Agenda **Public Meeting**	**Oregon Board of Pharmacy – Workgroup** **Compounding** **May 16, 2023 1:00PM** The committee will meet virtually. **Public Attendance Options:** **Virtually via Teams: Link** **Audio Only: (503) 446-4951 Phone Conference ID: 626 031 749#** *To sign up for Public Comment, email your request to pharmacy.rac@bop.oregon.gov by **12:00PM on 5/16/2023**.* *If you need accommodations under the Americans with Disabilities Act (ADA), complete and submit the online OBOP Request for ADA Accommodations for Public Meetings form located on our website.*

Agenda Item	Content
Welcome	❖ Roll Call
Workgroup Business	❖ Workgroup - Purpose and Responsibilities ❖ Anticipated Rules Timeline ❖ Review of Proposed Rules ❖ Committee Member Discussion
	❖ Public Comment (if applicable)
Good of the Order	❖ Closing Remarks ❖ Adjourn

The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

Compounding

OREGON BOARD OF PHARMACY

WORKGROUP– MAY 16, 2023

OBOP MISSION

- *The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.*

Roll Call

- Workgroup Participants Present
  - Dawn Calder, RPH
  - Sarah Fondse, RPH
  - Natalie Gustafson, RPH
  - Kim Julian, COPT
  - Laurie Marzell
  - Letitia Robarge, COPT
  - Cassandra Robertson, RPH
- Board Members Present
  - Shannon Beaman, RPH
  - Priyal Patel, RPH
- Staff Members Present
  - Jennifer Davis, Pharmacist Consultant
  - Rachel Melvin, Operations Policy Analyst
  - Joseph Schnabel, Executive Director

Reminders

- Please be aware that any investigatory information is confidential and should not be discussed in a public meeting.

- When using examples, it is suggested that you phrase as the examples as hypothetical.

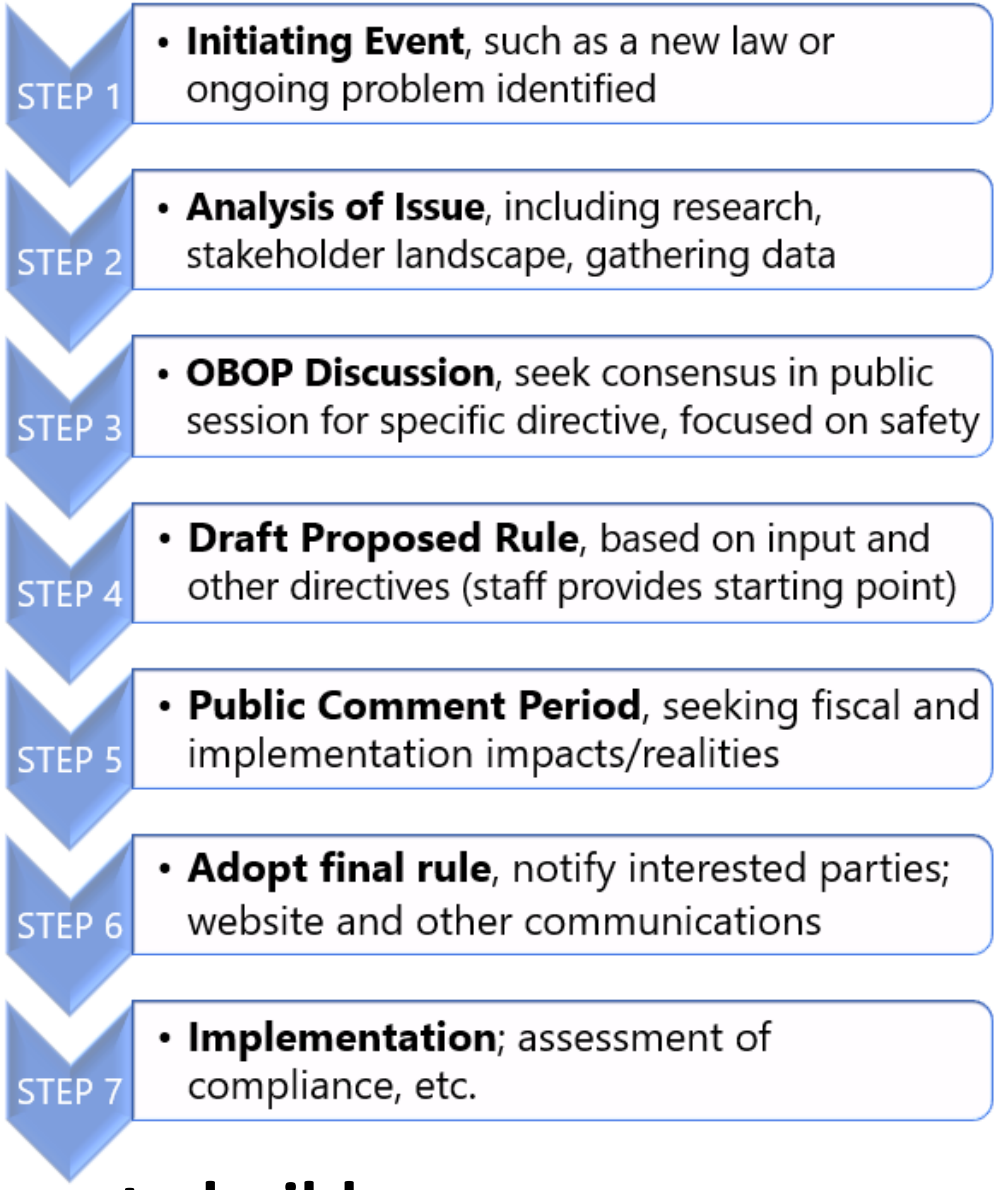
Workgroups

- *What is a Workgroup?*
  - A Workgroup may be established and used for to collect information on a specific topic and provide advice on rules in which there are issues that may substantially impact the interests of persons or entities (“stakeholders”), who will likely be affected by the proposed rulemaking.
- *What is the purpose of a Workgroup?*
  - Involve the public in the development of public policy
  - Estimate financial and racial equity impact on interested persons/entities
  - Members must represent the communities of persons likely to be affected by the rule

A Workgroup’s role is advisory only.

Rulemaking Process

- Workgroup provides advice to agency
- Agency drafts rules
- Draft rules are filed with Secretary of State and notice given to interested parties
- Public may comment on rules before rules are enacted
- Agency considers public comment, discusses and determines final rules
- Rules are filed with Secretary of State



Steps 3 & 4 are repeated as necessary to build consensus

Proposed Timeline- DRAFT

- February 2023-July 2023: Board staff draft proposed rules
- February 2023- July 2023: Workgroup meetings
- February 2023– July 2023: Board staff ongoing revision of proposed rules
  - June 2023: Board 1st look at proposed rules
  - August 2023: Board 2nd look at proposed rules
  - September 2023: Rulemaking
  - October 2023: Board adoption of proposed rules

Typical rules process can take 2-3 years
This timeline will be adjusted based on board priorities

Discussion Items - Compounding

- 855-006-0005 Definitions
- Division 045 -> 183
  - Applicability
  - Personnel & Responsibilities
  - General Requirements
  - Labeling
  - Policies & Procedures
  - Records
  - Prohibited Practices

- USP 795 (v. 11/1/2023)
  - 7. MASTER FORMULATION AND COMPOUNDING RECORDS
  - 9. LABELING

- USP 797 (v. 11/1/2023)
  - 11. MASTER FORMULATION AND COMPOUNDING RECORDS
  - 13. LABELING

Discussion Items: Compounding

- Should vs. Must
  - USP 795
  - USP 797

- Proposed Rules
  - Compounding Copies
  - Drug Recalls
  - Veterinary Use
  - Labeling
    - CNSP
    - CSP
    - For Future Use

#	Title
1	Applicability
5	Definitions
50	Personnel and Responsibilities
200	Compounding: General Requirements
205	Compounding: Technology
370	Delivery
400	Labeling: CNSP
410	Labeling: CSP
420	Labeling: CNSP and CSP for Future Use
450	Drug: Disposal
500	Policies & Procedures
520	Recalls
550	Records: General
560	Records: MFR- CNSP
565	Records: MFR- CSP
570	Records: CR- CNSP
575	Records: CR- CSP
600	Prohibited Practices
700	Compounding Services: Preparation According to FDA Approved Labeling
710	Compounding Services: Copies of an Approved Drug
730	Compounding Services: For Use by a Veterinarian

Future Meetings

- Please note that meetings may be cancelled or rescheduled as needed.
  - 6/20/2023
  - 7/18/2023

FINAL THOUGHTS

THANK YOU FOR YOUR PARTICIPATION!

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USP <795>

LIST OF STANDARD OPERATING PROCEDURES

Standard operating procedures (SOPs) must be reviewed initially and at least every 12 months by the designated person(s) to ensure that they reflect current practices, and the review must be documented. Any changes or alterations to an SOP must be made only by a designed person(s) and must be documented. Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgement of the communication.

Total SOPs required: 20

INTRODUCTION AND SCOPE (2)

- **Practices Not Subject to the Requirements in This Chapter**
  - The following practices are not considered compounding and are not required to meet the requirements of this chapter. Handling of nonsterile HDs should additionally comply with USP Chapter <800>. Refer to facility SOPs for additional safe practices (e.g., labeling).
    - Nonsterile radiopharmaceuticals
    - Reconstitution
    - Repackaging
    - Splitting tablets
    - Administration
- **Oversight by Designated Person(s)**
  - The designated person(s) must be identified in the facility's SOPs.

PERSONNEL TRAINING AND EVALUATION (2)

- **Personnel Training and Evaluation**
  - Other personnel, who do not compound and only perform functions such as in process checks, final verification, or dispensing of compounded nonsterile preparations (CNSPs), must undergo training as required by the facility's SOPs.
  - In addition to the initial and annual competency training and evaluation described in this section, the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel.

PERSONAL HYGIENE AND GARBING (2)

- **Garb and Glove Requirements**
  - Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs.
  - The facility's SOPs must describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment.

BUILDINGS AND FACILITIES (2)

- **Compounding Area**
  - » An area must be designated for nonsterile compounding. The method of designation must be described in the facility's SOPs.
  - » The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s).

EQUIPMENT AND COMPONENTS (4)

- **Equipment**
  - » Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients, added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented.
- **Components**
  - » The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP.
- **Component Receipt**
  - » The following information must be documented (see 14. Documentation) according to the facility's SOPs: receipt date, quantity received, supplier name, lot number, expiration date, and results of any in-house or third-party testing performed.
- **Component Spill and Disposal**
  - » The management and documentation of nonhazardous components spills and disposal must be described in the facility's SOPs.

MASTER FORMULATION AND COMPOUNDING RECORDS (1)

- **Creating Master Formulation Records**
  - » Any changes or alterations to the master formulation records must be approved and documented according to the facility's SOPs.

LABELING (1)

- **Labeling**
  - » Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups.

QUALITY ASSURANCE AND QUALITY CONTROL (4)

- **Quality Assurance and Quality Control**
  - » A facility's quality assurance (QA) and quality control (QC) programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction.
  - » The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.
- **Complaint Handling**
  - » Compounding facilities must develop and implement SOPs for handling complaints.
- **Adverse Event Reporting**
  - » Adverse events potentially associated with the quality of CNSPs must be reported in accordance with the facility's SOPs and all laws and regulations of the applicable regulatory jurisdiction.

CNSP PACKAGING AND TRANSPORTING (2)

- **Packaging of CNSPs**
  - The facility's SOPs must describe packaging of CNSPs.
- **Transporting of CNSPs**
  - If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed.

Special acknowledgment to **Sarah Hall, PharmD (candidate)***, UNC Eshelman School of Pharmacy, and* **Kevin Hansen, PharmD, MS, BCSCP***, Director of Pharmacy, Compounding Services and Data Analytics, Cone Health, for the development of this resource, and to* **Patricia Kienle, RPh, MPA, BCSCP, FASHP***, Director, Accreditation and Medication Safety, Cardinal Health, and* **Michael Ganio, PharmD, MS, BCSCP, FASHP***, Senior Director, Pharmacy Practice and Quality, ASHP, for peer-review.*

Kevin and Patti are members of the USP Compounding Expert Committee, but this resource is not affiliated with or endorsed by USP.

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USP <797>

LIST OF STANDARD OPERATING PROCEDURES

Standard operating procedures (SOPs) must be reviewed initially and at least every 12 months by the designated person(s) to ensure that the SOPs reflect current practices, and the review must be documented. Any changes or alterations to an SOP must be made only by a designed person(s) and must be documented. Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgement of the communication.

Total SOPs Required: 46

INTRODUCTION AND SCOPE (3)

- **Blood-Derived and Other Biological Materials**
  - When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), the manipulations must be clearly separated from other compounding activities and equipment used in compounded sterile preparation (CSP) preparation activities, and they must be controlled by specific standard operating procedures (SOPs) to avoid any cross-contamination.
- **Immediate-Use CSPs**
  - Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
  - Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.

PERSONNEL TRAINING AND EVALUATION (6)

- **Personnel Training and Evaluation**
  - Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs.
  - Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (see 1.3 Immediate-Use CSPs).
  - This program must equip personnel with the appropriate knowledge and train them in the required skills necessary to perform their assigned tasks, and SOPs should specify the training required for such tasks.
- **Media-Fill Testing Procedures**
  - The order of the incubation temperatures must be described in the facility's SOPs.
- **Initial & Ongoing Training and Competency**
  - Training and competency must be defined by facility SOPs for the personnel who do not compound nor have direct oversight of compounding personnel.
  - Training and competency should supplement facility SOPs for the designated person(s), personnel who compound, and personnel with direct oversight of compounding personnel.

PERSONAL HYGIENE AND GARBING (5)

- **Hand Hygiene**
  - The order of garbing must be determined by the facility and documented in the facility's SOPs.
- **Garbing Requirements**
  - The required garb, manner of storage, and order of garbing must be determined by the facility and documented in the facility's SOPs.
  - Category 1 and 2: The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.
  - Category 3: The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.
  - The restricted-access barrier system (RABS) sleeves and gloves and the pharmaceutical isolator sleeves and gloves should be changed per the manufacturer's recommendations and as defined in the facility's SOPs.

FACILITIES AND ENGINEERING CONTROLS (2)

- **Facility Design and Environmental Controls**
  - The temperature and humidity readings must be reviewed as described in the facility's SOPs.
- **Placement and Movement of Materials**
  - The designated person(s) is responsible for addressing other areas of risk in the facility's SOPs.

CERTIFICATION AND RECERTIFICATION (1)

- **Total Airborne Particle Sampling**
  - All sampling sites and procedures must be described in the facility's SOPs.

MICROBIOLOGICAL AIR AND SURFACE MONITORING (3)

- **General Monitoring Requirements**
  - The microbiological air and surface monitoring program must be clearly described in the facility's SOPs, which must include a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume or air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective action.
- **Viable Air Sampling Procedures**
  - The incubator temperature must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented as described in the facility's SOPs.
- **Monitoring Surfaces for Viable Particles:**
  - All sampling sites and procedures must be described in the facility's SOPs.

CLEANING, DISINFECTING, AND APPLYING SPORICIDAL DISINFECTS AND STERILE 70% ISOPROPYL ALCOHOL (4)

- All cleaning and disinfecting activities must be performed by trained and appropriately garbed personnel using facility-approved agents and procedures, which must be described in written SOPs.
- The frequency, method(s), and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants must be established in written SOPs, in accordance with the manufacturer's instructions, and must be followed by all cleaning personnel.
- All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs.
- Once opened, sterile cleaning and disinfecting agents and supplies (e.g., closed containers for sterile wipers) and sterile 70% isopropyl alcohol may be reused for a time period specified as by the manufacturer or described in the facility's written SOPs.

EQUIPMENT, SUPPLIES, AND COMPONENTS (3)

- **Equipment**
  - » Compounding personnel must follow established SOPs for the calibration, maintenance, cleaning, and use of equipment based on the manufacturer's recommendations.
  - » Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients, added substances, conventionally manufactured products) must be evaluated to determine if these activities must be performed in a PEC or other closed system processing device (e.g., single use containment glove bag) to reduce the potential exposure to personnel or contamination of the facility or CSPs (See 4.2.6 Facilities Preparing Category 2 or Category 3 CSPs from Nonsterile Starting Component(s)). The process evaluation must be carried out in accordance with the facility's SOPs and the assessment must be documented.
- **Components**
  - » Compounding personnel must follow the facility's SOPs, which must address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.

STERILIZATION AND DEPYROGENATION (4)

- A description of the terminal sterilization and depyrogenation process, including temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials must be included in the facility's SOPs.
- SOPs must include training and competency of personnel on all sterilization methods and equipment used by the facility.
- The SOPs must include a schedule and method for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment.
- **Depyrogenation**
  - » The effectiveness of the depyrogenation cycle must be re-established if there are changes to the depyrogenation cycle described in SOPs (e.g., changes in load conditions, duration, or temperature).

MASTER FORMULATION AND COMPOUNDING RECORDS (1)

- **Creating Master Formulation Records (MFRs)**
  - » Any changes or alterations to the MFR must be approved and documented according to the facility's SOPs.

RELEASE INSPECTIONS AND TESTING (2)

- All release testing procedures (e.g., visual inspections and testing) must be included in the facility's documentation (see 17. SOPs).
- **Visual Inspection**
  - » Defects that indicate sterility or stability problems must be investigated to determine the cause according to the facility's SOPs.

LABELING (1)

- Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CSP mix-ups.

SOPS (2)

- Facilities that prepare CSPs must develop SOPs for the compounding process and other support activities.
- SOPs must include the types of CSPs that are prepared (i.e., Category 1, Category 2, Category 3).

QUALITY ASSURANCE AND QUALITY CONTROL (5)

- A facility's quality assurance (QA) and quality control (QC) programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CSPs are conducted in accordance with the requirements in this chapter (<797>) and the laws and regulations of the applicable regulatory jurisdiction.
- The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.
- **Notification about and recall of out-of-specification dispensed CSPs**
  - » An SOP for recall of out-of-specification dispensed CSPs must contain: (1) procedures to determine the severity of the problem and the urgency for implementation and completion of the recall, (2) procedures to determine the distribution of any affected CSP, including the date and quantity of distribution, (3) procedures to identify patients who have received the CSP, (4) procedures for disposal and documentation of the recalled CSP, and (5) procedures to investigate and document the reason for failure.
- **Complaint Handling**
  - » Compounding facilities must develop and implement SOPs for handling complaints.
- **Adverse Event Reporting**
  - » Adverse events potentially associated with the quality of CSPs must be reported in accordance with the facility's SOPs and all laws and regulations of the applicable regulatory jurisdiction.

CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT (3)

- Processes and techniques for handling, storing, packaging, and transporting CSPs must be outlined in the facility's SOPs.
- Personnel who will be handling, storing, packaging, and transporting CSPs within the facility must be trained in accordance with the relevant SOPs, and the training must be documented.
- **Handling and Storing CSPs**
  - » The results of the temperature readings must be documented in a temperature log per facility SOPs or stored in the continuous temperature recording device and must be retrievable.

COMPOUNDING ALLERGENIC EXTRACTS (1)

- **Personnel Hygiene and Garbing for Compounding Allergenic Extract Prescription Sets**
  - » Before beginning compounding of allergenic extract prescription sets, personnel must perform hand hygiene (see Box 3) and garbing procedures according to the facility's SOPs.

Special acknowledgment to **Sarah Hall, PharmD (candidate)**, *UNC Eshelman School of Pharmacy, and* **Kevin Hansen, PharmD**, **MS, BCSCP**, *Director of Pharmacy, Compounding Services and Data Analytics, Cone Health, for the development of this resource, and to* **Patricia Kienle, RPh, MPA, BCSCP, FASHP**, *Director, Accreditation and Medication Safety, Cardinal Health, and* **Michael Ganio, PharmD, MS, BCSCP, FASHP**, *Senior Director, Pharmacy Practice and Quality, ASHP, for peer-review.*

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Divisions 006/041/045/183: Drug Compounding

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural review; Creates new Division 183 for Drug Compounding

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates a new Division 183 for Drug Compounding. Amends "Compounding" definition in Division 006. 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. Proposes relocating and revising existing rules from Division 045 as 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 per ORS 183.335(2)(b)(D):

USP Chapters: USP Compounding Compendium

For Use by a Veterinarian: Compounding Animal Drugs from Bulk Drug Substances Guidance for Industry (April 2023), Index of Legally Marketed Unapproved New Animal Drugs for 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

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): 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 licensure and compliance requirements will positively impact all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): TBD

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public), Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government or members of the public. In order to comply, drug outlet pharmacies, DPDOs, CFs and CHCs who engage in compounding will need to pay for access to the USP Compounding Compendium estimated to cost $250 per year per user.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed revisions to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. A Workgroup was convened per the board's direction.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): USP 795 (v. 11/1/2022) and USP 797 (v. 11/1/2022) become enforceable on 11/1/2023. Board rules related to compounding must be updated to reflect the new standards. Proposed amendments include revising the definition of "Compounding" in Division 006 to match the definition in the USP standards adopted by reference. Creates new Division 183 by revising and relocating existing rules from Division 045.

Creates proposed rules related to requirements for Compounding in the areas of "Applicability", "Definitions", "Designation", "Personnel", "General Requirements", "Compounding Technology", "Delivery", "Compounding Labeling" for both sterile (CSP) and non-sterile preparations (CNSP) and labeling requirements for future use, "Drug Disposal", "Policies and Procedures", "Compounded Drug Recalls", "Records" requirements including general, master formulation records (MFR), records for CNSP and CSP, "Prohibited Practices", "Compounding Services" for preparation according to FDA approved labeling requirements, copies of approved drugs and for use by a Veterinarian. Amends existing rules in Division 043 by adding "Drug Outlet Dispensing" general requirements for DPDOs, Correctional Facilities and Community Health Clinics. Will repeal Division 045 upon adoption of new Division 183.

Selected USP definitions relevant to Div 183.
Note: CNSP/CSP used below whereas the standard only uses CNSP for the definition in <795> and CSP in <797>.

Active pharmaceutical ingredient (API): *Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as Bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).*

Compounding: *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 CNSP/CSP.*

Designated person(s): *A person assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs/CSPs.*

Beyond-use date (BUD): *The date, or hour and date, after which a CNSP/CSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.*

Compounded nonsterile preparation (CNSP): *Preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.*

Compounded sterile preparation (CSP): *Preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.*

Compounding record (CR): *Record that documents the compounding of each CNSP/CSP.*

Master formulation record (MFR): *A detailed record of procedures that describes how each CNSP/CSP is to be prepared.*

POLICY DISCUSSION: Inclusion

DIVISION 006
DEFINITIONS

855-006-0005
Definitions

(11) "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**.**

DIVISION 183
DRUG COMPOUNDING

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 U.S.C. 353b (XX/XX/XXXX) must register with the board as a manufacturer in OAR 855-060.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0005
Definitions

Phrases or definitions used in OAR 855-183 are the same as included in the USP standard adopted by reference unless otherwise specified.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0010
Designation: General

Each Drug Outlet must maintain an accurate compounding status in the board's online registration system.

POLICY DISCUSSION: Registration type, CNSP/CSP

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

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 855-183-00XX.

(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 a Drug Outlet Pharmacy

(B) Practitioner with prescriptive and dispensing authority for a 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

855-183-0200
Compounding: General Requirements

(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 (XX/XX/XXXX), 659 (XX/XX/XXXX), 660 (XX/XX/XXXX), 661 (XX/XX/XXXX), 661.1 (XX/XX/XXXX), 661.2 (XX/XX/XXXX), 671 (XX/XX/XXXX), 797 (11/01/2022), 1136 (XX/XX/XXXX), 1151 (XX/XX/XXXX), 1160 (XX/XX/XXXX), 1163 (XX/XX/XXXX), 1176 (XX/XX/XXXX), 1191 (XX/XX/XXXX), 1231 (XX/XX/XXXX), and 1265 (XX/XX/XXXX);

(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (11/01/2022) and all chapters referenced therein, including but not limited to Chapters 7 (XX/XX/XXXX), (XX/XX/XXXX), 51 (XX/XX/XXXX), 71 (XX/XX/XXXX), 85 (XX/XX/XXXX), 659 (XX/XX/XXXX), 788 (XX/XX/XXXX), 789 (XX/XX/XXXX), 800 (XX/XX/XXXX), 825 (XX/XX/XXXX),1066 (XX/XX/XXXX), 1085 (XX/XX/XXXX), 1113 (XX/XX/XXXX), 1116 (XX/XX/XXXX), 1163 (XX/XX/XXXX), 1197 (XX/XX/XXXX), 1207 (XX/XX/XXXX), 1223 (XX/XX/XXXX), 1225 (XX/XX/XXXX), 1228.1 (XX/XX/XXXX), 1228.4 (XX/XX/XXXX), 1229 (XX/XX/XXXX), 1229.1 (XX/XX/XXXX), 1229.4 (XX/XX/XXXX), 1229.5 (XX/XX/XXXX), 1229.8 (XX/XX/XXXX), 1229.9 (XX/XX/XXXX), and (XX/XX/XXXX);

(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);

(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging (12/01/2020) and all chapters referenced therein, including but not limited to Chapters 71 (XX/XX/XXXX), 85 (XX/XX/XXXX), (XX/XX/XXXX), 659 (XX/XX/XXXX), 795 (11/01/2022), 797 (11/01/2022), 821 (XX/XX/XXXX), 823 (XX/XX/XXXX), (XX/XX/XXXX), 1066 (XX/XX/XXXX), 1072 (XX/XX/XXXX), 1113 (XX/XX/XXXX), 1116 (XX/XX/XXXX), 1163 (XX/XX/XXXX), 1821 (XX/XX/XXXX), (XX/XX/XXXX), and (XX/XX/XXXX);

(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. 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 855-183-00XX.

POLICY DISCUSSION: Essential Copies

(4) All sterile compounding must utilize an automated compounding device that incorporates:

(a) Barcoding to verify ingredients; and

(b) Imaging or gravimetrics to verify ingredient quantity and finished CSP volumes.

POLICY DISCUSSION: Patient Safety

(5) For CNSPs, the compounding area must have a line of visible 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

855-183-0205
Compounding: Technology

(1) A Drug Outlet Pharmacy, DPDO, or CHC may use an automated compounding device 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 automated compounding device 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 that a person must have to use the automated compounding device;

(b) The routine maintenance and cleaning required to be performed on the automated compounding device which, at a minimum, satisfies the requirements for maintenance and cleaning established by the manufacturer of the automated compounding device; and

(c) The testing required to be performed on the automated compounding device to ensure that the automated compounding device 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 automated compounding device 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 automated compounding device 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 automated compounding device cannot be programmed to cease the compounding process as described in (a):

(A) The automated compounding device 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 automated compounding device, 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

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

855-183-0400
Labeling: Compounded Non-Sterile Preparations (CNSPs)

In addition to the labeling requirements specified in USP <795> (v. 11/1/2022), 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 each active ingredient;

(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

855-183-0410
Labeling: Compounded Sterile Preparations (CSPs)

In addition to the labeling requirements specified in USP <797> (v. 11/1/2022), 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

855-183-0420
Labeling: CNSP and CSP Preparations 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;

(2) Internal lot number;

(3) The assigned beyond-use date;

(4) Indication that the preparation is compounded; and

(5) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary;

POLICY DISCUSSION: Batching

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0450
Drug: 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

855-183-0500
Policies & Procedures

(1) 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:

(a) Personnel qualifications, to include training and ongoing competency assessment;

(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, receipt, handling, and storage and disposal;

(g) 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;

(h) Creating compounding records;

(i) Establishing beyond-use dates (BUDs);

(j) Labeling;

(k) 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;

(l) Completed compounded preparations, to include handling, packaging, storage and transport;

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0520
Compounded Drug 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

855-183-0550
Records: General

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, 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;

(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; and

(B) CSPs prepared for more than one patient;

(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

855-183-0560

Records: Master Formulation Records (MFR) for CNSP

(1) 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:

(a) Appropriate calculations to determine and verify quantities and concentrations of components and strength or activity of the APIs;

(b) Compatibility and stability information, including references;

(c) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.

(d) Other information needed to describe the compounding process and ensure repeatability

(e) 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

855-183-0565

Records- MFR: CSP

(1) In addition to the MFR requirements specified in USP <797> (v. 11/1/2022), the MFR for a CSP must contain the following, at a minimum:

(a) 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;

(b) Compatibility and stability information, including references;

(c) Quality control procedures that includes the expected results and limits of tolerability; and

(d) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.

(e) 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

855-183-0570
Records- CR: CNSP

(1) In addition to the CR requirements specified in USP <795> (11/1/2022), the CR for a CNSP must contain the following, at a minimum:

(a) 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) Final CNSP product accuracy.

(b) Final yield;

(c) 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;

(d) Records of dispensing or transfer of all compounded preparations; and

(e) 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

855-183-0575
Records- CR: CSP

(1) In addition to the CR requirements specified in USP <797> (11/1/2022), the CR for a CSP must contain the following, at a minimum:

(a) 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) Final CSP product accuracy.

(b) Final yield;

(c) 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;

(d) Records of dispensing or transfer of all compounded preparations; and

(e) 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

855-183-0600
Prohibited Practices

The following practices are prohibited in the compounding of a drug preparation:

(1) Non-sterile to sterile compounding;

(2) Verification of components after their addition to the final container (e.g., proxy verification, syringe pull-back method);

(3) Use of preservative free component vials that exceeds 12 hours from initial puncture;

(4) Carpet in compounding area; and

(5) Animals in the compounding area.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0700
Compounding Services: 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 the drug is hazardous, must follow USP <800>.

(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>.

(b) Beyond-use dates (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

855-183-0710
Compounding Services: Copies of an 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, http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; or

(b) Drug shortages database published on the American Society of Health-System Pharmacists (ASHP) website, https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages

POLICY DISCUSSION: Essential Copies

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0730
Compounding Services: For Use by a Veterinarian

(1) The use of bulk drug substances for compounded drug preparations is prohibited except when:

(a) Compounding is pursuant to a patient-specific prescription for a non-food-producing animal or as an antidote to prevent animal suffering or death in food-producing animals;

(b) There is no marketed approved, conditionally approved, or indexed in *The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species* drug that can be used as labeled to treat the condition. The Index is available on the FDA's website at: https://www.fda.gov/animal-veterinary/minor-useminor-species/index-legally-marketed-unapproved-new-animal-drugs-minor-species;

(c) There is no marketed approved animal or human drug that can be used to treat the condition through off-label drug use;

(d) The drug cannot be appropriately compounded from an approved animal or human drug;

(e) Immediate treatment with the compounded drug preparation is necessary to avoid animal suffering or death; and

(f) The FDA has not identified a significant veterinary safety concern with the use of the bulk drug substance for compounding.

(2) It is acceptable for any Drug Outlet Pharmacy, DPDO or CHC to compound veterinary drug preparations to be used by veterinarians in their offices for administration to clients' animals.

(3) Compounded office use drug preparations may be dispensed by a veterinarian to clients only in an urgent or emergency situation for use in a single course of treatment, not to exceed a 120-hour supply.

(4) The compounded veterinary drug preparations must not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations. This does not prohibit administration of a compounded drug preparation in a veterinary health care setting or dispensing of a compounded drug preparation pursuant to a prescription executed in accordance with federal and state law.

(5) Providing samples of compounded veterinary drug preparations is prohibited.

(6) Upon becoming aware of any adverse event or preparation defect, the pharmacy must report the event on the FDA form 1932a for reporting a Veterinary Adverse Drug Reaction, Lack of Effectiveness, or Product Defect within 15 days and include the FDA statement about reporting adverse events on the prescription label.

POLICY DISCUSSION: OVMEB/OVMA

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

DIVISION 41
OPERATION OF PHARMACIES

855-041-1018
Outlet: General Requirements

A drug outlet pharmacy must:

(1) Ensure each:

(a) Prescription is dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031**,** OAR 855-041~~,~~ **and OAR 855-080**;

(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

DIVISION 43
PRACTITIONER DISPENSING

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 (01/01/2021), 16 CFR 1701 (01/01/2021) and 16 CFR 1702 (01/01/2021).

(5) Dispensed drugs must be packaged by the DPDO, a pharmacy, or a manufacturer registered with the board.

(6) A DPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(7) A DPDO may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(8) The DPDO must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(9) 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.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.305

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

(1) Policies and Procedures: The pharmacist and the practitioner representing the facility **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 **must** be reviewed and updated annually by the pharmacist and the practitioner, maintained in the facility; and be made available to the **b**oard for inspection. The facility **must** submit to the **b**oard 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 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 correctional facility 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 **b**oard:

(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 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: 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 who self-administer or who are given prescription drugs when they are released from the correctional facility.

(6) Administration: Drugs **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 **OAR** 851-047-0020. Drugs selected by registered nurses from manufacturer's or pharmacist's bulk drug containers **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

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

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.

(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.

(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.

(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.

(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2021), 16 CFR 1701 (01/01/2021) and 16 CFR 1702 (01/01/2021).

(7) Dispensed drugs must be packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the board.

(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(9) A CHC must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

(10) A CHC may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The CHC offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(11) The CHC must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(12) The CHC must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

(1**3**) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305