prescription drugs must be dispensed by a Pharmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system. The Correctional Facility (CF) must ensure that compounded preparations are dispensed in compliance with OAR 855-183.¶
(3) Unit Dose Dispensing System. The "Unit Dose Dispensing System" is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stock from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled:¶
(a) A unit dose dispensing system must:¶
(A) By nature of the system;¶
(i) Provide for separation of medications by patient name and location; and¶
(ii) Provide for separating medications by day of administration.¶
(B) By means of an individual patient medication record:¶
(i) Record the drug and dosing regimen of those drugs dispensed by the pharmacy;¶
(ii) Record the actual doses dispensed and returned to the pharmacy;¶
(iii) Record the date of the original order and the date the order is discontinued;¶
(iv) Provide a means for the Pharmacist to verify the prescriber's original order;¶
(v) Provide a means for the Pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient; and¶
(vi) Provide a mechanism to easily identify those drugs dispensed by pharmacy that are controlled substances.¶
(b) Each CF utilizing a unit dose dispensing system must establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies must be available in the pharmacy for inspection by the board:¶
(A) Proper utilization of the unit dose system requires that, in as far as is practicable, all medications be in unit dose packaging when dispensed.¶
(B) Controlled substances may be included in the unit dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.¶
(C) Drugs not dispensed in unit dose packaging must be labeled in accordance with (4).¶
(c) The Pharmacist must certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.¶
(d) All medication must be stored in a locked area or locked cart.¶
(4) Labeling: Except as described in ~~SB 450 (2023)~~ORS 689.813, prescription drugs dispensed in individual containers or medication cards must be labeled with the following information:¶
(a) Name and identifying number of the patient/inmate;¶
(b) Name, strength, and quantity of the drug dispensed. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;¶
(c) Name of the prescriber;¶
(d) Initials of the dispenser and the date of dispensing;¶

(e) Directions for use;¶
(f) Auxiliary labels and cautionary statements as required;¶
(g) Manufacturer's expiration date, or an earlier date if preferable; and¶
(h) Name of the pharmacy.¶
(5) Patient counseling:¶
(a) Upon receipt of a prescription drug order and following review by the Pharmacist of the patient's record, the Pharmacist must initiate and provide oral counseling to the patient or to the patient's agent or care giver in all ambulatory care settings and for discharge medications in institutions:¶
(A) Upon request; or¶
(B) On matters which a reasonable and prudent Pharmacist would deem significant; or¶
(C) Whenever the drug prescribed has not previously been dispensed to the patient; or¶
(D) Whenever the patient's medication record shows the drug has not been previously dispensed to the patient in the same dosage, form, strength or with the same written directions.¶
(b) When counseling is provided it must include information that a reasonable and prudent Pharmacist would deem necessary to provide for the safe and effective use of the drug. Such information may include the following:¶
(A) The name and description of the drug;¶
(B) The dosage form, dose, route of administration, and duration of drug therapy;¶
(C) The intended use of the drug and expected actions;¶
(D) Special directions and precautions for preparation, administration, and use by the patient;¶
(E) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;¶
(F) The possible dangers of taking the drug with alcohol, or taking the drug and then operating a motor vehicle or other hazardous machinery;¶
(G) Techniques for self-monitoring drug therapy;¶
(H) Proper storage;¶
(I) Prescription refill information;¶
(J) Action to be taken in the event of a missed dose; and¶
(K) Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.¶
(c) Patient counseling must be in person whenever practicable. Whenever the prescription is delivered outside the confines of the pharmacy by mail or other third party delivery, counseling must be in writing and by free access to the Pharmacist by phone.¶
(d) Subsections (a) and (b) of this section must not apply to those prescription drug orders for inpatients in hospitals or institutions where the drug is to be administered by a nurse or other individual authorized to administer drugs.¶
(e) Notwithstanding the requirements set forth in subsection (a), a Pharmacist is not required to provide oral counseling when a patient refuses the Pharmacist 's attempt to counsel, or when the Pharmacist, on a case by case basis and in the exercise of professional judgment, determines that another form of counseling would be more effective.¶
(f) Board rules for patient counseling must be observed for ~~patient/inmates~~each inmate/patient who self-administers or who ~~are given~~is dispensed prescription drugs when they are released from the CF.¶
(6) Administration: Drugs must be administered to each inmate/patient~~s~~ by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined by the Oregon State Board of Nursing in OAR 851-045-0060. Drugs selected by a registered nurse~~s~~ from ~~manufacturer's or Pharmacist's bulk drug containers~~a bulk drug container as defined in OAR 855-043-0610 must not be administered by an unlicensed person~~s~~, except under certain emergency and nonroutine situations as described in the facility's policies and procedures.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ~~2023 SB 450~~ORS 689.813

AMEND: 855-043-0740

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Amends rule by adding new (12) that a Community Health Clinic must ensure that compounded preparations are dispensed in compliance with OAR 855-183, renumbers the existing rule in (12) to (13) and adds "unless an exemption applies" and revises referenced versions of the Code of Federal Regulations (CFR).

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 (v. 01/01/2024~~4~~5), 16 CFR 1701 (v. 01/01/2024~~4~~5) and 16 CFR 1702 (v. 01/01/2024~~4~~5).¶
(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) ~~E~~The CHC must ensure that compounded preparations are dispensed in compliance with OAR 855-183.¶
(13) Unless an exemption applies, 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

REPEAL: 855-045-0200

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently repeals rule upon adoption of Division 183 Drug Compounding.

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 (01/01/2024); 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 (09/01/2023), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (10/01/2023), 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 (08/01/2022), 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~~

REPEAL: 855-045-0205

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently repeals rule upon adoption of Division 183 Drug Compounding.

CHANGES TO RULE:

~~855-045-0205~~
~~Compliance with New Standards~~
~~As an alternative to the requirements in OAR 855-045-0200(3)(a) and (3)(b) registrants may comply with any or all standards contained in: ¶~~
~~(1) USP <795> Pharmaceutical Compounding-Non-Sterile Preparations (11/1/2023).¶~~
~~(2) USP <797> Pharmaceutical Compounding-Sterile Preparations (11/1/2023).¶~~
~~[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~~

REPEAL: 855-045-0210

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently repeals rule upon adoption of Division 183 Drug Compounding.

CHANGES TO RULE:

~~855-045-0210~~
~~Registration~~
~~(1) A non-resident drug outlet that distributes a non-patient specific compounded drug into Oregon must be registered with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet. ¶~~
~~(2) A resident drug outlet that distributes a non-patient specific human compounded drug within or outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-045-0220

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently repeals rule upon adoption of Division 183 Drug Compounding.

CHANGES TO RULE:

~~855-045-0220~~
~~Personnel and Responsibilities ¶~~

~~(1) All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties.¶~~
~~(2) The Pharmacist-in-Charge (PIC) and the drug outlet must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR 855-045-0200(3) for all aspects of the compounding operation according to the type of compounding performed and must include written procedures for:¶~~
~~(a) Personnel qualifications, to include training, evaluation and requalification;¶~~
~~(b) Hand hygiene;¶~~
~~(c) Garbing;¶~~
~~(d) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;¶~~
~~(e) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;¶~~
~~(f) Components, to include selection, handling, and storage;¶~~
~~(g) Creating master formulation records, with documented pharmacist approval;¶~~
~~(h) Creating compounding records;¶~~
~~(i) Establishing beyond-use dates (BUDs);¶~~
~~(j) Continuous quality assurance program and quality controls, to include release testing, end-product evaluation, and quantitative/qualitative testing;¶~~
~~(k) Completed compounded preparations, to include handling, packaging, storage and transport;¶~~
~~(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug. ¶~~
~~(3) The Pharmacist-in-Charge (PIC) must annually complete a self-inspection using the board's Compounding Self-Inspection Form by July 1 and retain for board inspection.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-045-0240

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently repeals rule upon adoption of Division 183 Drug Compounding.

CHANGES TO RULE:

~~855-045-0240~~
~~Labeling of Compounded Drugs ¶~~

~~In addition to the labeling requirements specified in OAR 855-041, the label of a compounded drug dispensed or distributed must contain the following, at a minimum:¶~~
~~(1) The generic or official name of each active ingredient;¶~~
~~(2) The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation;¶~~
~~(3) The dosage form and route of administration;¶~~
~~(4) Rate of infusion, for a sterile parenteral preparation;¶~~
~~(5) The total quantity of the drug product;¶~~
~~(6) A beyond-use date (BUD), compliant with standards required in OAR 855-045-0200(3); and¶~~
~~(7) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-045-0270

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently repeals rule upon adoption of Division 183 Drug Compounding.

CHANGES TO RULE:

~~855-045-0270~~
~~Records ¶~~

~~(1) All records must be maintained in written or electronic format, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if then retrievable within three business days. Required records include, but are not limited to:¶~~
~~(a) Standard operating procedures, including documented annual review;¶~~
~~(b) Personnel training according to the type of compounding performed, including competency assessment, and qualification records, including corrective actions for any failures, including gloved fingertip and thumb sampling test and aseptic manipulation validation. The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations. At a minimum, the record must contain:¶~~
~~(A) Name and signature of the person receiving the training;¶~~
~~(B) Documentation of initial and continuing competency evaluation, to include dates and results of required elements outlined in the outlet's policies and procedures; and¶~~
~~(C) Name and signature of the pharmacist who is designated as responsible for validation of the completion of all training.¶~~
~~(c) Engineering and environmental control records, including equipment, calibration, certification, environmental air and surface monitoring procedures and results, as well as documentation of any corrective actions taken; and¶~~
~~(d) Cleaning and disinfecting of all compounding areas and equipment.¶~~
~~(2) Master formulation records, including as appropriate:¶~~
~~(a) The name, strength and dosage form of the preparation;¶~~
~~(b) Physical description of the final preparation;¶~~
~~(c) Ingredient identities and amounts;¶~~
~~(d) Complete instructions for preparing the product, including equipment, supplies, and a description of the compounding steps;¶~~
~~(e) Calculations needed to determine and verify quantities of components and doses of ingredients; ¶~~
~~(f) Compatibility and stability information, including references;¶~~
~~(g) Beyond-use date (BUD) assignment and storage requirements, including reference source;¶~~
~~(h) Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration;¶~~
~~(i) Quality control procedures and expected results; and ¶~~
~~(j) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.¶~~
~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:¶~~
~~(a) Drug name, strength, and dosage form of the preparation;¶~~
~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration; ¶~~
~~(c) Master formulation record reference for the preparation, when applicable;¶~~
~~(d) Quantity prepared;¶~~
~~(e) Date and time prepared;¶~~
~~(f) Pharmacy unique lot number;¶~~
~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;¶~~
~~(h) Beyond-use date;¶~~
~~(i) Pharmacist documented verification of order accuracy;¶~~
~~(j) Identity of all personnel involved in each step of the process;¶~~
~~(k) Documentation of the proper weight and measurement of each ingredient;¶~~
~~(l) Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used;¶~~
~~(m) Total quantity compounded;¶~~
~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master~~

~~formulation record;¶~~
~~(o) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;¶~~
~~(p) Records of dispensing or transfer of all compounded preparations; and ¶~~
~~(q) Any other information required by the pharmacy's policies and procedures.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

ADOPT: 855-183-0001

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently adopts new drug compounding applicability requirements for entities located in or outside Oregon who engage in the practice of compounding drugs for dispensing, delivery or distribution in Oregon.

CHANGES TO RULE:

855-183-0001
Applicability
(1) All Division 183 rules apply to sterile and non-sterile compounding of a drug for humans and animals.¶
(2) Entities that are located in or outside Oregon that engage in the practice of compounding a drug for dispensing, delivery or distribution in Oregon must register with the board as a Drug Outlet and comply with board regulations.¶
(3) Entities that are registered with the FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act in 21 USC 353b (03/05/2026) must register with the board as a Manufacturer in OAR 855-060.¶
(4) Compounding does not include: ¶
(a) Mixing, reconstituting, or other such acts that are performed in accordance with directions contained in FDA-approved labeling or supplemental materials provided by the product's manufacturer.¶
(b) Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's FDA-approved labeling when the:¶
(A) Product is prepared as a single dose for an individual patient; and¶
(B) Labeling includes information for the diluent, the resultant strength, the container closure system and Beyond Use Date.¶
(c) Docking and activation of a proprietary bag and vial system in accordance with the FDA-approved labeling for immediate administration to an individual patient. ¶
(d) The addition of flavoring to a drug intended for dispensation if the flavoring:¶
(A) Is inert, nonallergenic and has no effect other than imparting a flavor to the drug or¶
modifying the flavor of the drug; and¶
(B) Does not constitute more than five percent of the total volume of the drug. ¶
[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]
Statutory/Other Authority: ORS 689.205, ORS 689.608
Statutes/Other Implemented: ORS 689.155, ORS 689.608

ADOPT: 855-183-0005

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently adopts new drug compounding definitions for Division 183, including "Compounding Area" and "Compounding".

CHANGES TO RULE:

855-183-0005
Definitions
(1) Phrases or definitions used in OAR 855-183 are the same as provided in OAR 855-006, or as included in the USP standard adopted by reference unless otherwise specified.¶
(2) "Compounding Area" means a location designated by the registrant that limits personnel access when activities and items related to compounding may occur.¶
(3) "Compounding" means the process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance in accordance with a licensed practitioner's prescription drug order for a patient specific prescription. Compounding includes the following:¶
(a) Preparation of drug dosage forms for both human and animal patients;¶
(b) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing or ordering patterns;¶
(c) For sterile preparations, compounding includes repackaging; and¶
(d) Manipulation of commercial products for patient-specific needs beyond FDA-approved labeling.¶
[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

ADOPT: 855-183-0010

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently adopts new rule related to notification requirements for drug outlets who initiate sterile compounding, non-sterile compounding or both.

CHANGES TO RULE:

855-183-0010
Notification Requirements
Each Drug Outlet must notify the board within 15 days of initiation of sterile compounding, non-sterile compounding or both using a form provided by the board.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0015

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently adopts new general requirements rules for drug compounding. Adds requirements for following USP and NF standards, utilizing and completing self-inspection forms, records retention, requirements for Dispensing Practitioner Drug Outlets, Correctional Facilities, and Community Health Clinics, inspection requirements, accreditation requirements for Non-Resident Drug Outlets, and prohibitions in the compounding area.

CHANGES TO RULE:

855-183-0015
Requirements: General
(1) All drug compounding must adhere to the following standards of the United States Pharmacopeia (USP) and the National Formulary (NF) including:¶
(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (11/01/2023); ¶
(b) USP <797> Pharmaceutical Compounding - Sterile Preparations (02/01/2026); ¶
(c) USP <800> Hazardous Drugs - Handling in Healthcare Settings (11/01/2023); and¶
(d) USP <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging (01/01/2024).¶
(2) In addition to completing the appropriate drug outlet self-inspection form by July 1 of each year and within 15 days of becoming the Pharmacist-in-Charge (PIC), the PIC must also complete the Compounding Self-Inspection form provided by the board. ¶
(3) All compounding records must be maintained for 3 years in accordance with OAR 855-104-0055.¶
(4) A pharmacist for a pharmacy or prescriber with prescribing and dispensing privileges for a Dispensing Practitioner Drug Outlet, Correctional Facility or Community Health Clinic must;¶
(a) Supervise compounding;¶
(b) Ensure only authorized personnel are in the compounding area; and¶
(c) Verify and document verification of all compounded products, compounding records and master formulation records.¶
(5) Comply with all state and federal laws and rules.¶
(6) Effective November 1, 2027, Non-Resident Drug Outlets that prepare compounded products must be inspected and be in compliance with current USP standards. If a Drug Outlet's home state does not inspect and require compliance with current USP standards, the Drug Outlet, prior to obtaining or renewing a license, must provide evidence to the board that the Drug Outlet is accredited, certified or received an approved inspection within the last two years as follows: ¶
(a) Pharmacy Compounding Accreditation Board (PCAB) provided by the Accreditation Commission for Health Care (ACHC);¶
(b) Coalition for Compounding Excellence (CCE);¶
(c) National Association of Boards of Pharmacy (NABP); ¶
(d) The Joint Commission; or¶
(e) As otherwise approved by the board.¶
(7) The following is prohibited in the compounding area:¶
(a) Animal(s); and¶
(b) For non-sterile compounding, flooring that is not easily cleanable, is porous or particle generating. ¶
[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

ADOPT: 855-183-0020

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently adopts new rules for drug compounding including labeling requirements for both preparation of a compounded product, dispensing a compounding product and requirements for a drug outlet's policies and procedures.

CHANGES TO RULE:

855-183-0020
Labeling
(1) Labeling requirements for preparation of a compounded product must follow USP <795> (11/01/2023), and USP <797> (02/01/2026).¶
(2) Labeling requirements for dispensing a compounded product must follow OAR 855-041, OAR 855-043, and OAR 855-139.¶
(3) The Drug Outlet must maintain policies and procedures in compliance with all labeling requirements referenced in this rule.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0030

NOTICE FILED DATE: 04/15/2026

RULE SUMMARY: Permanently adopts new rules for drug compounding including requirements for pharmacies compounding drugs for a veterinarian for non-food producing animals.

CHANGES TO RULE:

855-183-0030
Pharmacy Compounding for a Veterinarian - Non-Food Producing Animals
(1) A patient specific prescription is not required to compound drugs for a licensed veterinarian when:¶
(a) The request for drug compounding is submitted by a licensed veterinarian; and¶
(b) The compounded drug will only be dispensed for use by non-food producing animals.¶
(2) The drug compounded in accordance with section (1) of this rule can only be delivered directly to the licensed veterinarian or their office.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155