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ARCHIVES DIVISION
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# NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

**FILED**
06/16/2023 1:00 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Proactive procedural review; Creates new Division 183 for Drug Compounding

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/26/2023 4:30 PM

*The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.*

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Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

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

DATE: 07/26/2023
TIME: 9:30 AM
OFFICER: Rachel Melvin

HEARING LOCATION
ADDRESS: Oregon Board of Pharmacy - Virtual Meeting , 800 NE Oregon St., Suite 150, Portland , OR 97232

REMOTE MEETING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 627978258
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.
If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name, email address and phone number to pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on July 26, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Creates a new Division 183 for Drug Compounding. Adds additional general requirements for Drug Outlet Pharmacies, Dispensing Practitioner Drug Outlets (DPDO)and Correctional Facilities and Community Health Clinics (CHC) related to dispensing compounded drugs in Divisions 041 and 043. Proposed amendments are a result of the board's 2022-2026 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

USP Chapters: USP Compounding Compendium https://www.usp.org/products/usp-compounding-compendium

Designated Person Responsibilities: ASHP List https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/compounding/docs/USP-Designated-Persons-Responsibilities.pdf

Sterile Compounding Technology:
ISMP Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology (2016 and 2022)
https://www.ismp.org/sites/default/files/attachments/2017-11/Guidelines for Safe Preparation of Compounded Sterile Preperations_ revised 2016.pdf
https://www.ismp.org/system/files/resources/2022-04/ISMP195-Compouding Guidelines v1-042722-2.pdf

Pedersen CA, Schneider PJ, Ganio MC, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: Dispensing and administration-2020. Am J Health Syst Pharm. 2021 Jun 7;78(12):1074-1093. doi: 10.1093/ajhp/zxab120. PMID: 33754638; PMCID: PMC8083667.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8083667/

Moniz TT, Chu S, Tom C, Lutz P, Arnold A, Gura KM, Patterson A. Sterile product compounding using an i.v. compounding workflow management system at a pediatric hospital. Am J Health Syst Pharm. 2014 Aug 1;71(15):1311-7. doi: 10.2146/ajhp130649. PMID: 25027539. https://pubmed.ncbi.nlm.nih.gov/25027539/

Speth SL, Fields DB, Schlemmer CB, Harrison C. Optimizing I.V. workflow. Am J Health Syst Pharm. 2013; 70(23):2076,2078-80 https://pubmed.ncbi.nlm.nih.gov/24249755/

Deng Y, Lin AC, Hingl J, Huang G, Altaye M, Maynard H, Mayhaus D, Penm J. Risk factors for i.v. compounding errors when using an automated workflow management system. Am J Health Syst Pharm. 2016 Jun 15;73(12):887-93. doi: 10.2146/ajhp150278. PMID: 27261239. https://pubmed.ncbi.nlm.nih.gov/27261239/

NV: NAC 639.67017 Use of automated compounding devices. https://www.leg.state.nv.us/NAC/NAC-639.html#NAC639Sec67017

Standard Operating Procedures: ASHP List 795 797 https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/compounding/docs/USP-795-List-Of-Standard-Operating-Procedures.pdf
https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/compounding/docs/USP-797-List-Of-Standard-Operating-Procedures.pdf

Compounded Drug Recalls: CA Law 4126.9. Recall of Nonsterile Compounded Drugs; 4127.8. Pharmacies that Compound Sterile Drug Products; Recalls; Requirements https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf

Requirements For Use by a Veterinarian: Compounding Animal Drugs from Bulk Drug Substances Guidance for Industry (August 2022), Index of Legally Marketed Unapproved New Animal Drugs for Minor Species
https://www.fda.gov/media/132567/download https://www.fda.gov/animal-veterinary/minor-useminor-species/index-legally-marketed-unapproved-new-animal-drugs-minor-species

Essential Copies: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product

Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (January 2018), FDA drug shortages database, ASHP drug shortages database https://www.fda.gov/media/98973/download

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

Reorganizing proposed rules may provide clarity, transparency and promote patient safety. No effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate registration and compliance requirements will positively impact all Oregonians in all communities.

FISCAL AND ECONOMIC IMPACT:

Compounding Workgroup members stated that in their experience, barcoding and imaging technology procurement, implementation, ongoing maintenance, and training is estimated to cost between $30,000 - $130,000 initially and $50,000 annually. This type of technology is typically customized, requires specialized training and requires extra staff to operate.
In order to comply, Drug Outlet pharmacies, Dispensing Practitioner Drug Outlets, Correctional Facility's and Community Health Clinics who engage in compounding will need to pay for access to the USP Compounding Compendium estimated to cost $250 per year per user. Previous versions of USP chapters included in the compounding compendium are available on the internet free of charge.

COST OF COMPLIANCE:

*(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).*

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

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

Small businesses were not involved in the development of proposed revisions to these rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

855-041-1018, 855-043-0545, 855-043-0630, 855-043-0740, 855-183-0001, 855-183-0005, 855-183-0010, 855-183-0050, 855-183-0200, 855-183-0205, 855-183-0370, 855-183-0400, 855-183-0410, 855-183-0420, 855-183-

0450, 855-183-0500, 855-183-0520, 855-183-0550, 855-183-0560, 855-183-0565, 855-183-0570, 855-183-0575, 855-183-0600, 855-183-0700, 855-183-0710, 855-183-0730, 855-183-0740

AMEND: 855-041-1018

RULE SUMMARY: Proposed amendments add compliance requirements related to dispensing compounded preparations and radiopharmaceutical prescriptions.

CHANGES TO RULE:

855-041-1018
Outlet: General Requirements
A drug outlet pharmacy must:¶
(1) Ensure each ~~p~~:¶
(a) Prescription is dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, OAR 855-041 and OAR 855-04~~1;80~~;¶
(b) Compounded preparation is dispensed in compliance with OAR 855-183; and¶
(c) 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 and enforce the drug outlet written procedures for use of Certified Oregon Pharmacy Technicians or Pharmacy Technicians as required by OAR 855-025-0035;¶
(5) Comply with the Pharmacist's determination in OAR 855-019-0200(4)(e).¶
(6) 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, 2022 HB 4034
Statutes/Other Implemented: ORS 689.151, 2022 HB 4034, ORS 689.508, ORS 689.155

AMEND: 855-043-0545

RULE SUMMARY: Proposed amendment adds compliance requirements for a DPDO who dispenses compounded preparations.

CHANGES TO RULE:

855-043-0545
Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery
(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by the practitioner's licensing board.¶
(2) Drugs dispensed from the DPDO must be dispensed in compliance with the requirements of the practitioner's licensing board.¶
(3) A DPDO must comply with all requirements of State or federal law.¶
(4) A DPDO must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).¶
(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) The DPDO must ensure that compounded preparations are dispensed in compliance with OAR 855-183.¶
(10) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0630

RULE SUMMARY: Proposed amendments include revising "shall" to "must" and adds that a correctional facility must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

CHANGES TO RULE:

855-043-0630
Correctional Facility - Drug Delivery and Control ¶

(1) Policies and Procedures: The ~~p~~Pharmacist and the practitioner representing the facility ~~shall~~must be 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 withing the facility. Policies and procedures ~~shall~~must be reviewed and updated annually by the ~~p~~Pharmacist and the practitioner, maintained in the facility; and be made available to the ~~B~~board for inspection. The facility ~~shall~~must submit to the ~~B~~board for approval, the name of any employee ~~p~~Pharmacist or a written agreement between the ~~p~~Pharmacist and the facility regarding drug policies and procedures. The facility ~~shall~~must notify the ~~B~~board of any change of ~~p~~Pharmacist within 15 days of the change.¶
(2) Dispensing: Prescription drugs shall be dispensed by a ~~p~~Pharmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system. The Correctional Facility 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 ~~shall~~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 correctional facility utilizing a unit dose dispensing system ~~shall~~must establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies ~~shall~~must be available in the pharmacy for inspection by the ~~B~~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 OAR 855-041-0177(4).¶
(c) The ~~p~~Pharmacist ~~shall~~must certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.¶
(d) All medication ~~shall~~must be stored in a locked area or locked cart.¶
(4) Labeling: Prescription drugs dispensed in individual containers or medication cards ~~shall~~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 ~~p~~Pharmacist of the patient's record, the ~~p~~Pharmacist ~~shall~~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 ~~shall~~must include information that a reasonable and prudent ~~p~~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 ~~shall~~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 ~~shall~~must be in writing and by free access to the ~~p~~Pharmacist by phone.¶
(d) Subsections (a) and (b) of this section ~~shall~~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 ~~p~~Pharmacist is not required to provide oral counseling when a patient refuses the ~~p~~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 who self administer or who are given prescription drugs when they are released from the correctional facility.¶
(6) Administration: Drugs ~~shall~~must be administered to inmate/ patients by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined in Nursing Board administrative rule 851-047-0020. Drugs selected by registered nurses from manufacturer's or ~~p~~Pharmacist's bulk drug containers ~~shall~~must not be administered by unlicensed persons, 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

AMEND: 855-043-0740

RULE SUMMARY: Proposed amendment adds that a CHC must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

CHANGES TO RULE:

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

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.¶
(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.¶
(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.¶
(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.¶
(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.¶
(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).¶
(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) The CHC must ensure that compounded preparations are dispensed in compliance with OAR 855-183.¶
(13) 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

ADOPT: 855-183-0001

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0200 to OAR 855-183-0001 related to applicability.

CHANGES TO RULE:

855-183-0001
Applicability
(1) Any person, including any business entity, located in or outside Oregon that engages 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.¶
(2) These rules apply to sterile and non-sterile compounding of a drug for humans and animals.¶
(3) Entities that are registered with FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act in 21 USC 353b (04/10/2023) must register with the board as a manufacturer in OAR 855-060.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0005

RULE SUMMARY: Proposed rule revises and relocates rule OAR 855-006-0005(11) to OAR 855-183-0005 and adds new language related to compounding definitions.

CHANGES TO RULE:

855-183-0005
Definitions
(1) Phrases or definitions used in OAR 855-183 are the same as included in the USP standard adopted by reference unless otherwise specified.¶
(2) "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 to create a compounded preparation.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0010

RULE SUMMARY: Proposed new rule adds general designation requirements for each Drug Outlet that practices drug compounding.

CHANGES TO RULE:

855-183-0010
Designation
Each Drug Outlet must maintain an accurate compounding status in the board's online registration system.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0050

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0220 to OAR 855-183-0050 related to personnel requirements.

CHANGES TO RULE:

855-183-0050
Personnel
(1) All personnel who prepare and supervise the preparation of a compound must obtain the education, training, and experience to demonstrate competency as required by the USP standards applicable to the preparation of compounded sterile and non-sterile products and be capable and qualified to perform assigned duties. ¶
(2) Training must be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that compounding pharmacy personnel remain familiar with applicable operations and policies and procedures.¶
(3) The training must be documented and records retained according to OAR 855-183-0550.¶
(4) A Pharmacist must be the designated person as required by the USP standards for each act that requires independent judgment or is the practice of pharmacy as defined ORS 689.005.¶
(5) Each Drug Outlet must: ¶
(a) Have a designated person as required by the USP standards who is a:¶
(A) Pharmacist for the Drug Outlet Pharmacy¶
(B) Practitioner with prescriptive and dispensing authority for the Dispensing Practitioner Drug Outlet or Community Health Center.¶
(b) Ensure only personnel authorized by the person supervising compounding are in the compounding area.¶
[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: 855-183-0200

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0200(3) to OAR 855-183-0200 and adds general requirements for drug compounding.

CHANGES TO RULE:

855-183-0200
Requirements: General
(1) 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 (11/01/2022) and all chapters referenced therein, including but not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 659 (04/01/2021), 797 (11/01/2023), 800 (07/01/2020), 1112 (2013), 1163 (12/01/2020), and 1231 (12/01/2021);¶
(b) USP <797> Pharmaceutical Compounding-Sterile Preparations (11/01/2022) and all chapters referenced therein, including but not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018), 659 (04/01/2021), 788 (05/01/2013), 789 (08/01/2015), 800 (07/01/2020), 825 (12/01/2020), 1066 (08/01/2015), 1085 (12/01/2020), 1113 (2013), 1116 (2013), 1163 (12/01/2020), 1197 (05/01/2021), 1207 (08/01/2016), 1223 (05/01/2018), 1225 (08/01/2017), 1228.1 (08/01/2016), 1228.4 (11/01/2019), 1229 (08/01/2022), 1229.1 (2013), 1229.4 (05/01/2018), 1229.5 (08/01/2022), 1229.8 (05/01/2018), and 1229.9 (08/01/2016);¶
(c) USP <800> Hazardous Drugs-Handling in Healthcare Settings (07/01/2020) and all chapters referenced therein, including but not limited to Chapters 795 (11/01/2022), and 797 (11/01/2022); and¶
(d) USP <825> Radiopharmaceuticals-Preparation, Compounding, Dispensing, and Repackaging (12/01/2020) and all chapters referenced therein, including but not limited to Chapters 71 (2013), 85 (05/01/2018), 659 (04/01/2021), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1113 (2013), 1116 (2013), and 1163 (12/01/2020); ¶
(2) A drug must only be compounded and dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs except as provided in OAR 855-183-0730. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.¶
(3) A drug may be compounded for a commercially available product according to OAR 855-183-0710.¶
(4) All sterile compounding must utilize a system that incorporates:¶
(a) Barcoding to verify ingredients; and¶
(b) Imaging or gravimetrics to verify ingredient quantity and finished CSP volumes.¶
(5) For CNSPs, the compounding area must have a visible line of demarcation.¶
[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: 855-183-0205

RULE SUMMARY: Proposed new rule adds compounding technology requirements related to Automated Compounding Devices (ACDs).

CHANGES TO RULE:

855-183-0205
Technology: Automated Compounding Devices (ACDs)
(1) A Drug Outlet Pharmacy, DPDO, or CHC may use an Automated Compounding Device (ACD) to:¶
(a) Assist with the compounding of a drug product; or¶
(b) Produce a final compounded drug product.¶
(2) If a Drug Outlet Pharmacy, DPDO, or CHC uses an ACD as described in (1), the outlet must establish and maintain written policies and procedures, in addition to the policies and procedures established and maintained pursuant to OAR 855-183-0500, that address:¶
(a) The qualifications and training that a person must have to use the ACD;¶
(b) The routine maintenance and cleaning required to be performed on the ACD which, at a minimum, satisfies the requirements for maintenance and cleaning established by the manufacturer of the ACD; and¶
(c) The testing required to be performed on the ACD to ensure that the ACD is measuring and dispensing the components of the compounded drug product and manufacturing the final compounded drug product within tolerances of not more than plus or minus 5 percent.¶
(3) If a Drug Outlet Pharmacy, DPDO, or CHC uses an ACD to assist with the compounding of a drug product for parenteral nutrition, the Drug Outlet Pharmacy, DPDO, or CHC must establish safe maximum limits for each additive that may be used in compounding such a drug product. The outlet must ensure that:¶
(a) The ACD will cease compounding the drug product for parenteral nutrition if a maximum limit for an additive will be exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order; or¶
(b) If an ACD cannot be programmed to cease the compounding process as described in (a):¶
(A) The ACD is equipped with an audible alarm or some other mechanism that will alert the pharmacist if a maximum limit for an additive has been exceeded; and¶
(B) The Drug Outlet Pharmacy, DPDO, or CHC has written policies and procedures to prevent the continuation of the compounding process once a maximum limit for an additive has been exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.¶
(4) If the Drug Outlet Pharmacy, DPDO, or CHC uses a computerized order entry system in conjunction with the ACD, the pharmacy must ensure that the computerized order entry system will cease processing the order if a maximum limit for an additive will be exceeded until a Pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.¶
(5) A Drug Outlet Pharmacy, DPDO, or CHC must make and maintain records that evidence compliance by the outlet with the policies and procedures required by this section.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0370

RULE SUMMARY: Proposed new rule adds delivery requirements for each Drug Outlet Pharmacy who ships or delivers compounded preparations.

CHANGES TO RULE:

855-183-0370
Delivery
Each Drug Outlet Pharmacy, DPDO and CHC, must ensure the environmental control, stability, and sterility of all preparations shipped. Therefore, any compounded preparation must be shipped or delivered to a patient or patient's agent in appropriate temperature-controlled delivery containers and stored appropriately according to USP <659> Packaging and Storage Requirements (04/01/2021). Information on appropriate storage must be provided to the patient or patient's agent.¶
[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: 855-183-0400

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0240 to OAR 855-183-0400 related to labeling requirements for compounded non-sterile preparations (CNSPs).

CHANGES TO RULE:

855-183-0400
Labeling: Compounded Non-Sterile Preparations (CNSPs)
In addition to the labeling requirements specified in USP <795> (11/01/2022), OAR 855-041, and 855-139, the label of a compounded preparation must also prominently and legibly contain the following, at a minimum:¶
(1) The strength of each active ingredient, to include the base;¶
(2) The route of administration;¶
(3) Indication that the preparation is compounded.¶
(4) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.¶
(5) Compounding facility name, and contact information if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded.¶
[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: 855-183-0410

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0240 to OAR 855-183-0410 related to labeling requirements for compounded sterile preparations.

CHANGES TO RULE:

855-183-0410
Labeling: Compounded Sterile Preparations (CSPs)
In addition to the labeling requirements specified in USP <797> (11/01/2022), OAR 855-041, and 855-139, the label of a compounded preparation must also prominently and legibly contain the following, at a minimum:¶
(1) The strength of each active ingredient, to include the base solution for a sterile parenteral preparation;¶
(2) The route of administration;¶
(3) Rate of infusion or titration parameters, for a sterile parenteral preparation;¶
(4) Indication that the preparation is compounded.¶
(5) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.¶
(6) Compounding facility name, and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded.¶
[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: 855-183-0420

RULE SUMMARY: Proposed new rule adds labeling requirements for Compounded Non-Sterile Preparations (CNSPs) and Compounded Sterile Preparations (CSPs) for future use.

CHANGES TO RULE:

855-183-0420
Labeling: Preparations CNSP and CSP for Future Use
Labels for a compounded drug that is prepared in anticipation of a patient-specific prescription must contain the following:¶
(1) The name, strength or concentration, and quantity of each active ingredient used in the compounded drug preparation;¶
(2) The total quantity or volume of the compounded drug preparation;¶
(3) Internal lot number;¶
(4) The assigned beyond-use date (BUD);¶
(5) Indication that the preparation is compounded; and¶
(6) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary;
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0450

RULE SUMMARY: Proposed new rule adds drug disposal requirements for hazardous and infectious waste.

CHANGES TO RULE:

855-183-0450
Disposal
The Drug Outlet Pharmacy, DPDO and CHC is responsible for ensuring that there is a system for the disposal of hazardous and infectious waste in accordance with applicable state and federal laws and USP <800> Hazardous Drugs - Handling in Healthcare Settings (07/01/2020).¶
[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: 855-183-0500

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0220 to OAR 855-183-0500 related to policies and procedures for registrants who practice drug compounding.

CHANGES TO RULE:

855-183-0500
Policies & Procedures
Each Drug Outlet Pharmacy, DPDO and CHC must establish, maintain and enforce written policies and procedures in accordance with the standards required in OAR 855-183-0200 for all aspects of the compounding operation according to the type of compounding performed (e.g., CNSP, CSP Type 1, 2 or 3) and must include written procedures for:¶
(1) Personnel qualifications, to include training and ongoing competency assessment;¶
(2) Hand hygiene;¶
(3) Garbing;¶
(4) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling and viable particles;¶
(5) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;¶
(6) Components, to include selection, receipt, handling, and storage and disposal;¶
(7) Creating master formulation records, with documented approval by a Pharmacist for a Drug Outlet Pharmacy or prescriber with prescribing and dispensing privileges for a DPDO or CHC;¶
(8) Creating compounding records;¶
(9) Establishing BUDs;¶
(10) Labeling; ¶
(11) Continuous quality assurance program and quality controls, to include:¶
(a) Release testing, end-product evaluation, and quantitative/qualitative testing;¶
(b) Complaint handling process; ¶
(c) Adverse event and error reporting process; and¶
(d) Recall procedure; and¶
(12) Completed compounded preparations, to include handling, packaging, storage and transport.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0520

RULE SUMMARY: Proposed new rule adds requirements for compounded drug recalls.

CHANGES TO RULE:

855-183-0520
Recalls
(1) Each Drug Outlet Pharmacy, DPDO and CHC that issues a recall regarding a compounded drug must, in addition to any other duties, contact each recipient pharmacy, prescriber and patient of the recalled drug and notify the board as soon as possible within 12 hours of the recall if both of the following apply:¶
(a) Use of or exposure to the recalled drug may cause serious adverse health consequences or death; and¶
(b) The recalled drug was dispensed, or is intended for use, in this state.¶
(2) A recall issued pursuant to (1)(a) must be made as follows:¶
(a) If the recalled drug was dispensed directly to the patient, notification must be made to the patient and the prescriber.¶
(b) If the recalled drug was dispensed directly to the prescriber, notification must be made to the prescriber who must notify the patient, as appropriate.¶
(c) If the recalled drug was dispensed directly to a pharmacy, notification must be made to the pharmacy, who must notify the prescriber or patient, as appropriate. ¶
(d) After issuing a recall, the Drug Outlet Pharmacy, DPDO, or CHC must attempt to notify the recipient pharmacy, prescriber, and patient of the recalled drug within 12 hours. If contact cannot be established within this timeframe, the Drug Outlet Pharmacy, DPDO, or CHC must make two additional attempts to provide notification within 48 hours of the initial recall. In the event that all attempts to inform the recipient are unsuccessful, the Drug Outlet Pharmacy, DPDO, or CHC must send notification via certified mail. Each recall attempt must be documented.¶
(3) A Drug Outlet Pharmacy, DPDO or CHC that has been advised that a patient has been harmed by using a compounded product potentially attributable to the Drug Outlet Pharmacy, DPDO or CHC must report the event to MedWatch within 72 hours of the Drug Outlet Pharmacy, DPDO or CHC being advised.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0550

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0270 to OAR 855-183-0550 related to general records requirements.

CHANGES TO RULE:

855-183-0550
Records: General Requirements
In addition to record-keeping and reporting requirements of OAR 855, the following records must be maintained: ¶
(1) All dispensing of CNSP and CSPs.¶
(2) Any other records required to conform to and demonstrate compliance with USP standards and federal law.¶
(3) 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. The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations.¶
(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;¶
(d) Cleaning, sanitizing and disinfecting of all compounding areas and equipment;¶
(e) Receipt, handling, storage and disposal of components;¶
(f) Master formulation records for all:¶
(A) CNSPs;¶
(B) CSPs prepared for more than one patient; ¶
(C) CSPs prepared from a non-sterile ingredient;¶
(g) Compounding records for all:¶
(A) CNSPs; ¶
(B) CSPs; and¶
(C) Immediate-use CSPs prepared for more than one patient; and¶
(h) Release testing, end-product evaluation and quantitative/qualitative testing;¶
(4) Information related to complaints and adverse events including corrective actions taken. ¶
(5) Results of investigations including corrective actions taken and recalls.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0560

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0270(2) to OAR 855-183-0560 related to master formulation records (MFR) for compounded non-sterile preparations.

CHANGES TO RULE:

855-183-0560
Records: Master Formulation Records (MFR) for CNSP
In addition to the MFR requirements specified in USP <795> (11/01/2022), the MFR for a CNSP must contain the following, at a minimum:¶
(1) Appropriate calculations to determine and verify quantities and concentrations of components and strength or activity of the APIs; ¶
(2) Compatibility and stability information, including references as available;¶
(3) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate;¶
(4) Other information needed to describe the compounding process and ensure repeatability; and¶
(5) Any other information required by the pharmacy's policies and procedures.¶
[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: 855-183-0565

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0270(2) to OAR 855-183-0565 related to master formulation records (MFR) for compounded sterile preparations.

CHANGES TO RULE:

855-183-0565
Records: Master Formulation Records (MFR) for CSP
In addition to the MFR requirements specified in USP <797> (11/01/2022), the MFR for a CSP must contain the following, at a minimum:¶
(1) Appropriate calculations to determine and verify quantities and concentrations of components and if performing non-sterile to sterile compounding the strength or activity of the APIs; ¶
(2) Compatibility and stability information, including references;¶
(3) Quality control procedures that include the expected results and limits of tolerability for quantitative results; ¶
(4) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and¶
(5) Any other information required by the pharmacy's policies and procedures.¶
[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: 855-183-0570

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0270(3) to OAR 855-183-0570 related to requirements for compounding records for compounded non-sterile preparations.

CHANGES TO RULE:

855-183-0570
Records: Compounding Records (CR) for CNSP
In addition to the CR requirements specified in USP <795> (11/01/2022), the CR for a CNSP must contain the following, at a minimum: ¶
(1) Pharmacist performance and documented verification that each of the following are correct:¶
(a) Formula; ¶
(b) Calculations;¶
(c) Quantities;¶
(d) Concentration of components;¶
(e) If applicable, strength or activity of the API; ¶
(f) Compounding technique; and¶
(g) Accurate preparation of the CNSP.¶
(2) Final yield;¶
(3) 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;¶
(4) Records of dispensing or transfer of all compounded preparations; and ¶
(5) Any other information required by the pharmacy's policies and procedures.¶
¶
[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: 855-183-0575

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0270(3) to OAR 855-183-0575 related to requirements for compounding records for compounded sterile preparations.

CHANGES TO RULE:

855-183-0575
Records: Compounding Records (CR) for CSP
In addition to the CR requirements specified in USP <797> (11/01/2022), the CR for a CSP must contain the following, at a minimum: ¶
(1) Total quantity compounded;¶
(2) Pharmacist performance and documented verification that each of the following are correct:¶
(a) Formula; ¶
(b) Calculations;¶
(c) Quantities;¶
(d) Concentration of components;¶
(e) If applicable, strength or activity of the API; ¶
(f) Compounding technique; and¶
(g) Accurate preparation of the CSP;¶
(3) Final yield;¶
(4) 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;¶
(5) Records of dispensing or transfer of all compounded preparations; and ¶
(6) Any other information required by the pharmacy's policies and procedures.¶
¶
[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: 855-183-0600

RULE SUMMARY: Proposed new rule adds prohibited practices related to compounded drug preparation.

CHANGES TO RULE:

855-183-0600
Prohibited Practices
The following practices are prohibited in the compounding of a drug preparation: ¶
(1) Verification of components after their addition to the final container (e.g., proxy verification, syringe pull-back method); ¶
(2) Carpet in compounding area; and¶
(3) Animals in the compounding area.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0700

RULE SUMMARY: Proposed new rule adds requirements for compounding services related to preparation according to FDA approved labeling.

CHANGES TO RULE:

855-183-0700
Service: Preparation According to FDA Approved Labeling
(1) Compounding does not include 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.¶
(2) Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's FDA approved labeling the:¶
(a) Product must be prepared as a single dose for an individual patient; and¶
(b) Labeling must include information for the diluent, the resultant strength, the container closure system, and storage time.¶
(3) If compounding a hazardous drug, USP <800> (07/01/2020) must be followed.¶
(4) Proprietary bag and vial systems: Docking and activation of proprietary bag and vial systems in accordance with the FDA approved labeling for immediate administration to an individual patient is not considered compounding and may be performed outside of an International Organization for Standardization (ISO) Class 5 environment.¶
(a) Docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in an ISO Class 5 environment in accordance with USP <797> (11/01/2023).¶
(b) BUDs for proprietary bag and vial systems must not be longer than those specified in the manufacturer's 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: 855-183-0710

RULE SUMMARY: Proposed new rule adds requirements for compounding services related to copies of an approved drug.

CHANGES TO RULE:

855-183-0710
Service: Copies of a FDA Approved Drug
A Drug Outlet Pharmacy, DPDO, CHC or outsourcing facility may only compound a drug preparation that is essentially a copy of a FDA approved drug if: ¶
(1) The compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. The relevant change and the significant clinical difference produced for the patient must be indicated on the prescription. ¶
(2) The approved drug is identified as currently in shortage on the:¶
(a) FDA drug shortages database published on the FDA website, www.accessdata.fda.gov/scripts/drugshortages/default.cfm; or¶
(b) Drug shortages database published on the American Society of Health-System Pharmacists (ASHP) website, www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages¶
(3) The Drug Outlet Pharmacy is unable to obtain the approved drug from a Wholesale Distributor Drug Outlet. Documentation of good faith effort must be retained by the Drug Outlet Pharmacy.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0730

RULE SUMMARY: Proposed new rule adds requirements for compounding services related to use by a veterinarian.

CHANGES TO RULE:

855-183-0730
Service: For Use by a Veterinarian
(1) This rule only applies to compounded drugs intended for animal use by licensed veterinarians.¶
(2) Compounded preparations must comply with state and federal law, USP standards and FDA guidance.¶
(3) A Drug Outlet Pharmacy may compound drugs intended for animal use:¶
(a) Based on a patient-specific prescription from a licensed veterinarian.¶
(b) For in-office use by a licensed veterinarian, specifically for a single treatment episode, not to exceed 120-hour supply.¶
(4) The compounded preparations must not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-183-0740

RULE SUMMARY: Placeholder for future rules.

CHANGES TO RULE:

855-183-0740
Service: Sterile Compounding with Non-Sterile Ingredients
Placeholder
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155