Meeting Minutes	**Oregon Board of Pharmacy – Workgroup Compounding** **July 18, 2023 1:00pm** The workgroup will meet virtually. **Public Attendance Options:** **Virtually via Teams: Link** **Audio Only: (503) 446-4951 Phone Conference ID: 340 673 813#** *To sign up for Public Comment, email your request to pharmacy.rac@bop.oregon.gov by **12:00PM on 7/18/2023**.* *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
	The meeting convened @ 1:02PM ❖ Mission ❖ Roll call

WORKGROUP MEMBERS	Here	Absent
Workgroup Member Dawn Calder, RPH	X	
Workgroup Member Sarah Fondse, RPH	X	
Workgroup Member Natalie Gustafson, RPH	X	
Workgroup Member Kim Julian, CPT	X	
Workgroup Member Laurie Marzell	X	
Workgroup Member Letitia Robarge, CPT		X
Workgroup Member Cassandra Robertson, RPH	X	
Board Member Shannon Beaman, RPH	X	
Board Member Priyal Patel, RPH	X	
Staff Member Jennifer Davis, RPH	X	
Staff Member Brianne Efremoff, RPH	X	
Staff Member Rachel Melvin	X	
Staff Member Joseph Schnabel, RPH	X	

❖ Reviewed housekeeping items, meeting etiquette and public comment

❖ July 18, 2023 Compounding Workgroup Presentation

❖ Reminders - Workgroup - Purpose and Responsibilities

Staff member Davis reviewed the definition and purpose of a workgroup and stated that their role is advisory.

❖ Anticipated Rules Timeline

Staff member Davis reviewed the rulemaking process and stated that the public comment period is currently open, and the board is accepting written comments or people can sign up to provide oral testimony during the rulemaking hearing. She stated the proposed Compounding rules the workgroup would review during the meeting are not the version currently in rulemaking and included proposed amendments to be discussed and potentially provided for board consideration at the August board meeting. She provided a list of topics the workgroup had reviewed at prior meetings. She reviewed the definition and difference between 503A – Traditional Compounding Pharmacy and 503B – Outsourcing Facilities and provided a breakdown of the Compounding Quality Act. She provided a compounding overview that included expectations for all compounded drugs by both 503A's and 503B's and stated that the FDA sees every compounded drug as a non-approved drug.

❖ Workgroup Member Discussion

Staff member Davis stated that the workgroup would review proposed rule amendments which are bolded and underlined for Division 183 Drug Compounding which would help inform board staff on proposed revisions that may be presented to the board at the August 2023 board meeting. She stated that if the board chooses to send the proposed revised rules to a September 2023 rulemaking hearing, the rules would be noticed for public comment in August with the option of board adoption in October 2023.

- *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>.*
- **OAR 855-183-0005 Definitions**

Staff member Davis stated that the following proposed language was derived from FDA guidance for 503B/outsourcing facilities and added based on workgroup feedback from the June Compounding Workgroup meeting. For a drug product compounded by an outsourcing facility to qualify for the exemptions under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), it must not be "essentially a copy of one or more approved drug products," and must meet the other conditions in section 503B. For 503B's, the FDA does not intend to take action against an outsourcing facility for failing to compound in accordance with section 503B(a)(5) if it fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

(2) "Clinically significant difference" encompasses a wide range of issues, such as formulation changes to exclude ingredients in the approved product that are harmful to a particular patient; strength or concentration changes to accommodate wide variations in patient size; and changes in flavoring or dosage form needed to achieve patient compliance or protect individuals administering the drug.

(3) "Commercially available drug" means a FDA approved drug that has not been discontinued and is no longer marketed.

Staff member Davis reviewed the proposed definitions and asked the workgroup members for feedback.

The workgroup members did not provide any comments.

Board member Beaman stated that the "clinically significant difference" language and "exclude ingredients in an approved product" is too restrictive and that it is hard for patients to prove what they are reacting to in a product and that practitioners don't have the time or resources to go down this path to confirm product in order to help patients in real time. She provided an example if a patient knows they have a reaction to corn, but the pharmacist cannot always confirm that the product has corn in it, but knowing the patient has a reaction to corn, the pharmacist can create a compound for them within minutes.

- **OAR 855-183-0050 Personnel**

Staff member Davis reviewed the proposed amendments and stated that the addition to (1) was added to be clear that the personnel in training may compound under the supervision of a qualified individuals in (2) and suggested removing "independent" in (4) because it is redundant.

> (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 **prior to independently engaging in compounding**.
>
> (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.

Staff member Davis asked the workgroup members for feedback.

Workgroup member Gustafson stated that staff should consider using "professional judgment" and believes a qualifier should be used in this instance because many situations require professional judgment, not just 'judgement".

- **OAR 855-183-0200 Compounding: General Requirements**

Staff member Davis stated the proposed rule had undergone a number of revisions that were made based on workgroup discussion from the June workgroup meeting. She stated that the workgroup provided a wide variety of opinions during the last workgroup meeting and the proposed modification provides 2 years for compliance and requires barcoding to verify all compounding ingredients.

She stated that at a previous meeting, workgroup members provided fiscal information on compliance with barcoding and imaging/gravimetrics- barcoding and imaging technology procurement, implementation, ongoing maintenance, and training is estimated to cost between $30,000 - $130,000 initially and $50,000 annually. She stated that the revisions in (5) separate out imaging and gravimetrics and makes it a "should" and only applicable to CSPs. She stated that the revisions in (6) moves this rule from a prohibition and makes it a "should" and the revisions in (7) relocated this rule from a separate rule and provides for a 2 year implementation.

> (4) **Beginning July 1, 2025** ~~A~~**a**ll ~~sterile~~ compounding must utilize a system that incorporates~~:~~
>
> ~~(a)~~ Barcoding to verify ingredients~~.; and~~
>
> (~~b~~**5**) **Verification of compounding should use a system that incorporates** ~~i~~**i**maging or gravimetrics to verify ingredient quantity and finished **Compounded Sterile Preparation (**CSP**)** volumes.
>
> **(6) Verification of compounding should not rely solely on the verification of components after they have been added to the final container. This includes methods such as proxy verification and the syringe pull-back method.**
>
> **(7) Beginning July 1, 2025, a Drug Outlet that performs sterile compounding with non-sterile ingredients must maintain current:**
>
> **(a) Compounding Pharmacy Accreditation through the Pharmacy Compounding Accreditation Board (PCAB) provided by the Accreditation Commission for Health Care (ACHC);**

(b) Compounding Pharmacy Accreditation through the National Association of Boards of Pharmacy (NABP); or

(c) Medication Compounding Certification through The Joint Commission.

(~~5~~**8**) For **Compounded Non-Sterile Preparations (**CNSPs**)**, the compounding area must have a visible line of demarcation.

Staff member Davis stated that staff research has identified that sterile compounding accreditation through PCAB/ACHC, NABP and TJC is estimated to cost between $2,200 to $4,500 for three-year accreditation. Staff member Davis asked the workgroup members if they had any additional insight on costs of compliance with the proposed revisions in (4) since it only requires barcoding and if they had additional insight on the cost of compliance with (7).

Workgroup members provided feedback including:

- Considering a longer implementation timeline due to the time for procurement, contracts and funding to be in place
- Agreement with language as written
- Request to use "should" at first and then amend later to a "must"
- With all of the requirements of this rule and USP, how can places compound without having a software, which has a barcode
- Allowing time for compliance and for new USP rules to become effective first
- Fiscal impact for PCAB is appximately$17,500 for 3 years
- The proposed rules are 100% reasonable.
- Technology is available and this is a huge patient safety item and feasible to do
- There is a substantial cost to this, consider financial costs of staffing when implementing, maybe 5 years for implementation.
- Some companies will not implement unless it is required by rule.

Board member Beaman stated that barcoding makes us feel good and is a false sense of safety, would like to see data related to how barcoding helps prevent errors, compounding is now a specialty and most chain pharmacies will not compound. Board member Patel stated that the new rules should not be more strict than USP and nothing in rule should be "must", mistakes are made with barcodes, should not restrict access because of barcode requirement, and strongly disagrees with language and believes it will be problematic to rural hospitals.

- **OAR 855-183-0400 Labeling: of Compounded Non-Sterile Preparations (CNSPs) and OAR 855-183-0410 Labeling: Compounded Sterile Preparations (CSPs)**

Staff member Davis stated that revisions in both rules included adding reference to OAR 855-043 because DPDO's and CHC's have labeling rules in Div 043. "Identity of the" was added to clarify that the identity of the base must be on the label but not the strength since many bases do not have strengths; however, if the base has a strength, it must be on the label.

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, **OAR 855-043,** 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 **identity of the** base;

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

In addition to the labeling requirements specified in USP <797> (11/01/2022), OAR 855-041**,** **OAR 855-043** 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 identity of the** base solution for a sterile parenteral preparation;

Staff member Davis asked the workgroup members for feedback on the proposed revisions for both rules.

The workgroup consensus was to remove "to include the identity of the base" from compounded non-sterile preparations.

- **OAR 855-183-0450 Drug: Disposal**

The Drug Outlet Pharmacy, DPDO and CHC ~~is responsible for ensuring that there is a system for~~ **must ensure** the disposal of hazardous ~~and infectious~~ **pharmaceutical** waste **is** in accordance with applicable state and federal laws and USP <800> Hazardous Drugs – Handling in Healthcare Settings (07/01/2020).

Staff member Davis reviewed the proposed amendments and stated that revisions were based on workgroup feedback to remove infectious waste and focus on pharmaceutical waste. She asked the workgroup for feedback.

The workgroup did not provide any comments.

- **OAR 855-183-0520 Compounded Drug Recalls**

Staff member Davis reviewed the proposed revisions and stated that board staff completely reworked this rule taking into consideration workgroup feedback and stated that this revisions includes different notification timelines depending on the severity of the recall. She stated that 503B pharmacies are required to notify MedWatch in the event of patient harm attributable to product made by the entity and that the FDA conducts active surveillance to identify issues. She stated that board staff believe it is in the best interest of patient safety for 503A pharmacies to also report harm from compounded products to Medwatch. She stated that the board does not need to be notified of a recall that is unlikely to cause injury or illness, but if it will cause serious injury, illness or death the board must be notified within 10 business days.

(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~~ **that was dispensed or intended for use in this state and document each attempt:**

(a) Within 12 hours of the recall if ~~both of the following apply:~~ use or exposure to the recalled **compounded** drug may cause serious ~~adverse health consequences~~ **injury** or death~~; and~~. **If contact cannot be established within this timeframe, the outlet must make two additional attempts to provide notification within 24 hours of the initial attempt.**

(b) Within 36 hours of the recall if use or exposure to the recalled compounded drug might cause serious injury or temporary illness. If contact cannot be established within this timeframe, the outlet must make two additional attempts to provide notification within 36 hours of the initial attempt.

(c) Within 72 hours of the recall if the recalled drug is unlikely to cause injury or illness, but violates state or FDA regulations. If contact cannot be established within this timeframe, the outlet must make two additional attempts to provide notification within 72 hours of the initial attempt.

(2) In the event that all attempts to inform the recipient are unsuccessful in (1), the outlet must send notification via certified mail.

~~(2) A recall issued pursuant to (1) 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~~ **outlet** must report the event to MedWatch within 72 hours of the ~~Drug Outlet Pharmacy, DPDO or CHC~~ **outlet** being advised.

(4) The board must be notified of a recall in (1)(a) and (1)(b) on a form provided by the board within 10 business days of issuing the recall.

Staff member Davis asked the workgroup for feedback.

The workgroup members provided feedback including:

- Based on the amount of compounding done at their organization, they would be able to comply with the rule as written but understands it would take longer for pharmacies who compound large amounts
- Suggested adding "within 12 hours of discovery of the recall by the pharmacy"
- Would be able to comply with this rule in their inpatient setting
- All of the hours listed are not business hours and 12 hours can be tricky because a lot come from outside companies
- Disagree with reporting to Medwatch because pharmacies are not operating under direct jurisdiction of the FDA

- Investigating all compounds using a specific manufacturer would require the need to review all drugs received and review everything a patient had received, recalls are time intensive to investigate, to get the patient to discontinue use and ensure continuity of care
- Agree with language as written, our facility would be able to uphold the timelines.

Board member Patel stated that it is an unrealistic expectation and if you work on weekends you cannot meet this requirement.

- **OAR 855-183-0560 Records: Master Formulation Records (MFR) for CNSP**

Staff member Davis reviewed proposed revisions and stated that a few revisions were necessary as some compounded products do not have compatibility and stability information.

(2) Compatibility and stability information, including **available** references ~~as available~~;

- **OAR 855-183-0565 Records- MFR: CSP**

(2) Compatibility and stability information, including **available** references;

Staff member Davis asked the workgroup for feedback.

The workgroup provided a couple of comments such as they interpret the rule as needing to include:

- Compatibility and stability information does not exist frequently
- References are required and when compatibility and stability information is not available, they use USP as a resource.

- **OAR 855-183-0570 Records- CR: 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~~**d**) ~~If applicable~~ **As available**, strength, **concentration** or activity of ~~the~~ **each** API and **component**;

(~~f~~**e**) Compounding technique; and

(~~g~~**f**) Accurate preparation of the CNSP.

- **OAR 855-183-0575 Records- CR: 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~~**1**) Pharmacist performance and documented verification that each of the following are correct:

(a) Formula;

(b) Calculations;

(c) Quantities;

~~(d) Concentration of components;~~

(~~e~~**d**) ~~If applicable~~ **As available**, strength, **concentration** or activity of ~~the~~ **each** API and **component**;

(~~f~~**e**) Compounding technique; and

(~~g~~**f**) Accurate preparation of the CSP.

Staff member Davis reviewed both rules and stated that board staff revised (1)(d) to combine (d) and (e) and (1) for CSPs was erroneously included in the last workgroup meeting and was removed as this is already required by USP. She asked the workgroup members for feedback.

Workgroup member Gustafson stated that it was confusing to have component in the rule, for inactive you just have quantities and was not sure if the component was needed.

- **OAR 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~~**1**) Carpet in compounding area; and

  (~~3~~**2**) Animals in the compounding area.

Staff member Davis stated that that (1) was moved to general requirements as a 'should' per previous workgroup input.

- **OAR 855-183-0700 Compounding Services: Preparation According to FDA Approved Labeling**

  (1) Compounding does not include**:**

(a) Mixing, reconstituting, or other such acts that are performed in accordance with directions contained in FDA approved labeling or supplemental materials provided by the product's manufacturer.

(~~2~~**b**) Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's FDA approved labeling **when** the:

(~~a~~**A**) Product ~~must be~~ **is** prepared as a single dose for an individual patient; and

(~~b~~**B**) Labeling ~~must~~ include**s** information for the diluent, the resultant strength, the container closure system, and ~~storage time~~ **BUD**.

~~(3) If compounding a hazardous drug, USP <800> (07/01/2020) must be followed.~~

(~~4~~**c**) ~~Proprietary bag and vial systems:~~ **The** ~~D~~**d**ocking and activation of **a** proprietary bag and vial system in accordance with the FDA approved labeling for immediate administration to an individual patient. ~~Preparation according to the labeling may be performed outside of an International Organization for Standardization (ISO) Class 5 environment.~~

~~(2) 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> (11/01/2022).~~

~~(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.]~~

Staff member Davis reviewed the proposed revisions and stated that board staff revised for clarity and she asked the workgroup for feedback.

The workgroup did not provide any comments.

- **OAR 855-183-0710 Compounding Services: Copies of an Approved Drug**

(2) "Clinically significant difference" encompasses a wide range of issues, such as formulation changes to exclude ingredients in the approved product that are harmful to a particular patient; strength or concentration changes to accommodate wide variations in patient size; and changes in flavoring or dosage form needed to achieve patient compliance or protect individuals administering the drug.

~~(3) "Commercially available drug" means a FDA approved drug that has not been discontinued and is no longer marketed.~~

A Drug Outlet Pharmacy, DPDO, CHC or outsourcing facility may ~~only~~ **regularly** compound **or compound inordinate amounts of** 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~~.~~**; or**

(2) The **FDA-**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) **American Society of Health-System Pharmacists (ASHP)** drug shortages database published on the ~~American Society of Health-System Pharmacists (ASHP)~~ **ASHP** website, www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages~~.~~**; or**

(3) The Drug Outlet Pharmacy is unable to obtain **an adequate supply to regularly meet patient need of** the **FDA-**approved drug from a Wholesale Distributor Drug Outlet. Documentation of good faith effort to **obtain the FDA-approved drug** must be retained by the Drug Outlet Pharmacy.

Staff member Davis reviewed the proposed revisions and stated that based on the last workgroup meeting, board staff reviewed the FDA guidance on essential copies and have added 'may regularly compound or compound inordinate amounts of a drug preparation' to the lead in. She asked the workgroup members to provide feedback.

The workgroup members provided such feedback as no issues with language as written, like "adequate supply" language in (3) to meet patient need, concerns about the documentation language not being clear if there was not an invoice available.

Board member Beaman stated that they should strike the entire section. Board member Patel stated that since FDA regulations apply, this section should be removed.

- **OAR 855-183-0730 Compounding Services: 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 the FDA guidance**, GFI #256 - Compounding Animal Drugs from Bulk Drug Substances (v. 8/2022).**

(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 **or dispensing pursuant to OAR 875-015-0040** 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.

Staff member Davis reviewed the proposed revisions and asked the workgroup for feedback.

Workgroup member Gustafson asked a clarifying question about guidance documents and suggested striking "GFI #256 – Compounding Animal Drugs from Bulk Drug Substances" and expressed concern that rule appears to be regulating veterinarian practice.

	➢ OAR 855-041-1018 Outlet: General Requirements ➢ OAR 855-043-0545 Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery ➢ OAR 855-043-0630 Correctional Facility - Drug Delivery and Control ➢ OAR 855-043-0740 Community Health Clinic (CHC) - Dispensing and Drug Delivery Staff member Davis reviewed the remaining revisions and asked the workgroup for feedback on the entire set of rules. The workgroup did not provide any additional comments.
	❖ Public Comment ➢ No one signed up to provide public comment. ❖ Closing Remarks Staff member Davis thanked the workgroup for volunteering their time and for their expertise and stated that this would most likely be the last Compounding Workgroup meeting. Meeting adjourned at: 3:23PM

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.