

**Oregon Board of Pharmacy – Workgroup  
Compounding  
June 20, 2023 1:00PM**

The committee will meet virtually.

**Public Attendance Options:**

Virtually via Teams: [Link](#)

**Audio Only: (503) 446-4951 Phone Conference ID: 736 914 922#**

*To sign up for Public Comment, email your request to [pharmacy.rac@bop.oregon.gov](mailto:pharmacy.rac@bop.oregon.gov) by **12:00PM on 6/20/2023**.*

*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  
Public Meeting**

Agenda Item	Content
Welcome	❖ Roll Call
Workgroup Business	<ul style="list-style-type: none"> <li>❖ Workgroup - Purpose and Responsibilities</li> <li>❖ Anticipated Rules Timeline</li> <li>❖ <a href="#">Review of Proposed Rules</a></li> <li>❖ Committee Member Discussion</li> </ul>
	❖ Public Comment (if applicable)
Good of the Order	<ul style="list-style-type: none"> <li>❖ Closing Remarks</li> <li>❖ Adjourn</li> </ul>

*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

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OREGON BOARD OF PHARMACY

WORKGROUP– JUNE 20, 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

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- Workgroup Participants Present

- Dawn Calder, RPH
- Sarah Fondse, RPH
- Natalie Gustafson, RPH
- 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

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- 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

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- *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 2-5 are repeated as necessary to build consensus**

# Public Comment

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- Workgroup public attendees and members have the opportunity to submit written comments/offer testimony at the rulemaking hearing on July 26, 2023 on the currently pending proposed rules.



# Proposed Timeline- DRAFT

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- 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~~ Board sent to rulemaking for public comment
  - July 26, 2023: Rulemaking hearing 9:30am
  - August 2023: Board ~~2nd~~ 1<sup>st</sup> look at proposed rules
  - September 26, 2023: Rulemaking hearing 9:30am
  - October 2023: Board adoption of proposed rules, effective 11/1/2023

**Typical rules process can take 2-3 years**

**This timeline will be adjusted based on board priorities**

# Discussion Items: Compounding

- Review revisions
  - New since last workgroup meeting
    - Sent to rulemaking
  - New since rules sent to rulemaking
- Topics
  - Veterinary use bulk compounding exemption
  - Barcode/Imaging/Gravimetrics
  - Automated Compounding Devices
  - Prohibited Practices
  - Copies of an Approved Drug
  - For Use by a Veterinarian
  - Sterile Compounding with Non-Sterile Ingredients

#	Title
1	Applicability
5	Definitions
10	Designation
50	Personnel
200	Requirements: General
205	Technology: Automated Compounding Devices (ACD)
370	Delivery
400	Labeling: CNSP
410	Labeling: CSP
420	Labeling: CNSP and CSP for Future Use
450	Disposal
500	Policies & Procedures
510	Quality Assurance
520	Recalls
550	Records: General Requirements
560	Records: MFR: CNSP
565	Records: MFR: CSP
570	Records: CR- CNSP
575	Records: CR- CSP
600	Prohibited Practices
700	Service: Preparation According to FDA Approved Labeling
710	Service: Copies of a FDA Approved Drug
730	Service: For Use by a Veterinarian
740	Service: Sterile Compounding with Non-Sterile Ingredients

# Future Meetings

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

# FINAL THOUGHTS

THANK YOU FOR YOUR  
PARTICIPATION!

