Meeting Minutes	**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 Items

The meeting convened at 1:01PM

- 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
- May 16, 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.

- Rulemaking Process, Anticipated Rules Timeline

Staff member Davis reviewed the rulemaking process and stated that she anticipates reviewing the draft proposed rules with the board during the June 2023 board meeting.

❖ Workgroup Member Discussion

Staff member Davis reviewed USP definitions relevant to Division 183 and explained that these select definitions were not added to the proposed rules. She asked the workgroup if they preferred to include any of the USP definitions in the proposed rules.

The workgroup did not provide any comments.

- OAR 855-006-0005 Definitions

Staff member Davis reviewed the definition of compounding and asked the workgroup for feedback.

The workgroup did not provide any comments.

- OAR 855-183-0001 Applicability

Staff member Davis reviewed the proposed rule language related to "Applicability" and asked the workgroup for feedback on the proposed rules.

A few workgroup members asked a few clarifying questions related to OBOP's broad statutory authority over drugs, distribution, dispensing and delivery and how this rule would apply to compounding for administration only.

- OAR 855-183-0005 Definitions

Staff member Davis reviewed the proposed rule language related to "Definitions" and asked the workgroup for feedback.

The workgroup did not provide any comments.

- OAR 855-183-0010 Designation: General

Staff member Davis reviewed the proposed rule language related to designation requirements for the drug outlet to inform the board of accurate compounding status and asked the workgroup for feedback.

Board member Patel asked a question about PIC responsibility for both the pharmacy and compounding practice. Staff member Efremoff explained that a PIC is required under the pharmacy registration and, in a pharmacy that does compounding, the PIC is responsible for all activities in that pharmacy.

There were no additional comments provided by the workgroup.

- OAR 855-183-0050 Personnel

Staff member Davis reviewed proposed language related to personnel requirements related to compounding and asked the workgroup for feedback.

Workgroup member Fondse inquired about pharmacy technicians being excluded from being a "designated person." Staff member Davis stated that pharmacy technicians assist in the practice of pharmacy and are prohibited from practicing pharmacy independently, therefore the designated

person needs to be a pharmacist. Staff member Davis clarified that there could be a different designated person for different USP standards or parts of a single USP standard.

- OAR 855-183-0200 Compounding: General Requirements

Staff member Davis reviewed proposed language related to compounding general requirements and asked the workgroup for feedback.

The workgroup discussed and provided comments relating to (4)(a)-(b) including that they agree that barcoding and imaging and have a large beneficial impact on patient safety, but requiring such technology may be a financial barrier/burden for smaller independent pharmacies and rural hospitals to set up and maintain and may result in a barrier to access. If rule is adopted, would ask for time to implement in order to be compliant, expensive to procure and implement, requires extra staff and specialized training estimated costs for a small pediatric specialized hospital $30k. Workgroup members provided feedback that the board may consider types of compounding to be separated out, barcoding adds accuracy and ease in recordkeeping, imaging is possible without ACD, barcoding and imaging are very useful and catch many mistakes but there still needs to be a manual process because the cameras go down and do not work on small dose mixing.

- OAR 855-183-0205 Compounding: Technology

Staff member Davis reviewed proposed language related to compounding general requirements and asked the workgroup for feedback regarding

Workgroup members provided feedback that the industry is heading in this direction, but it may be too soon to require ACD. Converting software to expand image capture for 15 workstations roughly estimated to be $130K initially and $50K per year, systems need to be customized and are very expensive to maintain, mandating this now is difficult, and concerns about patient's access to compounded drugs. Overall, the workgroup consensus was that they agreed the language as proposed is headed in the right direction to increase patient safety.

- OAR 855-183-0370 Delivery

Staff member Davis reviewed proposed language related to delivery and asked the workgroup for feedback.

One workgroup member provided feedback and stated that language concerning appropriate storage is typically on the container if the item does not require standard controlled room temperature storage conditions.

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

Staff member Davis reviewed proposed language related to labeling compounded non-sterile preparations and asked the workgroup for feedback.

The workgroup did not provide any comments.

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

Staff member Davis reviewed proposed language related to labeling compounded sterile preparations and asked the workgroup for feedback.

	The workgroup members had a few clarifying questions related to indication that the preparation is compounded, strength solution of the base or maybe listing inactive and active requirements separately. ➢ OAR 855-183-0420 Labeling: CNSP and CSP Preparations for Future Use Staff member Davis reviewed the proposed language related to labeling for both CNSP and CSP preparations for future use and asked the workgroup for feedback. The workgroup discussed and provided a few comments such as "Indication that the preparation is compounded" is not needed for internal use products but placing into an automated dispensing cabinet is probably required, and thus the language in (1) is important to have for internal use products. ➢ OAR 855-183-0450 Drug: Disposal Staff member Davis reviewed the proposed language related to drug disposal and asked the workgroup for feedback. The workgroup did not provide any comments. ➢ OAR 855-183-0500 Policies & Procedures Staff member Davis reviewed the proposed language related to policies and procedures and 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 language related to compounded drug recalls and asked the workgroup for feedback. Workgroup member Gustafson provided an example of a recall she experienced and had concerns about the 12-hour turnaround time to notify the required parties and reporting to Medwatch as the board typically does not require reporting to other organizations. ➢ OAR 855-183-0550 Records: General Staff member Davis reviewed the proposed language related to records and asked the workgroup for feedback. The workgroup provided a few comments such as is documentation concern maybe more about CNSPs prepared for more than one patient only applies for sterile and if non-sterile must still have a MFR for one patient and if non-sterile to sterile permitted would need to revisit this language, that cleaning sanitizing disinfecting may be too general as far as what was done and when, and the rules are very descriptive as well as standard operating procedures in regards to requirements.

	➢ OAR 855-183-0560 Records: Master Formulation Records (MFR) for CNSP Staff member Davis reviewed the proposed language related to records for master formulation records for CNSP and asked the workgroup for feedback. Workgroup member Gustafson requested clarification to (1)(b) stating that not all products have this information available and proposed to add "as applicable" to the rule. ➢ OAR 855-183-0565 Records- MFR: CSP Staff member Davis reviewed the proposed language related to records for master formulation records for CSP and asked the workgroup for feedback. The workgroup members provided a few comments such as the intent of quality control procedures that includes the expected results and limits of tolerability and suggested splitting out qualitative and quantitative measures because not all CNSPs have quantitative limits and some do permit product variability. ➢ OAR 855-183-0570 Records- CR: CNSP Staff member Davis reviewed the proposed language related to records for CR- CNSP and asked the workgroup for feedback. Workgroup member Gustafson commented that the language in (1)(a)(G) was a bit vague related to final CNSP product accuracy and inquired about linking dispensing or transfer records to a lot number. ➢ OAR 855-183-0575 Records- CR: CSP Staff member Davis reviewed the proposed language related to records for CR- CSP and asked the workgroup for feedback. The workgroup did not provide any comments. ➢ OAR 855-183-0600 Prohibited Practices Staff member Davis reviewed the proposed language related to prohibited practices and asked the workgroup for feedback. The workgroup members provided a few comments and clarifying questions such as does the rule apply to 503B pharmacies and could agree to more regulations for non-sterile to sterile compounding but believe that it should be permitted as they have not seen non-sterile to sterile prohibited in any other state and it can be done in a safe manner. Prohibiting this practice could send Oregon patients outside of the state to get compounded drugs which could be a safety issue. Regarding verifying components after addition to final container, workgroup members agreed it is not safe but expressed concern that this would require additional pharmacist staff unless there is a 1:2 ratio and would have a fiscal impact either way. Additional comments concerning non-sterile to sterile compounding for intrathecal pain pumps that patients' needs require a high level of commitment and regulation to permit, suggests requiring accreditation to perform this type of compounding and or a separate registration type.

	➢ OAR 855-183-0700 Compounding Services: Preparation According to FDA Approved Labeling Staff member Davis reviewed the proposed language related to compounding services preparation according to FDA approved labeling and asked the workgroup for feedback. The workgroup provided a couple of comments such as encourage to have this in rule for clarity and it adds value. ➢ OAR 855-183-0710 Compounding Services: Copies of an Approved Drug Staff member Davis reviewed the proposed language related to compounding services copies of an approved drug and asked the workgroup for feedback. The workgroup did not provide any comments. ➢ OAR 855-183-0730 Compounding Services: For Use by a Veterinarian Staff member Davis reviewed the proposed language related to compounding services for use by a veterinarian and asked the workgroup for feedback. Workgroup member Marzell asked if this rule should be in the veterinarian board rules instead of pharmacy board and staff member Davis clarified that these rules propose to regulate pharmacies not veterinarians. ➢ OAR 855-041-1018 Outlet: General Requirements Staff member Davis reviewed proposed language related to outlet general requirements and asked the workgroup for feedback. The workgroup did not provide any comments. ➢ OAR 855-043-0545 Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery Staff member Davis reviewed proposed language related to DPDO dispensing and drug delivery and asked the workgroup to provide feedback. The workgroup did not provide any comments. ➢ OAR 855-043-0630 Correctional Facility - Drug Delivery and Control Staff member Davis reviewed proposed language related to correctional facility drug and delivery and asked the workgroup for feedback. The workgroup did not provide any comments. ➢ OAR 855-043-0740 Community Health Clinic (CHC) - Dispensing and Drug Delivery Staff member Davis reviewed proposed language related to community health clinic drug and delivery and asked the workgroup for feedback.

	❖ Public Comment ➢ Luke Eilers, PharmD, Northwest Compounders ➢ Aaron Bohn, PharmD, Community Compounding Pharmacy ❖ Closing Remarks Staff member Davis thanked the workgroup for their expertise and for volunteering their time and provided the dates of future Compounding Workgroup meetings: 6/20/2023 and 7/18/2023. ❖ The meeting adjourned at: 3:59PM.

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.