Oregon Board of Pharmacy
*2nd REVISED BOARD MEETING AGENDA
August 9-11, 2023

Public Attendance Options:

1. **In-person: 800 NE Oregon St. Conference Room 1A, Portland, OR**
2. **Virtually via Teams: Link**
3. **Audio only: (503) 446-4951 Phone Conference ID: 348 428 455#**
4. ***If you experience audio issues upon joining the virtual meeting, send an email to pharmacy.board@bop.oregon.gov for assistance***

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.

Wednesday, August 9, 2023 @ 8:30AM
Thursday, August 10, 2023 @ 8:30AM
Friday, August 11, 2023 @ 8:30AM

- All OBOP meetings, except Executive Sessions, are open to the public. Pursuant to ORS 192.660(1)(2)(f)(L), Executive Sessions are closed to the public, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the board will return to Open Session
- To sign up for Public Comment, email your request to pharmacy.board@bop.oregon.gov by **12:00PM on 8/11/2023**

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.

WEDNESDAY, AUGUST 9, 2023

I. OPEN SESSION, Ian Doyle RPh, Presiding

***Please note that the board will meet in Executive Session for most of the day and anticipates resuming Open Session between 4:30-5:00PM.**

a. Roll Call
b. Agenda Review and Approval *Action Necessary*

II. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 192.660(1)(2)(f)(L), ORS 192.690(1) ORS 676.165, & ORS 676.175.

a. Legal Advice
b. Deliberation on Disciplinary Cases and Investigations
c. Contested Case Deliberation *if applicable

III. OPEN SESSION – PUBLIC MAY ATTEND – At the conclusion of Executive Session, the board may convene Open Session to review scheduled agenda items as time permits.

Adjourn *Action Necessary*

THURSDAY, AUGUST 10, 2023

I. OPEN SESSION, Ian Doyle RPh, Presiding

a. Roll Call

II. GENERAL ADMINISTRATION

a. Rules

i. Review Rulemaking Hearing Report & Comments – *Melvin* **#A** *Action Necessary*

ii. Consider Adoption of Temporary Rules – None

iii. Consider Adoption of Rules - *Melvin*

1. **Div 080 -** Schedule I – Xylazine **#C** *Action Necessary*
3. **Div 102 -** Board Administration **#C1** *Action Necessary*
4. **Div 104 -** Universal Rules **#C2** *Action Necessary*
5. **Div 115 -** Pharmacists - Procedural Rule Review **#C3** *Action Necessary*
6. **Div 120 -** Interns & Preceptors Procedural Rule Review **#C4** *Action Necessary*
7. **Div 125 -** Pharmacy Technicians - Procedural Rule Review **#C5** *Action Necessary*

iv. Rules in Development - *Davis*

v. Rulemaking Policy Discussion Items – *Davis*

1. **Div 007** – Compliance with OHA COVID-19 **#D** *Action Necessary*
2. **Div 006/041/043/045/183 -** Drug Compounding **#D1** *Action Necessary*
3. **Div 019/041/043/044/139** – Short-Acting Opioid Antagonist (2023 HB 2395 & 2023 SB 450) **#D2**
4. **Div 019/025/041/139** – Immunizations (2023 HB 2486 & 2023 HB 2278) **#D3**
5. **Div 115** – Short-Acting Opioid Antagonist (2023 HB 2395 & 2023 SB 450) **#D4**
6. **Div 115/125** – Immunizations (2023 HB 2486 & 2023 HB 2278) **#D5**
7. **Div 006/115** – CPA/CDTM **#D6** *Action Necessary*
8. **Div 045** – USP <795> and USP <797> Standards Adopted by Reference **#D7**

Adjourn *Action Necessary*

FRIDAY, AUGUST 11, 2023

I. OPEN SESSION, Ian Doyle RPh, Presiding

a. Roll Call

II. MOTIONS RELATED TO DISCIPLINARY ACTIONS – *Efremoff* *Action Necessary*

**At this time the board will vote on cases, including proposed disciplinary actions against licensees/registrants.*

III. GENERAL ADMINISTRATION

b. Discussion Items

i. Inspections/Staff Delegated Authority - *Efremoff* *Action Necessary*

ii. Recognition of outgoing Board Member Murray – *Schnabel*

iii. External Communications - *Schnabel*

iv. Board Meeting Summaries SBAR – *Schnabel* **#H**

v. Strategic Plan Update - *Schnabel*

vi. Financial/Budget Report – *MacLean* **#I**

vii. Board Best Practices Key Performance Measure Review **#J**

viii. Other Committee/Council Appointments
1. Council on Naturopathic Physicians Formulary **#K, Ka, Kb** *Action Necessary*
2. Rural Health Coordinating Council **#Kc, Kd, Ke** *Action Necessary*

IV. ISSUES AND ACTIVITIES* (*Items in this section may occur at any time during the meeting as time permits*)

2023 Board Meeting Dates

- October 11-13, 2023 Portland
- November 8-9, 2023 Newport, OR (Strategic Planning)
- December 13-15, 2023 Portland

2024 Board Meeting Dates

- February 7-9, 2024 Portland
- April 10-12, 2024 Portland
- June 12-14, 2024 Portland
- August 7-9, 2024 Portland
- October 9-11, 2024 Portland
- November 7, 2024 Portland (Strategic Planning)
- December 11-13, 2024 Portland

Rulemaking Hearing Dates

(The following dates are reserved for potential rulemaking hearings & identified only for planning purposes and approved by the board. Actual rulemaking activities will be noticed as required by law and may deviate from this schedule as needed.)

- November 21, 2023

Conferences/Meetings

- NABP Districts 6, 7, 8 Meeting – October 22-25, 2023 Jackson Hole, WY

V. APPROVE CONSENT AGENDA* *Action Necessary*

**Items listed under the consent agenda are considered routine agency matters and will be approved by a single motion of the Board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.*

a. License/Registration Ratification 5/24/2023 - 7/24/2023 - **# CONSENT-1**
b. Board Meeting Minutes – June 2023 - **# CONSENT-2**

VI. PUBLIC COMMENT

Adjourn *Action Necessary*

Oregon
Tina Kotek, Governor

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR, 97232
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Fax: 971-673-0002
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www.oregon.gov/pharmacy

Date: July 27, 2023
To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: July 26, 2023

Hearing Location: Virtual Hearing via Teams

Proposed Rules:

- Division 080 related to Schedule I – Xylazine
- Division 102 related to Board Administration
- Division 104 related to Universal Rules
- Division 115 related to Pharmacists
- Division 120 related to Interns and Preceptors
- Division 125 related to Pharmacy Technicians
- Divisions 041/043/183 related to Drug Compounding ***During the June 2023 board meeting, the board stated they did not intend to adopt these rules in August 2023, and were seeking public comment only.***

On June 16, 2023, the July 26, 2023 Rulemaking Hearing public notice was sent out via GovDelivery to 3,803 rulemaking/adopted rules subscribers and 23,430 licensees/registrants (27,233 total). Board staff sent out a separate GovDelivery notice for proposed rules in Divisions 041/043/183 related to Drug Compounding with clear language that the board did not intend to adopt these specific proposed rules in August 2023, but were only seeking public comment.

Stakeholders/public were invited to sign up to provide oral testimony during the virtual hearing, encouraged to email written comments to pharmacy.rulemaking@bop.oregon.gov and had an opportunity to call in to listen to the hearing.

The rulemaking hearing convened at 9:34AM and adjourned at 10:24AM. #34 people joined the public call to listen to the hearing. #7 people signed up to provide oral testimony, and #6 people provided testimony during the hearing. #53written comments were received during the open comment period from 6/16/2023 through 4:30PM on 7/26/2023. The hearing was recorded, and the notice of proposed rulemaking filings were available on our website.

The following board and staff members participated:

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Board President Doyle
Board Vice President Chinn
Staff Member Davis
Staff Member Melvin
Staff Member Schnabel

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Schedule I – Xylazine
AMEND: OAR 855-080-0021

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Board Administration

ADOPT: OAR 855-102-0010, OAR 855-102-0015, OAR 855-102-0020, OAR 855-102-0030, OAR 855-102-0040, OAR 855-102-0045, OAR 855-102-0050, OAR 855-102-0055, OAR 855-102-0060, OAR 855-102-0100, OAR 855-102-0105, OAR 855-102-0110, and OAR 855-102-0125.

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Universal Rules

ADOPT: OAR 855-104-0005, OAR 855-104-0010, OAR 855-104-0015, OAR 855-104-0050, OAR 855-104-0055, OAR 855-104-0060, OAR 855-104-0100, OAR 855-104-0105, OAR 855-104-0110, OAR 855-104-0115, and OAR 855-104-0150.

- No oral testimony was provided.

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SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Pharmacists

ADOPT: OAR 855-115-0001, OAR 855-115-0005, OAR 855-115-0010, OAR 855-115-0015, OAR 855-115-0020, OAR 855-115-0025, OAR 855-115-0030, OAR 855-115-0035, OAR 855-115-0040, OAR 855-115-0045, OAR 855-115-0050, OAR 855-115-0060, OAR 855-115-0065, OAR 855-115-0070, OAR 855-115-0105, OAR 855-115-0110, OAR 855-115-0115, OAR 855-115-0120, OAR 855-115-0125, OAR 855-115-0130, OAR 855-115-0140, OAR 855-115-0145, OAR 855-115-0150, OAR 855-115-0200, OAR 855-115-0210, OAR 855-115-0300, OAR 855-115-0305, OAR 855-115-0310, OAR 855-115-0315, OAR 855-115-0320, OAR 855-115-0330, OAR 855-115-0335, OAR 855-115-0340, OAR 855-115-0345, and OAR 855-115-0350.

- Albert Garcia, VP of Pharmacy - Ro
  - Joined the meeting @ 9:33AM and left the meeting @ 9:35AM prior to providing testimony. He did not rejoin the call.

- Alfred Lyman, Jr., Executive Director, Regional Pharmacy Services – Kaiser Permanente
  - OAR 855-115-0145 Counseling: Strong opposition to rule as proposed. Requirement that counseling be offered prior to delivery. Able to provide written information to patients when we mail prescriptions. 4M Rx mailed per year. Patients expect mail service. Efficient and economic way. Many patients do not answer their phones. Concerned significant time added resulting in further delays. Meds are usually received within 2 days. Think this could double delivery time. Cost impact- significant add of FTE and millions of dollars in technology changes that would need to happen. Urge board to leave rule as is. No data on harm from current practices.

- Michael Millard, OSHP
  - OSHP opposes 855-115-0145 Counseling. Agree with previous commenter. Inconsistency between (1) and (2)-(10) apparently, we don't decide what counseling should be. The board is deciding this. Significant change in practice for mail order. Major concern disruption and delays will occur resulting in harm and disruption. Pandemic taught us that disruption in normal flow of business results in some unfortunate outcomes. Fail to see any safety or public health reason for this change. Concerned patients affected by disruption will come to the ER. ERs cannot tolerate any additional load. Many health systems do ambulatory practice using telepharmacy to manage medications and provide counseling at this point rather than upon dispensing. (4) provided suggested language

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- OSHP opposes 855-115-0??? Laboratory test- Must only vs. may. Concerned with must language. Concerned this prohibits pharmacist from providing care while in process of developing protocol. Look at carefully. Consider may only to allow pharmacist to care for patient in this rare situation.

- Lauren Paul, Executive Director, Pharmacy Regulatory Affairs - CVS Health
  - Concerned about rulemaking notice. Difficult to compare since noticed as a brand-new division and everything was underlined/bold.
  - OAR 855-115-0145 Counseling: CVS supportive of counseling for each practice setting. No patient safety data to support extensive changes to counseling rules. Confusion as to what interactive counseling actually is. Would like board to provide clarification on 'interactive' Current language allows for attempts to counsel a patient which takes away pharmacist time to make attempts. Deliver to patients, we offer extensive written information to patients and includes how to reach a pharmacist. CVS focused on reducing outbound calls from pharmacists. Want pharmacist to be focused on dispensing and patient care services that includes counseling.

- Sandra Teeny, COO Home Delivery - Kaiser Permanente
  - OAR 855-115-0145 Counseling: Does not see benefits of this rule change for counseling. 43M per year in Kaiser. Growing business line. 4M in NW, 63% mail order utilization across the country. Providers believe in it. In 25 years in mail order, not aware of a single complaint or adverse event. 35K inbound calls. Trying to outreach to a member. Very difficult to get in touch with someone during the day. This includes text. Delay on prescription delivery would result in adverse effects. Typically 2 day delivery. Medication safety studies, 74% had better medication adherence for patients who use mail order. Burden to organization financially, $22-55M to implement this rule. FDA is making comment on providing online drug information. Board reconsider this, would like to see current rules stay in place.

- Kyle Zebley, Executive Director - ATA Action
  - OAR 855-115-0145 Counseling: Concerns about interactive counseling requirements. Attempt and document prior to delivery significant time and resources that will not result in increased patient safety. Written counseling may be more appropriate for certain patients. Appreciate consistency for counseling across different settings. Re-examine rules. Requests 12 months for implementation.

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SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Interns and Preceptors

ADOPT: OAR 855-120-0001, OAR 855-120-0005, OAR 855-120-0010, OAR 855-120-0030, OAR 855-120-0035, OAR 855-120-0040, OAR 855-120-0050, OAR 855-120-0105, OAR 855-120-0110, OAR 855-120-0115, OAR 855-120-0135, OAR 855-120-0150, OAR 855-120-0155, OAR 855-120-0190, OAR 855-120-0195, OAR 855-120-1010, OAR 855-120-1030, OAR 855-120-1040, OAR 855-120-1050, OAR 855-120-1070, OAR 855-120-1110, OAR 855-120-1115, OAR 855-120-1122, OAR 855-120-1150, OAR 855-120-1155, and OAR 855-120-1205.

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Pharmacy Technicians

ADOPT: OAR 855-125-0001, OAR 855-125-0005, OAR 855-125-0010, OAR 855-125-0030, OAR 855-125-0035, OAR 855-125-0040, OAR 855-125-0050, OAR 855-125-0105, OAR 855-125-0110, OAR 855-125-0115, OAR 855-125-0135, and OAR 855-125-0150.

- Michael Millard, OSHP
  - OAR 855-125-0150 Prohibited Practices: HB2486, Technician to administer vaccines. Delete section 855-125-0150(1)(l). OAR 855-125-0150(1)(c) seems contradictory to OAR 855-125-0135(1). many health systems have adopted technicians taking medication histories from patients. This practice is well documented to improve patient care. Believes OAR 855-125-0135(1) would allow medication history practice to continue. Technicians frequently call pharmacies to obtain prescription histories and talk to patient families. Want board to be clear that medication histories are allowed.
- Lauren Paul, Executive Director, Pharmacy Regulatory Affairs - CVS Health
  - Supports full pharmacist delegation model.
  - Urges board to re-examine prohibited practices in OAR 855-125-0150 and remove (1)(n) that prohibits receiving or providing transferred prescriptions. Decades of data that technicians can do this in other states.
  - Suggests that due to 2023 HB2486, maybe not move forward of this rule package at the August board meeting and redo the rule package with the changes needed to comply with the bill.

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- Kyle Zebley, Executive Director - ATA Action
  - OAR 855-125-0001 Applicability: Unclear if this rule requires technicians in non-Oregon pharmacies to now hold licensure. Request to add clarifying language to rule to not require technicians in non-Oregon pharmacy to be licensed.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Drug Compounding *Seeking Public Comment Only

AMEND: OAR 855-041-1018, OAR 855-043-0545, OAR 855-043-0630, and OAR 855-043-0740.

ADOPT: OAR 855-183-0001, OAR 855-183-0005, OAR 855-183-0010, OAR 855-183-0050, OAR 855-183-0200, OAR 855-183-0205, OAR 855-183-0370, OAR 855-183-0400, OAR 855-183-0410, OAR 855-183-0420, OAR 855-183-0450, OAR 855-183-0500, OAR 855-183-0520, OAR 855-183-0550, OAR 855-183-0560, OAR 855-183-0565, OAR 855-183-0570, OAR 855-183-0575, OAR 855-183-0600, OAR 855-183-0700, OAR 855-183-0710, OAR 855-183-0730, and OAR 855-183-0740.

- Jessica Adamson, Senior Vice President/Government Affairs - CFM PDX
  - OAR 855-183-0005 Definitions: Testifying on behalf of Chad Baker and FlavorRx. Request change to ensure continued patient access to flavoring products. 300+ pharmacies in Oregon offer this service mostly for liquid medication flavoring. Getting a child to take a medication is the most important thing. Bitter taste can be a barrier to getting child to take medication. 200M flavored medications with no adverse events. Hopeful that Oregon will permit this practice as all states permit this except for Washington.

All written comments received by the public comment deadline date of 7/26/2023 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 6/16/2023 Notice of Proposed Rulemaking.

July 18, 2023

Joseph Schnabel, PharmD
Executive Director
Oregon State Board of Pharmacy
800 N.E. Oregon Street, Suite 150
Portland, OR 97232

Re: New Division 115 for Pharmacists.

Dear Dr. Schnabel:

Albertsons Companies Inc. ("ACI") family of pharmacies is one of the largest pharmacy providers in the state of Oregon. We currently operate 106 locations in the state under both the Albertsons and Safeway banners. Nationwide, ACI operates 1728 pharmacies across 34 states and the District of Columbia.

We appreciate the steps the Board took to engage with stakeholders earlier in the process than is customary on these proposed regulations. We particularly appreciate the response to the feedback we provided in previous comments submitted during the November 2022 rulemaking hearing. While we believe the New Division 115 for Pharmacists has improved since the first iteration, we still have some concerns we believe could have unintended consequences.

855-115-0001 – Applicability

In (3) we appreciate the return of the word counsel to the approved list of professional tasks for a pharmacist working outside of Oregon in an Oregon licensed pharmacy that are exempted from requiring Oregon licensure. This will undoubtedly avoid unintended impacts on patient care in the state of Oregon. There was an additional modification to the previous language in this section that did not get discussed by the Board members, so it is difficult to understand the intention behind the change. In the second half of (3) it states, "except that a Pharmacist located in another state who is working for an out-of-state pharmacy…associated with the out-of-state pharmacy dispensing of a drug into Oregon, is not required to be licensed by the board." The use of dispensing of a drug into Oregon in that phrase seems to be permissive of a central fill or mail order situation, however, could be construed as inconsistent with existing regulations and interpretations applicable to remote processing and centralized filling by non-resident pharmacies.

With the current and ongoing staffing challenges in the state of Oregon, using innovative ways to support in-state pharmacies has become critical. We rely upon remote processing services provided by our Oregon-licensed Boise, Idaho remote processing location to support our Oregon pharmacies. Many of our Oregon pharmacies have longstanding pharmacist and technician openings, which are going unfilled

despite large sign on bonuses and other incentives being offered. Without the central support from an out-of-state Oregon licensed pharmacy under common ownership, many patients would be impacted and lose access to their prescriptions. We ask that the Board consider the following change to the language to prevent any unintended consequence.

(3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet, or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a Pharmacist located in another state who is working for an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling, and verification associated with the ~~out-of-state pharmacy~~ dispensing of a drug ~~into~~ to an Oregon patient, is not required to be licensed by the board.

855-115-0145 – Counseling

We appreciate the changes made to (4) that allow for the delivery of the prescription without first establishing contact with the patient. The addition of a reattempt to provide counseling after the prescription has been delivered to the patient will ensure the patient does not experience a delay in receiving their prescriptions.

Item (5) of this section is particularly concerning as it appears to go backwards from where the practice of pharmacy is today. Item (5) (a) requires a pharmacist to be the only person who can accept the refusal of counseling. Currently, a pharmacist or intern under the supervision of a pharmacist can accept the patient or patient's agent's refusal of counseling. Administratively requiring the pharmacist to accept all counseling refusals adds burden to the pharmacist and patient. After the first academic year of an intern's pharmacist education, they are permitted to counsel patients under the supervision of a pharmacist in accordance with the limits of their knowledge. A pharmacist should be able to determine if they are comfortable with an intern accepting the refusal of counseling. This has worked for as long as it has been allowed currently in Oregon, and we don't believe a change should be made at this time.

We recommend striking item (5) (a) in its entirety to not only allow interns to accept the refusal, but also allow this to be delegated to a technician or clerk. Doing so, would remove administrative burden from the pharmacist and allow patients with questions for the pharmacist greater time to discuss their medications without interruption or being hurried by other patients who do not have questions for the pharmacist.

855-115-0200 – Pharmacist-in-Charge: Qualifications and Limitations

Again, we appreciate the board responding to feedback and allowing a pathway for pharmacists with less than 1500 hours of experience to assume the role of PIC. This is essential to keep pharmacies open in rural areas of the state. As drafted, this section would require a pharmacist with less than 1500 hours experience to take the PIC class before they can assume the role of PIC. Considering Oregon does not have a grace period between the outgoing and incoming PIC the only way this will be accomplished is having all our newly graduated and licensed pharmacists go through the PIC training program. We see value in

having these pharmacists go through the program, however, we recognize that this may increase the burden on the board staff. Many states have a ten-to-thirty-day grace period between an outgoing and incoming PIC. This allows the drug outlet in those states to select the best equipped pharmacist available to become the PIC. Conversely, in Oregon it is not uncommon to select individuals who do not have a desire to be PIC or frankly are not the best choice, purely out of the necessity to have zero gap between the outgoing and incoming PIC. We believe this is counter to the objectives and mission of the board. Therefore, we suggest the board consider a grace period of 30 days at the soonest opportunity. Additionally, as a stop gap measure, we suggest reinstituting the allowance for the PIC training program to be completed within 30 days of assuming the PIC role. This will allow for better use of pharmacist and board staff time.

We appreciate this opportunity to provide feedback on these regulations and their significance to patient access to pharmacy care in Oregon. Should you have any questions or if you would like to discuss this matter in further detail, please do not hesitate to contact me. I can be reached by email at Rob.Geddes@albertsons.com or on my mobile phone at (208) 513-3470.

Sincerely,

Rob Geddes, PharmD, MBA
Director, Pharmacy Legislative and Regulatory Affairs

From:	Rob Geddes
To:	PHARMACY RULEMAKING * BOP
Subject:	Comments Division 115 and 125
Date:	Friday, July 21, 2023 1:02:21 PM
Attachments:	Division 125 Comments 7-21-23 Final.pdf Division 115 Comments - 7-17-23 Final.pdf

Rachel,

I hope you are doing well. Please accept our comments for the upcoming rulemaking hearing on Divisions 115 and 125.

Rob Geddes, PharmD, MBA
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July 21, 2023

Joseph Schnabel, PharmD
Executive Director
Oregon State Board of Pharmacy
800 N.E. Oregon Street, Suite 150
Portland, OR 97232

Re: New Division 125 for Technicians

Dear Dr. Schnabel:

Albertsons Companies Inc. ("ACI") family of pharmacies is one of the largest pharmacy providers in the state of Oregon. We currently operate 106 locations in the state under both the Albertsons and Safeway banners. Nationwide, ACI operates 1728 pharmacies across 34 states including the District of Columbia.

We appreciate the steps the Board took to engage with stakeholders earlier in the process than is customary on these proposed regulations. We particularly appreciate your response to our feedback to the comments we submitted during the November 2022 rulemaking hearing. While we believe the New Division 125 for Technicians has improved since the first iteration, we still have some concerns we believe could have unintended consequences.

Our pharmacies rely on pharmacy technicians tremendously and appreciate the value they provide in serving our patients and supporting our pharmacists. We could not be successful without our trained technician workforce. We also know based on our experience in other states that technicians can effectively be trained to do more than they are allowed to currently do in the state of Oregon. Other states have allowed technicians to expand their support when delegated by the supervising pharmacist to include participating in transfers of prescriptions between pharmacies, contacting the prescriber for technical clarification on prescriptions that do not require exercising professional judgement, receive new verbal prescriptions, administering CLIA waived tests prior to pharmacist interpretation, administering vaccinations, and many other innovative tasks. Recently, Oregon has allowed technicians to perform final verification of a prescription, working in a remote dispensing pharmacy and pursuant to HB 2486 will allow administration of vaccines with the Governor's recent approval. These are great steps forward, but we would encourage Oregon to lean on the experience of other states to identify additional ways technicians can be safely leveraged to support the pharmacist more effectively.

855-125-0150 – Prohibited Practices

As discussed above, technicians are a great resource for pharmacists. When trained and leveraged appropriately, they add tremendous value to the safe and efficient operation of a pharmacy. Oregon currently prohibits technicians from performing several tasks that other states permit:

(1) (c) Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription; …
(n) Receive or provide a new or transferred prescription orally;

Receiving a new verbal prescription, clarifying information on an illegible written prescription, and communicating prescription transfers are actions that are allowed in other states that have served to remove administrative burden from the pharmacist and allowed them to focus on patient related tasks that require their training and experience. Removing the language cited above would permit technicians to perform these tasks. There are several studies available which examine expanding the scope of the pharmacy technician's practice to include tasks as outlined above. One study in particular reviews the tasks of accepting verbal prescriptions and communicating prescription transfers.[1] One of the paragraphs in the conclusion of the journal article is particularly insightful and relevant to this topic:

> "As noted previously, the rate of verbal prescriptions has declined, and we envision this will continue as the rate of electronic prescribing continues to grow. Still, these interruptions will continue and creating opportunities to delegate these tasks to technicians will continue to represent an opportunity moving forward. While limited evidence is currently published on these tasks, there is little to suggest appropriately trained technicians cannot perform them safely and accurately, and the track record of success with these tasks spans four decades in some states. The law is, of course, just the minimum standard. Pharmacists are often required to go above and beyond what the law allows in order to provide optimal patient care, and pharmacists can adopt strong practice policies and procedures to mitigate the risk of harm from verbal orders. Such risk reduction strategies include instituting read-back, spell-back techniques, or requiring the indication for each phoned-in medication, among other risk reduction strategies. Pharmacists may also exercise discretion in deciding to whom to delegate these tasks. Pharmacists may be more comfortable with senior technicians who have more experience with medication names, or technicians who have previously conducted medication histories. In addition, extra-legal factors such as Joint Commission accreditation standards also provide checks and balances on the process"[2]

We have seen these practices benefit our pharmacists over the last several years after taking advantage of them in states where it is allowed. We suggest the following changes to this section of rules so that only the following is prohibited:

(1) (c) Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription that requires judgment;
~~*(n) Receive or provide a new or transferred prescription orally;*~~

[1] Frost TP, Adams AJ, Expanded pharmacy technician roles: Accepting verbal prescriptions and communicating prescription transfers, Research in Social and Administrative Pharmacy (2016), http://dx.doi.org/10.1016/j.sapharm.2016.11.010.
[2] *Id.*

Additionally, we believe there is an opportunity to provide much needed support to decrease interruptions to the pharmacist workflow by allowing technicians or clerks to accept the refusal of counseling. Currently, the pharmacist is pulled in multiple directions because everything in a pharmacy depends on the pharmacist. When the pharmacist is occupied with a patient or prescriber, everything else tends to come to a screeching halt. By allowing the technician or clerk to accept the refusal of counseling, the work at the out window can continue. As it currently works in practice, when a patient is told that the pharmacist must provide counseling, the patient will often decline without prompting. But the technician cannot accept that declination. They must instead interrupt the pharmacist and ask them to come to the register to accept the declination. Interruptions are both inefficient and present an opportunity for errors to occur. Appropriate guardrails through training and policies and procedures can be established by the pharmacy to ensure patient counseling is provided when requested by the patient or if the pharmacist deems it is necessary. We cannot force a patient to be counseled on their medication, and when they decline their right to counseling by a pharmacist, we should not require the pharmacist to drop everything they are currently doing to have the patient tell them this face-to-face. While the pharmacist may have something they absolutely need to address with a patient, this can be solved through robust policies and procedures that facilitate good patient care. This would also give pharmacists more time to counsel patients receptive to the offer to counsel.

We suggest the following change to Division 125 that lines up with comments we are submitting on Division 115 related to pharmacists:

~~*(e) Accept a patient or patient's agent's request to decline counseling;*~~

We appreciate this opportunity to provide feedback on these regulations and their significance to patient access to pharmacy care in Oregon. Should you have any questions or if you would like to discuss this matter in further detail, please do not hesitate to contact me. I can be reached by email at Rob.Geddes@albertsons.com or on my mobile phone at (208) 513-3470.

Sincerely,

Rob Geddes, PharmD, MBA
Director, Pharmacy Legislative and Regulatory Affairs

From: Bob Archer
To: PHARMACY RULEMAKING * BOP; Rep Evans
Subject: Veterinary xylazine
Date: Saturday, July 22, 2023 9:49:06 AM

To Whom it May Concern,
I'll keep it brief. Xylazine is very useful in large animal medicine, and very little of the veterinary drug makes it onto the street. Making it a schedule 1 drug would severely impact the ability of large animal veterinarians to care for their patients.
Thank you for your service.
Bob Archer, DVM
Ash Creek Animal Clinic

ata ACTION
Telehealth Policy to Transform Healthcare

July 21, 2023

Rulemaking Staff
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
pharmacy.rulemaking@bop.oregon.gov

RE: ATA ACTION CONCERNS WITH PROPOSED RULE DIVISION 115: PHARMACISTS AND DIVISION 125 PHARMACY TECHNICIANS

Dear Oregon Board of Pharmacy rulemaking staff,

On behalf of ATA Action, I am writing to express our concerns with certain proposed requirements in the Notice of Proposed Rulemakings regarding Division 115: Pharmacists issued June 16, 2023. We are concerned that, if implemented, the proposed rules could erect unnecessary barriers to patient care.

ATA Action, the American Telemedicine Association's affiliated trade association focused on advocacy, advances policy to ensure all individuals have permanent access to telehealth services across the care continuum. ATA Action supports the enactment of state and federal telehealth coverage and fair payment policies to secure telehealth access for all Americans, including those in rural and underserved communities. ATA Action recognizes that telehealth and virtual care have the potential to truly transform the health care delivery system – by improving patient outcomes, enhancing safety and effectiveness of care, addressing health disparities, and reducing costs – if only allowed to flourish.

Many members of the ATA and ATA Action offer patients the option to receive their medication through mail-order fulfillment. This option can increase patient access to medication and improve patient adherence to treatment, leading to better patient outcomes.

Proposed Counseling Requirements

Proposed Rule 855-115-0145 includes a number of new requirements related to pharmacist counseling, which would impose substantial and unique burdens on pharmacists who deliver care into Oregon and on patients who choose to have their medications delivered at home. Specifically, the rules redefine counseling to be "interactive," suggesting that the provider-patient interaction must be a real-time discussion and forecloses the use of (currently permitted) offers to counsel or written interactions. The proposed rules would also mandate pharmacists *to initiate* such interactive counseling prior to delivery of medication and by the end of the next business day (often within 24 hours) after delivery if the patient is not reached initially. Finally,

the rules would require the pharmacist to document each counseling attempt and the outcome "at the time of the attempt or interaction."

ATA Action echoes other stakeholders and has significant concerns with these proposed rules, which would make Oregon the first state in the country to mandate pharmacists provide "interactive" counseling and prohibit written counseling and offers to counsel for remote delivery.

First, the new requirement for real-time interactive counseling will require pharmacies offering mail-order or delivery to invest significant time and resources – some estimates in the millions of dollars – without any corresponding benefit to patient safety. ATA Action is aware of no safety data, study, or clinical evidence showing that current practice – such as an offer to counsel or written counseling – are insufficient for safely managing prescription medications. If the Board believes there is data to support a mandate for proactive counseling, ATA Action questions why the rules regarding dispensing and drug delivery for Community Health Clinics (CHC)[1] and Dispensing Practitioner Drug Outlets (DPDO)[2] will still allow for delivery or mail prescription with a written offer to provide counseling.

Second, ATA Action is not aware of any other state that requires the pharmacist to proactively initiate contact with a patient regarding their prescription prior to delivery as well as within a strict 24-hour time limit after delivery. There is a good reason why: 8-in-10 Americans do not answer calls from unknown telephone numbers,[3] meaning other states understand the futility of such a requirement. Furthermore, the proposed rule does not require any interactive contact to occur before dispensing the medication, meaning most of these proposed patient counseling contact attempts will merely function as a new, expensive administrative burden without any counseling occurring.

Third, the proposed rules' documentation requirement piles on these new unnecessary administrative burdens on pharmacists. Pharmacists will now be required to not only make dozens of unanswered phone calls, but must also file rote and often blank documentation that offers no discernable value to patients or pharmacies. If the Board insists on keeping this recordkeeping requirement, ATA Action sees no reason why the pharmacist must personally do this administrative task, rather than other members of the pharmacy team.

In contrast to how the above rules impose counseling mandates and unnecessarily restrict patient choice, ATA Action requests the Board rely instead on the proposed rule language that

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[1] Board of Pharmacy, 855-043-0740 Community Health Clinic (CHC) - Dispensing and Drug Delivery. https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=290866

[2] Board of Pharmacy, 855-043-0545 Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery. https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=290863

[3] Pew Research Center, *Most Americans don't answer cellphone calls from unknown numbers*, Dec. 14, 2020, https://www.pewresearch.org/short-reads/2020/12/14/most-americans-dont-answer-cellphone-calls-from-unknown-numbers/.

empowers pharmacists to use their judgement as to the patient and his or her circumstances. Specifically, the rules state: "for each prescription, the pharmacist must ***determine the manner*** and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient." ATA Action agrees that licensed practitioners should be able to utilize the full range of available modalities while delivering care, so long as the technologies being used are appropriate to meet the standard of care presented by the patient. It should be pharmacists, relying on their extensive education and clinical experience, who should have the ability to determine if written counseling and written offers to provide direct counseling meet the patient's needs, or if more direct or proactive real-time counseling is necessary.

Indeed, written offers to counsel or written counseling might be *more appropriate* for engaging many patients who have chosen mail-order fulfillment, particularly those in the telemedicine setting. Many of the reasons patients choose to receive medical care in the telehealth setting are the same reasons patients choose to receive medications via home delivery methods. Both care settings offer solutions for patients with limited mobility or transportation challenges, who cannot take time off work, who reside in underserved or rural areas who may not have convenient or easy access to a pharmacy to fill their prescription in person, or are part vulnerable or stigmatized populations, such as those seeking reproductive or sexual health care. While a pharmacist can easily counsel a patient (or attempt to) at the time they come to pick up their prescriptions in a brick and mortar pharmacy, initiating a separate interaction with patients for counseling in a mail-order delivery setting will be far more burdensome and is misaligned with patients' expectations.

Patients will be the ones who bear the burden of this rule being implemented. The potential confusion it would create for providers and patients alike, coupled with the fiscal impact to be borne by members, could have legitimate and sizable negative impacts upon the speed, cost, and availability of mail-order prescription fulfillment. For all these reasons, ATA Action requests the Board of Pharmacy consider revising 855-115-0145 to better reflect and account for the differences in patients accessing medications at their homes:

> **Division 115, 855-115-0005 Definitions**
> (1) "Counseling" or "Counsel" means an interaction, including through written communication, ~~interactive communication~~ between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.
>
> **Division 115, 855-115-0145 Counseling**
>
> (2) The pharmacist must counsel or offer to counsel the patient or patient's agent on the use of a drug or device:¶
> (a) Upon request;

(b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;
(c) When there has been a change in the dose, formulation, or directions;
(d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or
(e) For any refill that the pharmacist deems counseling is necessary.

(5) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation or does not respond to an offer to counsel. If refused,

(a) Only a pharmacist can accept a patient's or patient's agent's request not to be counseled, when counseling is required.
(b) The pharmacist may choose not to release the prescription until counseling has been completed.

…

(7) The pharmacist must ensure the offer ~~attempt~~ to counsel, ~~provides~~ counseling, or ~~accepts the~~ request not to be counseled is documented ~~their identity, each attempt to counsel and the outcome at the time of the attempt or interaction~~.

Pharmacy Technician Licensing Requirements (Division 125)

ATA Action appreciates that the Board's proposed rules in Division 115 clearly outline pharmacy activities in that a pharmacist located in another state who is working for an out-of-state pharmacy can perform without holding an Oregon pharmacist license. (see 855-115-0001(3)).

ATA Action seeks further clarity in the Division 125 rules, however, to ensure there are equivalent licensure exemptions extended to pharmacy technicians working under the supervision, direction, and control of a pharmacist operating under these exemptions. As drafted, the proposed rules in 855-125-0001(2-3) state that "only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may assist a Pharmacist in the practice of pharmacy…" and that "only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification when delegated to do so by a Pharmacist." ATA Action believes these proposed rules create confusion when read with 855-115-001 and could unintentionally suggest that *every pharmacy technician* working at an out-of-state pharmacy needs an Oregon license if the facility dispenses to an Oregon patient. We respectfully request the Board clarify these rules to ensure parity and consistency for licensure exemptions between out-of-state pharmacists and pharmacy technicians.

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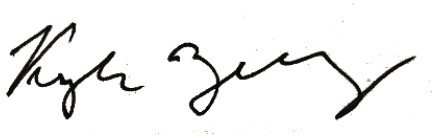
Rules Effective Date

Finally, the proposed rules currently do not include an effective date. ATA Action requests the effective date for compliance be at least a year from Board approval, as covered pharmacies will need sufficient opportunity to hire staff and implement frameworks to comply with these resource-intensive requirements.

We encourage you and your colleagues to reconsider these proposed rules to protect Oregon patients' access to affordable, high-quality care. Please let us know if there is anything that we can do to assist you in your efforts to adopt practical policy in Oregon. If you have any questions or would like to engage in additional discussion regarding the telehealth industry's perspective, please contact me at kzebley@ataaction.org.

Kind regards,



Kyle Zebley
Executive Director
ATA Action

ATA ACTION
901 N. Glebe Road, Ste 850 | Arlington, VA 22203
Info@ataaction.org

From: Adrian Brown, DVM
To: PHARMACY RULEMAKING * BOP
Subject: Oppose adding xylazine to Schedule 1 controlled substance list
Date: Friday, July 21, 2023 1:01:19 PM
Attachments: Outlook-gmyp45hg.png

This proposed rule change to add xylazine to the list of schedule 1 controlled substances will harm veterinarians, particularly large-animal veterinarians. There are limited medications to be used for safe sedation of large animals and adding barriers to veterinarians to the common use of xylazine for this purpose will negatively impact practice for these veterinarians as well as access for their clients and care for their patients. I urge OBOP to clearly exempt xylazine that is compounded by a pharmacist or a veterinarian from being designated as a Schedule I drug for this reason.

Dr. Adrian Brown
Veterinarian
Banfield Pet Hospital
3279 Crater Lake Hwy.
Medford, OR 97504
(541) 858-9686

Banfield PET HOSPITAL | bhere

From: Barbara Kahl
To: PHARMACY RULEMAKING * BOP
Subject: Xylazine scheduling concern
Date: Thursday, July 20, 2023 12:00:51 PM

To: Oregon Board of Pharmacy

Re: Xylazine potential scheduling.

As a veterinarian, our primary standard is to "Do no harm". Scheduling xylazine to disallow compounding violates this code of ethics.

Animals come in all shapes and sizes and various handling statuses from wild, feral to domesticated.

Our goals are to provide an animal with the least amount of handling to maintain the highest amount of manageability, providing low stress thereby decreasing stress-induced physiological changes that can lead to death. Multiple injections alters animal ability to cope by increasing their cortisol response, and decreasing their ability for wellness and manageability.

Compounding xylazine with other necessary pharmaceuticals allows for one injection. Many times, we don't get the chance for a second injection due to the fractious behavior an animal expresses either being feral or secondary to their cortisol response and increased sympathetic nervous system triggering.

Cats, for example, can be cuddly and soft. However, when needing an injection, just one needle poke initiates their fight and flight reflex. I've had to provide vaccinations to dogs over hundreds of pounds whose owners were afraid of them when excited...multiple injections are not an option as risking the safety of myself or staff is irresponsible. I have multiple scars from providing just one injection. I'm not novice to the profession.

For routine population control, injection of combined xylazine, ketamine, torbugesic for spay and neuter surgery is common before intubation providing anesthesia and analgesia together.

Animals do not react the same as people. One can explain to a person they are going to feel a "pinch/sting" multiple times, while our patients don't have that comprehending capability. They turn, bite, literally climb walls, cabinets, and those are domesticated pets with just one injection. That is why we compound medications. Our safety is at risk with each injection.

I've been involved in shelter medicine as well. Thousands of animals I've treated were feral, from bears and bobcats, snakes, birds, rabbits, etc. to dogs and cats. From feet away, I have had to inject sedation and pain medication via one syringe; there is no second injection opportunity.

In the rare occassion, there is always rabies unknown status in feral animals that may need to be euthanized to obtain a diagnosis. Pre-sedation with a compounded medication is necessary as their nervous systems and brain no longer function normally. People still can contract rabies. Eliminating potential stressors (multiple injections) to those questionable animals is imperative for safe practice.

I request your sincere, deep thought during your decision process. Anthropomorphising animals is erroneous in practice. Perhaps spend time in a large shelter or in a veterinary practice for a week to see, witness, how injections cause our patients to react. Gain a hands on understanding by holding a fractious animal yourselves while they are injected to gain clear perspective of why we, as veterinarians, compound medications for one injection only.

It is a "best known practice" methodology for the health and welfare of animals and the safety of our staff and ourselves, and our "Do no Harm" ethics.

Sincerely,
Dr Barbara J Kahl, DVM

From: Jackie Church
To: PHARMACY RULEMAKING * BOP
Subject: NO to Xylazine as controlled
Date: Thursday, July 20, 2023 12:16:00 PM

NO to Xylazine as a controlled substance. It currently is safely secured by most veterinarians. Adding this medication to controlled will not add further protection for drug abusers, but it will impinge on quality medical care for large animals.

Dr. Jacqueline Church
Bear Creek Animal Clinic
541-488-0120
1955 Ashland St.
Ashland OR 97520

From: Bob Archer
To: PHARMACY RULEMAKING * BOP
Subject: Veterinary compounding
Date: Tuesday, July 18, 2023 9:12:01 AM

To Whom it May Concern,
It is fairly common when dealing with cats or dogs to find a situation where a manufactured drug does not exist in a form that is small enough, or in a form that can be administered. This is an even bigger problem when dealing with exotic pets like hamsters or geckos where drugs need to be diluted or reformulated in a smaller dose. It is frequently a challenge to get the drugs in a form which the owner can successfully administer. Thank you for your help and giving us the flexibility we need while maintaining required safety standards.
Sincerely,
Bob Archer, DVM

From: Karen Collell
To: PHARMACY RULEMAKING * BOP
Subject: compounding rule making
Date: Wednesday, July 26, 2023 9:16:36 AM

Dear Oregon Board of Pharmacy,

I hope this email finds you well. I am writing to express my deep concern regarding recent rule changes that seem to be creating an unnecessary administrative and financial burden for stakeholders in the pharmacy industry. As a concerned member of the community, I believe it is essential to address these issues to ensure the well-being of both pharmacists and patients.

While I understand that the Board of Pharmacy's mission is to protect public health and ensure the safe distribution of medications, it is crucial to strike a balance between regulation and practicality. Unfortunately, some recent changes appear to be veering towards a direction that makes it increasingly challenging for pharmacies to function efficiently, ultimately impacting patient access to vital medications and healthcare services.

One of the primary issues is the frequency of rule changes. The continuous alteration of rules without proper justification can be disruptive to pharmacies' day-to-day operations. Pharmacies invest significant time and resources to adapt to these changes, diverting their focus from patient care. A more stable and well-thought-out regulatory framework would be highly beneficial for all parties.

Furthermore, some of these rule changes appear to lack a clear rationale or are not based on sufficient evidence to warrant their implementation. This uncertainty can lead to misinterpretations, conflicting guidance, and unintended financial and other consequences, further exacerbating the burden on pharmacies and licenses.

1. Chapter 855 Div 041/043/183 related to drug Compounding
    a. The USP provides guidance documents rather than imposing strict rules or laws. To my knowledge, no state has adopted compounding regulations that are more stringent than those outlined in the USP.
    b. 855-183-0005
        i. Compounding definition according to FDA : "Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. ***Compounding includes the combining of two or more drugs***. Compounded drugs are not FDA-approved." https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-

answers#:~:text=Drug%20compounding%20is%20often%20regarded%20as%20the%20process,or%20more%20drugs.%20Compounded

c. 855-183-0050
    i. 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.

        1. Does not clarify what education is required or recommended in terms of certificate etc.
        2. The current shortage of pharmacy personnel is exacerbated by this additional requirement and adds administrative burden, leading to an even more challenging situation.

c. 855-183-0200 (4) & 855-183-0205
    i. Financial Strain: Smaller, independent pharmacies, in particular, are feeling the financial strain of these rule changes. Compliance costs have risen significantly, and the additional financial burden threatens the viability of these essential community healthcare providers.
    ii. Fiscal and economic impact :
        1. Regrettably, pharmacies may try to transfer this needless extra cost to patients, resulting in further obstacles to accessing medication. As you know, the prescription business is very competitive and even slight increases at the point of sale is noted by customers and gives cause to question picking up their medications. This outcome stands in complete contradiction to our professional mission.
        2. Additionally, the use of barcoding, imaging techniques or Automated Compounding Devices lacks sufficient evidence to guarantee error-proof results, making it challenging to justify the associated expenses.

d. 855-183-0400 (1) (3) & 855-183-0410 (1) (4)
    i. Base Ingredient or solution & Indication that preparation is compounded : Does this only apply to sterile products? We already put “This is a compounded medication on non-sterile products. This requirement is unnecessary and clutters the label space .

f. 855-183-0420 - Unnecessary & create more administrative burden
g. 855-183-0520 Recalls

i. The expectations to adhere strictly to the timeline are unrealistic. Not all pharmacies can afford to have an on-call or 24-hour pharmacist, and once again, ORBOP has failed to assess the financial impact before implementing this rule.
ii. Establish a reasonable timeline for compliance, taking into account the resources and effort required for implementation. Rushed and unrealistic deadlines can hinder proper adaptation and may result in unintended non-compliance.

h. 855-183-0600 (1) & (2) Prohibited practices
    i. Lacks Sufficient evidence requiring rule change

I kindly request the Oregon Board of Pharmacy to review the recent rule changes with a focus on minimizing administrative and financial burdens while still upholding public safety and the highest standards of patient care. By striking the right balance, we can achieve a regulatory environment that promotes the delivery of quality healthcare services without unnecessarily burdening those who are striving to serve the community's needs.

From:	Dr. Christine Ortner
To:	PHARMACY RULEMAKING * BOP
Subject:	Compounded medications in Veterinary Medicaiton
Date:	Tuesday, July 18, 2023 10:56:17 AM

OBOP,
I have been a small animal veterinarian for 28 years. Having office stock of compounded medications is critical. Many of my patients are tiny chihuahuas, kittens, and other small breeds. I send home compounded liquid gabapentin with every tiny patient surgery every day. I send home a 10 day supply to help the patient with pain and also to help them stay calm so they are not overactive which will damage their incisions. I also dispense compounded liquid metronidazole to treat diarrhea almost daily.
My patients will suffer if there is a delay in getting their medications. The nearest compounding pharmacy is about 30 minutes away. If I see an animal that needs compounded medication at the end of the day, they would not be able to start treatment until at least the following day and only if the client had the time to go pick it up.
Please do not take away veterinarians' ability to help our patients.
Sincerely,
Christine Ortner, DVM, DABVP

Catizone, Luce, Menighan, LLC
PO Box 429
Mount Prospect, IL. 60005

7/24/23
Rulemaking Staff
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
Submitted electronically to pharmacy.rulemaking@bop.oregon.gov

RE: COMMENTS ON PROACTIVE PROCEDURAL RULE REVIEW, PROPOSED DIVISION 115 (PHARMACISTS) AND 125 (PHARMACY TECHNICIANS) RULES

Dear Oregon Board of Pharmacy,

Catizone, Luce, Menighan Pharmacy Advisors LLC (CLM) on behalf of its Oregon Pharmacy Clients respectfully submits the following comments in regard to Division 115 and 125 Rules proposed and under consideration by the Board. If the comments and suggested language are not accepted and the Board moves forward to implement the proposed Rules, CLM respectfully requests that the Board allow for an implementation timeline of no less than twelve (12) months and preferably eighteen (18) months.

CLM's comments specific to the proposed Rules are:

Division 115 Related to Pharmacists

- 855-115-0005 Definitions
  "Counseling" or "Counsel" means an interactive communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

  The proposed change to require "interactive" communication between a pharmacist and a patient or a patient's agent without sufficiently defining "interactive" would change the standard of care for patient counseling and create an excessive and unnecessary burden for patients and pharmacies. Correspondingly, without defining "interactive" to allow for the provision of counseling by mechanisms that have been utilized effectively by resident and non-resident pharmacies for more than thirty years, would place pharmacies and pharmacists in an almost untenable and unobtainable position, and inhibit access to patient care.

  The professional literature documents the effectiveness of counseling patients via interactive mechanisms other than face-to-face counseling and accessibility to a pharmacist for questions or follow-up via an "800 Number." Without a clear definition of "interactive" the resulting ambiguity would obstruct compliance and impose requirements on pharmacies that cannot be met because the feasibility and expense for compliance would be substantial and prohibitive.

Catizone, Luce, Menighan, LLC
PO Box 429
Mount Prospect, IL. 60005

Equally as important, numerous studies in the professional literature document and verify that the majority of patients do not need or request face-to-face counseling. Patients prefer to review the material and information provided to them with their medication and interact with their pharmacist when convenient for them to do so. The proposed Rule change would significantly and unnecessarily inconvenience patients and transform a positive interaction into a reluctant and possibly combative exchange between the patient, who simply desires their medication and counseling when they choose, and the pharmacist. The proposed change is particularly concerning for caregivers with young children or elderly parents who cannot afford to spend more time than necessary in the pharmacy. The proposed change could also place those fragile patient populations at risk while their caregiver was forced to wait in the pharmacy for the pharmacist to be available and provide undefined "interactive" counseling.

CLM respectfully requests that the Board consider deleting "interactive" from the proposed Rule and utilizing the following language:

Counseling" or "Counsel" means ~~interactive~~ communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

The adoption of the language proposed by CLM would correspond to the definition of counseling proposed in 855-115-0145 (1).

(The pharmacist must counsel <u>or offer to counsel</u> the patient or patient's agent on the use of a drug or device (a) upon request; (b) when the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy; (c) when there has been a change in the dose, formulation, or direction; (d) when the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or (e) for any refill that the pharmacist deems counseling is necessary.

- 855-115-0145 (2) Counseling
  For a prescription delivered outside of a Drug Outlet Pharmacy to a patient for self-administration, the pharmacist must (a) attempt to provide counseling prior to delivery as required in (1) and (2). (b) Reattempt to provide counseling by the end of the next business day if counseling does not occur prior to delivery to the patient (c) provide drug information in a format accessible by the patient, including information on how to contact the pharmacist with delivery.

  CLM further requests the Board's consideration to remove the requirement to counsel patients before delivery of their medication as proposed in 855-115-0145 (2). CLM submits that the proposed Rule change is impractical and would create significant harm to patients. In the overwhelming majority of cases, patients would not be reachable prior to delivery of the medication or would be hesitant to answer a call from a number unknown to them, particularly elderly patients. The end result would be the pharmacy

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withholding needed medications from patients for at least one day or longer depending on whether the pharmacy is open twenty-four hours and the pharmacy is permitted to contact the patient late in the evening and perhaps in the early hours of the morning.

The immediate questions that arise with the proposed Rule are if counseling prior to delivery is so vital then what is the value of … "reattempting to provide counseling by the end of the next business day?" If the medication can be delivered without counseling and simply a reattempt to counsel after one day, then why would counseling be required prior to the delivery for the initial dispensing? Additionally, if the reattempt on the second day is unsuccessful, the Rule obviates any counseling of the patient via any mechanisms, except the provision of information on how to contact the pharmacy.

In pharmacy practice, even brick and mortar pharmacies do not and, realistically, cannot provide counseling prior to delivery of medications. The proposed Rule is confounding, virtually impossible to implement, and detrimental to patient care.

CLM respectfully submits that the Rule should reflect current standards of practice and the language offered above regarding the definition of "counseling" as follows:

For a prescription delivered outside of a Drug Outlet Pharmacy to a patient for self-administration, the pharmacist shall (a) attempt to provide counseling ~~prior to~~ upon delivery as required in (1) and (2). (b) Reattempt to provide counseling by the end of the next business day if counseling did not occur upon delivery to the patient (c) provide drug information in a format accessible by the patient, including information on how to contact the pharmacist with delivery.

Division 125 Related to Pharmacy Technicians

- 855-125-0001 Applicability
  Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may assist a Pharmacist in the practice of pharmacy and must act in compliance with statutes and rules under the supervision, direction, and control of a Pharmacist.

CLM requests clarification of the proposed Rule and whether the change would now require technicians assisting in the practice of pharmacy in an Oregon-licensed, non-resident pharmacy would need to secure licensure with the Oregon Board. The current and long-standing regulatory framework and standard of care requires technicians in non-resident pharmacies to hold licensure (if so required) with the resident state and not be required to hold licensure with non-resident states. The proposed Rule seeks to change this long-standing regulatory framework and introduce an overly burdensome requirement that offers little enhancement to the protection of patients and delivery of patient care.

Catizone, Luce, Menighan, LLC
PO Box 429
Mount Prospect, IL. 60005

CLM respectfully requests the Board clarify the Rule and not require technicians assisting in the practice of pharmacy in a non-resident pharmacy to hold licensure in Oregon if appropriately licensed or in compliance with the requirements of the resident state.

- 855-125-0150 Prohibited Practices

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not (1)(c) ***consult with*** *any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription; (n)* ***receive or provide*** *a new or transferred prescription orally.*

CLM submits that the proposed Rule is contrary to the documented urgency for technicians to provide much needed assistance and support to the pharmacist, thus allowing the pharmacist to engage in patient care activities. We strongly agree that technicians should not engage in discussions with other healthcare professionals or authorized agents that constitutes the practice of pharmacy and the scope of practice of a pharmacist. However, Certified Technicians and appropriately trained technicians can engage with health professionals and authorized agents to receive or provide information concerning a patient's prescription, outside of the scope of practice for a pharmacist, that assists with the dispensing of the patient's medication and subsequent pharmacist care. In fact, other states do not impose this restriction on technicians and have allowed such activities for years with benefits to the patient and valuable assistance to the pharmacist.

Technicians with adequate training, under the supervision of a licensed pharmacist, should be allowed to perform tasks that don't require a pharmacist's professional judgement.

CLM respectfully requests the Board's consideration of the following language:

Technicians should be allowed to receive and provide information to other healthcare professionals or their authorized agents pertaining to the patient's prescription that does not engage in the practice of pharmacy and that does not require the pharmacist's professional judgment, under the direction, supervision, and control of a pharmacist.

Technicians are allowed to receive or provide a new or transferred prescription orally under the direction, supervision, and control of a pharmacist.

Catizone, Luce, Menighan, LLC
PO Box 429
Mount Prospect, IL. 60005

Thank you for the opportunity to comment on the proposed Rules. If you have any questions, require additional information, or CLM can be of any further assistance please do not hesitate to contact me.

Respectfully,

Dan Luce, RPh, MBA, FAPhA

President and Founding Partner

Catizone, Luce & Menighan LLC

CLM Pharmacy Advisors

Cell (847)942-6570

From:	Emily Colborn
To:	PHARMACY RULEMAKING * BOP
Cc:	Thomas Menighan; Carmen Catizone; Daniel Luce
Subject:	Comments for Oregon Board of Pharmacy Rules
Date:	Monday, July 24, 2023 10:48:45 AM
Attachments:	OR Division 115 125 Rules - Comments for Submission - 24July2023.pdf

Hello,

Please see the attached comments for the Oregon Board of Pharmacy Rules.

Thank you,
Emily Colborn

From: Carrie Casita
To: PHARMACY RULEMAKING * BOP
Subject: Opposed to new rules from OBOP
Date: Tuesday, July 18, 2023 5:17:53 PM

Good afternoon,

I am a small animal veterinarian of good standing in Springfield Oregon. I have some concerns about the proposed limit on supply of compounded medication for in hospital or initial start of medication use. As many of our patients are often of much smaller size than even the smallest human, compounded medication options are extremely important for correct dosing and administration of life saving drugs.

We have already been having a difficult time getting any compounding medications to keep in stock for patient use. Recently we had a patient with a case of giardia, confirmed by fecal float and snap test that was having severe diarrhea. Because of the difficulty in getting compounded medication either from our own stock or close by pharmacies, we were unable to get this patient started on liquid Metronidazole until a full week after diagnosis. During this time the patient continued to suffer and his other comorbidities, diabetes and heart disease, worsened due to his frequent diarrhea.

In regards to only allowing us to send an initial course of 5 days, it must be apparent that this stipulation can only worsen the possible issues with antibiotic resistance if a longer course of treatment is needed but there is a lapse between when the patient starts treatment and when they can get medications from another pharmacy.

This is in addition to the complications that could occur in the treatment of more chronic issues for which no human medications are of correct size or strength. A short lapse in treatment of lasix or vetmedin for severe congestive heart failure could result in treatment failure and sudden decompensation.

Please reconsider putting restrictions on compounded medications as it only complicates the already stressful workday of overworked veterinary staff, jeopardizes our patients, and potentially could worsen the antibiotic resistance crisis.

Thank you for your consideration,

Dr. Carrie Casita
DVM
Companion Animal Clinic
5620 Main Street
Springfield, OR 97402
541-747-2307

CONSONUS
PHARMACY

Comments for July 26, 2023 Rulemaking Hearing

Dear Oregon Board of Pharmacy Members and Staff

I am writing on behalf of Consonus Pharmacy, which is a long-term-care pharmacy with customers in 10 states and as a pharmacist that has been involved in compounding since 1981.
Thank you to the Board, Staff and Workgroup members for crafting new proposed compounding rules with the intent of providing clarity, transparency, and patient safety. In reading them, I have a few comments/suggestions.

1) 855-018-0200 It is unclear what "adhere to" means. In (1)(a) and (b) there are several USP Chapters listed, some of which are advisory, and some required by USP. Does the wording "and all chapters referenced therein, including but not limited to…" make them all required by OBOP? Please consider clarifying these sections of the rule so that the question of which chapters are advisory, and which are required is clear and the same as USP.
2) 855-183-0200(4) Consonus operates a sterile compounding program that has consistently gone above OBOP and USP standards in an effort to maximize patient safety. Most IVs are purchased as manufactured products in a pre-mixed/frozen format and require no manipulation by us, other than thawing and labeling. We maintain our program for those few hydration or antibiotic IVs that must be compounded and are critical to our customers. Please realize that this is already **not** a money-making endeavor for us. This section of the proposed rules would require that we spend a significant amount of money to comply with requirements that are not included in USP wording, nor in any other states in which we operate. While these technologies may be necessary to keep larger/very busy sterile compounding programs safe, it is unclear how they would provide a benefit to our customers. In fact, it is difficult to see a pathway forward for our program, given the costs mentioned in the *Notice of Proposed Rulemaking*. It is likely that we would need to shut it down, which would fragment any IV services received at the LTC facilities that we serve and lead to more ER visits and hospital admissions.
3) 855-183-0200(5) If this truly refers to non-sterile compounding (and not the line in a sterile compounding anteroom), please consider revising this to say something like "For CNSPs the compounding area must have a visible line of demarcation to designate the area used for this purpose. Other uses of the area inside the line are not permitted when compounding is occurring."
4) 855-183-0400(1) The wording of this section makes the base look as if it is an active ingredient. We currently list the base, but not the strength of the base. It is unclear what the benefit is of listing the strength of the base. What if it is a proprietary base with multiple ingredients? Would we need to find out the strength of each and list it? Please consider allowing the listing of the name of the base without any strength of the base ingredient(s).
5) 855-183-0500(7) Seems to require MFRs for all compounded products. This is a departure from USP rules. Please see comments re: 855-183-0565.
6) 855-183-0500(11)(a) Seems to require testing that USP only requires in some instances. I see that it says "according to the type of compounding performed", but it also says "must include". Can this be clarified?

7) 855-183- 0565 USP Chapter 797 only requires MFRs for those compounding for multiple patients or from non-sterile components. Given that we don't do either, we've not been using MFRs to the same extent as those that are required to do so. Is your intent that all sterile compounds would require an MFR? Please consider clarifying this and requiring an MFR in the same cases that they are required by USP.
8) 855-183-0700(2)(b) Container closure systems include many different components. Listing them all would require significant real estate on the label. It is unclear what this is intended to accomplish. Also, simply looking at the product would provide the same information. Can this requirement be deleted?

Thank you for your work on these rules and for considering these comments.

Sincerely,

Eric Lintner, RPh, BCPS
Consonus Pharmacy

From:	Eric Lintner
To:	PHARMACY RULEMAKING * BOP
Subject:	FW: Rulemaking Hearing on 7/26/23
Date:	Monday, July 17, 2023 1:53:26 PM
Attachments:	image006.png Comments re compounding.docx

Please accept the attached comments that I would like to submit for the 7/26/23 Rulemaking Hearing regarding proposed changes to compounding rules.

Thank you very much

Eric Lintner, **RPh, BCPS**
Clinical Projects Director
Consonus Pharmacy Services
p. 971-206-5188
f. 877-728-8799
e. elintner@consonushealth.com

CVSHealth

Lauren Paul, PharmD, MS | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

July 26, 2023

Joseph Schnabel, PharmD, RPh
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Rules of Division 001 Related to Procedural Rules

Dear Executive Director Schnabel:

I am writing to you in my capacity as Executive Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide care with diverse access points to patients in the state of Oregon through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to comment on proposed rules.

OAR 855-104-0115 Inspections

CVS Health has concerns with this rule as proposed. We feel it would provide more clarity and be beneficial to licensees for the Board to define "reasonable hours" as used in section (1). Without definition, we presume most compliance officers would conclude reasonable hours include *any hour* the pharmacy is open. If the timeframe for inspection is also the hour or more where script volume is highest, patient pick up is substantial and foot traffic is significant, pharmacy staff may determine the inspection time slot is unreasonable. Thus, a potential conflict may exist between what a PIC and compliance officer define as a reasonable hour. Additionally, if the inspection is refused due to a pharmacist deeming the hour not reasonable, they are subject to discipline. For these reasons, we request the Board address and define what "reasonable hours" are considering the pharmacist's perception of reasonable.

Additionally, we request the Board consider striking the requirement to respond to ALL compliance officer requests and questions at the time of inspection. A licensee may wish to consult with legal counsel prior to offering a response or providing materials requested during inspection. In the spirit of due process, we feel it is reasonable to allow such consultation by a licensee.

We also request the board considering amending section (2)(c) photographs and recordings be kept to the minimum necessary for investigations and that personal identifying information (PII) and protected health information (PHI) only be recorded if required for a specific investigation. An additional concern is the lack of exclusion for Patient Safety Work Product (PSWP), which includes patient safety event reports. CVS Health, and many other pharmacies, report through an Agency for Healthcare Research and Quality listed Patient Safety Organization (PSO) to enhance the patient safety and quality improvement activities. Confidentiality and privilege protections are provided for patient safety and quality improvement information through the Patient Safety Quality Improvement Act of 2005 (Patient Safety Act). We additionally request exceptions for this information to not be photographed, recorded or required to be produced upon inspection. Furthermore, we request language be added to not allow personal devices of the Compliance Officer be used for video and audio recording. Finally, we ask the Board to add language, in accordance with the NABP Model Act, Section 16, that requires Compliance Officers to secure photographs and recordings taken during the inspection as confidential and privileged. Without this proposed revision, proprietary information that may be copied or recorded during an inspection may be subject to a public records request.

CVSHealth

Lauren Paul, PharmD, MS | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

Suggested Language 855-102-0040 Inspections

(1) A Compliance Officer is a board authorized representative and must be permitted entry to any drug outlet to conduct inspections at all reasonable hours.

(2) The Compliance Officer is authorized and must be permitted to perform the following to determine compliance with ORS 475, ORS 689, and OAR 855 and board orders including but not limited to:

(a) Inspecting conditions, structures, equipment, materials, and methods for compliance;

(b) Inspecting all drugs and devices;

(c) Taking photographs, recording video and audio if:

(A) Photographs and recordings are kept to the minimum necessary for all investigations;

(B) Personal identifying information or protected health information are only obtained when required for a specific investigation;

(C) All patient safety work product, including patient safety event reports, that are protected under the Patient Safety Quality Improvement Act of 2005 are not photographed or recorded;

(D) Personal devices of the Compliance Officer are not used; and

(E) All photographs and recordings are securely stored remaining confidential and privileged.;

(d) Reviewing, verifying and making copies of records and documents;

(3) All licensees and employees must fully comply and cooperate with all questions and requests made by the Compliance Officer ~~at the time of inspection~~, except for those related to Patient Safety Work Product protected under the Patient Safety Quality Improvement Act of 2005.

(4) Refusal to allow inspection is grounds for discipline.

CVS Health appreciates the opportunity to submit comments to the Board for review. As you consider our comments, please contact me directly at 540-604-3661 if you have any questions.

Sincerely,

Lauren Paul, PharmD

Lauren Paul, PharmD., MS
Executive Director, Pharmacy Regulatory Affairs
CVS Health

From:	Paul, Lauren N.
To:	PHARMACY RULEMAKING * BOP
Cc:	Paul, Lauren N.
Subject:	CVS Health Comments on Proposed Amendments to Division 104, 115 and 125
Date:	Wednesday, July 26, 2023 7:36:08 AM
Attachments:	CVS Health Comments on Proposed Amendments to Division 104 Universal Rules.pdf CVS Health Comments on Proposed Amendments to Division 115 Pharmacists July 2023.pdf CVS Health Comments on Proposed Amendments to Division 125 Pharmacy Technicians July 2023.pdf

Good Morning,

Attached please find CVS Health's comments on proposed amendments to Division 104, 115 and 125. If there are any questions from the Board members when the comments are reviewed at the August meeting, I would be happy to engage in discussion.

Warm Regards,

Lauren

Lauren Paul, PharmD, MS | Executive Director, Pharmacy Regulatory Affairs

p 540-604-3661 | **f** 401-733-0479

1 CVS Drive, Mail Code 2325, Woonsocket, RI 02895

Planned Business Travel: July 31st-August 1st, August 16th-17th, August 24th-25th

PTO: July 27th, August 4th

CVSHealth

Lauren Paul, PharmD, MS | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

July 26, 2023

Joseph Schnabel, PharmD, RPh
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Amendments to Division 115 Pharmacists

Dear Executive Director Schnabel:

I am writing to you in my capacity as Executive Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide care with diverse access points to patients in the state of Oregon through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to comment on proposed rules.

OAR 855-115-0001 Applicability and OAR 855-115-0145 Counseling

CVS Health fully supports appropriate patient counseling based on individual pharmacy practice setting and appreciates the continued inclusion of counseling in the practice of pharmacy activities that a pharmacist who is in another state working for an out of state pharmacy can perform without holding an Oregon pharmacist license. CVS Health opposes the proposed language in OAR 855-115-0145 requiring an attempt and second attempt to reach a patient to counsel when a prescription in delivered outside of a Drug outlet pharmacy that requires counseling. We respectfully request the Board amend the proposed language to match the current requirements for counseling in OAR 855-019-0230(1)(3), which requires the pharmacist to provide an offer to counsel in writing as well as drug information and how to contact the pharmacist. There is an absence of negative safety data or clinical evidence showing a patient safety issue currently exists for patients in Oregon based on compliance with existing patient consultation requirements. Discussion at Board meetings over the past 9 months provided no patient safety data, study, or other evidence that would suggest the current offer in writing for a prescription being delivered, either by a resident or nonresident pharmacy and subsequent counseling that occurs post-delivery, is insufficient or causes safety issues for the patients of Oregon. We also have concerns that these amendments may cause potential delays in patient's receiving their medications as a prescription is held to ensure an attempt is made prior to delivery.

Additionally, the proposed language removes the clear allowance for a pharmacy intern to document the refusal of counseling. Documentation of a counseling refusal or the attempts to counsel are administrative tasks that should not be for a pharmacist only to complete. These types of administrative tasks are time consuming and take away from a pharmacist's time to provide patient care. Furthermore, paramount to a student's education and training is active participation in providing pharmacy services under the direct supervision of a pharmacist. In fact, 2016 ACPE standards reference "counseling" and educating patients. This is a requirement by ACPE that all Colleges of Pharmacy meet these standards to maintain their accreditation. Schools/Colleges are required to ensure students have adequate education/experiences on counseling in various fashions.[1] We understand the proposed rule language in Division 120, specifically OAR 855-120-0150(2)(b) allows an intern who has completed their first academic year to counsel patients, we are concerned that striking the intern language present in current rule OAR 855-019-0230, may cause confusion on the allowance. Therefore, we suggest the counseling language be amended to include the allowance of documentation by an intern or a technician under the direct supervision of a pharmacist as well as include the current intern allowance to perform counseling under the direct supervision of a pharmacist.

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Suggested Language OAR 855-115-0145 Counseling

(1) For each prescription, the pharmacist or intern under the direct supervision of a pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(2) The pharmacist or intern under the direct supervision of a pharmacist must counsel the patient or patient's agent on the use of a drug or device:

(a) Upon request;

(b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;

(c) When there has been a change in the dose, formulation, or directions;

(d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written, or electronic means; or

(e) For any refill that the pharmacist deems counseling is necessary.

(3) When communicating (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the pharmacist is proficient in the patient's preferred language.

(4) For a prescription delivered outside of a Drug Outlet Pharmacy to a patient for self-administration, the pharmacist must:

(a) Offer in writing to provide direct counseling ~~Attempt to provide counseling prior to delivery as required in (1) and (2);~~

~~(b) Reattempt to provide counseling by end of the next business day if counseling does not occur prior to delivery to the patient~~; and

(~~c~~b) Provide drug information in a format accessible by the patient, including information on how to contact the pharmacist with the delivery.

(5) A Pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused,

(a) Only the Pharmacist or intern under the direct supervision of a pharmacist can accept a patient's or patient's agent's request not to be counseled when counseling is required.

(b) The Pharmacist may choose not to release the prescription until counseling has been completed.

(6) A pharmacist or intern under the direct supervision of a pharmacist must initiate and provide counseling under conditions that maintain patient privacy and confidentiality

(7) The Pharmacist that attempts counseling, provides counseling, or accepts the request not to be counseled ~~must~~ may delegate the documentation ~~their identity, of~~ each attempt to counsel and the outcome at the time of the attempt or interaction to an intern, Certified Oregon Pharmacy Technician or Pharmacy Technician under the direct supervision of the pharmacist.

OAR 855-115-0120 Responsibilities: Personnel

Without context of intent and discussion, CVS Health has concerns with section (1)(i)) of this section which requires ongoing training to ensure continued competence. Since January 2015, Accreditation Council for Pharmacy Education (ACPE) addresses continued professional development for both “pharmacists and pharmacy technicians to meet and maintain defined competences in areas relevant to their respective professional responsibilities” as continuing professional development (CPD), which includes continuing pharmacy education (CPE).[2] As competency can be subjective, we ask the Board to consider this language to align with ACPE guidance on continuing professional development, as shown below.

Suggested Language OAR 855-115-0120

(1) When practicing pharmacy per ORS 689; each Pharmacist must:

CVSHealth

Lauren Paul, PharmD, MS | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

(i) Ensure continued ~~competency in tasks that are performed~~ professional development by the Pharmacist and persons under their supervision; and

OAR 855-115-0200 Pharmacist-in-Charge: Qualifications, and Limitations

CVS Health asks the Board to reconsider the Pharmacist-in-Charge requirements proposed in this section. On June 15, 2022, the New Hampshire Board of Pharmacy repealed rule Ph704.11 addressing practice requirements prior to becoming a PIC which included a practice requirement of 2 years as a pharmacist, obtaining an 80% passing score on an exam designed by the Board as well as hours requirements to be present and practicing within the pharmacy.[3] We also are not aware of any other state that requires additional PIC training at regular cadence after the appointment and acceptance of the position and are concerned this may drive interest away from the responsibility. CVS Health requests the Board not move forward with the requirements outlined in the proposed new rule and replace the language with requirements for practice or board approved training program as currently required in OAR 855-019-0300.

OAR 855-115-0330 Services: Prescribing – Formulary or Protocol Compendia

CVS Health is supportive of expansion in pharmacist prescribing allowance which allows a pharmacist to practice at the top of their education and training and provides patients with an option for access to care apart from their primary care provider, urgent care, or emergency department. We ask the Board to reconsider the requirement that physical assessments be performed face to face and in person versus allowing the assessment to occur through electronic means which is currently required and reflected in (5)(c). As technological advances continue through practice of telemedicine, we request a pharmacist be afforded the same allowances to perform an assessment using technology or in a manner they see fit for the patient and their ability to accurately assess the patient. Allowances for patient assessment to be performed using technology continues to improve and expand access to care for patients who may prefer interactions performed remotely or may be physically unable to travel to the pharmacy for an in-person assessment.

CVS Health appreciates the opportunity to submit comments to the Board for review. We have concerns that the totality of this new division creates barriers to patient care and add unnecessary administrative burden on our pharmacists. As you consider our comments, please contact me directly at 540-604-3661 if you have any questions.

Sincerely,

Lauren Paul, PharmD

Lauren Paul, PharmD., MS
Executive Director, Pharmacy Regulatory Affairs
CVS Health

References

1. ACCREDITATION STANDARDS AND KEY ELEMENTS FOR THE PROFESSIONAL PROGRAM IN PHARMACY LEADING TO THE DOCTOR OF PHARMACY DEGREE ("STANDARDS 2016"). Available from https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf (Accessed July 6, 2023)
2. Accreditation Counsel for Pharmacy Education Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy. Available from: https://www.acpe-accredit.org/pdf/CPDGuidance%20ProfessionPharmacyJan2015.pdf (Accessed July 6, 2023).

Lauren Paul, PharmD, MS | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

3. New Hampshire Board of Pharmacy, ph 700 Adopted Text 6/15/2022. Available from: https://www.oplc.nh.gov/sites/g/files/ehbemt441/files/inline-documents/sonh/ph-700-adopted-text-20220615.pdf (Accessed July 6, 2023).

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July 26, 2023

Joseph Schnabel, PharmD, RPh
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Amendments to Division 125 Pharmacy Technicians

Dear Executive Director Schnabel:

I am writing to you in my capacity as Executive Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide care with diverse access points to patients in the state of Oregon through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to comment on proposed rules.

855-125-0150 Prohibited Practices

As we review the proposed changes with new Division 125, it is apparent that OAR 855-025-0040 detailing pharmacy technician tasks and guidelines was struck with proposed limited language included in section OAR 855-125-0135. While CVS Health supports the simplicity of the rule without a list of tasks, we have concerns with proposed language in OAR 855-125-0150 and the prohibited practices which are outlined. Pharmacist delegation is individualistic and takes into account the individual technician's capabilities, the pharmacist's comfort level, facility policies, and the risk mitigation strategies present at the facility, among other factors.[1] Pharmacist discretion in delegation creates control of which functions to delegate in the interest of patient care, and to whom, rather than supplanting the professional judgment of pharmacists with one-size-fits-all rules.[2] The pharmacist delegation model sets forth a strong vision for pharmacy technician practice, which aligns pharmacy technician roles related to dispensing medications and supporting patient care services with their current education and training.

Despite a growing need for increased access to patient care services, community pharmacists spend only 21% of their professional time performing patient care services that are not associated with dispensing prescriptions.[3] To further enhance and optimize patient care services delivered at community pharmacies, leveraging trained pharmacy technicians to take on roles that have proven to not require the professional judgment of a pharmacist should be considered. Paramount and centric to all Board rules, including pharmacy technician roles and responsibilities, is patient safety. The national landscape reveals an overwhelming safety history of success and shift towards pharmacy technicians:

- Transferring prescriptions (currently allowed in twenty-four states in some format)
- Accepting verbal prescriptions (currently allowed in eighteen states)
- Contacting prescriber offices for clarifications (currently allowed in nineteen states)

Increasing the scope of pharmacy technician practice to include administrative and supportive tasks for pharmacist-provided patient care services will allow pharmacists to provide for patients' medication-related needs more effectively and efficiently.[4] Most importantly, some states have a patient safety record of success with expanded pharmacy technicians' roles that spans over four decades.[5]

As with any intervention, new service, workflow redesign, or regulation, the primary concern should be the public interest and safety. If evidence suggests that technicians can perform a function safely and effectively relative to usual care, *that alone* should compel the function's allowance in practice. Freeing up pharmacist time for higher-

order care is indeed a positive corollary to technician advancement, but it need not be a precondition for it. Therefore, we ask the Board to consider amending this section of the rule to allow for a Certified Oregon Pharmacy Technician or Pharmacy Technician to accept new prescriptions and receive or provide transferred prescriptions.

Additionally, CVS Health has concerns with the restrictions outlined in OAR 855-125-0105(3)(h) which only allow access to the pharmacy area when a pharmacist is physically present, or the outlet is operating under a RDSP registration in compliance with Division 139. Division 139 was promulgated with onerous and unnecessary requirements not found in any other states laws or rules for operating a remote site. Three states, Colorado, Virginia and most recently Alabama have promulgated rules which allow a technician to access the pharmacy area when a pharmacist is not present to obtain already filled prescriptions to provide to patients. Another state, Louisiana, motioned to send proposed language to rulemaking during their Regulation Revisions Committee meeting held on July 18, 2023. The access is granted in an emergency when a pharmacist may be running late or is unable to work while other coverage is found or in the case of Alabama, when a state of emergency is declared. This allows pharmacies to still provide medications to patients in these types of situations without requiring additional licensure/registration with onerous requirements to operate. We request the Board to consider the below suggested language, incorporating language from Virginia, to allow access without a pharmacist present.

Suggested Language

(3) A Certified Oregon Pharmacy Technician and Pharmacy Technician must:

(h) Only access the pharmacy area when a Pharmacist is physically present. ~~at the Drug Outlet Pharmacy or when the Drug Outlet Pharmacy is operating under a Remote Dispensing Site Pharmacy (RDSP) registration and following requirement in OAR 855-139-:~~ However, upon a request by a patient to obtain an already-dispensed prescription, may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient. Records of the entrance into the pharmacy must be kept including the date and time of entry; the name and signature of the pharmacy technician; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.

Virginia Reference Language

18VAC110-20-190. Prescription department enclosures; access to prescription department.

E. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;
2. Alternate pharmacist coverage cannot immediately be obtained;
3. The technician is accompanied by a member of the pharmacy's management or administration; and
4. All requirements of subsection F of this section are met.

F. Requirements for entry into the prescription department in the absence of a pharmacist.

1. The requirements for prescriptions awaiting delivery in subsection A of 18VAC110-20-200 are followed.
2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal permission from the PIC or another pharmacist regularly employed by that pharmacy to obtain and use the emergency key or other access and alarm access code and enter the pharmacy.
3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry; the name and signature of the pharmacy technician; the name, title, and signature of

the person accompanying the pharmacy technician; the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.
4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is resecured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.
5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises

CVS Health appreciates the opportunity to submit comments to the Board for review. As you consider our comments, please contact me directly at 540-604-3661 if you have any questions.

Sincerely,

Lauren Paul, PharmD., MS
Executive Director, Pharmacy Regulatory Affairs
CVS Health

References

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2. Adams AJ. Advancing technician practice: Deliberations of a regulatory board. Research in Social and Administrative Pharmacy. 2018;14(1):1-5.
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4. Zellmer WA, et al. Toward uniform standards for pharmacy technicians: Summary of the 2017 Pharmacy Technician Stakeholder Consensus Conference. Am J Health Syst Pharm. 2017;74(17):1321-1332.
5. Frost TP, Adams AJ. Expanded pharmacy technician roles: Accepting verbal prescriptions and communicating prescription transfers. Res Social Adm Pharm. 2017;13(6):1191-1195.

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July 26, 2023

VIA ELECTRONIC MAIL:

pharmacy.rulemaking@bop.oregon.gov
Rachel Melvin
Rules Coordinator
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Re: Comments in Opposition to Notices of Proposed Rulemaking Dated June 16, 2023, Concerning Proposed Rules 855-115-0145 and 855-125-0150

Dear Ms. Melvin:

We are writing on behalf of Express Scripts Pharmacy, Inc., ESI Mail Pharmacy Service Inc. (collectively "Express Scripts"), and Accredo Health Group, Inc. ("Accredo") (referred to collectively in this letter as "Express Scripts/Accredo") to provide comments to the Oregon Board of Pharmacy's ("Board") Notices of Proposed Rulemaking dated June 16, 2023 (collectively, "Notices").

The Board proposes to repeal rule 855-019-0230 and recodify it under new Division 115 as 855-115-0145 with significant changes.[1] Among other things, the Board seeks to require that only a pharmacist can accept a patient's request not to be counseled when counseling is required. Likewise, proposed rule 855-125-0150 seeks to revise and relocate portions of existing rule 855-019-0200, which would prohibit pharmacy technicians from accepting a patient's request to decline counseling.

These portions of the proposed rules will create an unjustified and significant operational burden for Express Scripts/Accredo without a commensurate positive effect on patient safety. All Express Scripts/Accredo pharmacies are opposed to the proposed rule changes. We respectfully submit these comments for the Board's consideration.

[1] Express Scripts/Accredo previously submitted comments on November 22, 2022, on a prior version of the subject rule (proposed as 855-115-0084 at the time) and other proposed rules.

I. Proposed rule 855-115-0145(5)(a) – Counseling.

> *(5) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused,*
>
> *(a) Only a pharmacist can accept a patient's or patient's agent's request not to be counseled, when counseling is required.*
>
> *(b) The pharmacist may choose not to release the prescription until counseling has been completed.*

Subsection (5)(a) of the proposed rule places an unnecessary administrative burden on pharmacists, whose time would be better served on numerous professional tasks. Hundreds of times a day, pharmacists in all settings will have to stop what they are doing at a given moment only to get on the phone, or walk to another counter, just to make a record that a patient has refused counseling. There is nothing clinical about this task, nor does it require any exercise of professional judgment. Requiring pharmacists to accept the declination of counseling places them back into the simple mindset of viewing pharmacists as only dispensers of drugs. Of course, pharmacists are more than that, and the remainder of the proposed rule recognizes that.

Offers to counsel made by Express Scripts and Accredo pharmacies are not trivial, but given that no professional judgment is required, other pharmacy personnel are perfectly capable of accepting and documenting a patient's refusal of counseling. This is standard practice throughout the nation.

Express Scripts and Accredo understand the importance of patient counseling. Indeed, from 7/1/2022 through 7/24/2023, Express Scripts pharmacists counseled 1,862,937 patients nationwide, and 63,734 patients in the state of Oregon. Accredo pharmacists counseled 52,756 and 1,752 patients, respectively. The current processes followed by Express Scripts and Accredo, which comply with current pharmacy regulations in every state, including Oregon, are adequate to protect the public. These processes combine proactive patient outreach, written information, and a toll-free telephone number to allow patients to contact a pharmacist 24/7/365. Further, Express Scripts and Accredo have reliable systems in place to document and maintain records confirming a proactive offer to counsel was made and a patient's (or their agent's) refusal of counseling.

Along with the modernization of the practice of pharmacy, patients' communication preferences have evolved. Many patients now prefer to communicate electronically. Based on these preferences, and operational challenges reaching patients live on the phone, Express Scripts has developed robust technology that uses an automated system to capture and document a patient's refusal to accept counseling and which provides the patient with additional information on how to reach a pharmacist should they later have any questions. Likewise, any patient refusal of counseling given live over the phone is of course documented. As for Accredo, which is high touch specialty pharmacy for patients with complex disease states, refusals of counseling would be provided live over the phone.

Express Scripts/Accredo also understands the Board's position that Oregon in-state pharmacists are already prohibited from allowing non-pharmacist personnel to accept patient refusal of counseling. However, by their very nature, mail-order pharmacies operate differently than community pharmacies, which enables mail-order to provide innovative and convenient care to patients. For instance, the Accredo model leverages Therapeutic Resource Centers of Excellence with clinical pharmacists located across the country, who have expertise on certain disease states and specialty medication therapy, and counseling calls are routed to the appropriate clinical pharmacist. With pharmacy services available on a 24/7/365 basis for both Express Scripts and Accredo, Oregon patients currently have a higher level of access to counseling than they can obtain from an in-person community pharmacy, but such access may be hindered if pharmacists are required to accept hundreds of interruptions simply to document the patient's refusal of counseling.

Further, from a practical standpoint, patients using mail-order pharmacies are unlikely to wait for a pharmacist to get on the phone simply to repeat that they decline counseling. As noted above, Express Scripts and Accredo conduct the appropriate patient outreach/offer to counsel when a prescription is filled. If the patient refuses, they are reminded that they may contact the pharmacy at any point via toll-free phone number or online with any questions or for more information.

Based on the foregoing, we request the Board consider the following proposed revisions:

> *(5) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused,*
>
> *(a) Only a pharmacist**, pharmacist intern, certified Oregon pharmacy technician, pharmacy technician, or authorized pharmacy personnel** can accept a patient's or patient's agent's request not to be counseled, when counseling is required. **For a prescription delivered to a patient, such request to not be counseled may be accepted via an automated system if the request is maintained by the pharmacy as part of the patient's record.***
>
> *(b) The pharmacist may choose not to release the prescription until counseling has been completed.*

II. Proposed rule 855-115-0145(7)

> *(7) The pharmacist that attempts counseling, provides counseling or accepts the request not to be counseled must document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction.*

If changes are made to subsection (5) consistent with the comments above, commensurate changes to subsection (7) would be needed. Further, if the outreach attempt to counsel can be documented, there would be no need to document the identity of the person making the attempt. The same would only be relevant if in fact counseling is provided. As such, we request the Board consider the following proposed change below:

> *(7) The ~~pharmacist that~~ attempts **at** counseling **shall be documented.~~,~~ The pharmacist that** provides counseling**,** or **the pharmacist, pharmacist intern, certified Oregon pharmacy technician, pharmacy technician, or authorized pharmacy personnel that** accepts the request not to be counseled**,** must document their identity**~~, each attempt to counsel~~** and the outcome at the time of the **~~attempt or~~** interaction. **For a prescription delivered to a patient, if the request to not be counseled is accepted via an automated system, such request shall be documented.***

III. Proposed rule 855-125-0150(1)(e) – Prohibited Practices.

> *Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:*
>
> *(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0105(4), including but not limited to the following tasks:*
> *...*
> *(e) Accept a patient or patient's agent's request to decline counseling[.]*

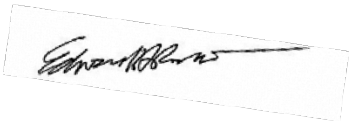
If changes are made to subsection (5) of proposed rule 855-115-0145 consistent with the comments above, commensurate changes to proposed rule 855-125-0150 would be needed by deleting subparagraph (1)(e).

IV. Conclusion.

Based on the foregoing, we respectfully request that the Board consider these comments and revise the proposed regulations consistent with the comments above. We likewise request that these comments be considered during the Board's next meeting on the proposed regulations.

Should you have any questions or require additional information, we would be happy to assist. Thank you for your consideration.

Very truly yours,



Edward D. Rickert
Michael S. Elkins

From:	Elkins, Michael S.
To:	PHARMACY RULEMAKING * BOP
Cc:	Rickert, Edward D.
Subject:	Comments on proposed rules 855-115-0145 and 855-125-0150 [QBLLP-ACTIVE.FID43188660]
Date:	Wednesday, July 26, 2023 12:20:21 PM
Attachments:	ProdSignaturelogo160x38_0e221f31-43e9-45d6-ae24-fca9fde99c3d.png Express Scripts and Accredo"s Comments on proposed counseling rule changes.pdf

Good afternoon,

We hope this email finds you well. Attached please find Express Scripts' and Accredo's comments to the Oregon Board of Pharmacy on proposed rules 855-115-0145 and 855-125-0150. We request that the Board consider these comments and revise the proposed regulations consistent with the comments in the attached. We likewise request that these comments be considered during the Board's next meeting on the proposed regulations.

Thank you very much,

Mike Elkins

Quarles

Michael S. Elkins | (he/him) | Attorney
Michael.Elkins@quarles.com | D. 239-434-4908 | M. 561-305-1836
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July 26, 2023

Dr. Joe Schnabel, R.Ph.
Executive Director, Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232

Sent via email to: pharmacy.rulemaking@bop.oregon.gov

RE: Rulemaking on Divisions 041/043/183 related to Drug Compounding

Executive Director Dr. Schnabel and members of the Rulemaking team,

On behalf of the tens of thousands of Oregon children who rely on flavoring each year to ease their way in taking important medications for their health, I respectfully request a change in the proposed drug compounding rule to ensure continued patient access to flavoring products.

Flavoring products have been on the market in Oregon for decades. Today, over 300 pharmacies in Oregon offer flavoring to their customers, primarily for commercially available liquid medications. Nearly 600,000 children under the age of 11 live in Oregon, and when they become ill, they primarily take liquid medications. Tens of thousands of medications are flavored every year in Oregon pharmacies – depending on the severity of the cold/flu season. The most commonly flavored medications in Oregon include Amoxicillin, Augmentin, Cleocin, Tamiflu, and Zithromax. The most popular flavors include Bubblegum, Grape, Cherry, Watermelon and Strawberry.

Oregon parents, pediatricians, and pharmacists all know that without flavoring, getting a child to take these medications can lead to a meltdown. The medication is absolutely necessary to reduce the symptoms of flu, cure an ear infection, or solve other serious medical problems. But the bitter taste of liquid medicines can lead to serious difficulties for sick kids and their exhausted parents navigating the medicine routine. A small amount of flavoring can change all of that – and it has for decades. In the 25+ years of operations, over 200 million medications have been flavored using the FLAVORx system with no adverse events or incidents of harm.

The current approach to implementation of the 2022 United States Pharmacopoeia (USP) standard in Oregon would change a system that has worked for families, pharmacists and pediatricians for years, adding complexity that will impact patient access to flavoring. The approach would treat flavoring as a compounding activity – requiring doctors to prescribe flavoring and adding significant complexity for pharmacies who face no barriers to flavoring today. As a result, pharmacies will stop offering this vital service to families, increasing the frustration for families and making it more difficult for Oregon's children to take their important medications.

With the exception of the state of Washington, all other states either through explicit rulemaking or through board guidance and enforcement discretion, do not consider flavoring as compounding per USP guidance. FLAVORx implores Oregon to adhere to the patient safety data and the common practice in the United States and provide clarification that despite USP's guidance, flavoring will not be treated as compounding in Oregon. There are multiple approaches to achieving this outcome including simply defining compounding as not to include flavoring. Some states have both defined compounding as to not include flavoring and further defined flavoring so as to ensure it closely adheres to current practices. (See Attachment A for approaches from other states.)

FLAVORx requests the Oregon Board of Pharmacy adopt a similar approach to the other states listed below. This approach is consistent with the patient safety data showing no adverse effects or incidents of harm from flavoring. Significantly, for the thousands of Oregon families our product serves every year, it preserves patient access to flavoring without imposing new requirements on already overburdened clinicians and pharmacists.

Thank you for your consideration. The team at FLAVORx welcomes the opportunity to answer any questions or provide consultation on any changes should that be of assistance to the rulemaking team.

Sincerely,

Chad Baker
Senior Vice President, Government Affairs
FLAVORx, Inc.

Attachment A
Approaches to Flavoring by other States

Note: FLAVORx shares these examples in an effort to provide language and other approaches to flavoring exemptions. While the whole regulation is listed, FLAVORx takes no position as to whether other non-flavoring pharmacy products should or should not be exempted from the definition of compounding.

Illinois

https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1318&ChapterID=24

(o) "Compounding" means the preparation and mixing of components, excluding flavorings,

(1) as the result of a prescriber's prescription drug order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice or

(2) for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing.

Iowa

https://www.legis.iowa.gov/docs/iac/chapter/657.20.pdf

Compounding does not include the use of a flavoring agent to flavor a drug pursuant to rule 657—20.13(124,126,155A), nor does it include mixing or reconstituting a drug according to the product's manufacturer label.

"Flavoring agent" means a therapeutically inert, nonallergenic substance consisting of inactive ingredients that is added to a drug to improve the drug's taste and palatability.

657—20.13(124,126,155A) Use of flavoring agents. A flavoring agent may be added to a drug at the discretion of the pharmacist or upon the request of the prescriber, the patient, or the patient's agent. The pharmacist may add flavoring agents not to exceed 5 percent of the total volume of the drug to which the flavoring agents are added. The pharmacist shall label the flavored drug with a beyond-use date no greater than 14 days past the date the flavoring agent is added if the drug is required to be stored in a refrigerator. A different beyond-use date or alternate storage conditions may be indicated if such variation is supported by peer-reviewed medical literature. The pharmacist shall electronically or manually document that a flavoring agent was added to a drug, and such documentation shall be made available for inspection and copying upon the request of the board or an agent of the board.

Kentucky

https://apps.legislature.ky.gov/law/kar/201/002/076.pdf

201 KAR 2:076. Compounding.

Section 2. (1) All non-sterile compounded preparations shall be compounded pursuant to United States Pharmacopeia (USP) 795, unless specified portions submitted by a pharmacist have been waived by the board. Notwithstanding any USP guidance to the contrary, the addition of flavoring to a drug shall not be considered non-sterile compounding, if the additive:

(a) Is inert, nonallergenic, and produces no effect other than the instillation or modification of flavor; and

(b) Is not greater than five (5) percent of the drug product's total volume.

Michigan

https://www.michigan.gov/-/media/Project/Websites/lara/bpl/Folder41/4-8-2020_Pharmacy_Full_Approved_Minutes_with_attachments.pdf?rev=1895ca8fd73348c88042c19076c7234d

(e) "Compounding" does not include any of the following:

(i) Except as provided in section 17748c of the code, MCL 333.17748c, the compounding of a drug product that is essentially a copy of a commercially available product.

(ii) The reconstitution, mixing, or other similar act that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product.

(iii) The compounding of allergenic extracts or biologic products.

(iv) Flavoring agents added to conventionally manufactured and commercially available liquid medications. Flavoring agents must be nonallergenic and inert, not exceeding 5% of a drug product’s total volume.

From: Jessica Adamson
To: PHARMACY RULEMAKING * BOP
Subject: FLAVORx Comment Letter on Compounding Rules
Date: Wednesday, July 26, 2023 9:26:02 AM
Attachments: 2D91DCF08C4547BC89BCF575AABF7229.png
FLAVORx Board of Pharmacy Comment Letter.072623.pdf

Good morning! On behalf of FLAVORx, please accept this comment letter on Divisions 041/043/183 rules concerning Drug Compounding.

Sincerely,

Jessica

Jessica Adamson
Senior Vice President, Government Affairs

phone: 503.294.9120
mobile: 503.381.8362

cfm advocates

495 State Street, #541
Salem, OR 97301
www.cfmadvocates.com

From:	Gail Colbern
To:	PHARMACY RULEMAKING * BOP
Subject:	Scheduling of xylazine
Date:	Tuesday, July 18, 2023 6:52:00 AM

Dear OBOP Members, please consider ALL the aspects of this scheduling on the humane care of animals. This drug is CRITICALLY important to the treatment of colic in horses, both to allow diagnostics and to determine how severe the disease is based on duration of relief from pain. It is also critically important to allowing manipulation of horses difficult to restrain for the safety of both the animal and the handler and veterinarian. Reduced availability of this medication would happen with scheduling and would result in the injury and/or death of horses and possibly the injury and/or death of people handling these animals. It is critical that this medication remain easily available for legitimate veterinary use. Thank you for your consideration.

Gail T. Colbern, DVM, MS, DACT
Greensprings Veterinary Service
Ashland, Oregon
541-200-8236
gtcolbern@gmail.com

Sent from my iPhone

From: Charles Hurty
To: PHARMACY RULEMAKING * BOP
Subject: Xylazine Rules - Some commentary and thoughts - Thank you!
Date: Thursday, July 20, 2023 9:54:36 AM

Dear OBOP,

Thank you for taking time to consider this email and my thoughts on the current rules about xylazine being considered by you.

As a member of the Oregon veterinary community, my intention of this letter is to ask for some clarification from the OBOP on the current scheduling rules being considered. I also want to share some additional information about the drug, xylazine, to ensure that there is a clear understanding of the significant difference between the illegal powdered xylazine (Tranq) that is finding its way onto the streets and the injectable liquid xylazine that is utilized for compassionate patient care in veterinary medicine.

From this point forward, I will refer to illegal xylazine as “Tranq.” The term “xylazine” will be reserved for the legal, FDA-approved, critical veterinary medication that it is.

Illegally trafficked Tranq (not xylazine) is a powdered bulk substance that is being smuggled into the United States by brutal cartels based in Mexico. Tranq is being manufactured with ingredients that are primarily sourced from suspicious actors in China. Powdered, illegal Tranq is then being mixed with fentanyl and illegal drugs (heroin, cocaine, etc) to create a dangerous drug cocktail that is resulting in harm and death to addicts. This is Tranq. Tranq is not used in veterinary medicine, nor should anyone assume that Tranq is being diverted from veterinary practice. I share the OBOP’s concern about the illegal use of Tranq in our communities. I believe that actions need to be taken by law enforcement to prevent the entry of Tranq into our communities. Scheduling the compounded versions (non-FDA-approved versions) of the medication Xylazine used in veterinary medicine as Schedule I will not solve the issue of Tranq being present in on the streets of Oregon. There is absolutely no evidence that I can find that states that Xylazine is being diverted from the veterinary profession into our communities... As stated above, xylanzine and tranq are literally not the same substances; they are completely different in form and source.

Xylazine is utilized in the practice of compassionate and professional veterinary medicine. It is a bottled, liquid injectable pain-relieving sedative that contributes to successful patient outcomes; if fact, it has become a cornerstone to successful and safe equine, zoo, large animal, and shelter-oriented veterinary practice. My concern is that xylazine often has to be combined with

other medications in a single syringe in order to provide appropriate care and interventions. Often, it is combined with other medications for remote sedation of a patient or wildlife; a care provider may literally only get one shot at that time of intervention. This combining of an FDA-approved xylazine product with another medicine can be defined as compounding, which would then designate the xylazine-containing drug as Schedule I – which would render it illegal for veterinarians to handle, possess, and administer. This is a dilemma for the veterinary profession in Oregon.

I please ask that the OBOP clearly exempt xylazine that is compounded by a pharmacist or a veterinarian from being designated as a Schedule I drug.

An additional concern... Xylazine (not Tranq) is a medication that has been primarily manufactured by only three (3) companies in North America, one of which (Akorn Pharmaceuticals) has now gone out of business. Another company, Bimeda Animal Health, has paused production due to the regulatory confusion over this issue. Dechra is the only company continuing to manufacture and distribute the often-times mission-critical veterinary drug. As this important medication finds itself approved for use only in veterinary medicine, it represents a small profit center for the remaining two companies that produce the medicine. Why is this fact critically important to this conversation?

It has been stated that the manufacture of the medication (at its current price) will no longer be profitable for these companies if xylazine were to become “prohibitively scheduled” or regulated as a “controlled substance.” The additional regulatory activity attached to scheduling a medication places significant cost burdens on the manufacturers; they no longer have a profitable medication. This results in removal of the medication from the company’s product offerings (i.e. this important medication that is proven to improve patient outcomes is lost from our profession; our patient outcomes are less successful and ours animal patients suffer).

In fact, at the time of this letter, Bimeda Animal Health has already stated that they are winding down production as xylazine due to the future forecast. This company has hinted that it would no longer be able to financially justify the continued manufacturing of a scheduled xylazine medication.

If production were left to a single manufacturer that is willing to walk the additional regulatory path that would be imposed by the OBOP, I have concerns about the future financial accessibility of the medication. As a scheduled medication, xylazine has the potential to become financially unapproachable for many clients, owners of large animals, and production settings. Beyond just our concerns about treating patient pain and suffering, we are now wading into

other current and important issues; this leads us to include a discussion about inclusion, equity and accessibility of veterinary care within the ever-changing veterinary ecosystem. Assuming access to xylazine is not altogether lost, we can expect a significant increase in xylazine's cost, which will result in a significant drop in accessibility. When the cost of healthcare increases due to these types of actions, treatment and care interventions are delayed, which we know results in worse outcomes for patients and their families.

The loss of this medication or the loss of the ability to compounded it will have significant negative impacts for the veterinary ecosystem, that is tasked with achieving good patient outcomes and ending patient suffering; the loss of xylazine negatively impacts outcomes and the goals of veterinary medicine.

The veterinary community needs to be involved more directly in these discussions about xylazine. A quick environmental scan of this issue shows that the people who are speaking the loudest do not have a clear understanding of the distinction between the medication, xylazine, and the illegal substance, Tranq. For some reason, MDs and politicians are speaking the loudest and making the most noise. Just because they are loud does not mean they are accurate or enlightened. Apparently, there is little to no engagement of the veterinary community for their input and insights on the xylazine issue.

Veterinarians are hyper aware of this issue, have studied it, and understand it. We also appreciate the significant task that the drug epidemic in the United States presents to lawmakers. The veterinary community can be a critical ally in this battle against illicit drugs. Our hope is that this commentary and additional conversation and investigation will reveal that xylazine, the medication, is critical to veterinary practice and is not part of the problem. The current situation involves adulteration of fentanyl and illegal drugs with Tranq, an illicit substance that is in no way attached to veterinary medical practice.

The loss of this medication or the ability to compound or combine it with other medications in veterinary medicine will have a significant impact, and we fear that a reactive scheduling of non-FDA approved xylazine medication (i.e. compounded xylazine preparations) will result in its disappearance, which will impact the veterinary medicine community and our patients significantly.

Sincerely,

Charles Hurty, DVM
Grove Veterinary Clinic
Newport, Oregon. 97365

541-961-2250

PS: I would gladly offer my time to you if there are any additional questions you might have of me. Again, thank you for your time and consideration.

--
Stay curious.
Find the work you can't not do.

From: Danielle Arthurs
To: PHARMACY RULEMAKING * BOP
Subject: Guide Dogs for the Blind- compounding medications
Date: Tuesday, July 18, 2023 10:28:48 AM
Attachments: image001.png

At any given time, we have 80-100 dogs on our Boring, OR campus. A part of our deworming protocol when a new group of training dogs arrive on campus, is to give compounded capsules of Pancur. We order 500mg capsules in a quantity of #500 capsules at a time to dispense to our kennels for use, based on the weight of the dogs, and treated for 3 consecutive days. Financially it is important for us to have a "hospital stock" of this compounded medication (cheaper than using the powder Panacur and faster by not having to measure out each individual dose- which is not feasible with the number of dogs we treat), as we treat roughly 30 dogs per month as a part of our protocol. We also use compounded Ponazuril for Coccidia treatment. Again, because we have so many dogs within our care, it is important to have the large quantity readily on hand for use.
By discontinuing "office stock" compounded medications in the quantity our clinic requires, our non-profit organization will take a huge financial hit, not only from the medication themselves, but the amount of time we will have to spend dispensing the medication in other ways. Overall, the proposed change would negatively impact our patient care. We are an AAHA certified clinic, and pride ourselves on doing what is best for our program dogs.

Guide Dogs for the Blind
Elite FEAR FREE CERTIFIED Professional

Guide Dogs for the Blind
Danielle Arthurs | OR Vet Clinic Practice Manager
Certified Veterinary Technician
darthurs@guidedogs.com | 503.668.1552
32901 SE Kelso Road, Boring OR 97009
Guidedogs.com

From: Shanna Sallee
To: PHARMACY RULEMAKING * BOP
Subject: Importance of compounded medications
Date: Tuesday, July 18, 2023 11:21:35 AM

To whom it may concern,

I want to address the importance of having a stock supply of compounded medications. Living in a rural area shipping is not always consistent and may take several days to receive orders. Having a time limit of supply is not always practical. Especially when the limit is 120 hours, which does not compensate for weekends when shipments are not possible. Also I want to stress the importance of compounding in veterinary medicine because it is essential to compliance. In human medicine you can tell your patients to take medication, but in veterinary medicine the medication must be easy for the client to administer and the patient to accept. We have a duty to not put our clients at risk of injury when giving medication. Compounded medications give us more options for route of administration and flavorings. This helps improve compliance and therefore effectiveness of the medication.

Sincerely,

Shanna Sallee, DVM
Hermiston Veterinary Clinic
1995 S. Hwy 395
Hermiston, OR 97838
541-567-6466

hims & hers

VIA EMAIL: **pharmacy.rulemaking@bop.oregon.gov**

July 24, 2023

Dr. Joe Schnabel
Executive Director, Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

RE: Hims & Hers' Concerns on the Proposed rules relating to Division 115: Pharmacists

Dear Dr. Schnabel:

Per the June 16, 2023 Notice for Proposed Rulemaking relating to Division 115: Pharmacists, Hims & Hers offers our feedback after review of the proposed language in 855-115-005 and 855-115-0145. We are concerned that such rules, if implemented, will create a substantial barrier, greatly impacting a patient's ability to access care safely and conveniently, increasing costs on mail fulfillment and increasing the workload on an already overworked pharmacist provider. Therefore, respectfully, our team joins with the many other stakeholders in opposition of the Board's proposed aforementioned rules.

At Hims & Hers, we connect customers to independent licensed healthcare providers who provide medical consultations and treatment across all 50 states. Since our founding, we've powered millions of digital healthcare visits across a variety of conditions through our platform. During the COVID-19 pandemic, our convenient telehealth platform has connected patients and providers from the safety of their own home, lessening burdens on our health systems benefitting both patients and healthcare providers.

Our platform maintains relationships with licensed mail order pharmacies, which provide prescription fulfillment services to Hims & Hers customers. These pharmacies fill prescription orders for customers who have received, when appropriate, a prescription from a licensed healthcare provider through the Hims & Hers websites and mobile applications. We are committed to operating a safe mail-in fulfillment, which is why we are members of the Alliance for Safe Online Pharmacies.

The Pharmacy Board's Proposed Rules 855-115-0005 and 855-115-0145 modified Oregon's Pharmacy standard by requiring a number of new requirements related to pharmacist counseling. First, the definition of counseling is revised to an ***interactive*** communication between a pharmacist and a patient providing advice regarding the safe and effective use of a drug or device. In addition, the proposed rules mandate that the pharmacist attempt to provide such interactive counseling prior to delivery making a reattempt within 24 hours if the first attempt does not occur and, finally, for the pharmacist to document all such attempts in writing. Please note that in the proposed rules, interactive is not defined.

Our summarized general concerns around the proposed rules are as follows:

The former rules were effective in promoting and protecting public health, safety and welfare.

As cited on the header of your website, the Oregon Board of Pharmacy serves to ***promote and protect public health, safety and welfare*** by ensuring standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs. There is nothing in the record that reflects that the former counseling rules did not serve this stated purpose. Since the Board's modifications will create a significant impact on the industry's standard on how patients are counseled, not just locally but nationally, it seems arbitrary to implement such rules without evidence that Oregonians have been harmed by the former counseling rules.

The new requirements will place an extra burden on the already overburdened pharmacy provider.

The new requirements on pharmacists to provide interactive counseling prior to delivery, to reattempt the counseling within 24 hours if counseling does not occur and also to document every such attempt is excessive and burdensome. It is very well known and documented that there is a national shortage of healthcare providers; that also includes pharmacists. The National Institutes of Health (NIH) published a study in November 2022 demonstrating the burnout prevalence of pharmacy providers due to such shortage. The research demonstrated that the prevalence of this systemic burnout has a capacity to compromise patient care. These mandates will add another layer of complexity and liability to the already overburdened provider professional in Oregon.

To address the issues around the overburdened pharmacy provider in these proposed rules, we would request to include the allowance of 'written communication' in the definition of counseling. We would also request that, if necessary, the documentation requirement be done by another member of the pharmacist's team to alleviate some of the provider's mandated workload.

The proposed rules will deny equity and access to patient care.

Mail-order pharmacy fulfillment lowers prescription costs and provides access to patient care for all communities and demographics. Imposing the proposed aforementioned rules will create substantial work for the pharmacists burdening the system, increasing costs and impeding access. This will cause many stakeholders who offer the option of mail-order fulfillment to make difficult decisions as it relates to their Oregon operations.

That is unfair to the people of Oregon. For example, there are many communities throughout the state cited as living in pharmacy deserts. These are locations where access to in-person pharmacies are especially difficult. Telehealth and mail-order prescription fulfillment are making access to healthcare easier for Oregonians living in these locations. Adopting the proposed rules will provide additional barriers to both patient care and patient choice moving Oregon's healthcare conveniences backwards.

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Requiring interactive counseling interferes with the patients' choice; Oregon an outlier.

By requiring real time "interactive" counseling, the proposed rules will not only place an undue burden on pharmacy providers, but seemingly undermine the legislative intent of 2022 HB 4034, which granted increased flexibility for the practice of telemedicine and telepharmacy. HB 4034 allows licensed providers to use their clinical training and discretion to best determine how to effectively and safely provide care to their patients in accordance with the standard of care. . The proposed rules will have the unintended results of placing a substantial barrier on licensed providers, taking decision making out of their hands and forcing them to provide interactive counseling to patients who may not need, want, desire, or benefit from interactive counseling. These rules may have the unintended consequences of impeding convenient access to care to many residents throughout Oregon.

From our knowledge, Oregon will become an outlier state by requiring pharmacists to provide "interactive" counseling while prohibiting written counseling and offers to counsel for mail-order prescription fulfillment.

Proposed Solution

If the Board decides to move forward with making changes, our team would join in on the proposed modification of the rules congruent with the American Telemedicine Association to address the concerns as listed in this letter. We believe that these modifications are necessary to resolve the issues we have raised.

855-115-0145

(1) "Counseling" or "Counsel" means an exchange, including through written communication, ~~interactive communication~~ between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

(2) The pharmacist must counsel or offer to counsel the patient or patient's agent on the use of a drug or device:¶

(a) Upon request;

(b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;

(c) When there has been a change in the dose, formulation, or directions;

(d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or

(e) For any refill that the pharmacist deems counseling is necessary.

(5) For a prescription delivered directly to a patient or patient's agent inside a Drug Outlet Pharmacy, a pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused,

(a) Only a pharmacist can accept a patient's or patient's agent's request not to be counseled, when counseling is required.

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(b) The pharmacist may choose not to release the prescription until counseling has been completed.

...

(7) The pharmacist must ensure the attempt to counsel, ~~provides~~ counseling, or ~~accepts the~~ request not to be counseled as required by (1) and (2) is documented ~~their identity, each attempt to counsel and the outcome at the time of the attempt or interaction~~.

The effective date must be extended at least one year from Board's approval.

In the event that the Board proceeds with these proposed rules mandating these new pharmacists' duties, we would request that the Board include an effective date one year from the date of the Board's approval of the rules to allow stakeholders enough time to reasonably comply under the circumstances. Currently, the proposed rules do not indicate an effective date in the modification. Considering the substantial operational and fiscal impact that the interactive counseling and documentation requirements will have on industry, all licensed pharmacies providing fulfillment services for customers through our platforms will need additional runway time to make the necessary adjustments.

Summary

Mail-order prescription fulfillment is known to maximize convenience and access for the patient, as well as lower the cost of prescriptions. Moving away from a counseling model that has not been deemed ineffective or inefficient inconveniences Oregonians and places a barrier to their care. After recently experiencing a global pandemic, we have all witnessed the need for government leadership and the healthcare industry to continue to find ways to expand access to health care as much as reasonably possible. The proposed changes of the Board seem to go in the opposite direction of such a premise.

As stated, our team does not believe the proposed rule modifications in 855-115-005 and 855-115-0145 adding requirements for counseling prior to prescription delivery and adding requirements for the pharmacists to document their attempts to counsel will result in improved patient care. The rules will burden and add to the burn-out of healthcare professionals. The rules will also ultimately increase the cost of delivering pharmacy services in the State of Oregon.

Thank you for your service and the opportunity to provide feedback during this process. We appreciate your consideration of our concerns. If you would like to further discuss, please do not hesitate to contact us with any questions.

Sincerely,

Dartesia Pitts
Senior Government Relations Manager

Hims & Hers
dpitts@forhims.com
forhims.com
forhers.com

cc: Oregon Board of Pharmacy Members

About Hims & Hers
Hims & Hers is a direct-to-consumer, digital health company. We connect patients to licensed healthcare providers for telemedicine consultations and treatment across all 50 states. Since our launch in 2017, we've powered millions of digital healthcare visits[1] across a variety of conditions.

From:	Dotty Pitts
To:	PHARMACY RULEMAKING * BOP
Cc:	April Mims; Madison Owens
Subject:	Hims & Hers' comments on the Proposed rules Division 115: Pharmacists
Date:	Monday, July 24, 2023 4:22:03 PM
Attachments:	OR Pharmacy Board letter 7_24_23 Final.pdf

Hello:

Per the notice of proposed rulemaking, please see attached Hims & Hers comments on whether other options should be considered for achieving the rule's substantive goals relating to Division 115.

Thank you.

--

Dartesia A. Pitts
"Dotty"
Senior Government Relations Manager
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July 25, 2023

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pharmacy.rulemaking@bop.oregon.gov

Dear Officer Melvin,

Re: Proposed Rules - Division 183 - related to Drug Compounding

Thank you for the opportunity to provide comment on the proposed rulemaking. Below you will find our comments or suggested edits to the draft Compounding rules that were sent out for public comment.

855-183-0005 Definitions

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

(2) ~~"Compounding" means the process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a compounded preparation.~~

Including a definition of compounding that is different from the referenced standards creates more confusion. USP<795> and USP<797> have different definitions for compounding. It would be clearer to either reference the standards, as described in (1), or include both definitions here.

855-183-0010 Designation

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

It is unclear what purpose or value this requirement would provide. Compounding is just one of many types of pharmacy practice and services a pharmacy may choose to offer. These services can change quickly depending on the needs of the community at any point in time. Having a random reporting requirement different than any other reporting requirement creates an unnecessary administrative burden and creates a potential for violation and discipline for a Drug Outlet and/or PIC. We would request the Board reconsider this requirement.

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855-183-0200 Requirements: General

(4) All sterile compounding ~~must~~ should utilize a system that incorporates:¶
(a) Barcoding to verify ingredients; and¶
(b) Imaging or gravimetrics to verify ingredient quantity and finished CSP volumes.¶

While utilizing barcoding, imaging or gravimetrics is certainly a goal to work toward, these should not be a requirement for implementation 11/1/2023. As described in the Fiscal and Economic Impact section of the Notice of Proposed Rulemaking, '*Compounding Workgroup members stated that in their experience, barcoding and imaging technology procurement, implementation, ongoing maintenance, and training is estimated to cost between $30,000 - $130,000 initially and $50,000 annually. This type of technology is typically customized, requires specialized training and requires extra staff to operate.*'

This type of financial investment, especially for small businesses or rural clinics/hospitals, as well as the necessity to integrate the technology into existing systems can take years to plan and implement successfully.

Secondly, when using 'must', if there is issue with the technology and it is not operational, it would indicate that compounding would have to cease.

855-183-0570 Records: Compounding Records (CR) for CNSP

(1) Pharmacist performance and documented verification that each of the following are correct:¶
(a) Formulation; ¶
And
855-183-0575 Records: Compounding Records (CR) for CSP
(2) Pharmacist performance and documented verification that each of the following are correct:¶
(a) Formulation; ¶

We would recommend using consistent language. USP uses the term 'formulation' and OBOP also uses formulation in the previous section 855-183-0565 Records: Master Formulation Records.

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); ¶

Please see previous comment for 855-183-0200. The additional technology required to perform verification in lieu of proxy verification or syringe pull-back method will be difficult to implement by the November deadline. We need these alternate verification strategies as an option until it is feasible for

pharmacies to financially plan to purchase and install the proper equipment, update workflows and train personnel.

Thank you for taking the time to consider our comments.

Respectfully,

Alfred Lyman (Jul 26, 2023 15:28 PDT)

Alfred Lyman, Jr., PharmD, BCPS
Executive Director, Regional Pharmacy Services
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Elizabeth Bentley (Jul 26, 2023 14:52 PDT)

Elizabeth Bentley, MSJ, PharmD, BCPS
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Kela Edvalson (Jul 26, 2023 14:16 PDT)

Kela Edvalson, RPh
Director, Home Infusion, Oncology, Compounding and Community Care Pharmacy
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From:	Cynthia M Vaznaugh
To:	PHARMACY RULEMAKING * BOP
Cc:	DEBARMORE Rachael; Junior Lyman
Subject:	Re: Proposed Rules - Division 183 - related to Drug Compounding
Date:	Wednesday, July 26, 2023 3:32:51 PM
Attachments:	Kaiser Permanente_Division 183 - related to Drug Compounding_Rulemaking Comments 7.25.23.pdf

Good afternoon, Officer Melvin,

Attached is the signed document – KP Proposed Rules – Division 183.

Please reach out to Rachael or Junior if you have any questions or concerns. They are copied on this email.

Best regards,

Cynthia Vaznaugh

Executive Assistant to:

Alfred E. Lyman, Jr., Executive Director, Regional Pharmacy Services
Rachael DeBarmore, Director of Pharmacy Regulatory & Professional Affairs
Jane Zimmer, Manager, Pharmacy Informatics & Analytics

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July 11, 2023

To: All Oregon Board of Pharmacy Members

RE: Proposed rule to revise and relocate existing rule from OAR 855-019-0230 to OAR 855-115-0145 related to counseling.

We appreciate this opportunity to express our significant concerns over the proposed rule changes below:

- Require, for any prescription not previously dispensed by that pharmacy, a prescription with a change in dose, formulation or directions, or a prescription transferred to that pharmacy, counseling that includes an interactive communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device

- For a prescription delivered outside of a Drug Outlet Pharmacy to a patient for self-administration, the pharmacist must:

    - Attempt to provide counseling prior to delivery
    - Reattempt to provide counseling by end of the next business day if counseling does not occur prior to delivery to the patient; and
    - Provide drug information in a format accessible by the patient, including information on how to contact the pharmacist with the delivery
    - Require the pharmacist that attempts counseling, provides counseling or accepts the request not to be counseled must document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction

The rise in popularity of mail order and home delivery services reflects patients' preferences for convenience. Millions of prescriptions each year are mailed or delivered to patients in Oregon with comprehensive written medication information included and directions for how to contact a pharmacist by phone, email or via online communication. This practice has been in place for many years with similar low adverse outcome rates as retail pharmacies and -- for many patients – improved medication adherence. This practice is also acceptable and allowed by Boards of Pharmacy across the country.

Due to massive telemarketing efforts directed at all consumers, patients routinely ignore calls from phone numbers they do not recognize. Eighty percent of Americans say they don't generally answer their cellphone when an unknown number calls, according to Pew Research Center web survey of U.S. adults conducted in 2020. To require that pharmacists – and only pharmacists – make and document calls offering counseling (or accepting the refusal of counseling) not just once, but twice, could result in patient dissatisfaction from unsolicited calls while diverting the pharmacist away from tasks that provide higher value for medication safety, quality, and affordability.

We fully support pharmacists providing appropriate and effective counseling to patients and have long incorporated into our operations ample opportunity for counseling to occur when requested by the patient and when a pharmacist determines that counseling is necessary for

positive health outcomes. When pharmacists provide counseling under these circumstances, we believe they are working at the top of their license and using their time and clinical expertise to provide the greatest value for the patient.

Pharmacy providers, like all aspects of the healthcare system, are contending with personnel shortages and increased fiscal pressures. These rule changes would place additional burdens on our staff and systems at a time when it is more important than ever to manage our resources to continually improve health outcomes, improve access and service to patients, and deliver on affordability.

We believe the proposed rule changes would not significantly advance medication safety but will put additional pressure on the already stressed and stretched pharmacists serving our community, potentially create delays in medication delivery, and negatively impact patient care and safety. We are not aware of any other state Board of Pharmacy requiring pharmacists to make phone calls offering counseling.

The potential costs to implement the proposed rule change will be significant for many pharmacies and health care systems. Adopting these changes will reduce patient choice, and for some, access, as pharmacies make the difficult decision whether or not to provide delivery services or to mail prescriptions to patients in Oregon.

We would ask the Board to consider, and would like to collaboratively work with the Board to find, an alternative solution for all practice settings. As was expressed during the Board meeting by Board members, the intent of the language change is to align counseling requirements between in-person vs. mailed or delivered prescriptions. To maximize patient safety and care, decreasing the interruptions pharmacists experience and allowing them to determine the appropriate level of counseling required is incredibly important.

We continue to innovate with our interactive systems to enhance how prescription information is provided and communications can occur with a patient. Patients benefit when pharmacists have time to focus on more comprehensive drug utilization review and meaningful consultations, which can reduce the delays patients are currently facing in community pharmacies and improve the work environment.

We share the Board's commitment to medication safety and improved health outcomes and hope that we can work together to advance these goals.

Thank you for your consideration and your service to the residents of Oregon.

Sincerely,

Mary Beth Lang, DSc, MPM, R.Ph.
Senior Vice President and Chief Pharmacy Officer
Kaiser Permanente

Alfred Lyman
Alfred Lyman (Jul 11, 2023 11:54 PDT)

Alfred Lyman, Jr., PharmD, BCPS
Executive Director, Regional Pharmacy Services
Kaiser Permanente

From:	Junior Lyman
To:	PHARMACY RULEMAKING * BOP
Subject:	Written Testimony Related to Opposition of New Proposed Counseling Rule
Date:	Friday, July 21, 2023 4:59:24 PM
Attachments:	OR BOP Letter_Counseling_7.11.2023.pdf

Attaching a letter to all Oregon Board of Pharmacy members. Thanks.

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From: KENNETH F DEREMER
To: PHARMACY RULEMAKING * BOP
Subject: Rulemaking Regarding Compounding Medication
Date: Tuesday, July 25, 2023 10:00:57 PM

I am writing regarding the use of compounded medication in Veterinary Practice. It is often that we encounter patients that need medications in a form that is not commercially available. This may be due to the small size of the patient requiring lower concentrations. Frequently we need a form of the medication that is more palatable as some patients are resistant to treatment. We must be able to **dispense** the medication on diagnosis and provide enough for a treatment course. This requires us to maintain an in office supply to dispense from. We can not have a 3 to 5 day delay in starting medication as our patients are often emergent and need immediate treatment. It is not practical for the client to start medication with us and then have to request a refill for a supply to finish the treatment course. Please do not pass legislation to limit patient care.

Sincerely,

Kenneth DeRemer DVM

Subject: Comments on proposed compounding rules division 183

Dear Board of Pharmacy,

I wanted to submit comments on the following sections of the proposed Division 183 compounding rule changes that will be discussed in the upcoming rulemaking hearing. I am a member of the compounding workgroup and mentioned some of these comments verbally, but wanted to expand and provide them in writing for the Board's convenience as well.

Thank you for your consideration,

Natalie Gustafson, PharmD

Director of Pharmacy
Lloyd Central Compounding Pharmacy
2606 NE Broadway St Suite B
Portland, OR 97232

Comments

855-183-0050 Personnel

Recommendation: Adjust the wording that requires technicians be trained in compounding to clarify that compounding while being trained is allowed. Specifically, add the word "independently" to the following sentence: "prior to **independently** engaging in compounding," [a technician must be fully trained].

This language would be most in line with that of USP <795> and <797> which states that personnel must be trained and qualified before being allowed to perform their job functions independently. Adding this language would allow personnel to practice compounding under observation, assistance and guidance during the training process, then perform the tasks themselves while under direct supervision to ensure proficiency prior to being authorized to engage in compounding independently under standard supervision.

855-183-0200 Requirements: General

Recommendation: remove the requirement to adhere to USP chapters above 1000 in section (1)(a), (b), (c) and (d).

Referencing USP chapters above 1000 as enforceable in the rule is confusing when they are intended to be informational only. Here is language that has been presented by APC (Alliance for Pharmacy Compounding) previously:

“This is a misapplication of the USP Chapters in a way that USP itself states the chapters above 1000 are not intended to be applied. While pointing a compounder to the USP chapters referenced to carry out best practices and to learn more about a given subject is encouraged, according to USP General Notices, General chapters numbered 1000 to 1999 are for informational purposes only. They contain no mandatory tests, assays, or other requirements applicable to any official article, regardless of citation in a general chapter numbered below 1000, a monograph, or these General Notices.”

855-183-0205 Technology: Automated Compounding Devices (ACDs)

(1) Currently says: “A Drug Outlet Pharmacy…. may use an ACD to…”

Recommendation: keep the term “may” in (1) and not change to “must”

In the compounding workgroup there was a discussion regarding whether the term “may” in (1) should be changed to “must” either for ACDs or IV workflow management. Recommend maintaining “may” not “must” as these systems and devices are not applicable to all types of compounding, including non-sterile compounding.

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

(1) Currently says: “The strength of each active ingredient, to include the base”

Recommendation: remove “to include the base” from (1)

Stating the strength of the base does not make sense on a label, as bases typically have no strength given that they are inactive. Recommend putting dosage form on label instead in order to be consistent with USP <795>.

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

(1) Currently says: “The strength of each active ingredient, to include the base solution for a sterile parenteral preparation”

Recommendation 1: remove “to include the base solution for a sterile parenteral preparation” from (1).

Stating the strength of the base does not make sense on a label, as bases typically have no strength given that they are inactive. Recommend putting dosage form on label instead as required by USP <797>.

Recommendation 2: Remove “(3) Rate of infusion or titration parameters, for a sterile parenteral preparation.”

Putting the rate of infusion on the label could cause errors to occur if that rate is changed for a specific patient, especially in batch items that are used for multiple patients and could have different rates of infusion. Rates of infusion are often specified in the medication order or to the person administering the medication, not always on the prescription itself.

855-183-0420 Labeling: Preparations CNSP and CSP for future use

Recommendation: Remove the requirement “(5) Indication that the preparation is compounded.”

This labeling is for internal pharmacy use only. There is no benefit to adding this indication, and is already obvious as this product has no NDC or other commercial labeling markers. Not all pharmacy software prints that on the label as it is already assumed the product is compounded, so would need to be added manually for many labels.

855-183-0520 Recalls

Recommendation: Change time requirements specified in (1) (currently says 12 hours) and remove section (3) the requirement to report to MedWatch. The time requirement should either be extended overall, or adjusted to prioritize patient safety and account for logistical realities.

Only allowing 12 hours to notify patient, provider and board of a recall that may cause serious health consequences and was dispensed in state is not logistically feasible in many cases. For example, staffing limitations before a weekend or holiday could make it impossible to contact patients as well as all doctors and write a letter to the Board, or a notification of a recall by a manufacturer could occur when a pharmacy is closed or end of day.

Recalls are incredibly time intensive to handle. For accredited pharmacies, there already exists extensive patient and doctor communication to complete immediately to ensure optimal patient safety. Even small, inconsequential recalls can take significant amounts of time to process. Staff needs to be prioritizing time in the early hours of a recall communicating with patients and investigating other needs related to the recall. Once patients have been contacted, then the prescribers need to be contacted in most cases.

It is also time intensive to write letters to the Board with all relevant information. In the early hours of a recall this time is needed to communicate with patients, then doctors, and investigate the details of a recall and ensure minimal disruption to therapy. There is no gain to patient safety by a reporting requirement to the Board within 12 hours, as the action the Board may take is not typically time sensitive nor directly involved in patient or doctor communication. The current requirement of reporting to the Board within 10 days seems reasonable.

In addition, there is a requirement in this section for all serious adverse events to be submitted to FDA MedWatch. We are not aware of any other Oregon pharmacy rules that specifically require data to be given to another agency or website that is not under Board oversight, nor is it a federal requirement. Oregon pharmacies that classify as 503a are under the oversight of the Oregon Board of Pharmacy, not the FDA. We suggest striking that language.

855-183-0565 Records: Master Formulation Records (MFR) for CSP

(2) currently says: [MFR must contain] “Compatibility and stability information, including references”

Recommendation: Change the language in (2) to say “if available.”

This was previously discussed in the compounding workgroup that not all products have compatibility/stability information and thus USP BUD requirements are used for these products. Thus, requiring compatibility and stability information in the MFR is not possible. If the wording is changed as recommended it will match 855-183-0560 for CNSP.

855-183-0570 Records: Compounding Records (CR) for CNSP

Recommendation: remove (1)(d) “concentration of components” or add “as applicable.”

USP <795> requires the weight or measurement of each component already, along with the strength or activity (also explicitly required in these rules) so always requiring the concentration of each component is not typically necessary nor relevant (e.g. concentration of a base solution with no active). This would be a burdensome addition and would not improve patient safety.

855-183-0575 Records: Compounding Records (CR) for CSP

Recommendation: remove (2)(d) “concentration of components” or add “as applicable.”

USP <797> requires the weight or measurement of each component already, along with the strength or activity (also explicitly required in these rules) so always requiring the concentration of each component is not typically necessary nor relevant (e.g. concentration of a base solution with no active). This would be a burdensome addition and would not improve patient safety.

855-183-0600 Prohibited Practices

(1) currently says: Verification of components after their addition to the final container (e.g. proxy verification, syringe pull back method)

Recommendation: This rule is overly broad and, as worded, applies to both sterile and non-sterile compounds. Suggest either removing this wording, or specifying that it only disallows

syringe pull-back verification method in sterile compounding (and require pharmacist verification live, via image capture or gravimetrics depending on the situation).

In non-sterile compounding, verification of the final compounded product after addition of all ingredients, when barcoding and weight measurements are recorded by the computer, is the standard practice. Many ingredients are measured by weight, which can be recorded electronically with an analytical balance connected to the pharmacy software. In addition, each ingredient can be barcoded so all that information is also captured with the compounding record. Those items that are by volume can be done with visual second checks with a high degree of accuracy. It is not clear with this language if all of this would be allowed.

Pharmacists are supervising all compounding, but they are not having to document each ingredient prior to their use as the pharmacy software is already doing that. As written, for all non-sterile and sterile compounds, a technician would have to stop at each step for the pharmacist to record some form of additional verification that they also see the weight already recorded by the scale or data recorded from the barcode, which does not add any appreciable safety or accuracy component. Pharmacist oversight of compounding, along with verification of final product and that each step is documented on a compounding record, is sufficient.

This requirement could also mean a pharmacist would have to be in the cleanroom while the non-sterile portion of a sterile compound was being prepared to do the additional “check” of the already recorded weights and barcoded data, adding a safety concern for additional personnel in a sterile environment.

855-183-0710 Service: Copies of a FDA Approved Drug

Recommendation: Strike this rule. If that is not an option, remove the current opening language and replace with “A drug outlet pharmacy, DPDO, CHC or outsourcing facility may not compound inordinate amounts of a drug preparation that is essentially a copy of a FDA approved drug unless.” In addition, change (3) to make it clearer that this is an alternative reason allowed instead of an additional requirement.

In short, this rule is not needed as there is already a federal law to reference and adhere to for pharmacies.

The language in the federal DQSA law states: “does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.” The proposed rule would be stricter than federal law, and instead of helping patient safety, could create a significant patient safety concern due to lack of access to important medications.

The language used in this section appears to be modeled after the language of the FDA guidance document on essential copies, not DQSA, and in some ways is even stricter. FDA guidance documents are not regulations or laws, are not enforceable either through

administrative actions or the courts, and have not undergone public comments or stakeholder input. FDA has used guidance documents to establish compounding and inspection standards that are inconsistent with USP, DQSA, federal laws, congressional intent and have no legal or regulatory backing.

There are significant concerns over adopting language into rules that come from a document that has not gone through the proper legal process, has not had public comment or stakeholder input, has been contested by stakeholders and various organizations as being illegal and incorrect, often changes, and states on every page that it is not legally binding. Adopting this language into Oregon pharmacy rules would change that language to become legally binding.

The U.S. is experiencing drug shortages at an unprecedented rate, and patients are often struggling to find access to necessary medications. It is in these situations that compounders can provide a valuable service to these patients. This rule adds cumbersome documentation in addition to all the other extensive compounding documentation required for a product without apparent benefit to patient safety. If a medication isn't available and a physician requests it for their patient, how does having to record every search for that product on wholesalers and shortages list improve patient safety? All it appears to do is delay patient access to that medication, as it cannot be dispensed until all documentation is in order.

In addition, what if a commercial product looks available on the wholesaler website, but due to shortages and allocations, it is not really available? For example, it is not uncommon to place an order for a larger quantity of these products that look to be in stock but only receive 1 or none due to allocation limits. It is challenging and time consuming to show not only what seems to be available, what we ordered, and what we actually got, and then attach it to each prescription for that product. If a product looks to be available, but won't actually be sent to the pharmacy, would that meet the qualifications of this rule? Switching back and forth for products with extremely limited availability can be challenging for a pharmacy and really confusing for patients.

We are concerned that pharmacies will just choose to not provide these needed medications due to the cumbersome nature of the paperwork, or uncertainty with regulatory enforcement of this new rule when patients are already struggling with access.

Our pharmacy follows the provisions laid out in this rule and the FDA guidance document already so we know the impact this rule will have. In our experience, providers have significant confusion over the delays required in obtaining clarification on why this product must be compounded or what a "clinically significant difference is" for a product. Patients often have to wait many days to get their needed medication while we wait for a prescriber to respond. When the prescribers do respond, they are confused why we are questioning their judgment when they have deemed it necessary for a patient to have a compounded medication. We have found these products are requested to be compounded by a prescriber because the medication isn't available, or there is something about the commercial product that makes it unsuitable for that patient (e.g. filler is an allergen, different flavor, different dosing, dosage form needs to be changed). In our experience, prescribers are typically requesting compounded "copies" not for

cost savings, but due to drug shortages or one of these other reasons, but due to the restrictions of the guidance document sometimes we still cannot compound the medication. Being able to provide these medications for patients increases their safety, not decreases it.

Overall, adding this language will not increase patient safety. It seems to be more about protecting drug manufacturers' financial interests than anything else.

855-183-0730 Service: For Use by a Veterinarian

Recommendation: Remove the language “FDA guidance” from section (2).

To our knowledge, there is no other Oregon pharmacy rule or law that states a pharmacy must follow an agency’s guidance. The ambiguity of this requirement is confusing and concerning as it is not based on a law or rule. Does “guidance” mean the non-legally binding guidance documents published by the FDA, what a pharmacy is told by an inspector on-site, or their internal documents that are not publicly available? How does a pharmacy prove they are following FDA guidance, or that it was even FDA guidance if given verbally, when there is no law or rule to reference to show they are in compliance? This language in the rule would be best removed.

855-183-0740 Service: Sterile Compounding with Non-Sterile Ingredients

We are in support of this new rule requiring accreditation for non-sterile to sterile compounding. This adherence to a higher level of compounding practice helps mitigate risk and improves patient safety and the timeline is feasible.

From: Pharmacist Lloyd Central Pharmacy
To: PHARMACY RULEMAKING * BOP
Subject: Comments for Division 183 Rulemaking Hearing 7.26.23
Date: Friday, July 7, 2023 1:43:53 PM
Attachments: LCRX OBOP Div 183 Compounding Comments 7.26.23.pdf

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Hello Oregon Board of Pharmacy,

Please see attached comments for Division 183 for the rulemaking hearing.

Thank you for your consideration,
Natalie Gustafson, PharmD

--
Lloyd Central Compounding Pharmacy
2606 NE Broadway St, Suite B, Portland OR 97232
Phone: 503-281-4161
Fax: 503-281-1990

Subject: Comments on proposed rules divisions 104, 115 and 125

Dear Board of Pharmacy,

Thank you for your consideration when reviewing my comments on the following sections of the proposed Divisions 104, 115 and 125.

Sincerely,
Natalie Gustafson, PharmD

Director of Pharmacy
Lloyd Central Compounding Pharmacy
2606 NE Broadway St Suite B
Portland, OR 97232

855-115-0120 Responsibilities: Personnel

Recommendation: Change the responsibilities listed in (a) to be the responsibility of the PIC, and not individual pharmacists. It is impractical and logistically challenging for all pharmacists to ensure all these things.

Specifically (a) says: “Ensure personnel that require licensure have been granted and maintain licensure with the board; (i) Ensure initial and ongoing training is completed that is commensurate with the tasks that the Pharmacist and persons under their supervision will perform, prior to the performance of those tasks; and (j) Ensure continued competency in tasks that are performed by the Pharmacist and persons under their supervision”

This responsibility for ensuring licensure, training and competency has always been under the pharmacist-in-charge’s duties, which make sense. It is impractical and doesn’t make sense for every pharmacist to be responsible for checking this licensure and training as well. Many pharmacists are part-time, float or don’t have that type of responsibilities and these duties would be beyond their scope of practice. It makes sense that the pharmacy employer and PIC are responsible for ensuring that licensure and training is appropriate and maintained.

If staff pharmacists have a concern about another licensee’s training or licensure, they should address it with the PIC and/or licensee and adjust their workflow accordingly, depending on the situation.

855-115-0145 Counseling

Recommendation: Remove the requirement that interactive counseling occurs prior to delivery and remove the requirement in (4)(b) to make a second attempt. Perhaps some language that says “within a reasonable amount of time” or similar would allow pharmacists to use clinical judgment on whether counseling is more effective before or after receipt of medication.

Currently, our pharmacy follows all counseling requirements for Oregon for prescriptions which are delivered to patients, which include a written offer for direct counseling and information about the drug from the pharmacist, information on how to contact the pharmacist, along with direct phone conversation counseling with patients as needed and appropriate. The pharmacists use professional judgment to determine when counseling needs to occur prior to delivery.

Many patients are confused when counseling is attempted prior to them receiving their prescription, as it can be challenging for them to understand how to use a medication before they’ve seen it or its packaging. In compounding, many prescriptions are dispensed in specialty devices that have their own instructions and are much easier to discuss when in hand.

855-125-0030 Licensure: Application - certified Oregon pharmacy technician or pharmacy technician

Recommendation 1: Allow for an exception in expiring a technician license application if not complete within 90 days for situations in which the license is delayed due to Board review of active case, or Board delay in processing.

Currently, (5) reads: “(5) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.”

It is not uncommon for applicants applying for technician licensure to have some sort of minor non-violent criminal record (e.g. misdemeanor DUI from 12 years ago). This means they cannot answer “no” to all questions in the moral turpitude section, and that their application must be reviewed by the Board at one of their meetings held every other month.

In order to even be considered for review by the Board, the application and request for review must be submitted typically at least one month prior to the next meeting. Even then, it is extremely common, due to the heavy caseload of the Board for these reviews, to be delayed for an additional 1-2 meetings. In our experience, it has taken most of these applicants 4-6 months to get approved. It doesn’t make any sense to have to reapply after 90 days when in the middle of a Board review.

So, we request exception for these cases when they are undergoing an active case review process by the Board.

Recommendation 2: Do not require full Board case review for applicants with certain kinds of criminal records older than a certain number of years (e.g. 7 years).

We are uncertain if a full Board review of these applications is required by a rule or a statutory law, or if it is an internal policy that can be changed. We understand that the Board has had to review an unprecedented number of cases which has made their review process longer. Given this heavy case load, and the current shortage in technicians, if possible it would be extremely helpful to reduce the caseload of the Board by not requiring all situations to undergo a full review.

Specifically, the lookback period for the moral turpitude section has no limit. There is no cutoff for having to report something on a criminal record, even if it occurred over 20 years ago. Applicants with older records often struggle to get the paperwork from the police, as they don't keep records that long, but because they are missing this paperwork they are ineligible to become technicians. Many of these cases are due to records at least 10 years old and are no longer even applicable to the applicant.

855-125-0150 Prohibited Practices

Recommendation 1: Do not make a prohibited practice that prevents technicians from being supervisors. Many supervisory responsibilities that a technician can perform have nothing to do with clinical judgment (e.g. setting a schedule, handling callouts, training tasks).

Current proposed rule: "(o) Supervise, direct, or control another licensee in the licensee practicing or assisting in the practice of pharmacy"

It appears the intent of this rule may be to prevent technicians from supervising other technicians in any capacity. While a pharmacist is always the supervising licensee and responsible for their technicians' actions, many technicians have workflow and logistical responsibilities that fall under a supervising capacity, but have nothing to do with making clinical judgments. There are many operational and logistical aspects to running a pharmacy that are unrelated to the clinical aspect of pharmacy, but are involved in "assisting in the practice of pharmacy." For example: scheduling employees, handling call outs, shifting workflow responsibilities, resolving minor HR issues, training tasks, ensuring high quality customer service, insurance billing, ordering, ensuring timeliness of processing prescriptions, etc.

Putting complete supervisory limitations on technicians is especially confusing, given the recent change allowing technicians to perform final verification in certain situations.

There is no reason why only a pharmacist should be required to handle these tasks. To require a pharmacist to handle all these tasks would be a huge financial burden without an increase in patient safety. There is a current pharmacist shortage which would make it very challenging as well.

While we agree that technicians should not be involved in clinical/professional judgment, we strongly disagree that technicians should be prohibited from all supervising activities. The current wording of this rule could be interpreted that way and would be detrimental.

Recommendation 2: In section (3), add the word “professional” to the following: “Perform any task while assisting in the practice of pharmacy that requires **professional** judgment unless it is verified by a Pharmacist.”

As currently written in the proposed rules, the prohibition on making judgments is extremely broad. How is “judgment” defined? Technically, it requires judgment to select a bottle of medication that you believe matches the label, which technicians are now allowed to do final verification of in certain situations. Judgments extend to basic tasks done while assisting in the practice of pharmacy, such as choosing which printer to use, size vial when filling, prioritization of tasks, color of pen when writing notes, etc.

It appears the intent of this rule is to limit technicians from using professional or clinical judgment instead of pharmacists. Current Oregon rules state that technicians cannot “perform any task that requires the professional judgment of a Pharmacist.” Changing the wording slightly in this rule would be consistent and align with current restrictions.

From: Pharmacist Lloyd Central Pharmacy
To: PHARMACY RULEMAKING * BOP
Subject: Comments for Division 104, 115 and 125 Rulemaking Hearing 7.26.23
Date: Friday, July 7, 2023 1:43:17 PM
Attachments: LCRX OBOP Div 104 115 125 Comments Rulemaking 7.26.23.pdf

---

Hello Oregon Board of Pharmacy,

Please see attached comments for Division 104, 115 and 125 for the rulemaking hearing.

Thank you for your consideration,
Natalie Gustafson, PharmD

--
Lloyd Central Compounding Pharmacy
2606 NE Broadway St, Suite B, Portland OR 97232
Phone: 503-281-4161
Fax: 503-281-1990

From:	Marianne Mackay, DVM
To:	PHARMACY RULEMAKING * BOP
Subject:	I have been a mixed animal practitioner for over 43 years. The use of Xylazine has changed sedation, anesthesia and analgesia into a much safer procedure for both the patient,owner and doctor. If Xylazine is turned into a Scheduled drug class, it would:
Date:	Wednesday, July 26, 2023 3:32:33 PM

#1 Increase the price for owner and veterinarian.
#2 Limit our use through overwhelming record keeping and waste valuable time in administering it
#3 It would increase tracking by government agencies(yet another waste of taxpayer dollars. Since this drug is not shelf stable, it would requiring veterinarians to restock as expiration dates approach.

Because only a minority of people choose to abuse this drug, the rest of State licensed, accredited and DEA licensed professions should not have to tolerate limitations of such a valuable drug.

Please reconsider making Xylazine into a Scheduled drug.

Sincerely,

Marianne Mackay DVM, DABVP

From: Monica Pollock
To: PHARMACY RULEMAKING * BOP
Subject: Compounding
Date: Monday, July 24, 2023 3:49:38 PM

It has been well established that veterinary patients have a dramatic range of needs that do not fit standard medications. Pharmacy companies have little motivation to expand offerings. If fact, it seems there is less available every year. Alternatives, low profit margin, and generic medications are less profitable. These are dropped during company mergers. We are already feeling the pressure from trying to come up with alternatives when medications disappear.

Compounding pharmacies are few. They are at a long distance (out of range for some of my elderly clients). Mail takes time. Requiring off site sources, of the exact same medication, will mean that compliance drops, my ability to monitor drops, and care of the patient drops.

Each of these legislative moves to limit access to medications is a limitation for care.

Monica Pollock, DVM

From: Mountain View Animal Hospital
To: PHARMACY RULEMAKING * BOP
Subject: Compounded medication for use by Veterinarians
Date: Tuesday, July 18, 2023 9:37:00 AM

Please change the rules to include ***dispensed*** as not all situations allow for hospitalization of pet for medicating and treatment of the patient. This would allow clarification if the medication can be sent home for the owners to medicate their pet with. Without this clarification I have had several cases where the clients cannot afford to hospitalize for those 5 days duration of treatment, or they cannot transport the pet to and from their home to the hospital for medicating. We have several clients that do not drive or rely on family members to transport them to and from the hospital, and delays in treatment or this inconvenience can lead to poor compliance, antibiotic resistance, or delayed response to treatment. There are also certain cases where the anxiety, stress, and fear the pet has during hospital visits and examination alone is too great to have the pet be hospitalized or transported for treatment.

Also consider changing the duration to ***at least 14 days***. This increase in the time frame allows for adequate time for longer term medications to be delivered to the patient's home as we have seen significant delays from compounding pharmacies whether it be from decreased stock, employee shortage, delivery delays (ie. there is an upcoming UPS strike, or over a holiday weekend, etc.). We also treat pocket pets as well as many small dogs that the standard medication is just too high of a dose. There are many examples that my patients require short term relief of medications and waiting for the longer term medication from a compounding pharmacy will do more harm than good on my patients. One such example is the 8 pound poodle who needs an antianxiety medication for a newly developed nose phobia the week of fourth of July as the neighbors start fireworks (even though illegal) a week before July 4th, even if we sent the 5 day course, there will be a lapse in treatment while they wait for the delivery of compounded medication causing distress to the pet and even self harm (some dogs will injury them when they are so stressed). Another example is a rabbit who needs end-of life care due to severe underlying disease (such as cancer) and the owners would like to make the pet comfortable until they are ready to decide to put their pet down. If there is a lapse in treatment and the pet gets painful again or stops eating due to pain they may decide to prematurely end the pets life.

Also, my treatment of patients is limited by the funds and means of the clients. Veterinary medicine is not cheap and can be a burden on some clients. Adding additional expense of getting short term medications form the clinic AND then additional medication from an online pharmacy may make treatments for some clients unattainable. Please let the veterinarian make the decision on how to

treat and how long to treat with compounded medications. These situations are the exception to the rule but I do not want to see my patients and their owners in distress due to rules and regulation. I am on the front line and can already see the many problems I will have and suffering that my patients may have to go through due to this rule.

Thank you for your consideration,

Danielle Huff DVM
Owner and veterinarian
Mountain View Animal Hospital
865 SW 17th Street, Ste 201-301
Redmond, OR 97756
541-460-0828

From: Lisa Kimbrough
To: PHARMACY RULEMAKING * BOP
Subject: Proposed regulations
Date: Wednesday, June 21, 2023 1:08:29 PM

I am reviewing the proposed changes to the Oregon pharmacy regulations and I was hoping you could clarify something for me. The proposed language reads: 855-115-0001

Applicability

(1) This Division applies to any Pharmacist who engages in the practice of pharmacy.¶

(2) Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance withstatutes and rules unless exempt under ORS 689.225. ¶

(3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug

outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a Pharmacist located in another state who is working for an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with the out-of state pharmacy dispensing of a drug into Oregon, is not required to be licensed by the board.

The existing language reads: (4) A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon, is not required to be licensed by the Board unless they are the pharmacist-in-charge (PIC).

Does this mean that the Board intends that all pharmacists working in a pharmacy that ships prescriptions to a patient in Oregon must be licensed in Oregon, not just the PIC?

Thank you for your help.

--

Lisa Kimbrough
Associate Director, Health Policy **MultiState**

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1000 Wilson Blvd, Suite 1800, Arlington, VA 22209

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OFA
OUTSOURCING FACILITIES ASSOCIATION

Lee H. Rosebush
Chairman | OFA
Partner | BakerHostetler
1050 Connecticut Avenue, NW
Suite 1100
Washington, D.C. 20036-5403

July 26, 2023

VIA E-MAIL [pharmacy.rulemaking@bop.oregon.gov]

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
pharmacy.rulemaking@bop.oregon.gov

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

Dear Members of the Oregon Board of Pharmacy,

The Outsourcing Facilities Associates (OFA) is writing to provide comments on the proposed rules from Divisions 041/043/183 related to Drug Compounding issued by the Oregon Board of Pharmacy. We commend the Board's efforts to ensure the safety and quality of compounded drugs for patients in Oregon. OFA fully supports the objective of promoting patient health and access to safe medications.

The Outsourcing Facilities Association ("OFA") is the trade association representing FDA-registered outsourcing facilities ("503Bs") operating pursuant to Section 503B of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). OFA's members provide compounding services to patients, healthcare providers, and healthcare facilities, and strive to ensure the specific needs of both providers and patients are met with safe and effective compounded and/or repackaged medications. OFA has been actively following U.S. Food and Drug Administration's (the "FDA") implementation of the Compounding Quality Act[1] ("CQA") and has brought together members of industry to advocate for a safe, reasonable and practical rollout of the CQA and state implementation of regulations affecting compounding.

OFA respectfully submits this comment in response to the Board's proposed new Division 183 for Drug Compounding.

First, we urge the Oregon Board of Pharmacy to confirm that FDA-registered outsourcing facilities, upon being registered with the Board as manufacturers, as proposed under 855-183-0001, will not be subject to the Board rules governing pharmacy compounding, as those rules apply to pharmacies and not manufacturers. Imposing any restrictions on the activities

[1] Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (codified at 21 U.S.C. § 353b)

outsourcing facilities may engage in as a registered manufacturer is problematic, as outsourcing facilities already adhere to stringent FDA regulations and cGMP standards, which differ from the USP standards that apply to compounding pharmacies. It is essential to avoid duplicative oversight that could potentially hinder outsourcing facilities' ability to provide vital compounded medications efficiently under the most robust quality standards.

Furthermore, with regard to drug shortage products covered under 855-183-0710, we strongly advocate for the prioritization of FDA-registered outsourcing facilities as a source for obtaining compounded drug products. By encouraging Drug Outlet Pharmacies, DPDOs, and CHCs to first explore the availability of compounded drugs from these facilities, Oregon patients will have a greater assurance of receiving medications compounded under the highest quality standards (cGMP). Prioritizing outsourcing facilities enhances access to essential medications for patients. These facilities often have the capacity to produce larger quantities of compounded drugs, at higher standards (USP vs cGMP), allowing them to meet the increased demand during shortages. As a result, patients can receive the medications they need promptly, preventing any potential disruptions in their treatment plans. This approach not only helps ensure the safety and efficacy of compounded drugs but also facilitates access to essential medications during periods of drug shortages.

Additionally, the currently proposed language in Section 855-183-0730(4) provides:

> "(4) The compounded preparations must not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations."

As you know, the United States Pharmacopeia has adopted amendments to Chapters 795, 797 and 800 that will become effective November 1, 2023. These requirements will severely limit BUDs of sterile drugs and make it significantly more expensive and complicated to make hazardous drugs. We strongly expect that these new regulations will result in it being economically unfeasible for many smaller, local pharmacies to continue to produce veterinary drugs. If local pharmacies could buy these products from 503B Outsourcing Facilities and dispense these products to customers, they would be able to facilitate care while utilizing medications compounded under cGMP standards. FDA has indicated that it much prefer products to be made under cGMP standards by outsourcing facilities and we believe that they will be supportive of this kind of provision. In addition, FDA has recently released its Draft Guidance Document[2] on the Wholesale Prohibition Under Section 503B that further clarifies the ability of outsourcing facilities to sell medication to a compounding pharmacy who subsequently dispenses the medication via a patient prescription as provided in Section 503B and now confirmed in guidance. Accordingly, we recommend that provision (4) be revised as follows:

> "(4) The compounded preparations, other than preparations produced by an outsourcing facility, must not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations."

[2] U.S. FOOD & DRUG ADMIN. PROHIBITION ON WHOLESALING UNDER SECTION 503B OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, DRAFT GUIDANCE (June 2023).

Further, we encourage the Board to align any regulation of dispensing compounded drugs with both Section 503B and the draft guidance put forth by the FDA which permits an outsourcing facility to distribute a drug it compounded to a state-licensed pharmacy, federal facility, or licensed physician, which subsequently dispenses the drug pursuant to a prescription. State-licensed healthcare practitioners dispensing compounded drug products sourced from outsourcing facilities, ensures that patients receive the highest quality compounded drugs.

In conclusion, we appreciate the Oregon Board of Pharmacy's commitment to safeguarding public health through effective regulation. We hope that our suggested points will be taken into consideration during the finalization of the proposed rule. OFA is eager to collaborate with the Board in any capacity necessary to support the development and implementation of rules that best serve the healthcare needs of Oregon patients.

Thank you for the opportunity to provide our input on this matter.

Sincerely,

LR

Lee H. Rosebush

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OFA
OUTSOURCING FACILITIES ASSOCIATION

Lee H. Rosebush
Chairman | OFA
Partner | BakerHostetler
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Suite 1100
Washington, D.C. 20036-5403

OREGON MEDICAL ASSOCIATION

July 26, 2023

Via Email pharmacy.rulemaking@bop.oregon.gov
Rachel Melvin, Rules Coordinator
Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland OR 97232

Re: Proposed rulemaking on Division 183, Drug Compounding

Dear Ms. Melvin,

The Oregon Medical Association (OMA) is a nonprofit organization that represents physician and physician assistant (PA) members in the State of Oregon. We are offering public comment on proposed new Division 183 for drug compounding specifically as it applies to Dispensing Practitioner Drug Outlets (DPDOs) and Community Health Clinics (CHCs).

We understand that the proposed rules will not be acted upon in August 2023 and the Board is seeking public comment. Our members work within DPDOs and CHCs. As such, there is separate regulatory oversight of dispensing activity by physicians and PAs through the Oregon Medical Board. Specifically, ORS 677.089 provides oversight for dispensing activity including drugs that are compounded.

From the proposed rule, it appears as though DPDOs and CHCs would be swept up into the new regulatory oversight of compounded drugs no matter how incidental to the practice of medicine. The cost of compliance with a new regulatory program as outlined in Division 183 likely would make routine access to certain compounded drugs too costly and burdensome and could reduce access to patient services statewide. We do not believe that is the intent of the Board in establishing a new regulatory program.

In the fiscal and economic impact section of the preamble to the proposed rule, there is reference to a Compounding Workgroup. A few and significant cost figures are referenced there. Under the section cost of compliance, however, there is the statement there are no known economic impacts. And in the section, describe how small businesses were involved in the development of these rules, there is the statement there were no small businesses involved.

We are concerned about the impacts of a regulatory approach intended for larger scale compounding operations that simply is overlaid on top of small businesses like medical clinics. We believe there should be some tailoring of the rules or specific exceptions provided to reduce unintended consequences. Before the Board proceeds with further rulemaking activity, we strongly urge the formation of a Rules Advisory Committee and one that includes locations potentially impacted by the rules such as DPDOs and CHCs of various sizes and locations.

Thank you for your consideration of our comments, and we would be glad to supplement our comments with further information as needed.

Sincerely,

Mark Bonanno, JD, MPH
General Counsel and Vice President of Health Policy

From: Mark Bonanno
To: PHARMACY RULEMAKING * BOP
Subject: Proposed rule comment
Date: Wednesday, July 26, 2023 3:59:00 PM
Attachments: 2023-07-26 OMA Comments on Proposed Compounding Rules.pdf

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Ms. Melvin,

Please see the attached proposed rule comment from the Oregon Medical Association.

Thank you,

Mark

Mark A. Bonanno, JD, MPH
General Counsel and Vice President of Health Policy
Oregon Medical Association
mark@theOMA.org
Direct 503-619-8117

From: J Wilson DVM, CAC
To: PHARMACY RULEMAKING * BOP
Subject: Xylazine Comment
Date: Tuesday, July 18, 2023 2:49:11 PM

Dear Pharmacy Board Members:

I practice equine veterinary medicine in the state of Oregon.
Xylazine is commonly combined in the field to treat horses. I am concerned about the proposed rules for xylazine use.

The proposed rule on using xylazine must clarify and allow the following uses in equine veterinary medicine.

1. Xylazine is mixed with butorphanol in the same syringe for a single intravenous injection in horses for better standing sedation and analgesia during procedures.
2. Xylazine is used as a "triple drip" (in combination with ketamine and guafenacin) during the maintenance of injectable general anesthesia for surgery.

Thank you.
Dr. Wilson

--

Janine Wilson DVM, CAC
Oregon Equine Inc
www.oregonequine.com

Oregon Society of Health-System Pharmacists
Testimony on Proposed Oregon Board of Pharmacy Rules

Rule considered by the Board of Pharmacy on July 26, 2023

1. The Oregon Society of Health-System Pharmacists STRONGLY OPPOSES the adoption of OAR 855-115-1045 as proposed. OSHP feels that the adoption of the rules as proposed in 855-115-0145 would be catastrophic to the delivery of health care to millions of Oregonians. Many, if not a majority, Oregonians receive their routine refill chronic medications through the mail. This change to the process in the delivery of medications directly to the home would be disruptive and crippling for pharmacy practitioners and their patients for no public health and safety benefit. What these rules would quickly accomplish is to worsen the access to pharmaceuticals for all Oregonians, increase delays in treatment, increase treatment failures and patient non-compliance with medication regimens. With the current crisis in rural pharmacy access, this change is particularly detrimental to patients in rural areas of Oregon, where mail may be the only feasible manner of medication supply. The current rules in 855-019-0230 have served the public for decades, and OSHP is not aware of any patient safety concerns that have arisen from these practices.
In **November of 2022** OSHP was concerned that the addition of 855-155-0145(1) did not include the language included in 855-019-0230 as noted in our testimony.

> *OSHP feels that the deletion of 855-019-0230 without replacement allows mail and package delivery of prescriptions to patients without providing direct contact information for a pharmacist should they have questions regarding their medications. OSHP suggests retaining (e) in the regulation.*

The position of OSHP has not changed. We encourage the board to strike proposed (4)(a)(b)(c) and replace with the language in 019-0230: For example:
(4) For a prescription delivered to a patient, except at a pharmacy or a pharmacy prescription locker, the Pharmacist must Provide drug information in a format accessible by the patient, including information on how to contact the pharmacist.

OSHP requests the Oregon Board of Pharmacy to reject 855-115-1045 as written. OSHP suggests a revision that continues the current regulatory scheme (above) for mail order prescription counseling.

Expected impacts of 855-115-1045 as proposed

Disruption of medication supply for chronic refill medication

Recent surveys (post pandemic) reveal that over half of patients are now receiving their medications through the mail or by a combination of mail and direct delivery. In 2019 Oregon filled 1.33 million mail order prescriptions, probably many more by now. [1] Given the current environment in community pharmacy, especially in independent and rural

[1] Number of Mail Order Prescriptions Drugs by Payer | KFF

areas of the state with limited or no pharmacy access except for mail, has the Board really assessed the impact of millions phone calls on patients and pharmacies? (At 5 minutes a call, an estimated 53 Pharmacists working for a year) (With an estimate of 1.7 attempts per patient, it represents over 2 million unsolicited calls to patients). As the Board is aware, there are not adequate pharmacists available to complete this additional workload. Compliance with 855-115-1045(4)(a) requires this call to be made before delivery is attempted, meaning before placing in the delivery process. If the counseling attempt ques are backlogged, by days or weeks, then delivery to the patient will be delayed by a similar time. It should be assumed that the period from ordering a refill of chronic medication to receipt of the medication will be significantly extended. Current experience reveals that any disruption in medication supply results in medication non-compliance and interruption in therapy. These interruptions sometimes result in bad health outcomes.

Immediate and clinically significant harm to patients

Given the large number of patients and prescriptions affected by this drastic revision in pharmacy regulation, mail pharmacies will be unable to respond quickly to the requirements. The immediate result will be lengthy unanticipated delays in medication refills, resulting in patient inconvenience as well as some unavoidable serious patient outcomes due to lack of needed medication. While urban patients can conceivably go to a pharmacy outlet to receive their medication, it may require prescription transfer, loss of pharmacy benefits, administrative delays, or long waits at local outlets. However, some rural patients, disabled patients, and those served by specialty services may not have the ability to access a local licensed drug outlet to meet their needs. These patients may suffer delays in treatment due to this drastic change in the regulatory requirements. The duration of these delays is uncertain, given that the number of pharmacists needed to provide this level of compliance is unknown, and whether there are enough pharmacists willing to provide this level of compliance.

Inconsistent with recent advances in telemedicine

Current Practices in telemedicine and telepharmacy have the ambulatory pharmacist practitioner reaching out to the patient to coordinate any visits, labs and monitoring required, and providing any modifications needed in the medication regimen needed, including extension of current therapy and refills. The pharmacist would have completed all needed counseling during this telepharmacy visit, so the regulatory requirement to call yet again when the product was shipped is wasteful and confusing to the patient. (Why are you calling me again? Is something wrong?) Provisions in 855-155-0145(1) seem adequate to cover this situation, as it allows professional judgement in the reasonable and necessary counseling needed under the circumstances.

Increased cost of care

The additional effort and expense of this change has been submitted to the Board of Pharmacy by various organizations as requested by the Fiscal Impact Request sent by the Board. OSHP is not a recipient of these estimates, but professional experience and common sense would place these impacts in the 10's of million dollars in excess cost. Given the millions of prescriptions involved, and the requirement that only professional staff provide the counselling, this service must by necessity be quite expensive. Regardless of the exact expense needed, it would seem difficult to justify any large expenditure given the very low expectation of any return. This would only make the prescription drugs more expensive for the patients. This increase in expense seems in conflict with so many efforts to reduce and control the cost of prescriptions and medication therapy across the policy spectrum. As OSHP members focus daily on reducing the cost of care for patients, this seems counterproductive.

Additional OSHP Objections to 855-115-1045 as proposed

Language is internally inconsistent.

Section (1) of the proposed rules allows the pharmacist to determine the manner and amount of counseling necessary for each prescription. Sections (2)-(10) then proceed to tell the pharmacist what is necessary for counseling. Which is

it? Does the Board determine the manner and necessity of counseling, or does the pharmacist? It would be difficult for a regulatory body to determine each patient's circumstance and write rules specifying the exact elements of counseling most appropriate for that patient. The patient and the Oregon Board rely on the professional judgement and experience of the pharmacist to act in the patient's best interests. It seems to OSHP that (1) is sufficient to require appropriate consultation for prescription medication.

Trivializing pharmacy and medication management

Medication use will only be made more complicated and intrusive for patients, forcing them to take phone calls mandated by the Board of Pharmacy that they do not want. As Pharmacists we know that patients do not retain information that they do not want and comes out of context with their health care concerns. This call will place pharmacy with the telemarketers among the pests whose calls will be screened out to voice mail. OSHP wants a call from a pharmacist to be considered an important and useful event, with important information and outcomes for the patient.

Lack of any public health or safety concern or perceived benefit

While effective patient consultation is beneficial to patients, it is problematic in all pharmacy settings, due to the limited time available at most community outlets. Patients have been shown to disregard information that is not provided at a time or place that is not in the context of their health concerns. The written information provided by both community and mail-order pharmacies is a validated, standard process of providing useful drug information outlined by the Board. OSHP is not aware of any published study or concern that the information provided by mail order or home delivery pharmacies to patients has resulted in any negative patient outcome or patient safety concern. OSHP does not see any possible benefit to the people of Oregon by changing the current pharmacy practices that have served the people and profession over the last 20 years. This change in regulation will not result in any benefit to the public. Patients want an efficient, online, direct way to refill their prescription medications, choosing the time and place to receive the information they need to pursue their best interests.

Reputational Damage to the Oregon Board of Pharmacy

OSHP is proud of its long association with the Oregon Board of Pharmacy, and the participation of many of its leaders on the Board over the years. We value our profession and professionalism and seek to participate in the regulation of the profession to preserve the health and safety of our patients as well as all Oregonians. We believe that this needless and seemingly disastrous change will only cause disruption, confusion and increase the cost of care. For no discernable benefit to the public. The immediate disruption in medication supply for many Oregonians will undoubtedly be attributed to the Board of Pharmacy and this regulatory action. The damage done to the Board and the profession is unknown, and regrettable.

ADOPT: 855-115-0145

CHANGES TO RULE:
855-115-0145
Counseling
(1) For each prescription, the pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.
(2) The pharmacist must counsel the patient or patient's agent on the use of a drug or device:
(a) Upon request.
(b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy.
(c) When there has been a change in the dose, formulation, or directions.
(d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written, or electronic means; or
(e) For any refill that the pharmacist deems counseling is necessary.
(3) When communicating (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the pharmacist is proficient in the patient's preferred language.
(4) For a prescription delivered outside of a Drug Outlet Pharmacy to a patient for self-administration, the pharmacist must:
(a) Attempt to provide counseling prior to delivery as required in (1) and (2);
(b) Reattempt to provide counseling by end of the next business day if counseling does not occur prior to delivery to the patient; and
(c) Provide drug information in a format accessible by the patient, including information on how to contact the pharmacist with the delivery.
(5) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused,
(a) Only a pharmacist can accept a patient's or patient's agent's request not to be counseled when counseling is required.
(b) The pharmacist may choose not to release the prescription until counseling has been completed.
(6) A pharmacist must initiate and provide counseling under conditions that maintain patient privacy and confidentiality.
(7) The pharmacist that attempts counseling, provides counseling, or accepts the request not to be counseled must document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction.
(8) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.
(9) Counseling on a new prescription may include, but is not limited to, the following elements:
(a) Name and description of the drug.
(b) Dosage form, dose, route of administration, and duration of drug therapy;
(c) Intended use of the drug and expected action.
(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) Techniques for adherence and self-monitoring drug therapy.
(g) Proper storage and appropriate disposal method(s) of unwanted or unused medication.
(h) Refill information.
(i) Action to be taken in the event of a missed dose; and
(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.
(10) Counseling on a refill prescription may include, but is not limited to, the following elements:
(a) Name and purpose of the medication.
(b) Directions for use, including technique.
(c) Perceived side effects; and
(d) Adherence.

2. The Oregon Society of Health-System Pharmacists opposes the adoption of OAR 855-115-0310 as proposed.

Pharmacists fill a critical role in access to health care, especially in rural areas. Currently pharmacists assist in critical health care access including utilizing laboratory testing as noted in bullet (1) and (2) of proposed rule 855-115-0310. However, the statement in bullet (1) "A Pharmacist must only order and receive laboratory test when" restricts the ability for pharmacist to expand into other critical areas of care while waiting for rules to be revised and protocols to be generated. Restricting the ability of pharmacists to order and review laboratory tests could inadvertently prevent access to care in areas across the state that may not have access to other healthcare providers in a timely manner and may restrict appropriate pharmacist duties as federal laws allow for expanded practice by pharmacists. We encourage the board to strike proposed "must only" language and replace with "may" For example:

(1) A Pharmacist may order and receive laboratory test when:

OSHP requests the Oregon Board of Pharmacy to reject 855-115-0310 as written. OSHP suggests a revision that allows pharmacists to order and receive laboratory tests when clinically indicated.

ADOPT: 855-115-0310
Services: Laboratory
(1) A Pharmacist must only order and receive laboratory test when:
(a) Managing drug therapy pursuant to the terms of a clinical pharmacy agreement or collaborative drug therapy management agreement with a provider under OAR 855-115-0315;
(b) Providing patient care services pursuant to the terms of the post diagnostic formulary listed in OAR 855-115-0340 that is developed under ORS 689.645 and adopted by the board under ORS 689.649;
(c) Providing patient care services pursuant to and as allowed by the terms of a protocol listed in OAR 855-115-0345 that is developed under ORS 689.645 and adopted by the board under ORS 689.649;
(d) Permitted under a Health Screen Testing Permit pursuant to ORS 438.010(8); ORS 438.060; ORS 438.130(2); ORS 438.150(5), (6) and (7); OAR 333-024-0370, OAR 333-024-0375, OAR 333-024-0380, OAR 333-024-0385, OAR 333-024-0390, OAR 333-024-0395, and OAR 333-024-0400; or
(e) Monitoring a therapeutic response or adverse effect to drug therapy under ORS 689.005.
(2) A pharmacy may perform a laboratory test as permitted under ORS 689.661.
(3) Records and documents must be retained according to OAR 855-104-0055.

3. The Oregon Society of Health-System Pharmacists opposes the adoption of OAR 855-125-0150 as proposed.

OSHP supports the ability of trained and certified pharmacy technicians to administer vaccines, as was a common practice during the COVID pandemic and the CDC approved guidelines. The Board has allowed this practice, and it has been beneficial to public health. The Oregon Legislature has passed **HB 2486** which allows pharmacy technicians to administer vaccines. The deletion of (l) is required by statute.

(a) A pharmacist, or a pharmacy technician under the supervision of a pharmacist, may administer vaccines:

OSHP has implemented medication history review in many of its health-systems for patients upon admission into the hospital. Some institutions are utilizing pharmacy technicians to interview patients regarding their home medications taken prior to admission to ensure that they are included in the comprehensive medication history provided to the pharmacist and physician as part of the past medical history for the medical record and continued appropriate treatment of the patient in the hospital. These technicians also contact community pharmacies to obtain outpatient medication profiles as well as interview patients' families, especially if the patient is medically unable to provide a medication history personally. This practice has been well documented to reduce mortality and morbidity, reduce mediation errors and omissions, and improve the quality of care for patients. It is not in the patient's best interest to prevent this activity through 855-125-0150(c) below. This practice is covered by (2) in the rule as this practice is assisting in the practice of pharmacy by permission of the pharmacist. However, this inconsistency in rule should be addressed by the Board, clarifying that the authorized and policy driven medication history taken by a pharmacy technician is not prohibited by section (c) of the rule, rather covered and permitted by 855-125-0135 Responsibilities: Permitted Practices Certified Oregon Pharmacy Technicians or Pharmacy Technicians: (1) Must only assist in the practice of pharmacy as authorized by the rules of the board and as permitted by the Pharmacist providing supervision, direction, and control

OSHP requests the Oregon Board of Pharmacy to reject 855-125-0150 as written. OSHP suggests deleting (l) and clarifying the application of 855-125-0135 to Medication History taking programs.

ADOPT: 855-125-0150
Prohibited Practices
Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:
(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0105(4), including but not limited to the following tasks:
(a) Evaluate and interpret a prescription.
(b) Conduct a Drug Utilization Review or Drug Regimen Review.
(c) Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription.
(d) Counsel a patient or the patient's agent regarding a prescription.
(e) Accept a patient or patient's agent's request to decline counseling.
(f) Advise on therapeutic values, content, hazards and use of drugs and devices.
(g) Interpret the clinical data in a patient record system or patient chart.
(h) Conduct Medication Therapy Management.
(i) Practice pursuant to a Clinical Pharmacy Agreement or Collaborative Drug Therapy Management.
(j) Practice pursuant to Statewide Drug Therapy Management Protocols.
(k) Prescribe a vaccine, drug, or device.
(l) Administer a vaccine, drug, or device.
(m) Order, interpret or monitor a laboratory test.
(n) Receive or provide a new or transferred prescription orally.
(o) Supervise, direct, or control another licensee in the licensee practicing or assisting in the practice of pharmacy.
(p) Delegate tasks to healthcare providers; and
(q) Deny the patient or the patient's agent request to speak to the Pharmacist.
(2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.
(3) Perform any task while assisting in the practice of pharmacy that requires judgment unless it is verified by a Pharmacist.
(4) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace.
(5) Refuse a request from a patient, patient's agent, or practitioner to interact with a pharmacist.

From: millardmi@gmail.com
To: PHARMACY RULEMAKING * BOP
Subject: Oregon Society of Health System Pharmacists Comments on Proposed Rules Division 115 and 125
Date: Friday, July 21, 2023 1:28:23 PM
Attachments: OSHP testimony Mail order July 26 final OSHP .docx

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Please find attached, OSHP comments in opposition on proposed rules 855-115-1045; 855-115-0310; and 855-125-0150.
Thank You.

Michael Millard M.S. B.Pharm. FOSHP
Professor Emeritus Pacific University
A lie is not the truth, because you believe it

Oregon Society of Health-System Pharmacists
Testimony on Proposed Oregon Board of Pharmacy Rules

Rule considered by the Board of Pharmacy on July 26, 2023

1. The Oregon Society of Health-System Pharmacists STRONGLY OPPOSES the adoption of OAR 855-115-1045 as proposed. OSHP feels that the adoption of the rules as proposed in 855-115-0145 would be catastrophic to the delivery of health care to millions of Oregonians. Many, if not a majority, Oregonians receive their routine refill chronic medications through the mail. This change to the process in the delivery of medications directly to the home would be disruptive and crippling for pharmacy practitioners and their patients for no public health and safety benefit. What these rules would quickly accomplish is to worsen the access to pharmaceuticals for all Oregonians, increase delays in treatment, increase treatment failures and patient non-compliance with medication regimens. With the current crisis in rural pharmacy access, this change is particularly detrimental to patients in rural areas of Oregon, where mail may be the only feasible manner of medication supply. The current rules in 855-019-0230 have served the public for decades, and OSHP is not aware of any patient safety concerns that have arisen from these practices.
In **November of 2022** OSHP was concerned that the addition of 855-155-0145(1) did not include the language included in 855-019-0230 as noted in our testimony.

> *OSHP feels that the deletion of 855-019-0230 without replacement allows mail and package delivery of prescriptions to patients without providing direct contact information for apharmacist should they have questions regarding their medications. OSHP suggests retaining (e) in the regulation.*

The position of OSHP has not changed. We encourage the board to strike proposed (4)(a)(b)(c) and replace with the language in 019-0230: For example:
(4) For a prescription delivered to a patient, except at a pharmacy or a pharmacy prescription locker, the Pharmacist must Provide drug information in a format accessible by the patient, including information on how to contact the pharmacist.

OSHP requests the Oregon Board of Pharmacy to reject 855-115-1045 as written. OSHP suggests a revision that continues the current regulatory scheme (above) for mail order prescription counseling.

Expected impacts of 855-115-1045 as proposed

Disruption of medication supply for chronic refill medication

Recent surveys (post pandemic) reveal that over half of patients are now receiving their medications through the mail or by a combination of mail and direct delivery. In 2019 Oregon filled 1.33 million mail order prescriptions, probably many more by now. [1] Given the current environment in community pharmacy, especially in independent and rural

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areas of the state with limited or no pharmacy access except for mail, has the Board really assessed the impact of millions phone calls on patients and pharmacies? (At 5 minutes a call, an estimated 53 Pharmacists working for a year) (With an estimate of 1.7 attempts per patient, it represents over 2 million unsolicited calls to patients). As the Board is aware, there are not adequate pharmacists available to complete this additional workload. Compliance with 855-115-1045(4)(a) requires this call to be made before delivery is attempted, meaning before placing in the delivery process. If the counseling attempt ques are backlogged, by days or weeks, then delivery to the patient will be delayed by a similar time. It should be assumed that the period from ordering a refill of chronic medication to receipt of the medication will be significantly extended. Current experience reveals that any disruption in medication supply results in medication non-compliance and interruption in therapy. These interruptions sometimes result in bad health outcomes.

Immediate and clinically significant harm to patients

Given the large number of patients and prescriptions affected by this drastic revision in pharmacy regulation, mail pharmacies will be unable to respond quickly to the requirements. The immediate result will be lengthy unanticipated delays in medication refills, resulting in patient inconvenience as well as some unavoidable serious patient outcomes due to lack of needed medication. While urban patients can conceivably go to a pharmacy outlet to receive their medication, it may require prescription transfer, loss of pharmacy benefits, administrative delays, or long waits at local outlets. However, some rural patients, disabled patients, and those served by specialty services may not have the ability to access a local licensed drug outlet to meet their needs. These patients may suffer delays in treatment due to this drastic change in the regulatory requirements. The duration of these delays is uncertain, given that the number of pharmacists needed to provide this level of compliance is unknown, and whether there are enough pharmacists willing to provide this level of compliance.

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Trivializing pharmacy and medication management

Medication use will only be made more complicated and intrusive for patients, forcing them to take phone calls mandated by the Board of Pharmacy that they do not want. As Pharmacists we know that patients do not retain information that they do not want and comes out of context with their health care concerns. This call will place pharmacy with the telemarketers among the pests whose calls will be screened out to voice mail. OSHP wants a call from a pharmacist to be considered an important and useful event, with important information and outcomes for the patient.

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While effective patient consultation is beneficial to patients, it is problematic in all pharmacy settings, due to the limited time available at most community outlets. Patients have been shown to disregard information that is not provided at a time or place that is not in the context of their health concerns. The written information provided by both community and mail-order pharmacies is a validated, standard process of providing useful drug information outlined by the Board. OSHP is not aware of any published study or concern that the information provided by mail order or home delivery pharmacies to patients has resulted in any negative patient outcome or patient safety concern. OSHP does not see any possible benefit to the people of Oregon by changing the current pharmacy practices that have served the people and profession over the last 20 years. This change in regulation will not result in any benefit to the public. Patients want an efficient, online, direct way to refill their prescription medications, choosing the time and place to receive the information they need to pursue their best interests.

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ADOPT: 855-115-0145

CHANGES TO RULE:
855-115-0145
Counseling
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(2) The pharmacist must counsel the patient or patient's agent on the use of a drug or device:
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(b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy.
(c) When there has been a change in the dose, formulation, or directions.
(d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written, or electronic means; or
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(a) Attempt to provide counseling prior to delivery as required in (1) and (2);
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(5) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused,
(a) Only a pharmacist can accept a patient's or patient's agent's request not to be counseled when counseling is required.
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(6) A pharmacist must initiate and provide counseling under conditions that maintain patient privacy and confidentiality.
(7) The pharmacist that attempts counseling, provides counseling, or accepts the request not to be counseled must document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction.
(8) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.
(9) Counseling on a new prescription may include, but is not limited to, the following elements:
(a) Name and description of the drug.
(b) Dosage form, dose, route of administration, and duration of drug therapy;
(c) Intended use of the drug and expected action.
(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) Techniques for adherence and self-monitoring drug therapy.
(g) Proper storage and appropriate disposal method(s) of unwanted or unused medication.
(h) Refill information.
(i) Action to be taken in the event of a missed dose; and
(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.
(10) Counseling on a refill prescription may include, but is not limited to, the following elements:
(a) Name and purpose of the medication.
(b) Directions for use, including technique.
(c) Perceived side effects; and
(d) Adherence***.***

2. The Oregon Society of Health-System Pharmacists opposes the adoption of OAR 855-115-0310 as proposed.

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Services: Laboratory
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(d) Permitted under a Health Screen Testing Permit pursuant to ORS 438.010(8); ORS 438.060; ORS 438.130(2); ORS 438.150(5), (6) and (7); OAR 333-024-0370, OAR 333-024-0375, OAR 333-024-0380, OAR 333-024-0385, OAR 333-024-0390, OAR 333-024-0395, and OAR 333-024-0400; or
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(3) Records and documents must be retained according to OAR 855-104-0055.

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OSHP supports the ability of trained and certified pharmacy technicians to administer vaccines, as was a common practice during the COVID pandemic and the CDC approved guidelines. The Board has allowed this practice, and it has been beneficial to public health. The Oregon Legislature has passed **HB 2486** which allows pharmacy technicians to administer vaccines. The deletion of (l) is required by statute.

(a) A pharmacist, or a pharmacy technician under the supervision of a pharmacist, may administer vaccines:

OSHP has implemented medication history review in many of its health-systems for patients upon admission into the hospital. Some institutions are utilizing pharmacy technicians to interview patients regarding their home medications taken prior to admission to ensure that they are included in the comprehensive medication history provided to the pharmacist and physician as part of the past medical history for the medical record and continued appropriate treatment of the patient in the hospital. These technicians also contact community pharmacies to obtain outpatient medication profiles as well as interview patients' families, especially if the patient is medically unable to provide a medication history personally. This practice has been well documented to reduce mortality and morbidity, reduce mediation errors and omissions, and improve the quality of care for patients. It is not in the patient's best interest to prevent this activity through 855-125-0150(c) below. This practice is covered by (2) in the rule as this practice is assisting in the practice of pharmacy by permission of the pharmacist. However, this inconsistency in rule should be addressed by the Board, clarifying that the authorized and policy driven medication history taken by a pharmacy technician is not prohibited by section (c) of the rule, rather covered and permitted by 855-125-0135 Responsibilities: Permitted Practices Certified Oregon Pharmacy Technicians or Pharmacy Technicians: (1) Must only assist in the practice of pharmacy as authorized by the rules of the board and as permitted by the Pharmacist providing supervision, direction, and control

OSHP requests the Oregon Board of Pharmacy to reject 855-115-0310 as written. OSHP suggests deleting (l) and clarifying the application of 855-125-0135 to Medication History taking programs.

ADOPT: 855-125-0150
Prohibited Practices
Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:
(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0105(4), including but not limited to the following tasks:
(a) Evaluate and interpret a prescription.
(b) Conduct a Drug Utilization Review or Drug Regimen Review.
(c) Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription.
(d) Counsel a patient or the patient's agent regarding a prescription.
(e) Accept a patient or patient's agent's request to decline counseling.
(f) Advise on therapeutic values, content, hazards and use of drugs and devices.
(g) Interpret the clinical data in a patient record system or patient chart.
(h) Conduct Medication Therapy Management.
(i) Practice pursuant to a Clinical Pharmacy Agreement or Collaborative Drug Therapy Management.
(j) Practice pursuant to Statewide Drug Therapy Management Protocols.
(k) Prescribe a vaccine, drug, or device.
(l) Administer a vaccine, drug, or device.
(m) Order, interpret or monitor a laboratory test.
(n) Receive or provide a new or transferred prescription orally.
(o) Supervise, direct, or control another licensee in the licensee practicing or assisting in the practice of pharmacy.
(p) Delegate tasks to healthcare providers; and
(q) Deny the patient or the patient's agent request to speak to the Pharmacist.
(2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.
(3) Perform any task while assisting in the practice of pharmacy that requires judgment unless it is verified by a Pharmacist.
(4) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace.
(5) Refuse a request from a patient, patient's agent, or practitioner to interact with a pharmacist.

Thank you for the opportunity to comment on the proposed rulemaking for your consideration. We look forward to opportunities for additional discussion to ensure safe and quality care for all Oregonians. OSHP will continue to collaborate with the Board to advocate for legislation to advance the practice of pharmacy further. We look forward to engaging with you in this matter to assess current rules and opportunities for process improvement.

Lam Nguyen
Lam Nguyen (Jul 25, 2023 12:38 PDT)

Lam Nguyen, PharmD, MBA
OSHP President

Joshua Free (Jul 25, 2023 12:47 PDT)

Joshua Free, PharmD, MBA
The Oregon Pharmacy Coalition

Alfred Lyman
Alfred Lyman (Jul 25, 2023 12:50 PDT)

Alfred Lyman, Jr. PharmD, BCPS
Executive Director
Kaiser Permanente Northwest Region

Amy R Watson
Amy R Watson (Jul 25, 2023 12:51 PDT)

Amy Watson, PharmD, MBA, FACHE
Director of Pharmacy Services & Chief Pharmacy Officer
Asante

Majid Tanas, PharmD, MHA, MS, FASHP
VP, Pharmacy Services, Chief Pharmacy Officer
Legacy Health

Jennifer Zanon
Jennifer Zanon (Jul 25, 2023 12:57 PDT)

Jennifer Zanon, RPh
Director, Pharmacy Services Regulatory Compliance, & Supply Chain
OHSU

Tavis B. Smith, PharmD, MBA
Senior Manager
Credena Health/Providence

Corey Rahn, PharmD, BCPS
System Director of Pharmacy
Salem Health

Dan Rackham
Dan Rackham (Jul 25, 2023 13:38 PDT)

Daniel M. Rackham, PharmD, BCPS
Chief Pharmacy Officer
Samaritan Health Service

Michael Powell
Michael Powell (Jul 25, 2023 13:52 PDT)

Michael Powel, RPh
Chief Pharmacy Officer
St. Charles Health System

20230725 OSHP Testimony Mail Order

Final Audit Report 2023-07-25

Created:	2023-07-25
By:	Majid Tanas (mtanas@lhs.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAA7hkyaG3D38nwq0dvVTRF0_-uq-7J4nIk

"20230725 OSHP Testimony Mail Order" History

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2023-07-25 - 6:54:00 PM GMT

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2023-07-25 - 7:37:54 PM GMT- IP address: 137.53.241.2

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2023-07-25 - 7:38:24 PM GMT- IP address: 137.53.241.2

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2023-07-25 - 8:14:53 PM GMT

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2023-07-25 - 8:38:31 PM GMT- IP address: 136.226.54.179

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Signature Date: 2023-07-25 - 8:38:33 PM GMT - Time Source: server- IP address: 136.226.54.179

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2023-07-25 - 8:52:44 PM GMT- IP address: 104.47.51.126

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Signature Date: 2023-07-25 - 8:52:59 PM GMT - Time Source: server- IP address: 67.59.90.162

Agreement completed.

2023-07-25 - 8:52:59 PM GMT

OREGON STATE PHARMACY ASSOCIATION
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July 20, 2023

Oregon Board of Pharmacy
c/o Joe Schnabel
800 NE Oregon St., Suite 150
Portland, OR 97232

Dear Joe,

The Oregon State Pharmacy Association (OSPA) has several concerns pertaining to the upcoming July 2023 rulemaking hearing, as well as the selection process for a new executive director for the Oregon Board of Pharmacy. A summary list of our concerns follows, with further detailed description of each line item below:

1. **Too many rule changes were proposed to receive appropriate feedback from the public.**
2. **Rules are being pushed through to hearings without prior discussion at an OBOP meeting. All feedback from the public, regardless of when it's submitted, should be shared with board members.**
3. **We have received feedback from OSPA members in multiple work environments and practice settings expressing their concern about the undue burden that "counseling all patients, regardless of their particular situation," will put upon their pharmacy and we urge you to not implement these rules.**
4. **OSPA, by statute, should be involved with the Governor's selection of all pharmacist board members. OSPA wants to be involved immediately, so we can provide a comprehensive list of candidate options to Governor Kotek.**

1) In my November 2022 rulemaking letter, OSPA wrote, "*To begin, the proposed rules under consideration on November 22, 2022, are excessive, too detailed, and seem overly burdensome for pharmacy personnel yet do not clearly define how the changes serve to protect the public. It appears the Board voted to send these proposed changes to rulemaking for feedback from the public; however, several of the rules were not even discussed in public comment during either the August or October Board of Pharmacy meetings. As such, thorough feedback is difficult, especially given the massive quantity of proposed rule changes. We encourage you to use a Rules Advisory Committee (RAC) to provide feedback on the impact these rules will have and prevent this from happening in the future. We fear the current implementation process has unintended consequences which will endanger our patients*."

   Unfortunately, the same concerns exist for the current rulemaking process as it seems there has been no improvement in your process since the last round of rulemaking. The board staff have proposed so many unnecessary rules that are frankly overwhelming for any pharmacist or pharmacy staff to attempt to review and provide appropriate comments. During discussion

at the board of pharmacy meetings you ask for public comment, though if you don't receive it, you assume the public agrees with everything proposed. It's simply unrealistic to expect public comment on this magnitude of rule changes, especially where one word or even a capital letter versus lowercase, can make a huge difference in how a rule is implemented or enforced.

2) Your staff has again pushed through rules to the point of implementation without having necessary conversations with the public. Without providing an explanation of the need for these proposed rules at your meetings, you cannot expect the public to feel comfortable providing comments. Since the Board continues to push through rules changes, the board members should at the very least, be allowed to review all feedback that the board staff receives regardless of when it is submitted. Pharmacists are doing their best to provide valuable information throughout the year, but if it's not within the allowable date range of the comment period, the board members don't see it. This further speaks to the heart of the unrealistic expectations your staff have for public comment.

3) The following concerns pertain to the proposed rules from the Oregon Board of Pharmacy (https://content.govdelivery.com/accounts/ORBOP/bulletins/35c65b6) that require a pharmacist to provide counseling to all patients with the following rules:
   - Provide counseling prior to delivery.
   - Provide drug information in a format accessible by the patient, including information on how to contact the Pharmacist with the delivery; and
   - Reattempt to provide counseling with 24 hours of delivery if counseling does not occur prior to delivery.

   The financial impact of this proposed rule varies significantly based on pharmacy practice situations, such as practice setting and size of the pharmacy, but the feedback was unanimous that the implementation of this rule would likely require at least one new pharmacist on staff to counsel full-time and document the process throughout. This is not a productive use of a pharmacist's time and puts a huge administrative strain on the pharmacy. Pharmacies are struggling to keep their doors open, struggling to hire technicians, and simply don't have the financial means to hire an additional pharmacist to satisfy the requirements of this proposed rule. Not to mention the current pharmacist shortage in the state of Oregon. Finding someone to staff these "administrative" positions will be difficult.

   In addition, we believe that the new requirements for Pharmacists-In-Charge (PIC) add another layer of complexity to the already highly liable role of a PIC. While we understand and agree that pharmacists in other states should be held to similar rules as those within the state, we do not believe that the additional requirements (such as completing xxxx hours of pharmacy practice within the last yyyy years) provides more value than it does

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questions (ie: what are we defining as pharmacy practice?). And, while we agree that pharmacies should be regulated similarly when in state versus out, we do need to recognize that there is a legitimate chance, based on feedback, that out-of-state pharmacies will decide to no longer fill prescriptions for Oregon patients. A situation that will further increase the patient access-to-medication issues already developing across the state.

4) You have not included OSPA with the selection process for a new pharmacist board member, which is required by statute ORS 689.115 (see below)..

> ***689.115 Membership; qualifications; term; vacancy; compensation.*** *(1) The State Board of Pharmacy consists of nine members appointed by the Governor and subject to confirmation by the Senate in the manner provided in ORS 171.562 and 171.565. All members of the board must be residents of this state. Of the members of the board:*
> *(a) Five must be licensed pharmacists.*
> *(b) Two must be licensed pharmacy technicians.*
> *(c) Two must be members of the public who are not licensed pharmacists or a spouse, domestic partner, child, parent or sibling of a pharmacist.*
> ***(2)(a) Board members required to be licensed pharmacists may be selected by the Governor from a list of three to five nominees for each vacancy, submitted by a task force assembled by the Oregon State Pharmacy Association to represent all the interested pharmacy groups.***

It is OSPA's understanding that you have already submitted a list of potential candidates to Governor Kotek's office for consideration. **Please send details of your candidates, so we can form a task force to review them and also provide our own comprehensive list of qualified candidates to her office for the appointment.**

Thank you for acknowledging and addressing our concerns and thank you to the Board of Pharmacy for their work and commitment to the Oregon pharmacy profession.

Sincerely,

Brian Mayo
Executive Director

OREGON VETERINARY
medical association

July 14, 2023

Rachel Melvin, Rules Coordinator
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Proposed Rule: New OAR 855-183-0730 / Compounding: Service for Use by a Veterinarian

Dear Ms. Melvin and the Oregon Board of Pharmacy:

The spectrum of therapeutic need in veterinary medicine is large, and the availability of approved drug products for all veterinary species and indications is relatively small. For this reason, compounding is an essential part of veterinary clinical practice and is necessary when approved drugs need to be modified to sufficiently treat the patient (e.g., through flavoring, diluting, combining, or changing the form of medications from tablet to suspension).

For example, if a veterinarian prescribes methimazole for a hyperthyroid cat, but the owner says the cat will not allow the owner to "pill" it, the veterinarian might need to have the product compounded into a liquid form so the cat can be adequately treated. Other examples of compounding include the following:

- Mixing two injectable drugs in the same syringe to avoid giving a patient two separate injections.

- Adding flavoring to a commercially available drug to increase palatability.

- Combining two solutions for instilling into the ear when no OTC preparation of the required drug(s) or strength is available.

- Creating a transdermal gel for a drug typically given through other routes to increase compliance.

- Requiring a higher concentration of medication (e.g., cisplatin for intralesional injection in horses) than is available in non-compounded medications.

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Compounding might also be necessary when no approved drug exists, or if the approved drug isn't commercially available to treat a patient's diagnosed condition. In such circumstances, it may be necessary to use bulk drug substances to provide patients with essential medications.

Concerns with the Proposed Rule

Historically, veterinarians have relied on compounded medications to meet a specific patient's medical needs but also have had access in Oregon for non-patient specific compounded medications to administer in the clinic and to dispense to the client, when necessary, for treatment of the animal outside of the practice. We appreciate that the Oregon Board of Pharmacy has worked with the OVMA and other stakeholders to ensure that veterinarians have had access to "office stock" compounded drugs when needed.

1. The proposed rule notes that compounding pharmacies may prepare medications "For in-office use by a licensed veterinarian, specifically for a single treatment episode, not to exceed 120-hour supply."

   Given the 120-hour (five-day) timeframe stated in the rule, it appears that veterinarians may dispense compounded office stock to their clients to begin treatment of the animal patient. However, that is not what the proposed language says, and it could be interpreted to mean that veterinarians can only administer such compounded preparations in the clinic and only for up to a 120-hour (5-day) period, should the patient be hospitalized.

   Veterinarians need compounded drugs as office stock for urgent and emergent cases presented to them. It is vital that veterinarians have certain preparations in the facility to begin treatment upon diagnosis of the patient, and enough compounded medication to send home with the client for continuation of treatment at home. Thus, veterinarians need "office stock" on hand to both administer and dispense.

   In a "draft" version of the proposed rules by the Compounding Workgroup, compounded preparations were allowed to "be used by veterinarians in their offices for administration to clients' animals," and to "be dispensed by a veterinarian to clients." This is essential in veterinary medicine to start treatment of the patient right away and to best ensure that there isn't any interruption of that treatment until a "patient-specific" compounded preparation becomes available.

   The word "dispense," however, is not included in the proposed rule filed with the Secretary of State's Office. **While allowance for dispensing is implied, noting the 120-hour timeframe, it is crucial that this be clearly spelled out – and "dispense" be re-inserted – so there is no ambiguity on this point by the veterinarian and the compounding pharmacy.**

2. The proposed rule includes a 120-hour (five-day) limit, presumably for the dispensing of office stock compounded preparations. This is both practically and therapeutically problematic and could lead to substandard care and treatment of the patient.

- A compounding pharmacy of the veterinarian's choice might not be able to fill and deliver a patient-specific preparation by the 6th day of treatment. The proposed rule does not take into account whether a compounding pharmacy is open on weekends and holidays (most are not) or the time it might take for an out-of-state compounding pharmacy to prepare and deliver patient-specific medications.

- Any delay in a patient receiving its important medications could lead to interrupted therapy and a poor outcome for the animal. With antibiotic therapy of a patient, poor compliance (including delayed or interrupted treatment) can lead to re-infection, and antimicrobial resistance.

- In a 2019 survey by the OVMA, only 26% of respondent veterinarians stated that a 5-day (120-hour) supply of compounded preparations from office stock would be an adequate duration for treating the patient. Some of the most common compounded medications dispensed as office stock by veterinarians that require more than a 120-hour (five-day) supply include:
  - Amlodipine for high blood pressure
  - Cisapride for gastrointestinal issues and constipation
  - Gabapentin Solution for neuropathic pain, chronic arthritis, and refractory idiopathic epilepsy
  - Metronidazole for certain bacterial or protozoal infections, digestive issues, and inflammatory bowel disease
  - Oral and injectable buprenorphine for mild or moderate pain in cats with cystitis or following surgery, including dental extractions
  - Sterile ophthalmic preparations (Cidofovir, Cyclosporine, Desmopressin, Tacrolimus, etc.) for conjunctivitis, keratitis, central diabetes insipidus, etc.
  - Oral enrofloxacin for the treatment of severe, susceptible bacterial infections in horses

OVMA believes that veterinarians should be allowed to determine the appropriate duration of treatment and therefore the appropriate amount of medication to dispense for the initial therapeutic treatment (as long as it does not exceed the expiration date of the compounded product). Once that first course of therapy is completed, any ongoing need for compounded medications would then be patient-specific.

- This is in alignment with the FDA's *Guidance for Industry #256: Compounding Animal Drugs from Bulk Drug Substances*, which does not have a provision that limits the dispensing of office stock compounded preparations to a predetermined number of days.

The veterinary profession's need for, and reliance of, compounded preparations, cannot be overstated. The unique and varied patients Oregon veterinarians care for and the compliance concerns they encounter daily necessitates that they have the decision-making discretion to prescribe and dispense compounded medications in the best interest of patient care.

We appreciate the opportunity to comment on the proposed rules (OAR 855-183-0730) regarding Compounding: Services for Use by a Veterinarian. Please do not hesitate to contact us with any questions about compounding's essential role in animal health.

Thank you for your time and consideration.

Sincerely,

Glenn

Glenn M. Kolb
Executive Director

From:	Glenn Kolb
To:	PHARMACY RULEMAKING * BOP
Cc:	glenn.kolb@oregonvma.org
Subject:	Public Comments: OAR 855-183-0730 / Compounding: Service for Use by a Veterinarian
Date:	Friday, July 14, 2023 5:29:24 PM
Attachments:	OVMA Letter on Compounding Rule by OBOP.pdf

To whom it may concern:

Please find attached submitted comments on the OBOP's proposed rulemaking that relates to compounding – specifically, to compounding use by veterinarians. Thank you for the opportunity for us to share our practical experiences and insights.

Sincerely,

Glenn

Glenn M. Kolb, Executive Director

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OREGON VETERINARY medical association

July 14, 2023

Rachel Melvin, Rules Coordinator
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Proposed Rule: Amending OAR 855-080-0021 / Scheduling Xylazine

Dear Ms. Melvin and the Oregon Board of Pharmacy:

The Oregon Veterinary Medical Association shares the Oregon Board of Pharmacy's concerns about the illicit use of xylazine ("tranq") and the threat it poses to public health. We also appreciate that the agency recognizes that the chemical xylazine (powder form imported from overseas) that has been found mixed with illicitly manufactured fentanyl and other narcotics in all 50 states **is not** the same injectable medication used in veterinary medicine. This is an important distinction because any regulations that result in limited or restricted access to legitimate veterinary use of xylazine would dramatically change the way veterinarians are able to care for their patients and would raise animal welfare and human safety issues.

Xylazine has been approved in the United States since 1972 for veterinary use only. It is an important medication in large animal species, particularly horses and cattle (there is **no** practical alternative for sedation in cattle), as well as some wildlife and laboratory animal species because it is an effective, relatively-safe, non-opioid drug that provides sedation and analgesia needed to perform certain medical evaluations, treatments and procedures, as well as temporarily relieve some types of acute pain, such as colic due to intestinal obstructions in horses. Xylazine is also an important drug with many humane shelters, where it is used for sedating pets as part of the euthanasia process.

While there is no reversal agent for xylazine that is safe for use in humans, atipamezole, tolazoline, and yohimbine are drugs that have been used for this purpose in animals. In addition to providing essential analgesia and sedation in animals, use of xylazine makes veterinary practice safer for veterinarians, technicians, producers, and animal owners when working with animals that can easily injure people (or themselves) during procedures, because of their size and typical behavior.

Needing Clarification
As proposed, the rule would add xylazine to Oregon's list of Schedule I drugs, "… unless in the form of a FDA-approved product." This raises a couple of serious questions for us:

1. While the proposed rule exempts the FDA-approved xylazine as manufactured and supplied, does it also include any FDA-approved product that is compounded to help veterinarians meet the treatment needs of their patients?

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2. Is the compounding of xylazine, either by a pharmacist or a veterinarian, allowed under the proposed rule?

While we do not believe that OBOP's intentions are to limit a veterinarian's access to and use of xylazine, clarification of the proposed language is important. Both "forms" are essential in veterinary medicine, where xylazine is administered either as a stand-alone drug for short and moderate-length procedures, or in combination with other anesthetics.

Compounded xylazine is typically prepared by pharmacists or veterinarians and permitted under the Federal Food, Drug and Cosmetic Act, when the source of the active ingredient is a finished FDA-approved drug, and not a bulk drug substance. This could include combining, diluting, mixing, or altering ingredients to create a medication tailored to the needs of an animal patient or a small group of animals.

Following are examples of compounded xylazine that are essential in veterinary medicine here in Oregon:

Clinical practice

- Mixed with butorphanol in the same syringe for single intravenous injection in horses for better standing sedation and analgesia during procedures.

- Diluting xylazine from its labeled use to provide sedation and/or analgesia to small ruminants, i.e., goats.

- Used as a "triple drip" during maintenance of injectable general anesthesia. Most commonly, xylazine, ketamine, and quafenacin in horses; xylazine, ketamine, and butorphanol in ruminants; as well as other combinations.

Fish & Wildlife

Combining xylazine with ketamine as a sedative for darting deer, black bears, and sea lions. (Xylazine is compounded by veterinarians but often administered by field biologists who are trained in its handling and use; however, the biologists are not allowed to handle Schedule I and II drugs).

Animal Shelters

Mixing xylazine with ketamine in the same syringe to sedate a pet prior to the administration of sodium pentobarbital for euthanasia – and to avoid an additional injection. (It is unclear whether a Certified Euthanasia Technician could access and administer such a compounded preparation if it were considered to be a Schedule I drug).

It is critical that compounding, as noted in the examples above, is allowed under the revised rule and not considered to be a Schedule I drug. Otherwise, the rule would hamper veterinarians as to how best to treat their patients and to protect themselves and others and could lead to unnecessary animal suffering.

Xylazine Compounded from a Bulk Drug Substance

On occasion, there also is a need in veterinary medicine for xylazine to be compounded in a more concentrated dose or in combination with another drug, using a bulk drug substance (BDS). While

animal drugs compounded from a BDS are not FDA-approved, there is allowance for this to occur. According to the FDA's Guidance for Industry #256: Compounding Animal Drugs from Bulk Drug Substances:

- Compounding from bulk drug substances is limited to "when a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal."

Although this is a less common practice for the compounding of xylazine, such allowance is vital when there is a need, yet OBOP's proposed rule appears to prohibit this.

Why is this a concern? At the end of 2022, there were three manufacturers of the FDA-approved product for the U.S. market. However, Akorn Pharmaceuticals closed its business in late February, and Bimeda Animal Health has paused production until there is more regulatory clarity and certainty about xylazine. Only Dechra is currently manufacturing xylazine. The availability of 20 mg/ml xylazine has been affected by the current situation with xylazine. Should there be any additional interruption with the production of this important drug, the compounding of xylazine from a BDS could become necessary for veterinarians.

OVMA Recommendation
We strongly encourage OBOP to amend its proposed rule to exempt any FDA-approved product, or compounded product by a licensed pharmacist or veterinarian in order to maintain the ability for veterinarians to provide necessary sedation and analgesia to animal patients. This would be in alignment with H.R. 1839 and S. 993, the Combatting Illicit Xylazine Act, which are under consideration by Congress and does not schedule "the manufacturing, importation, or use of a xylazine bulk chemical for pharmaceutical compounding by licensed pharmacists or veterinarians."

Revising the proposed rule to allow for the compounding and use of such preparations in veterinary medicine would clearly establish that veterinarians, wildlife biologists, and Certified Euthanasia Technicians could continue using xylazine, as needed, and, as they have been, without interruption and unnecessary limitations.

Thank you for the opportunity to comment on OAR 855-080-0021. If we can help answer questions that you might have about the need for xylazine in veterinary medicine and its clinical applications, please do not hesitate to contact us.

We appreciate your consideration.

Sincerely,

Glenn

Glenn M. Kolb
Executive Director

From: Glenn Kolb
To: PHARMACY RULEMAKING * BOP
Cc: glenn.kolb@oregonvma.org
Subject: Public Comments: OAR 855-080-0021 Scheduling Xylazine
Date: Friday, July 14, 2023 4:05:23 PM
Attachments: Xylazine OVMA Letter on OBOP Rule.pdf

To whom it may concern,

Attached is our comments with regard to the Oregon Board of Pharmacy's proposed rule on scheduling xylazine. Thank you for the opportunity to share our comments.

Sincerely,

Glenn

Glenn M. Kolb, Executive Director

Oregon Veterinary Medical Association
1880 Lancaster Dr. NE, #118
Salem, OR 97305
800-235-3502
www.oregonvma.org / glenn.kolb@oregonvma.org

OREGON VETERINARY
medical association

July 19, 2023

Rachel Melvin, Rules Coordinator
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Addendum: Comments on OAR 855—080-0021 / Scheduling Xylazine

Dear Ms. Melvin and the Oregon Board of Pharmacy:

We would like to submit a few additional comments to our earlier letter regarding the classification of xylazine as a Schedule I drug in Oregon.

The proposed rule amends Oregon's list of Schedule I drugs by adding "Xylazine, unless in the form of a FDA-approved product."

In veterinary medicine, this essential drug is administered mostly as a sedative and/or analgesic either as a stand-alone medication for short and moderate-length procedures, or in combination with other anesthetics. While it is clear that any use of an FDA-approved stand-alone injectable drug would be exempt from being scheduled, we are uncertain as to whether the exemption would also apply to any compounded form of the injectable xylazine.

When compounded, xylazine no longer is an FDA-approved product, although compounded preparations by pharmacists and veterinarians are permitted under the Food, Drug and Cosmetic Act, when the source of the active ingredient is a finished FDA-approved drug, and not a bulk drug substance (BDS).

Veterinarians need the following clarifications:

1. If adopted as written, does the rule prohibit pharmacists and veterinarians from compounding xylazine to treat animal patients? Our concern is that if this particular drug no longer is allowed to be compounded, animals will suffer poorer health outcomes and the safety of any handler of the patient, including veterinarians, will be at risk.

2. If pharmacists and veterinarians are allowed to compound an FDA-approved xylazine product, will this be considered a Schedule I drug or will it not be scheduled? This is important because if

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oregonvma.org | contact@oregonvma.org

the compounded preparation is viewed as a Schedule I drug, veterinarians do not have allowance in their DEA Registration to handle and access such drugs.

3. On occasion there is a need for xylazine to be compounded from a BDS. This is allowed under the FDA's *Guidance for Industry #256: Compounding Animal Drugs from Bulk Drug Substances.* Would this be permitted under the proposed rule?

As you can understand, there are some specific needs – and many complexities – veterinarians encounter with their animal patients that differ from what their counterparts in human medicine experience with their patients. We want to best assure veterinarians that they can continue to have access to and use xylazine – either the FDA-approved product or a compounded preparation – to effectively treat their patients, when necessary.

Thank you for your time and consideration.

Sincerely,

Glenn

Glenn M. Kolb
Executive Director

June 9, 2022

Rachel Melvin
Rule Coordinator
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
EMAIL: pharmacy.rulemaking@bop.oregon.gov

SUBMITTED VIA EMAIL

Re: Proposed Rule – Division 115 for Pharmacists

On behalf of Pharmaceutical Care Management Association ("PCMA"), I write to respond to the Oregon Board of Pharmacy's ("Board") Notice of Proposed Rulemaking regarding a proposed rule that would create a new Division 115 for pharmacists. Of the proposed rules, PCMA's greatest concern is the requirement for an Oregon-licensed pharmacist to provide counseling prior to shipment.

PCMA is the national trade association representing pharmacy benefit managers ("PBMs"). PCMA's PBM member companies administer drug benefits for more than 275 million Americans, including 3.6 million Oregonians, who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries.

As set-forth in detail below, PCMA is concerned that the Board will adopt rules that will deny Oregon residents timely access to medicine by adding barriers to the delivery of necessary prescriptions.

Specifically, our concerns include:

- The requirement for proactive patient outreach prior to shipping and following shipping if patient contact is not made prior to shipping are both new processes not currently in place that will have to be created by OR state-licensed non-resident pharmacies shipping medicines into OR. This will require financial and personnel resources to create these systems.

- We support and have systems in place to ensure all patients receiving medicines via mail from non-resident licensed pharmacies have access to pharmacists for counseling needs. Currently mail service pharmacies have toll free telephone numbers with 24/7 access to pharmacists for any questions they may have. This 24/7 access is a clear distinction of our commitment to ensuring patients have access to pharmacists whenever they have a question and exceeds what community and retail pharmacies provide.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

- The foundation of our concern with the proposed rule is not that we oppose or do not support patient access to pharmacists, rather we are concerned these rules could delay shipment of needed medicines to patients who have either submitted their prescriptions to mail service pharmacies or have asked their providers to submit their prescriptions to a mail service pharmacy. It is important to understand mail service pharmacies are just like all other pharmacies in that we do not fill or ship anything without a prescription received from either the patient or their provider.

- Our stance is this 24/7 access meets the needs of patients and ensures there is access to pharmacists for any questions that may arise while not placing an unnecessary consent requirement that will result in delays in therapy and negative patient outcomes.

- During and following the pandemic, the public's use of mail-delivery of many goods and services shifted out of need. This reliance on mail delivery of goods and services has continued post-pandemic as the public became more familiar with this type of service.

- We support the need for patient access to pharmacists for medication questions and feel the systems already in place meet these needs and, in fact, exceed what is provided in other pharmacy practice settings.

- The Board has a long history of recognizing various pharmacy practice settings and setting rules that meet the objectives of the Board (in this case ensuring patient access to a pharmacist) while recognizing the differences that exist in various pharmacy practice settings such as hospital, long term care, mail service, etc. We ask that the Board continue this practice by acknowledging that current 24/7 access to pharmacists meets the requirement to have access to a pharmacist for counseling about any medicines received via mail.

Again, we appreciate the opportunity to provide comments on behalf of our member companies regarding the Board's proposed rules. We look forward to continuing the discussion.

Please feel free to contact either myself or Tonia Sorrell-Neal, PCMA's Senior Director of State Affairs (tsorrell-neal@pcmanet.org), with any questions or for further discussion.

Sincerely,

Peter Fjelstad

Peter Fjelstad
Director, State Regulatory & Legal Affairs

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

From:	Tonia Sorrell-Neal
To:	PHARMACY RULEMAKING * BOP
Subject:	Comment for OR BOP proposed Rule
Date:	Wednesday, July 12, 2023 11:37:23 AM
Attachments:	06.09.23 - Final - PCMA letter to OR BoP - proposed rules.pdf

I am attaching our written comments for your consideration as you move toward the July 26th meeting regarding the proposed rule for Division 115 on pharmacists. Please let me know if you have any questions.

Thank you.

Tonia

Tonia Sorrell-Neal | PCMA | *Senior Director, State Affairs* | O:202.756.5709 | M:202.993.5323
325 7th Street NW, 9th Floor, Washington, DC 20004
Tsorrell-Neal@pcmanet.org

Postal Prescription Services
3500 SE 26th Ave.
Portland, OR 97202

OR Pharmacy License # RP0002910

July 26, 2023

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

State of Oregon Board of Pharmacy to whom it may concern,

In response to the State of Oregon Board of Pharmacy request for comments on proposed Rule changes under Division 115 related to Pharmacists, Postal Prescription Services (PPS) submits the following.

Postal Prescription Services has been in operation since 2000 and under the current Oregon Pharmacy Rules has achieved incredible results related to patient care including accuracy, accessibility, and adherence. We respectfully request that current OR pharmacy regulations related to patient counseling remain unchanged.

We submit the following *comments* regarding the proposed Rule changes.

A) Definitions:

855-115-0005
Definitions

(1) "Counseling" or "Counsel" means an interactive communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

Recommend this change not be adopted or clarified and reopened for public comment.

Clarify definition of "interactive consultation". For Mail Order Pharmacies, if this is defined as live interaction, this will create significant delays in therapy for patients, confusion when product delivery and counseling not synchronized, and significant labor and technology expense.

If adopted, we recommend that "interactive consultation" definition be clarified and include written product and administration information with access to contact a pharmacist with questions as a qualified option. Also, confirmation this Rule is satisfied when a pharmacist determines that written product and administration information with the option to contact a pharmacist with questions is "reasonable and necessary" as referenced in (855-115-0145 Counseling (1)).

> 855-115-0145 Counseling (1): For each prescription, the pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(4) For a prescription delivered outside of a Drug Outlet Pharmacy to a patient for self-administration, the pharmacist must:
(a) Attempt to provide counseling prior to delivery as required in (1) and (2);
(b) Reattempt to provide counseling by end of the next business day if counseling does not occur prior to delivery to the patient; and

Recommend this change not be adopted or clarified and reopened for public comment.

Dependent on clarification of (855-115-0005 Definitions (1)).

If "interactive consultation" is defined as live interaction via telephone call, this will create significant delays in therapy for patients, confusion when product delivery and counseling not synchronized, and significant labor and technology expense.

Clarification that email, automated telephone messaging, and/or text messaging requesting a patient response if they have questions about their prescription order qualifies as an attempt to provide counseling.

It will be overly burdensome both technologically and financially to determine the exact date of delivery for all prescription orders and time calls accordingly, further confusing patients.

(7) The pharmacist that attempts counseling, provides counseling or accepts the request not to be counseled must document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction.

Recommend this change not be adopted.

This documentation will require significant pharmacy management system enhancement expense that put unequal financial burden on mail order and specialty pharmacy practice settings.

B) Applicability:

855-115-0001
Applicability

(1) This Division applies to any Pharmacist who engages in the practice of pharmacy.
(2) Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance with statutes and rules unless exempt under ORS 689.225.
(3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a Pharmacist located in another state who is working for an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with the out-of-state pharmacy dispensing of a drug into Oregon, is not required to be licensed by the board.

Recommend this change not be adopted or clarified and reopened for public comment.

Clarification. Would the consultation Rule change apply to out-of-state mail order pharmacies when servicing OR residents? If so, how will the OR Board of Pharmacy enforce? If the consultation Rule change applies to out-of-state pharmacies, and it is not enforced, this puts Oregon based pharmacies at a competitive disadvantage.

Clarification. Would the consultation Rule change apply to OR based mail order pharmacies when servicing patients residing in states other than OR? If so, this puts Oregon based pharmacies at a competitive disadvantage.

C) Fiscal and Economic Impact:

Postal Prescription Services estimates the cost to comply with this Rule change is closer to the high end of the range provided in the summarized Fiscal and Economic Impact results collected by the Board.

Dependent on clarification of (855-115-0005 Definitions (1)).

Mandatory telephone consultation attempts for new prescriptions by mail order pharmacies will require significant investment in pharmacist labor and technology enhancements. The economic hardships this Rule change would create will increase cost for patients, drive in-state pharmacies to consider relocation, and out of state pharmacies to consider elimination of service for OR residents.

Rule changes that would mandate live consultation will create an unequal burden on mail order pharmacy (and Specialty) practice settings, will cause confusion and delays with patient therapy, will be difficult for the Board to enforce for out-of-state pharmacies, and will increase healthcare cost.

Postal Prescription Services appreciates to opportunity to provide comment on these proposed Rule changes and look forward to our continued partnership with the OR Board of Pharmacy. Please contact me if there are any questions regarding the comments provided.

Sincerely,

Camille Tackett

Camille Tackett Pharm.D, RPh.
Pharmacy Manager
Postal Prescription Services
3500 SE 26th Ave.
Portland, OR 97202
503-797-2156
Camille.tackett@ppsrx.com

From:	Tackett, Camille M
To:	PHARMACY RULEMAKING * BOP
Cc:	Scott, Jeff; Anderson, Justin
Subject:	July 26, 2023 Rulemaking Hearing Written Comments from Postal Prescription Services
Date:	Wednesday, July 26, 2023 11:46:55 AM
Attachments:	Rulemaking Hearing Comments from PPS July 26, 2023.pdf

Please see attached written comment from Postal Prescription Services for the July 26th rulemaking hearing.

Camille Tackett, Pharm.D, RPh
Portland Central Fill Pharmacy manager
Postal Prescription Services
503-797-2156
Camille.tackett@ppsrx.com

July 26, 2023

Joseph Schnabel, PharmD, RPh
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Amendments to Division 115 Pharmacists

Dear Executive Director Schnabel,

On behalf of Ro, we appreciate the opportunity to comment on the Board of Pharmacy's Notice of Proposed Rulemaking regarding Division 115: Pharmacists, specifically the proposed rules on Counseling 855-115-0145.

Ro is a patient-driven digital health company that puts patients in control of their health. With our provider network, diagnostics and a network of mail order pharmacies, Ro provides high-quality, affordable healthcare to Oregon patients without the need for insurance. Ro currently owns seven pharmacies (Roman Health Pharmacy LLC, "RHP") that can serve Oregon-based patients through mail-order fulfillment. Ro's custom-built EMR and pharmacy management software enables pharmacists and pharmacy technicians to interact directly with doctors, nurses and customer service teams to provide coordinated care.

Ro appreciates the Board's ongoing work to review the counseling requirements, and we share the Board's goal to ensure patients receive appropriate counseling "to promote safe and effective use or administration of [a] drug or device, and to facilitate an appropriate therapeutic outcome." Indeed, in compliance with current rules,[1] RHP's pharmacy team provides all Oregon patients a written offer to counsel, which gives patients the option to call a toll-free telephone number (from 9AM to 8PM EST, Mon thru Fri; 8AM to 2PM EST on Sat) to receive counseling; conducts such counseling upon patient request; provides drug information and pharmacy contact information; and reaches out to patients if needed according to RHP's pharmacists judgment.

Ro has significant concerns how the proposed rules would upend Oregon's existing framework and instead prescriptively mandate that pharmacists now attempt "interactive" outreach to counsel a patient (at least twice) when a prescription is delivered to a patient and document each such attempt. First, these proposed rules undermine the Board's stated intent for pharmacists to "determine the manner and amount of counseling that is reasonable and necessary under the circumstance." Second, Ro echoes many other stakeholders in

[1] OAR 855-019-0230(1)(e): "For a prescription delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist[.]"

highlighting there has been no evidence or data to indicate the current counseling rules jeopardize Oregon patients' safety in the mail-order setting or to warrant the substantial costs and resources that will be required to implement these proposed changes.

Third, the proposed rules disregard many Oregon patients' expectations of how they prefer to engage with healthcare providers and thus are unlikely to result in improved patient outcomes. For example, Oregon patients using Ro's mail-order pharmacy services to fulfill medications prescribed through Ro's telemedicine platform are always *electing* to do so. Patients engage with Ro because our platform conveniently allows them to initiate care and follow-up with their provider team at times of their choosing through an asynchronous online interview and secure messaging tools.[2] Ro's model is preferred by patients and providers because it removes the burdens of scheduling all parties to be available at a specific time and reduces the shame that some patients experience when discussing their conditions live.

To the extent the new rules would require Ro-affiliated pharmacists – and pharmacists alone– to conduct and document phone calls to every patient, regardless of their individual circumstances, the rules would yield negligible patient engagement. The rules would, however, impose substantial costs in terms of diverting pharmacists' limited time away from other critical care activities and financial resources that ultimately may be impossible for RHP (and other pharmacies) to undertake.

We appreciate that the Board seeks to bring consistent standards to different pharmacy care settings and ensure that certain information is always communicated to Oregon patients. Ro believes the Board's intent can still be met without prohibiting modalities–such as written communication–that might be more appropriate in reaching patients in these varied care settings and will not require such upheaval to existing pharmacy operations. Towards that end, Ro respectfully requests the Board maintain the current requirements for mail-order counseling in OAR 855-019-0230(1)(e) or, at a minimum, make the following changes:

855-115-0005 Definitions

(1) "Counseling" or "Counsel" means an interactive communication, including through asynchronous written communication, between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

855-115-0145 Counseling

(2) The pharmacist must counsel or attempt to counsel the patient or patient's agent on the use of a drug or device:¶

[2] Oregon law specifically contemplates the use of asynchronous telehealth. Governor Brown signed HB 4034 into law in 2022, which made clear that telemedicine means the provision of health care services to a patient from a distance using synchronous ("real time") or asynchronous (non-real time) technologies.

(a) Upon request;
(b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;
(c) When there has been a change in the dose, formulation, or directions;
(d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or
(e) For any refill that the pharmacist deems counseling is necessary.

***

(5) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation or does not respond to an attempt to counsel. If refused,

(a) Only a pharmacist can accept a patient's or patient's agent's request not to be counseled, when counseling is required.
(b) The pharmacist may choose not to release the prescription until counseling has been completed.

***

(7) ~~The pharmacist that~~ Attempts to counsel~~ing~~, ~~provides~~ counseling, or a ~~accepts the a~~ request not to be counseled must be documented ~~their identity, each attempt to counsel and the outcome at the time of the attempt or interaction~~.

Ro thanks the Board for the opportunity to provide feedback on these proposed rules. We would happily participate in ongoing discussions as appropriate and as needed to assist the Board.

Thank you,

Ruey Ju, PharmD, JD
Director, Assistant General Counsel
Roman Health

From: Ruey Ju
To: PHARMACY RULEMAKING * BOP
Subject: Ro Comment on NOPM Division 115
Date: Tuesday, July 25, 2023 3:39:14 PM
Attachments: Ro Comments on NOPM Division 115.pdf
Ro Comments on NOPM Division 115.pdf

> You don't often get email from ruey.ju@ro.co. Learn why this is important

Hello Ms. Melvin-

Please see the attached comment from Ro on the NOPM for Division 115.

Thank you,
Ruey

--

Ruey Ju | He/him
Director, Assistant General Counsel | Ro

From: Sage Country Veterinary Service
To: PHARMACY RULEMAKING * BOP
Subject: xylazine
Date: Thursday, July 20, 2023 2:08:11 PM

Dear Pharmacy Board -

I'm a mixed animal veterinarian in rural Eastern Oregon. I'm writing in regards to the current rule proposal regarding compounding xylazine. From my understanding the xylazine that is a concern with illicit drug use is a different form compared to the xylazine I use in daily practice. I understand that the current proposed rule is to control the compounding of xylazine. However in the simplest terms I "compound xylazine" on a daily basis.

We use xylazine on a daily basis to sedate large animals for our safety and for the animals safety. Its common practice to mix xylazine with butorphanol when sedating large animals. Its impractical and at times unsafe to IV stick a horse twice (sometimes getting it done once is difficult enough) to get the same effect as safe mixture of the drugs. We also use xylazine in IV fluids bags to be used for prolonged procedures where a horse can have a standing level of sedation or maintenance under general anesthesia without the risk of a horse violently waking up in the middle of a surgery. We used xylazine in combination in darts to help sedate cattle that are injured, injured cattle are defensive and can become dangerous to handle to themselves and people. There is no practical alternative to xylazine when we are talking about cattle sedatives.

For the small animal side of my practice we often use xylazine prior to euthanasia and especially for aggressive animals prior to euthanasia. There are other options but the consistency of effect and the way it doesn't cause cardiac collapse in small animals makes it a good premedication for these situations. We even use it as an emetic drug because the emetic drugs are no longer available unless compounded.

Lastly there is only one manufacturer of xylazine, this means at times we are required to used compounded injectable xylazine to do our jobs safely as there are times when the medication in on backorder and compounded drug is the only option.

I'm not very eloquent with my words, but I know the use of xylazine is literally a life and death safety issue for veterinarians and their staff and I agree with the OVMA strongly encouraging OBOP to amend the proposed rule to exempt any FDA-approved product, or compounded product by a licensed pharmacist or veterinarian in order to maintain the ability for veterinarians to provide necessary sedation and analgesia to their patients.

Thank you for you time.
--
Katy Wallace MS DVM
Sage Country Veterinary Service
Burns, OR
541-589-1836
sagecountryvetservice@gmail.com

From: John Shavel
To: PHARMACY RULEMAKING * BOP
Subject: Rulemaking Hearing Written Comment - Rule 855-183-0050
Date: Tuesday, July 25, 2023 1:36:38 PM
Attachments: image001.png

> You don't often get email from john.shavel@saintalphonsus.org. Learn why this is important

Hello,

Could you clarify rule 855-183-0050(4) and 855-183-0050(5)(a). I cannot find anything in USP 797 to suggest that the designated person is required to be a pharmacist.

Per section 1.1.3 in USP 797, there can be more than one designated person. Are all designated persons required to be pharmacists, or is it a minimum of one of the designated persons in each facility must be a pharmacist?

Thanks,

John Shavel | CPhT
Pharmacy USP Specialist
Saint Alphonsus Health System
1055 N. Curtis Rd., Boise, ID 83706
Phone: 208-367-8894
John.Shavel@saintalphonsus.org

From: Kathleen Hanifen
To: PHARMACY RULEMAKING * BOP
Cc: Kathleen Hanifen
Subject: veterinary use of xylazine
Date: Tuesday, July 18, 2023 1:55:29 PM

I would like to provide some input for consideration for the use of xylazine in veterinary medicine. I own a mixed animal practice treating horses, dogs and cats. I use xylazine for all of my patients. While there are other sedation options for dogs and cats, there are very limited alternatives for my equine patients. In addition, alternative sedation options I could use for all my patients are far more expensive and would drive up the costs for my clients. Xylazine is a safe, reliable, predictable and cost effective drug that is critical to my practice.

Maintaining the ability to have xylazine compounded for my small animal patients is also very important. At this time 20mg/ml xylazine is not available from any source. I need to be able to obtain 20mg/ml xylazine from a professional source to provide my patients with the best care possible.

Veterinary xylazine is not the problem. Please don't limit my ability to care for my patients.

Sincerely,

Kathleen E. Hanifen, DVM
Salem Park Veterinary Clinic
503-588-1151

"Life is not a journey to the pearly gates with the intention of arriving safely in a pretty and well preserved body, but rather to skid in broadside, reins in one hand, saddle in the other; thoroughly used up, totally worn out and loudly proclaim: "Wow! What a ride!!"."

From: Jennifer Tripp
To: PHARMACY RULEMAKING * BOP
Subject: Compounding rules comment
Date: Wednesday, July 26, 2023 2:13:00 PM

I appreciate the opportunity to provide comment on the following rule proposals/changes.

RULE SUMMARY: Proposed rule revises and relocates existing rule OAR 855-045-0240 to OAR 855-183-0410 related to labeling requirements for compounded sterile preparations. CHANGES TO RULE: 855-183-0410 Labeling: Compounded Sterile Preparations (CSPs) In addition to the labeling requirements specified in USP (11/01/2022), OAR 855-041, and 855-139, the label of a compounded preparation must also prominently and legibly contain the following, at a minimum:¶ (1) The strength of each active ingredient, to include the base solution for a sterile parenteral preparation;¶ (2) The route of administration;¶ (3) Rate of infusion or titration parameters, for a sterile parenteral preparation;¶ (4) Indication that the preparation is compounded.¶ (5) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.¶ (6) Compounding facility name, and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded.¶ [Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.] Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.155

COMMENT: (3) rates change frequently, and printed labels could quickly be out of date in a hospital setting. Would advocate to not require rate be printed on label and use the MAR as the most accurate source of truth for rate. (4) hospital compound products are obvious, please clarify how hospitals would meet this requirement outside of it is a hospital applied label.

Thank you,

Jennifer Tripp, Pharm.D.
Director of Pharmacy
541-706-7723 (Office) | 770-861-5385 (Cell)
jntripp@stcharleshealthcare.org
St. Charles Health System | 2500 NE Neff Road | Bend, OR 97701 | www.stcharleshealthcare.org

From: Jennifer Tripp
To: PHARMACY RULEMAKING * BOP
Subject: June 26th hearing
Date: Wednesday, July 26, 2023 12:06:50 PM

I appreciate the opportunity to provide comment on the following rule proposals/changes.

855-115-0200 Pharmacist-in-Charge: Qualifications and Limitations Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:¶ (1) Complete a board-provided PIC training course as described below:¶ (a) A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90-days after appointment.¶ (b) A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to the appointment.¶ (2) Complete a board-provided PIC training course at least every five years. Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.151, ORS 689.155

Comment: If the 5 year rule is adopted , I ask the Board to consider online and virtual options for participation to not increase the burden on PICs in rural parts of the state.

855-125-0150 Prohibited Practices Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:¶ (1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0105(4), including but not limited to the following tasks: ¶ (a) Evaluate and interpret a prescription;¶ (b) Conduct a Drug Utilization Review or Drug Regimen Review;¶ (c) Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription; ¶ (d) Counsel a patient or the patient's agent regarding a prescription; ¶ (e) Accept a patient or patient's agent's request to decline counseling; ¶ (f) Advise on therapeutic values, content, hazards and use of drugs and devices;¶ (g) Interpret the clinical data in a patient record system or patient chart;¶ (h) Conduct Medication Therapy Management;¶ (i) Practice pursuant to a Clinical Pharmacy Agreement or Collaborative Drug Therapy Management; ¶ (j) Practice pursuant to Statewide Drug Therapy Management Protocols;¶ (k) Prescribe a vaccine, drug or device;¶ (l) Administer a vaccine, drug or device;¶ (m) Order, interpret or monitor a laboratory test; ¶ (n) Receive or provide a new or transferred prescription orally;¶ (o) Supervise, direct, or control another licensee in the licensee practicing or assisting in the practice of pharmacy; ¶ (p) Delegate tasks to healthcare providers; and ¶ (q) Deny the patient or the patient's agent request to speak to the Pharmacist.¶ (2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.¶ (3) Perform any task while assisting in the practice of pharmacy that requires judgment unless it is verified by a Pharmacist.¶ (4) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace.¶ (5) Refuse a request from a patient, patient's agent, or practitioner to interact with a Pharmacist. Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.155, ORS 689.22

Comment: Ask the board to add clarifying language to state that “consult with” does not include communication with the listed parties in order to collect historical and current information relevant to the pharmacy technician preforming medication history duties. Pharmacy driven medication history programs are vital to patient safety in the hospital setting. Pharmacy technicians under the supervision of a pharmacist are the ideally positioned to accurately collect medication histories.

Thank you for considering these comments,

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July 20th, 2023

Oregon State Board of Pharmacy
Attention: Joe Schnabel, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232

Via Email: joseph.schnabel@oregon.gov

RE: Division 041 - Compounding

Dear Dr. Schnabel and Board Members,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in Oregon, we thank the Board for the opportunity to comment on the proposed rules regarding Division 041, Compounding. We thank the board for the continued discussion of these rules with the compounding workgroup. We feel the discussions held on 7/18/2023 are moving these rules in an appropriate direction that will continue the board's mission without impacting patient access. We encourage the board to continue to allow this workgroup to meet and continue discussions which include our concerns below.

As the Board contemplates the upcoming change to the USP guidance in Chapter 795, we encourage the Board to consider the minimum changes needed to ensure patient safety while maintaining access to compounded services for Oregonians. As drafted, this version of the regulations is more stringent than the USP guidance, which will already be extremely costly and challenging for community pharmacies to comply with.

As discussed at the NABP 119th Annual Meeting this May, the USP guidance regarding adding flavoring agents is not a new opinion of the USP expert committee. Nor is this opinion explicated stated as a portion of the published USP 795 chapter; instead, the guidance is memorialized as a "FAQ" to the chapter. As proposed in OAR 855-183-0005, the definition of compounding would include adding flavoring agents. While on the surface, this would seem to be a minimal concern, however, the inclusion of flavoring in the definition would devastate access to this service in Oregon. For example, a parent presenting a prescription for clindamycin suspension for their child on a Saturday evening at their community pharmacy, if flavoring is considered compounding, the Pharmacist would need to contact the prescriber for authorization before dispensing the prescription simply for the addition of flavoring to improve adherence with the product. If the Pharmacist cannot reach the prescriber, what options remain for the parent; delay therapy or add products at home? Neither option is as safe as the Pharmacist providing the service to the patient's parent upon dispensing. We would encourage the Board to consider modifying the proposed definition to exclude certain products, like flavoring agents, from being considered compounding. Most states have adopted regulations or guidance to exempt these products. Below are two approaches to address this concern that we would suggest.

Mississippi: TITLE 30: PROFESSIONS AND OCCUPATIONS PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS ARTICLE XXXI COMPOUNDING GUIDELINES

> *For the purpose of this Article, the combining of commercially manufactured, ready[1]to-use products shall be exempt from USP 795 compounding standards under the following conditions:*
>
> a. *i. No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used;*
> b. *ii. Compounding is not done in anticipation of medication orders;*
> c. *iii. Must follow USP 795 beyond use dates (BUDs);*
> d. *iv. A valid prescription shall serve as the compounding record;*

Iowa*: 657.20.13*

a. *"Compounding" means the combining, mixing, diluting, pooling, flavoring, or otherwise altering of a drug or bulk drug substance to create a drug. Compounding includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription products. Compounding does not include the use of a flavoring agent to flavor a drug pursuant to rule 657—20.13(124,126,155A), nor does it include mixing or reconstituting a drug according to the product's manufacturer label.*

b. *"Flavoring agent" means a therapeutically inert, nonallergenic substance consisting of inactive ingredients that is added to a drug to improve the drug's taste and palatability.*

When reviewing the personnel requirements proposed in 855-183-0050, several requirements are more stringent than USP, 855-183-0050(4), and 855-183-0050(5)(a)(A). Specifically, USP does not require that a designated person must be a pharmacist. We request that the Board strike both provisions as indicated below to align with the requirements in USP 795. Additionally, we would ask that the Board add a qualifier statement, "when compounding activities are occurring," to 855-183-0050(5)(B)(b). For most pharmacies that compound, compounding is not occurring all the time, and USP 795 4.1 states, *"Other activities must not be occurring in the compounding area **at the same time** as compounding."*

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

Neither proposed OAR 855-183-0205 nor USP 795 include a definition of Automated Compounding Devices (ACDs.) Additionally, OAR 855-183-0205 does not address the type of compounding; sterile vs. non-sterile that it applies to. Based on the absence of such references in USP 795 and their sole inclusion in USP 797, one could assert that this should only apply to sterile compounds. Community pharmacies may use equipment, such as unguators, which may be unintentionally impacted by this regulation as proposed. We request that the board add a definition of Automated Compounding Devices (ACDs) while considering the additional burdens this could place on community pharmacies for devices that were not originally intended by the USP Expert Committee.

When reviewing the proposed requirements for labeling for compounded non-sterile preparations, again, there are requirements in OAR 855-183-0400(1) that are above requirements from USP 795 and do not improve patient safety and would be nearly impossible for pharmacies to comply with. There is no strength of many bases, and it would be impossible to provide the information for all ingredients. We request the following amendment to bring in alignment with USP 795 requirements:

855-183-0400
Labeling: Compounded Non-Sterile Preparations (CNSPs)
In addition to the labeling requirements specified in USP <795> (11/01/2022), OAR 855-041, and 855-139, the label of

a compounded preparation must also prominently and legibly contain the following, at a minimum:
(1) The strength of each active ingredient~~, to include the base;~~

When reviewing the proposed regulation in OAR 855-183-0500 regarding policies and procedures, the requirement for a Oregon licensed Pharmacist to approve master formulation records is an extra burden that does not contribute to additional patient safety. Many pharmacies utilize services, including Professional Compounding Centers of America (PCCA) that provide master formulations or use other centralized and highly trained pharmacist to provide these formulations. This requirement, as proposed, is too restrictive and should be eliminated to enhance patient safety and reduce the workload for the pharmacists in the in-state Oregon pharmacy. We respectfully request the following amendment:

855-183-0500
Policies & Procedures
Each Drug Outlet Pharmacy, DPDO and CHC must establish, maintain and enforce written policies and procedures in accordance with the standards required in OAR 855-183-0200 for all aspects of the compounding operation according to the type of compounding performed (e.g., CNSP, CSP Type 1, 2 or 3) and must include written procedures for:
(1) Personnel qualifications, to include training and ongoing competency assessment;
(2) Hand hygiene;
(3) Garbing;
(4) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling and viable particles;
(5) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;
(6) Components, to include selection, receipt, handling, and storage and disposal;
~~(7) Creating master formulation records, with documented approval by a Pharmacist for a Drug Outlet Pharmacy or prescriber with prescribing and dispensing privileges for a DPDO or CHC;~~

The proposed requirements in OAR 855-183-0520 Recalls are far too burdensome for pharmacies to comply with and are more extensive than the intent of USP 795. Adoption of this regulation as proposed would add significant administrative burdens to comply and may force some pharmacies to further limit access to compounded services for patients in Oregon. It is reasonable to notify the patient within 72 hours of a recall that may cause serious adverse health consequences or death, but the additional specificity of this rule provides significant operational concerns. Recalls of traditionally dispensed products do not include such stringent requirements. Adoption of this regulation as proposed would add significant administrative burdens to comply and may force some pharmacies to further limit access to compounded services for patients in Oregon. We respectfully request that the board consider the amendments below.

855-183-0520 Recalls
(1) Each Drug Outlet Pharmacy, DPDO and CHC that issues a recall regarding a compounded drug must, in addition to any other duties, contact each recipient pharmacy and patient of the recalled drug as soon as possible within 72 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.~~
~~(e) 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~~

The proposed requirements in OAR 855-183-0600(2) are more restrictive than USP 795, which states that carpeting **should not** be in the compounding area and that the area must be able to be cleaned and sanitized. There are other more reasonable solutions, for example, cleanable mats placed over carpet in the compounding area, that would be deemed in compliance with the intent of USP 795. This requirement is too restrictive and will add unnecessary costs to ensure compliance for pharmacies. We respectfully ask that the Board consider the following amendment.

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

As stated in the previous comments regarding the definition, we request that the Board carefully consider adding a carve-out for adding flavoring agents from the compounding practice. Including flavoring, a well-established safe practice in the regulation will cause patient harm by effectively eliminating this practice in the state.

855-183-0700
Service: Preparation According to FDA Approved Labeling
(1) Compounding does not include the addition of flavoring agents, 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.

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,

Lorri Walmsley, RPh, FAzPA

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July 20th 2023

Oregon State Board of Pharmacy
Attention: Joe Schnabel, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232
Via Email: joseph.schnabel@oregon.gov

RE: Division 102 – Board Administration

Dear Dr. Schnabel and members of the Oregon Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. Licensed in the State of Oregon, we thank the Board for the opportunity to comment on the proposed rules. The interactive process of engaging with the public is critical in the rulemaking process to ensure there are no unintended consequences for the public.

Walgreens respectfully requests the board to review the comments, suggested edits and discuss the proposed changes indicated below.

Walgreens appreciates the boards efforts in providing flexibility for the Compliance Directors and Officers to allow appropriate deadline extensions, however this rule change does not provide transparency or uniformity for the process of how these exceptions will be addressed. Without clear expectations or a definition of what is 'appropriate', stakeholders are left guessing as to how they will ensure compliance and are unable to validate if their requests are addressed in a consistent manner and managed in a timely fashion. Walgreens requests the board to strike 855-102-0055(2) and discuss alternative ways to provide the needed flexibility in deadline setting for the Compliance Directors and Officers.

855-102-0055: Board Compliance Director and Officers

The board's Compliance Director and Compliance Officers:

1) Must be Pharmacists licensed in the State of Oregon; and
~~2) Are authorized to provide appropriate deadline extensions~~

Sincerely,

Lorri Walmsley

Lorri Walmsley, RPh, FAzPA

From:	Walmsley, Lorri
To:	PHARMACY RULEMAKING * BOP
Cc:	SCHNABEL Joseph * BOP
Subject:	Walgreens Comments for July 26, 2023 Proposed Rulemaking
Date:	Thursday, July 20, 2023 6:10:04 PM
Attachments:	OR Comment Letter DIV 115 Pharmacist.pdf OR Comment Letter DIV 120 Interns and Preceptors.pdf OR Comment Letter Div 104 Universal Rules.pdf OR Comment Letter Div 102 Board Administration.pdf OR Comment Letter DIV 041 Compounding.pdf

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Hello,

Please accept the attached comments on behalf of Walgreens for the July 26th proposed rulemaking.

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs

Walgreen Co.
Telephone 602-214-6618

Member of Walgreens Boots Alliance ¦ MyWalgreens.com

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July 20th, 2023

Oregon State Board of Pharmacy
Attention: Joe Schnabel, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232

Via Email: joseph.schnabel@oregon.gov

RE: Division 104– Universal Rules

Dear Dr. Schnabel and members of the Oregon Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of Oregon, we thank the Board for the opportunity to comment on the proposed rules. The interactive process of engaging with the public is critical in the rulemaking process to ensure there are no unintended consequences for the public. Walgreens respectfully requests the board to review the comments, suggested edits and have meaningful discussion the proposed changes indicated below.

Walgreens believes that the proposed rules in OAR 855-104-0010 may have significant unintended consequences when suggesting that all licensees must report **any** suspected violation of ORS (Oregon Revised Statute) 475, ORS (Oregon Revised Statute) 689, and OAR (Oregon Administrative Rules) 855. While it is imperative that all licensees take appropriate action when they have knowledge that another licensee has committed a prohibited or unprofessional act, the language suggests that licensees should report to the board any violations without good faith proof. Further the inclusion of any suspected violations of **all** Oregon Board Rules and Statues is excessive. For example, if a technician types a prescription incorrectly or puts the incorrect tablet in a bottle and it is caught and corrected by the pharmacist before dispensing, is this a suspected violation? The previous language in OAR 855-019-0205(4) was sufficient to ensure appropriate reporting of violations and support the board's mission to promote and protect public health, safety, and welfare. Walgreens asks the board to discuss the consequences of including 'any suspected violation' and the impact on the board's staff's ability to investigate and address actual violations and significant risks to patient safety.

855-104-0010
Responsibilities: Duty to Report

1. Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each licensee must report to the board without undue delay, but within
   a. 10 days if they:
      A. Are convicted of a misdemeanor or a felony; or
      B. Are arrested for a felony; or
      C. Have reasonable cause to believe that another licensee of the Board of Pharmacy has engaged in prohibited or unprofessional conduct as defined in OAR 855-006-0020. ~~any suspected violation of ORS 475, ORS 689 or OAR 855 has occurred.~~

Regarding OAR 855-104-1115, while Walgreens and its team members will make every effort to comply with a Compliance Officer's request, we believe that our team members and our patients also have rights to be considered as well. Licensees should have the right to consult with legal counsel before providing written or verbal statements at the time of inspection. Additionally, the recording of audio and or video may unintentionally contain HIPAA-protected information that does not pertain to the investigation/inspection and may compromise patient confidentiality. The board can improve working conditions in all pharmacy settings by working cooperatively with the Pharmacist-in-Charge to schedule routine inspections and allow time to educate the pharmacy staff as well as inspect for compliance at the time of the scheduled inspections. While there is a meaningful purpose to have unannounced inspections and visits by Board Compliance officers, these visits can create unnecessarily stressful situations for team members. We strongly encourage the board to consider scheduling routine biannual inspections in advance. This would improve inspection efficiencies by ensuring sufficient personnel are present and allow for additional educational opportunities to improve safety and compliance.

855-104-0115

Inspections

1. A Compliance Officer is a board authorized representative and must be permitted entry to any drug outlet to conduct inspections at all reasonable hours.
2. The Compliance Officer is authorized and must be permitted to perform the following to determine compliance with ORS 475, ORS 689, and OAR 855 and board orders including but not limited to:
   a. Inspecting conditions, structures, equipment, materials, and methods for compliance;
   b. Inspecting all drugs and devices;
   ~~c. Taking photographs, recording video and audio; and~~
   d. Reviewing, verifying, and making copies of records and documents.
3. All licensees and employees must fully comply and cooperate with all questions and requests made by the Compliance Officer within a reasonably allowed timeframe ~~at the time of inspection.~~
4. ~~Refusal to allow inspection is grounds for discipline.~~

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,

Lorri Walmsley, RPh, FAzPA

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July 20th, 2023
Oregon State Board of Pharmacy
Attention: Joe Schnabel, Executive Director
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Via Email: joseph.schnabel@oregon.gov

RE: Divisions 115 – Pharmacists

Dear Dr. Schnabel and members of the Oregon Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of Oregon, we thank the Board for the opportunity to comment on the proposed rules. The interactive process of engaging with the public is critical in the rulemaking process to ensure there are no unintended consequences for the public. Walgreens respectfully requests the board to review the comments, suggested edits, and discuss the proposed changes indicated below.

Walgreens commends the board for its discussion in its previous meetings regarding 855-115-0001 and for continuing to allow non-resident outlets with non-Oregon licensed pharmacists the ability to provide a patient's consultation. Allowing all licensed pharmacists to provide this service serves three purposes; first, to decrease workload for in-state pharmacies, second to allow for pharmacists with special disease-state specific training and expertise that may not be Oregon-licensed to provide specialized consultation for patients; and third, to allow for Pharmacists located in non-resident outlets that provide prescriptions via home delivery to have the flexibility to enable consultation for patients by any pharmacist that may be available to provide the service. Any potential changes to regulations that may reduce the number of pharmacists that may be able to assist patients in Oregon should be carefully considered.

We respectfully request the board to ensure there is clarity for non-Oregon licensed pharmacists to complete the compounding and final verification of the drug products dispensed to patients in Oregon. The rules as drafted do not specify these allowances. Additionally, the language below is problematic and does not contemplate all models of pharmacy services provided by an out-of-state pharmacy for patients located in Oregon such as remote processing, central fill, and shared services. OAR 855-019-0100(4) previously had sufficient language and ensured every non-resident pharmacy, independent of its ability to dispense drugs into the state of Oregon, had a Pharmacist in Charge that was licensed by the State of Oregon. The proposed rules will limit non-dispensing pharmacies from utilizing non-Oregon licensed pharmacists to perform the professional tasks of interpretation, evaluation, DUR, counseling, and verification. Walgreens requests the board to avoid confusion with the updated and reorganized language from OAR 855-019-0100(4) in the proposed rule OAR 855-115-0001(3) and ensure that non-Oregon licensed pharmacists working in a non-dispensing pharmacy are able to continue to provide services to patients in Oregon. Moving forward with these proposed rules as drafted will increase the workload for in-state pharmacists by removing the ability to utilize out of state support by pharmacists licensed in other jurisdictions working in Oregon licensed non-resident outlets. Walgreens respectfully requests the board to consider the edits suggested below.

855-115-0001
Applicability

1. This Division applies to any Pharmacist who engages in the practice of pharmacy.
2. Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance with statutes and rules unless exempt under ORS 689.225.
3. A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a pharmacist located in another state who is working for an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling, verification associated with the ~~out-of-state pharmacy dispensing of a drug into Oregon~~, dispensing of a drug to a patient in Oregon, is not required to be licensed by the Board unless they are the pharmacist-in-charge (PIC).

Within the noticed changes for definitions, Walgreens has several concerns that we believe may have unintentional consequences of limiting patient access and increasing workload within Oregon-licensed pharmacies. Adding the word 'interactive' to 855-115-0005(1) creates a potential burden for patients who choose to receive medications not at a traditional physical pharmacy site or via home delivery methods. All pharmacies that offer delivery or alternative dispensing options offer some type of verbal communication and counseling for patients, requiring counseling to be completed interactively may delay care since it is not uncommon for patients not to answer their phones. Walgreens data shows that up to 70% of patients do not answer their phone upon 1st attempt of outreach by our home delivery services. Based on the proposed rules, we expect that a delayed delivery of prescriptions will occur in up to 70% of patients receiving prescriptions via home delivery or mail. Walgreens supports the offering of interactive communication for counseling patients and currently has processes in place to ensure patients are able to interact with pharmacists when they choose. However, Walgreens does not support this as the definition of counseling. The fiscal and staffing burden pharmacies would face to ensure that the interactive form of counseling always occurs prior to delivery puts tremendous strain on already limited resources in addition to concerns of clinically significant delays in care. Additionally, many patients in urban and rural pharmacy deserts or with economic and transportation challenges who rely on home delivery as the primary way to receive pharmaceuticals will be disproportionally affected by this rule change. We respectfully request the amendments indicated below to address these concerns.

855-115-0005
Definitions

1. "Counseling" or "Counsel" means a~~n interactive~~ communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

Walgreens asks the board to clarify and specify what records are required to be maintained in 855-115-0125. The definition of the practice of pharmacy in the ORS is quite broad and the current language may result in unintended consequences. The rule may be interpreted to require pharmacies to create new systems to capture more records and information than what is currently required. This may be interpreted to require records that include the date and time of all consultations including for non-prescription OTC products, all phone interactions, or questions, and when products are reconstituted. Walgreens request the board to clarify their intent with this rule update and provide clearer language for the licensees.

855-115-0125
Responsibilities: Drugs, Records and Security

8. Document accurately and maintain records ~~in the practice of pharmacy including, but not limited to:~~ related to the dispensing, prescribing, or administration of regulated drugs or devices.
   ~~a. Services provided;~~
   ~~b. The date, time and identification of the licensee and the specific activity or functions performed; and~~

Walgreens also requests the board to consider striking the language that would imply to require an outlet to ensure the elements of a prescription are present and accurately dispensed when the true responsibility for these elements is on the pharmacist involved with the review of the prescription. Does the board intend to hold accountable the permit holder for missing information or bad decision making by the pharmacist in control of the review and dispensing of the prescriptions and record maintenance? While the outlet has some responsibility for actions that occur within a pharmacy and a role to play in ensuring systems and processes are set up to provide ease of compliance for the pharmacist on duty, there are many activities that may occur by a pharmacist, for example, a prescription filling error or the failure to counsel by a pharmacist, that the outlet may have no direct control over. Additionally, from a regulatory construction standpoint, this section addresses the responsibilities of a pharmacist not an outlet. The board should not add additional requirements for outlets in this manner. We respectfully request the amendments outlined below.

Responsibilities: Drug Outlet

1. When practicing pharmacy per ORS 689 for a Drug Outlet, each Pharmacist must:
   a. Be responsible for the daily conduct, operation, management and control of the Drug Outlet pharmacy;
   b. Ensure that only a Pharmacist has access to the Drug Outlet pharmacy when the pharmacy is closed, except as permitted in OAR 855-041-6310;
   ~~c. Ensure each prescription contains all the elements required in OAR 855-041 or OAR 855-139;~~
   ~~d. Ensure the patient record contains the elements required in OAR 855-041 or OAR 855-139;~~
   ~~e. Ensure prescriptions, prescription refills, and drug orders are dispensed:~~
      ~~A. Accurately;~~
      ~~B. To the correct party;~~

C. Pursuant to a valid prescription;
D. Pursuant to a valid patient-practitioner relationship; and
E. For a legitimate medical purpose;

f. Ensure the Drug Outlet pharmacy is operated in a professional manner at all times;

g. Ensure the drug outlet reports data as required by federal and state regulations, including but not limited to:

Drug utilization reviews are an essential part of a pharmacist's role in evaluating medications for patients and improving outcomes. To reduce clinical abuse and misuse of prescription drugs Walgreens supports the boards position that DURs are needed. However, as Oregon contemplates workload demands for pharmacists, it is not imperative for patient safety to require a pharmacist to complete a manual DUR on a refilled prescription. Machine-automated DUR is a standard of care for all pharmacies to identify drug utilization concerns, which prompts pharmacists when there is a specific concern that may require their attention. We respectfully ask the Board to consider amending the DUR requirement to only require a manual DUR upon dispensing a new prescription and make allowances for computer-automated and assisted DUR review .

855-115-0140
Drug Utilization Review (DUR)

1. A Pharmacist must complete ensure a drug utilization review (DUR) is completed by reviewing the patient record prior to dispensing each new prescription drug or device for the purpose of identifying the following.
   a. Over-utilization or under-utilization;
   b. Therapeutic duplication;
   c. Drug-disease contraindications;
   d. Drug-drug interactions;
   e. Incorrect drug dosage or formulation;
   f. Inappropriate duration of treatment;
   g. Drug-allergy interactions; and
   h. Drug abuse or misuse.
2. Upon recognizing a concern with any of the items in (1)(a)-(h), the Pharmacist must take steps to mitigate or resolve the problem and document the steps taken and outcome.

Walgreens commends the board for its thoroughness in language regarding counseling, as it is an integral part of ensuring positive health outcomes and reducing medication errors for all patients. However, multiple items in the proposed language will have a significant negative impact to the patients in Oregon and put additional financial and workload strains on the Oregon licensed pharmacies. When contemplating the new requirement to counsel on all transferred prescriptions in 855-115-0145(2), the board should consider the additional burdens on the already strained pharmacist workforce. Will the perceived benefits to the patient out way the additional work placed on the pharmacist and actually improve patient safety? Once again, the decision to counsel on a prescription that was transferred should be under the direction and control of the individual pharmacist involved in the dispensing of the prescription based on their professional judgment. Additionally, in 855-115-0145(4,6&7) the fiscal impact to requiring multiple attempts to reach a patient prior to delivery as well as limiting who a patient or patient's agent may decline a consultation to must be considered. As stated previously, Walgreens data shows that up to 70% of patients do not answer their phone upon their 1st attempt for home delivery. Delays in the dispensing of prescriptions will occur with the current language as proposed and will disproportionally affect those who rely on home delivery services and may be located in urban or rural pharmacy deserts. Of note, 855-115-0145(9,10) unnecessarily lists the practice recommendations for consultations. The determination of what may be included in an appropriate, professional consultation should be left to the professional judgement of the pharmacist and held to general standard of care practices. Walgreens strongly encourages the board to have deep and thoughtful discussions on the proposed additions and changes to the counseling requirements that will negatively and significantly impact the patients in Oregon. Walgreens suggests the following edits to address our concerns.

855-115-145 Counseling

1. For each prescription, the pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.
2. The pharmacist must counsel the patient or patient's agent on the use of a drug or device:
   a. Upon request;
   b. When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;
   c. When there has been a change in the dose, formulation, or directions
   d. When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or

e. For any refill that the pharmacist deems counseling is necessary.

3. When communicating (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the pharmacist is proficient in the patient's preferred language.
4. For a prescription delivered outside of a Drug Outlet Pharmacy to a patient for self-administration, the pharmacist must:
   a. ~~Attempt to provide counseling prior to delivery as required in (1) and (2);~~ offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist;
   b. ~~Reattempt to provide counseling by end of the next business day if counseling does not occur prior to delivery~~ to the patient; and
   c. ~~Provide drug information in a format accessible by the patient, including information on how to contact the pharmacist with the delivery~~.
5. A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused,
   a. ~~Only a pharmacist can accept a patient's or patient's agent's request not to be counseled,~~ When counseling is required refusal by the patient or patient's agent must be documented by the licensed pharmacy staff.
   b. The pharmacist may choose not to release the prescription until counseling has been completed.
6. ~~A pharmacist~~ Counseling must be initiated and provided ~~counseling~~ under conditions that maintain patient privacy and confidentiality.
7. ~~The pharmacist that attempts counseling, provides counseling or accepts the request not to be counseled must document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction.~~
8. Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.
9. ~~Counseling on a new prescription may include, but is not limited to, the following elements:~~
   ~~a. Name and description of the drug;~~
   ~~c. Dosage form, dose, route of administration, and duration of drug therapy;Intended use of the drug and expected action;~~
   ~~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. Techniques for adherence and self-monitoring drug therapy;~~
   ~~g. Proper storage and appropriate disposal method(s) of unwanted or unused medication;~~
   ~~h. Refill information;~~
10. ~~Action to be taken in the event of a missed dose; andPharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drugCounseling on a refill prescription may include, but is not limited to, the following elements:~~
    ~~a. Name and purpose of the medication;~~
    ~~b. Directions for use, including technique;~~
    ~~c. Perceived side effects; and~~
    ~~d. Adherence.~~

While Walgreens has no suggested edits for 855-115-0200 and 855-115-0305, we ask the board to discuss the impacts to licensees for both proposed sections. Walgreens commends the board for recognizing the important work of the Pharmacist-in-charge of a drug outlet. However, with the proposed language we request the board to consider a manner to track and publicly share the completion of the board provided PIC training course, similar to the Preceptor licensure process. For drug outlets to ensure compliance with the proposed rule, a system must be set up by the board to validate and track PICs completion of the approved training course every 5 years.

855-115-0200

Pharmacist-in-Charge: Qualifications and Limitations

Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a pharmacist must:

1. Complete a board-provided PIC training course as described below:
   a. A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90-days after appointment.
   b. A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to the appointment.
2. Complete a board-provided PIC training course at least every five years.

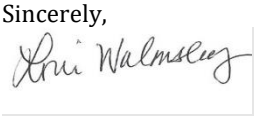
Walgreens also looks forward to the board's work on developing a statewide drug therapy management protocol as allowed in OAR 855-115-0305 and asks the board to utilize the Advisory Committee on Immunization Practices (ACIP) to expedite the publishing of Oregon's protocols for pharmacists. ACIP provides advice and guidance to the Director of the CDC regarding use of vaccines and related agents for control of vaccine-preventable diseases in the civilian population of the United States. The ability to make newly ACIP approved vaccines or recommendations quickly and readily available is critical to the health and safety for the people of Oregon. The board plays a critical role in keeping protocols current and aligned with national public health standards and must focus on reducing possible confusion for the public and providing clinical clarity for pharmacists. As we learned thru the COVID vaccine rollout, the public is quick to reach out to pharmacies to receive guidance on newly eligible vaccines or changing recommendations. We expect high demand for the continued updates to COVID vaccine recommendations as well as the rollout of the newly approved RSV vaccine. These updates will continue to put pharmacy teams at the front lines of providing vaccine administration and sharing with the public clear vaccine recommendations. Any delay in the publishing of these protocols will continue to cause additional stress for pharmacists statewide.

855-115-0305
Services: Administration of Vaccines, Drugs, or Devices

4. The Pharmacist must be acting:
   a. Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; or
   b. In accordance with a statewide drug therapy management protocol per OAR 855-115-0345 or clinical pharmacy agreement or collaborative drug therapy management agreement per OAR 855-115-0315; or
   c. In accordance with a written administration protocol issued by the Oregon Health Authority and approved by the board.

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,



Lorri Walmsley, RPh, FAzPA

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Lorri.Walmsley@walgreens.com

July 20th, 2023

Oregon State Board of Pharmacy
Attention: Joe Schnabel, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232

Via Email: joseph.schnabel@oregon.gov

RE: Division 120 – Interns and Preceptors

Dear Dr. Schnabel and members of the Oregon Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of Oregon, we thank the Board for the opportunity to comment on the proposed rules. Walgreens respectfully requests the board to review the comments, suggested edits and have meaningful discussion on the proposed changes indicated below.

Walgreens also appreciates the board's efforts in providing clarity for what an intern may not do under the supervision of a pharmacist, however, we feel the proposed language continues to be too specific and restrictive. Not all interns have the same background or level of training, and we believe the preceptor or supervising pharmacist should be allowed to determine what tasks are appropriate for the intern to participate in as defined in ORS (Oregon Revised Statute) 689.005. Also, the language does not provide the board with flexibility in enforcement and accountability as pharmacy practice and standards continue to change. Walgreens suggests simplifying the language to allow the supervising pharmacist the autonomy to use professional judgment when determining what activities, the intern may participate in and what should be prohibited based on the interns' capabilities, knowledge, and professionalism. Walgreens requests the board to have meaningful discussions on the proposed edits to 855-120-0150(2):

855-120-0150
Prohibited Practices - Intern

2. Until an Intern has successfully completed their first academic year, an Intern may perform the duties of an intern only with the permission of their supervising pharmacist ~~observe~~, but must not:
   - ~~a. Conduct a Drug Utilization Review or Drug Regimen Review;~~
   - ~~b. Counsel a patient or the patient's agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in the patient's record or chart;~~
   - ~~c. Advise on therapeutic values, content, hazards and use of drugs and devices;~~
   - ~~d. Conduct Medication Therapy Management;~~
   - ~~e. Practice pursuant to a Clinical Pharmacy Agreement or engage in Collaborative Drug Therapy Management;~~
   - ~~f. Practice pursuant to Statewide Drug Therapy Management Protocols;~~
   - ~~g. Prescribe a vaccine, drug, or device; or~~
   - h. Perform verification as defined in OAR 855-006-0005.

Sincerely,

Lorri Walmsley

Lorri Walmsley, RPh, FAzPA

wedgewood PHARMACY

GREAT CARE, DELIVERED.™

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR, 97232

July 26, 2023

Re: Proactive Procedural Review - OAR 855-183-0730 and OAR 855-080-0021

Dear Members of the Oregon State Board of Pharmacy:

Wedgewood Pharmacy has specialized in the practice of compounding sterile and non-sterile medications for animal use for over 25 years. We have locations in New Jersey, Arizona, Wyoming, and California (a 503B Outsourcing Facility), and are licensed as a Non-Resident Pharmacy or Outsourcing Facility in the state of Oregon. Our pharmacy locations have passed NABP VPP Inspections and are accredited by the Pharmacy Compounding Accreditation Board (PCAB).

We appreciate the opportunity to comment on the proposed rules in OAR Section 855-183-0730 concerning Compounding Services: For Use by a Veterinarian and OAR Section 855-080-0021 Schedule I (the "*Proposed Rules*"). The Proposed Rules are a welcome reflection of the Oregon Board of Pharmacy's ("OBOP") recognition that compounded medications for veterinary office use are important for the proper treatment of animals as well as addressing the current rise in the illicit use of xylazine. Like OBOP, we are dedicated to ensuring that animal patients receive quality compounded medication in a manner that ensures safe and effective treatment. We wish to note that although the Proposed Rules are a significant step in the right direction, there are several provisions that cause concern. Accordingly, we offer the following comments to the Proposed Rules:

PHONE: 800.331.8272
FAX: 800.589.4250
ADDRESS: 405 HERON DRIVE, STE. 200 | SWEDESBORO, NJ 08085
WEDGEWOODPETRX.COM

1. **Veterinarians Must Be Able to Dispense Compounded Medications from Non-Patient Specific Office Stock**

There are 2 concerns with the proposed language in regard to the use by veterinarians of office stock or non-patient specific compounded preparations. Veterinarians often treat animals in situations where a few hours, let alone several days, can make a significant difference in health outcomes. This is especially true for small or exotic animal patients whose treatment must often begin immediately in order to avoid further morbidity or mortality. Many compounded medications that veterinarians prescribe are not available at a local pharmacy and must be ordered from pharmacies that specialize in compounding veterinary medication. It is therefore crucial for veterinarians to not only have certain medications in their offices to begin treatment at the moment of diagnosis, but the medication must be available in enough supply to provide to the animal's owner for administration at home. This ensures that treatment is uninterrupted while a prescription is filled for the animal patient by a compounding pharmacy, as it can take several days to over a week for an animal's owner to receive the compounded medication. Thus, it is essential that veterinarians be able to dispense enough compounded medication at the time of treatment to avoid preventable animal suffering (and death) which may occur while prescriptions for compounded medication are filled by a specialty pharmacy.

In the original language proposed by the Compounding Workgroup, compounded preparations were allowed to "be used by veterinarians in their offices for administration to clients' animals," and to "be dispensed by a veterinarian to clients." The currently proposed language, Section 855-183-0730 (3)(b) allows "For in-office use [of compounded drugs] by a licensed veterinarian, specifically for a single treatment episode, not to exceed 120-hour supply." The word "dispense" has been removed from the language, thereby introducing vagueness as to the permissibility of the act. While it may be inferred that dispensing from compounded office stock is permissible in light of the 120-hour time frame, the language specifies "in office use." This could also be taken to mean that an animal hospitalized and/or boarded in a veterinary clinic would need to secure a patient specific supply of medication if their stay were to last longer than 120-hours. In the best interest of patient care, it is strongly recommended that the term "dispense" be re-introduced into this provision

2. **Veterinarians Should be Able to Determine the Appropriate Amount of Medication to Dispense to a Patient.**

The second concern lies with the 120-hour dispensing limit. In a 2016 survey conducted by the Florida Veterinary Medical Association, 92% of respondent veterinarians claimed that

the imposition of a restriction on the days' supply of compounded medication that could be dispensed to a patient from office stock would have a negative to very negative effect on their ability to care for their patients. In a 2019 survey by the Oregon Veterinary Medical Association, only 26% of respondent veterinarians stated that a 5-day (120-hour) supply would be adequate for optimal patient care.

The reasons why a short days supply is problematic are both therapeutic and practical. A standard course of antibiotic is 7 to 10 days. However, it is likely that an animal will show signs of recovery by 5 days. In many cases it has been found that the animal owner will not bother to fill the additional 2 to 5-days' supply of medication to complete the therapy, believing instead that the patient is cured. (This is true with FDA-approved products as well). Furthermore, the added expense of purchasing a 5-day supply of medication from the veterinarian as well as purchasing the remainder from a compounding pharmacy may cause animal owners to not comply or to refuse therapy altogether. As pharmacists and health professionals, we know that incomplete antibiotic therapy can lead to re-infection, superinfection, and antimicrobial resistance.

Recently, the FDA released a final version of its guidance document regarding compounding of veterinary drugs. *Guidance for Industry #256: Compounding Animal Drugs from Bulk Drug Substances* specifically permits office stock sales and has **no provisions limiting dispensing to any predetermined days' supply.** Furthermore, of the 16 items currently on the *List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals* (also known as the Positive List), 5 are sterile ophthalmic drops, 1 is a sterile ophthalmic ointment and 9 are sterile injectable preparations. Most compounding (503A) pharmacies and all 503B Outsourcing Facilities will produce larger batches of sterile preparations to increase safety, quality, and efficiency. Fewer batches mean fewer chances for error or contamination and allows for more post-production quality testing that can be performed by allowing costs to be spread over more units. Because of this, sterile preparations tend to come in uniform sizes: 5ml, 7.5ml and 15ml bottles for ophthalmic drops, 3.5gm tubes for ophthalmic ointment and 10ml, 30ml, 50ml and 100ml for injectable preparations. How will a veterinarian who receives a 15ml bottle of sterile ophthalmic drops for office use (e.g.: Tacrolimus 0.03%) dispense a 5-day supply to a pet owner? Is the veterinarian expected to open the bottle of eye drops and pour 1 ml into another bottle? How will sterility be maintained, and what will become of the remaining 14mls?

Many states, including Florida, Illinois and Minnesota, allow veterinarians to dispense from office use stock with no restrictions on days' supply. While we strongly believe that veterinarians should be permitted to apply their own therapeutic judgement in determining what days' supply of medication should be dispensed, if the Oregon Board of Pharmacy

believes that days' limits are important, we would urge them to permit the veterinarian to dispense the full course of therapy. In other words, if a course of therapy is 10-days then a veterinarian should be permitted to dispense a ten day course of therapy.

In order to account for the comments in both sections 1 and 2 of this letter, we recommend that provision (b) be revised as follows:

> (b) For in-office use by a licensed veterinarian, and dispensed specifically for a single treatment episode, not to exceed the longer of the length of such single treatment's recommended course of therapy or a 120-hour supply.

3. Pharmacies Should be Permitted to Distribute or Dispense Compounded Drugs that are Produced by 503B Outsourcing Facilities

The currently proposed language in Section 855-183-0730(4) provides: "(4) The compounded preparations must not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations." As you know, the United States Pharmacopeia has adopted amendments to Chapters 795, 797 and 800 that will become effective November 1, 2023. These requirements will severely limit BUDs of sterile drugs and make it significantly more expensive and complicated to make hazardous drugs. We strongly expect that these new regulations will result in it being economically unfeasible for many smaller, local pharmacies to continue to produce veterinary drugs. If local pharmacies could buy these products from 503B Outsourcing Facilities and dispense these products to their customers, they would be able to facilitate care while utilizing medications compounded under cGMP standards. FDA has indicated that they much prefer products to be made under cGMP standards by outsourcing facilities and we believe that they will be supportive of this kind of provision. Accordingly, we recommend that provision (4) be revised as follows:

> "(4) The compounded preparations, other than preparations produced by a 503B outsourcing facility, must not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations."

4. Compounded Xylazine Preparations Are Necessary for Proper Care of Equine and Other Large Animal and Wildlife Patients

Xylazine is a drug used in veterinary medicine as a sedative with analgesic and muscle relaxant properties. It is used on many different animal species such as horses, dogs, bear, deer, rats, elk, and numerous large species of wildlife to calm and facilitate handling, perform diagnostic and surgical procedures, relieve pain, or act as a local anesthetic. Xylazine is approved by the U.S. Food and Drug Administration (FDA) for veterinary use only. It is available in liquid solutions at 20, 100, and 300 mg/ml. Typically, this drug is administered either alone or

in conjunction with other anesthetics (e.g., ketamine or barbiturates) intravenously, intramuscularly, or orally for sedative and relaxant properties. In certain animal species (e.g. Brown Bears) and for certain procedures, xylazine must be compounded in more concentrated doses or in combination with another drug. The ability to have xylazine compounded for these animals and procedures is critical to their success. Reports and alerts indicate an increased prevalence of xylazine as an adulterant in drugs of abuse mixtures, and we applaud the OBOP for taking measures to address this rising problem.

The OBOP has proposed language that amends OAR 855-080-0021 by adding "Xylazine, unless in the form of a FDA-approved product" to Schedule I. Schedule 1 is reserved for drugs with no approved (human) medical purpose and that are deemed unsafe for use (in humans). At a Federal level, HR 1839: The Combating Illicit Xylazine Act, allows a specific protection for compounded xylazine, exempting, " the manufacturing, importation, or use of a xylazine bulk chemical for pharmaceutical compounding by licensed pharmacists or veterinarians;" Unlike the proposed Federal legislation and because compounded preparations are not FDA-approved, compounding xylazine for veterinary use would be prohibited under Oregon law, severely handicapping veterinarians and causing unnecessary animal pain and suffering. We strongly urge the OBOP to add language [e.g.: (g) Xylazine, unless in the form of a FDA-approved product, or compounded for veterinary use.] allowing for pharmacies to compound xylazine for veterinary use.

5. Conclusion

In summary, we very much appreciate the opportunity to comment on the Proposed Rules and we applaud the OBOP's decision to promulgate regulations for compounded veterinary office stock and for combatting illicit xylazine use. Nevertheless, we believe that the Proposed Rules require further consideration and clarity to ensure that compounding pharmacies and veterinarians dispensing medication for animal health can provide optimal care for their patients while ensuring the safety of the general public.

Yours truly,

Michael Blaire, R.Ph., FAPC

Vice-President – Government and Regulatory Affairs

From: Michael Blaire
To: PHARMACY RULEMAKING * BOP
Subject: Proactive Procedural Review: 855-183-0730
Date: Wednesday, July 26, 2023 1:44:49 PM
Attachments: 7_26_23 Oregon BOP Comments Final.pdf

Dear Members of the Oregon State Board of Pharmacy:
Please find attached comments relevant to your discussion of proposed new rule 855-183-0730 addressing compounding services related to use by a veterinarian.
Please feel free to contact me if you require clarification or additional information.
Yours truly,
Michael Blaire

_____

Michael Blaire, R.Ph., FAPC
Vice President - Government and Regulatory Affairs
Wedgewood Pharmacy
480-221-8511

Help us preserve patient access to compounded hormones. Learn more at www.compounding.com .

Once in a while, you get shown the light
In the strangest of places if you look at it right
- Jerry Garcia

Division 080: Scheduling Xylazine as a Schedule I

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Schedule I; Adds Xylazine

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amends Schedule I rule by adding language related to xylazine.

Documents Relied Upon per ORS 183.335(2)(b)(D):

Scheduling Xylazine-
Federal Bill: Combating Illicit Xylazine Act – Discussion Draft
DEA Public Safety Alert 3/21/2023
National Institute on Drug Abuse- Xylazine
OAR 875-015-0040 Minimum Standards for Veterinary Drugs
Xylazine: FDA Prescription Animal Drug Label

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. This is an urgent public health need that does not affect licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Amends OAR 855-080-0021 by adding "Xylazine, unless in the form of a FDA-approved product" to Schedule I. Proposed amendments are necessary due to the widespread public health threat that xylazine poses. According to the DEA, xylazine and fentanyl drug mixtures place users at a higher risk of suffering a fatal drug poisoning. Because xylazine is not an opioid, naloxone (Narcan) does not reverse its effects. People who inject drug mixtures containing xylazine also can develop severe wounds, including necrosis—the rotting of human tissue—that may lead to amputation.

Division 080
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0021
Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.11 (04/01/2022), and unless specifically exempt or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;

(b) Gamma-butyrolactone

(c) Methamphetamine, except as listed in OAR 855-080-0022;

(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)

(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.

(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,

(A) Methylmethcathinone (Mephedrone);

(B) Methylenedioxypyrovalerone (MDPV);

(C) Methylenedioxymethylcathinone (Methylone);

(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);

(E) Fluoromethcathinone (Flephedrone);

(F) 4-Methoxymethcathinone (Methedrone).

(g) Xylazine, unless in the form of a FDA-approved product.

(2) Schedule I also includes any compounds in the following structural classes (2a–2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);

(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;

(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and

(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) is not an FDA approved drug or is exempted from the definition of controlled substance in ORS 475.005(6)(b)(A)-(E).

(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.

(5) Schedule I also includes any compounds in the following structural classes (a – b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Benzodiazepine class: A fused 1,4-diazepine and benzene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Clonazolam, Flualprazolam

(b) Thienodiazepine class: A fused 1,4-diazepine and thiophene ring structure with a phenyl connected to the 1,-4-diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Etizolam

(6) Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;

(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;

(c) The following substances per ORS 475.005(6)(b):

(A) The plant Cannabis family Cannabaceae;

(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;

(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;

(D) The seeds of the plant Cannabis family Cannabaceae; or

(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055 & ORS 475.065

Division 102: Board Administration (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adopts new Division 102 for Board Administration rules

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 102. Relocates and amends existing board policy and administration rules from Division 010 to new Division 102. Relocates OAR 855-019-0125 to OAR 855-104-0035. After the board permanently adopts and publishes Division 102, repeals Division 010 on the effective date of Division 102.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 OBOP Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rules provide clarity for licensees, and registrants. It is anticipated that the proposed rules will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

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, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of the proposed rule amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommends adopting the proposed rules for transparency and clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Relocates existing rules from Division 010 to newly created Division 102 Board Administration. Relocates OAR 855-001-0000 to OAR 855-102-0125, relocates OAR 855-001-0005 to OAR 855-102-0045, relocates OAR 855-010-0130 to OAR 855-104-0150 and relocates OAR 855-019-0125 to OAR 855-102-0050. Proposed new language includes adding administration meeting requirements for the Public Health and Pharmacy Formulary Advisory Committee and adds compliance requirements for the board related to public records and public meetings laws. After the board permanently adopts and publishes Division 102, repeals Division 010 on the effective date of Division 102.

Division 102
BOARD ADMINISTRATION

855-102-0010
Board Meetings

(1) Board meetings must be held not less than once every three months as designated by the board.

(2) The President of the board has the power to call special meetings, subject to ORS 689.185, when it may be deemed necessary or upon request of a majority of members.

(3) The board must hold an annual meeting each year for the election of officers, the reorganization of the board and the transaction of other business.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135, ORS 689.185

855-102-0015
Public Health and Pharmacy Formulary Advisory Committee (PHPFAC)

(1) A PHPFAC meeting must be held not less than once every six months.

(2) The PHPFAC must periodically review the formulary and protocol compendium and recommend the revisions to the board for adoption by rule.

(3) The PHPFAC must recommend to the board, for adoption by rule, a formulary of drugs and devices from which a Pharmacist can prescribe and dispense to a patient pursuant to a diagnosis by a qualified healthcare practitioner or a protocol from which a Pharmacist can prescribe and dispense.

Statutory/Other Authority: ORS 689.649
Statutes/Other Implemented: ORS 689.645, ORS 689.649

855-102-0020
Board and PHPFAC Member Compliance

Board members and PHPFAC members must comply with the requirements of all Oregon public records and public meeting laws.

Statutory/Other Authority: ORS 192.001, ORS 192.620
Statutes/Other Implemented: ORS 192.630

855-102-0030
Board and PHPFAC Member Compensation

(1) A board member and Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) member of the Oregon Board of Pharmacy who is entitled to compensation under ORS 292.495 is eligible to receive an amount equal to the per diem amount paid to members of the Legislative Assembly under ORS 171.072 when engaged in the performance of official duties for each day or portion thereof.

(2) For the purpose of compensation, a board member or PHPFAC member is considered engaged in the performance of official duties when:

(a) The activity furthers the board's mission, such as attending a board meeting;

(b) Engaged in an activity at the request of the board chair or authorized by a vote of the board in advance of the activity; or

(c) Attending an authorized meeting.

(3) Except as otherwise provided by law, all members, including those employed in full-time public service, may receive actual and necessary travel or other expenses actually incurred in the performance of their official duties within the limits provided by law or by the Oregon Department of Administrative services under ORS 292.210, ORS 292.220, ORS 292.230, and ORS 292.250.

(4) A board member or PHPFAC member is not required to accept compensation or reimbursement of travel expenses while performing their official duties as a board or appointed committee member.

Statutory/Other Authority: ORS 689.115 & ORS 689.205
Statutes/Other Implemented: ORS 689.115, ORS 292.495, ORS 689.175, ORS 689.645, ORS 689.649, ORS 171.072

855-102-0040
Adoption by Reference - General

(1) The board adopts standards and other publications by reference, as necessary, through administrative rule. When a matter is included in a referenced publication that is in conflict with Oregon Revised Statutes or Oregon Administrative Rules, the statute or rule applies and the standard provision does not. All remaining parts or application of the standard remain in effect.

(2) All outside standards, statutes, rules and publications referred to in any rules adopted by the board are by those references made a part of those rules as though fully set forth. Copies are available for inspection in the office of the Board of Pharmacy.

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

855-102-0045
Adoption by Reference - Model Rules of Procedure

Pursuant to the provisions of ORS 183.341, the Board of Pharmacy adopts the Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act effective 07/2019. These rules must be controlling except as otherwise required by statute or rule.

[ED. NOTE: The full text of the Attorney General's Model Rules of Procedure is available from the office of the Attorney General or Board of Pharmacy.]

Statutory/Other Authority: ORS 183.341 & ORS 689.205
Statutes/Other Implemented: ORS 183.341

855-102-0050
Coaching from Board and Staff

A board member or board employee must not:

(1) Discuss the contents of an examination, its preparation or use with any candidate or other person;

(2) Coach a candidate or any other person on materials that may be used in the examination; or

(3) Accept any fees for any act of assistance that would bear on the examination.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.195

855-102-0055
Board Compliance Director and Officers

The board's Compliance Director and Compliance Officers:

(1) Must be Pharmacists licensed in the State of Oregon; and

(2) Are authorized to provide appropriate deadline extensions

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.195

855-102-0060
License Verification

For purposes of license verification, a person may rely upon the licensing information as it is displayed on the board's website that includes the issuance and expiration dates of any license issued by the board.

Statutory/Other Authority: ORS 689.151, ORS 689.205, ORS 689.490
Statutes/Other Implemented: ORS 689.151, ORS 689.490

855-102-0100
State and National Criminal Background Checks for Licensure and Registration

(1) The purpose of this rule is to provide for the reasonable screening of applicants for licensure; and individuals subject to investigation by the board, in order to determine if they have a history of criminal behavior such that they are not fit to be granted or retain a license or registration issued by the board.

(2) "Subject individual" means a person from whom the board may require legible fingerprints for the purpose of a state or nationwide criminal records check and fitness determination. In this rule, subject individual means applicants for licensure or renewal of a license and individuals subject to an investigation by the board.

(3) Criminal records checks and fitness determinations are conducted according to ORS 181A.170, ORS 181A.190, ORS 181A.195, ORS 670.280, ORS 676.303, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, OAR 125-007-0310, and OAR 125-007-0330.

(a) The board will request that the Oregon Department of State Police conduct a state and nationwide criminal records check, using fingerprint identification of subject individuals. The board may conduct state criminal records checks on subject individuals and any licensee through the Law Enforcement Data System maintained by the Oregon Department of State Police in accordance with rules adopted, and procedures established, by the Oregon Department of State Police. Criminal history information obtained from the Law Enforcement Data System must be handled in accordance with ORS Chapter 181A, OAR 257-010 and OAR 257-015 and applicable Oregon Department of State Police procedures.

(b) The applicant or licensee must disclose all arrests, charges, and convictions regardless of the outcome or date of occurrence. Disclosure includes any military or criminal records.

(c) The board may require additional information from the applicant or licensee, such as, but not limited to, proof of identity, previous names, residential history or additional criminal, judicial or other background information.

(4) In making licensing fitness determinations subject to the requirements of ORS 670.280, the board will consider the following:

(a) The nature of any criminal record that reflects:

(A) Drug or alcohol offense;

(B) Felony;

(C) Misdemeanor;

(D) U.S. military or international crime;

(E) Offense involving fraud, theft, identity theft or other instance of dishonesty;

(F) Offense involving violation of federal importation or customs laws or rules;

(G) Offense requiring registration as a sex offender;

(H) Condition of parole, probation, or diversion program, or

(I) Unresolved arrest, charge, pending indictment or outstanding warrant.

(b) Intervening circumstances relevant to the responsibilities and circumstances of the license or registration. Intervening circumstances include but are not limited to:

(A) The passage of time since the commission of the crime;

(B) The age of the subject individual at the time of the crime;

(C) The likelihood of a repetition of offenses or of the commission of another crime;

(D) The subsequent commission of another relevant crime;

(E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and

(F) A recommendation of an employer.

(c) The facts that support the conviction or indictment, or that indicate the making of a false statement;

(d) The relevancy, if any, of the crime or the false statement to the specific requirements of the subject individual's license or registration; and

(e) Any false statement or omission made to the board regarding the individual's criminal history.

(f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint identification;

(g) Any other pertinent information obtained as part of an investigation.

(h) The board must evaluate a crime or offense on the basis of the law of the jurisdiction in which the crime or offense occurred.

(i) Under no circumstances must an applicant be denied under these rules because of a juvenile record that has been expunged or set aside pursuant to ORS 419A.260 and ORS 419A.262.

(j) Under no circumstances must an applicant be denied under these rules due to the existence or contents of an adult record that has been set aside pursuant to ORS 137.225.

(5) Criminal offender information is confidential. Dissemination of information received under this rule may only be made to people with a demonstrated and legitimate need to know the information. When the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS 676.175. Any fingerprint cards used to conduct a check must be destroyed by either the Federal Bureau of Investigation or the Oregon Department of State Police as specified in ORS 181A.195.

(6) The board will permit the subject individual for whom a fingerprint-based criminal records check was conducted to inspect the individual's own state and national criminal offender records and, if requested by the subject individual, provide the individual with a copy of the individual's own state and national criminal offender records.

(7) If an applicant, licensee or registrant is denied a license, they are entitled to a contested case hearing pursuant to ORS chapter 183.

(8) A challenge to the accuracy or completeness of information provided by the Oregon Department of State Police, Federal Bureau of Investigation and agencies reporting information must be made through the Oregon Department of State Police, Federal Bureau of Investigation or reporting agency and not through the contested case process.

(9) Request for re-evaluation following correction. If the subject individual successfully contests the accuracy or completeness of information provided by the Oregon Department of State Police, the Federal Bureau of Investigation or other agency reporting information to the board, the board will conduct a new criminal history check and re-evaluate the criminal history upon submission of a new criminal history request form.

(10) The applicant or licensee must pay a criminal records check fee for the actual cost of acquiring and furnishing the criminal offender information.

Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195
Statutes/Other Implemented: ORS 676.303, ORS 181A.195, ORS 181A.170, ORS 181A.215 & ORS 676.175

855-102-0105
State and National Criminal Background Checks for Employees, Volunteers and Employment Applicants

(1) The board requires a criminal records check and fitness determination for board employees, volunteers or applicants for employment with the board.

(2) Criminal records checks and fitness determinations are conducted pursuant to ORS 181A.170, ORS 181A.190, ORS 181A.195, ORS 670.280, ORS 676.303, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, OAR 125-007-0310 and OAR 125-007-0330.

(a) To complete the criminal records check and fitness determination, the board may require additional information from the employee, volunteer or applicant, such as, but not limited to, proof of identity or additional criminal, judicial or other background information.

(b) If the employee, volunteer or applicant has potentially disqualifying criminal offender information, the board will consider factors listed in ORS 181A.195 before making a fitness determination.

(c) An approved fitness determination does not guarantee employment.

(d) An incomplete fitness determination does not entitle the employee, volunteer or applicant the right to appeal under OAR 125-007-0300.

(3) Pursuant to ORS 181A.195, and OAR 125-007-0310, information obtained in the criminal records check is confidential and will not be disseminated by the board except to persons with a demonstrated and legitimate need to know the information.

Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195
Statutes/Other Implemented: ORS 181A.195, ORS 181A.170, ORS 676.303

855-102-0110
Criminal Background Checks – Costs

The applicant or licensee must pay the board the cost of acquiring and furnishing the criminal offender information. The amount will not exceed the cost to the board to obtain such information on behalf of the applicant or licensee, including fees charged to the board by the Oregon Department of State Police and the Federal Bureau of Investigation.

Statutory/Other Authority: ORS 676.303 & ORS 689.205
Statutes/Other Implemented: ORS 676.303, ORS 181A.195 & ORS 689.207

855-102-0125
Notice of Proposed Rule

(1) Prior to the permanent adoption, amendment, or repeal of any rule, the State Board of Pharmacy must give notice of its intended action as required in ORS 183.335;

(2) The board will notify and provide a reasonable opportunity for interested persons to be notified of the agency's proposed action in the following ways:

(a) In the bulletin referred to in ORS 183.360 at least 21 days prior to the effective date;

(b) To persons who have requested notice pursuant to ORS 183.335(8) at least 28 days before the effective date;

(c) To persons specified in ORS 183.335(15) at least 49 days before the effective date; and

(d) To persons or organizations the board's Executive Director determines, pursuant to ORS 183.335, are interested persons in the subject matter of the proposed rule, or would be likely to notify interested persons of the proposal:

(A) Oregon State Pharmacy Association; and

(B) Oregon Society of Health System Pharmacists.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 183.335, ORS 183.341

Division 104: Universal Rules

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adopts new Division 104 for Universal Rules

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 104. Relocates and amends existing procedural rules from Division 001 to new Division 104. Relocates OAR 855-010-0130 to OAR 855-104-0150. After the board permanently adopts and publishes Division 104, repeals Division 001 and OAR 855-010-0130 on the effective date of Division 104.

Documents Relied Upon per ORS 183.335(2)(b)(D): None available.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Proposed rules provide clarity for licensees, and registrants. It is anticipated that the proposed rules will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): Reporting, Recordkeeping and Administrative Activities Cost: Professional Services, Equipment/ Supplies, Labor Cost, Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of the proposed rule amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommends adopting the proposed rules for transparency and clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Creates new Division 104 for universal rules. Relocates and amends existing rules from Division 001 to Division 104. Newly proposed language adds requirements for duty to report, confidentiality, records and document retention and adds a placeholder for public records requests. Adds "intern" to Military Spouse Domestic Partner licensure process rules. Relocates OAR 855-041-1167 to OAR 855-104-0050, relocates OAR 855-010-0130 to OAR 855-104-0150. After the board permanently adopt and publishes Division 104, repeals OAR 855-041-1167, OAR 855-010-0130 and Division 001 on the effective date of Division 104.

Creation of Division 104 and adoption of universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

Division 104
UNIVERSAL RULES

855-104-0005
Duty to Cooperate

(1) Applicants, licensees, and registrants must timely comply with all board requests, including responding accurately, fully and truthfully to inquiries and providing requested materials within the time allowed by the board and complying with a subpoena.

(2) Applicants, licensees, and registrants must comply with the terms of board orders and agreements.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.612

855-104-0010
Responsibilities: Duty to Report

(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each licensee must report to the board without undue delay, but within

(a) 10 days if they:

(A) Are convicted of a misdemeanor or a felony; or

(B) Are arrested for a felony; or

(C) Have reasonable cause to believe that any suspected violation of ORS 475, ORS 689 or OAR 855 has occurred.

(b) 10 working days if they have reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct to that licensee's board; or

(c) 15 days, if any change in:

(A) Legal name;

(B) For Pharmacists and Interns, name used when engaging in the practice of pharmacy and for Certified Oregon Pharmacy Technicians and Pharmacy Technicians, name used when assisting in the practice of pharmacy.

(C) Preferred email address;

(D) Personal phone number;

(E) Personal physical address;

(F) Personal mailing address; and

(G) Employer.

(2) A licensee who reports to a board in good faith as required by ORS 676.150 is immune from civil liability for making the report.

(3) A Pharmacist, Certified Oregon Pharmacy Technician or Pharmacy Technician who reports to a board in good faith as required by ORS 689.455 is not subject to an action for civil damages as a result thereof.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.150, ORS 689.155, ORS 689.455, & ORS 689.486

855-104-0015
Responsibilities: Confidentiality

(1) No licensee or registrant of the board who obtains any patient information may disclose that information to a third-party without the consent of the patient except as provided in (2)(a)-(e) of this rule.

(2) A licensee or registrant may disclose patient information:

(a) To the board;

(b) To a practitioner, Pharmacist, Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician or registrant, if disclosure is authorized by a Pharmacist and disclosure is necessary to protect the patient's health or well-being; or

(c) To a third-party when disclosure is authorized or required by law; or

(d) As permitted pursuant to federal and state patient confidentiality laws; or

(e) To the patient or to persons as authorized by the patient.

(3) A licensee or registrant of the board may not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (2)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-104-0050
Patients Access to Pharmacy Records

(1) Licensees and registrants of the board must make health information in the pharmacy record available to the patient or the patient's representative upon their request, to inspect and obtain a copy of health information about the individual, except as provided by law and this rule. The patient may request all or part of the record. A summary may substitute for the actual record only if the patient agrees to the substitution. Board licensees and registrants are encouraged to use the written authorization form provided by ORS 192.566.

(2) For the purpose of this rule, "health information in the pharmacy record" means any oral, written or electronic information in any form or medium that is created or received and relates to:

(a) The past, present, or future physical or mental health of the patient.

(b) The provision of healthcare to the patient.

(c) The past, present, or future payment for the provision of healthcare to the patient.

(3) Upon request, the entire health information record in the possession of the board licensee will be provided to the patient. This includes records from other healthcare providers. Information which may be withheld includes:

(a) Information which was obtained from someone other than a healthcare provider under a promise of confidentiality and access to the information would likely reveal the source of the information;

(b) Psychotherapy notes;

(c) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(d) Other reasons specified by federal regulation.

(4) Registrants who have permanently closed must notify patients according to OAR 855-041-1092.

(5) A reasonable cost may be imposed for the costs incurred in complying with the patient's request for health information pursuant to ORS 192.563.

(6) A patient may not be denied summaries or copies of pharmacy records because of inability to pay.

(7) Requests for pharmacy records must be complied with within a reasonable amount of time not to exceed 30 days from the receipt of the request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 192.553, ORS 192.556, ORS 192.558, ORS 192.563 & ORS 192.566

855-104-0055
Record and Document Retention

(1) Each licensee and registrant must create documents and retain records required by ORS 475, ORS 689, and OAR 855. Documents and records:

(a) May be in written or electronic format;

(b) Must be stored securely;

(c) Must be made available to the board upon request; and

(d) Must be retained for 3 years except that:

(A) Clinical pharmacy records must be retained for 7 years; and

(B) Training records for immunization administration and protocol and formulary compendia prescribing, must be retained for 6 years or uploaded into the licensee's electronic licensing record with the board;

(2) Records generated by a registrant:

(a) Must be stored on-site by the registrant for at least 12 months and must be provided to the board immediately upon request at the time of inspection;

(b) May be stored in a secured off-site location after 12 months of storage at the registrant and must be provided to the board upon request within 3 business days;

(3) Records generated in the practice of pharmacy that do not belong to a registrant must be stored by a Pharmacist in a secure manner and provided to the board upon request within 3 business days;

(4) Records must be retained for longer periods of time than required under this rule if:

(a) Federal law provides for a longer retention schedule; or

(b) Licensee or registrant has received notice of a Board investigation to which the records would be relevant;

(c) Licensee or registrant has received a Board request to retain the records for a longer period of time.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.508

855-104-0060
Public Records Request to the Board

Placeholder

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 192.440

855-104-0100
Time for Requesting a Contested Case Hearing

A request for a contested case hearing must be in writing and must be received by the board within 21 days from the date the contested case notice was served. When the board has issued a denial of a license, a request for a contested case hearing must be in writing and must be received by the board within 60 days from the date the licensure denial was served.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 183.435

855-104-0105
Filing Exceptions and Argument to the Board

After a proposed order has been served on a party, the party has 30 days to file written exceptions with the board from receipt of the proposed order.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

855-104-0110
Petition for Reconsideration or Rehearing as Condition for Judicial Review

All parties, including limited parties, must file a petition for reconsideration or rehearing with the board as a condition for obtaining judicial review of any order of the board.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

855-104-0115
Inspections

(1) A Compliance Officer is a board authorized representative and must be permitted entry to any drug outlet to conduct inspections at all reasonable hours.

(2) The Compliance Officer is authorized and must be permitted to perform the following to determine compliance with ORS 475, ORS 689, and OAR 855 and board orders including but not limited to:

(a) Inspecting conditions, structures, equipment, materials, and methods for compliance;

(b) Inspecting all drugs and devices;

(c) Taking photographs, recording video and audio; and

(d) Reviewing, verifying and making copies of records and documents.

(3) All licensees and employees must fully comply and cooperate with all questions and requests made by the Compliance Officer at the time of inspection.

(4) Refusal to allow inspection is grounds for discipline.

Statutory/Other Authority: ORS 475.125 & ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-104-0150
Military Spouse or Domestic Partner Licensure Process

(1) "Military spouse or domestic partner" means a spouse or domestic partner of an active member of the Armed Forces of the United States who is the subject of a military transfer to Oregon.

(2) To qualify for licensure under this rule, the military spouse or domestic partner must meet the following requirements:

(a) Meet the qualifications for licensure as stated in OAR 855-115, OAR 855-120 or OAR 855-125.

(b) Be married to, or in a domestic partnership with, a member of the Armed Forces of the United States who is assigned to a duty station located in Oregon by official active duty military order;

(c) Applicant must complete an application for licensure, provide the board with a valid email address, and complete and pass a national fingerprint-based criminal background check ;

(d) Provide evidence of current licensure as a pharmacist, intern or pharmacy technician issued by another state;

(e) Provide to the board, in a manner determined by the board, sufficient proof that the person is in good standing with the issuing out-of-state professional licensing board; and

(f) Demonstrate competency as a pharmacist, intern or pharmacy technician by having at least one year of active practice during the three years immediately preceding the application.

(3) A temporary authorization under this section is valid until the earliest of the following:

(a) Two years after the date of issuance;

(b) The date the spouse or domestic partner of the person to whom the authorization was issued completes the spouse's term of service in this state; or

(c) The date the person's authorization issued by the other state expires.

(4) A temporary authorization issued under this section is not renewable.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.265, ORS 670.400 & ORS 670.403

Division 115: Pharmacists (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 115 for Pharmacists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 115 for Pharmacists. Relocates, reorganizes and amends existing Pharmacists rules from Divisions 019, 020, and 041. After the board permanently adopts and publishes Division 115, repeals Division 019 on the effective date of Division 115.

Documents Relied Upon per ORS 183.335(2)(b)(D):
OBOP 2022-2026 Strategic Plan
- Alkhateeb, Fadi M., et al. "Review of National and International Accreditation of Pharmacy Programs in the Gulf Cooperation Council Countries." *American Journal of Pharmaceutical Education* 82.10 (2018). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6325464/
- FPGEC Certification Candidate Application Bulletin Spring 2022-Spring 2023. National Association of Boards of Pharmacy. //read.nxtbook.com/nabp/bulletin/fpgec_2022/cover.html
- ACPE List of Programs Accredited by State https://www.acpe-accredit.org/accredited-programs-by-state/, see +For International for information on Lebanese American University

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): On 5/24/2023, board staff sent out a fiscal impact request via GovDelivery to licensees/registrants requesting estimated fiscal impacts associated with compliance, implementation and operation related to any of the following proposed rules:

-Requiring each pharmacist who provides counseling to a patient located in Oregon to be licensed with the board as a Pharmacist

-Providing counseling that includes an interactive communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device

-For a prescription delivered to a patient except at a Drug Outlet Pharmacy, Pharmacy Prescription Kiosk or Pharmacy Prescription Locker, requiring the pharmacist to attempt to:
1. Provide counseling prior to delivery
2. Provide drug information in a format accessible by the patient, including information on how to contact the Pharmacist with the delivery; and
3. Reattempt to provide counseling with 24 hours of delivery if counseling does not occur prior to delivery.

-Requiring each pharmacist that attempts counseling, provides counseling, or accepts the request not to be counseled to document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction;

- Requiring clinical pharmacy records to be securely retained for 7 years in written or electronic format and available to the board upon request

-Requiring the Pharmacist-in-Charge for each Drug Outlet Pharmacy located both in and out of Oregon to:
1. Complete 1000, 1500, or 2000 hours of pharmacy practice within the last 1, 2, or 3 years in a US state or its jurisdiction
2. Complete a board provided PIC training course either before the appointment or within 90 days after the appointment and every 5 years thereafter
3. Be employed by the outlet
4. Be physically onsite at the Drug Outlet Pharmacy a minimum of 20 hours per work week or fifty percent (50%) of the hours of operation of the pharmacy, whichever is less.

As of 6/2/2023, the board has received two estimated fiscal impact statements.
- A company with 13 retail pharmacies in Oregon estimates it will impact their operations ranging from $54,054 to $144,144 per outlet annually (the estimate did not provide information on the components that contributed to the estimate).
-An institutional pharmacy estimated it will cost $150,000/year for RPH to provide counseling to patients located in OR, they estimate $350,000 year/or 1-1.5 FTE to comply with the counseling with interactive communication, 1-2 FTE/or $400,000 year to comply with counseling requirements for delivered drugs, $75,000/or 0.5 FTE productivity to comply with documentation requirements for attempts or providing counseling, $75,000 year to manage and comply with securely retaining records for 7 yrs., $2000 annually for course time to complete a PIC training course before or within 90 days of being appointed PIC, $200,000 yearly for the employment cost of the PIC as 1.0 FTE to ensure compliance of the PIC being employed by the outlet, For PICs in the reserves, it may be a severe personal financial impact in excess of $400,000 per year as they have mandatory and required military training off-site which would cost the organization $50,000 annually to find and employ contract PICs to comply with the proposed rule related to being physically on-site 20 hours per week or 50% of the hours of operation.

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, small businesses or members of the public.

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. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Creates new Division 115 for Pharmacist rules. Relocates, reorganizes and amends existing Pharmacist rules from Division's 019, 020, and 041 to Division 115 in alignment with the board's strategy to systematically organize all Divisions.

Proposed amendments include revising titles, clarifying requirements for applicability, definitions, general qualifications for all Pharmacists license types, licensure requirements for all Pharmacist license

types, licensure application, license renewal, license reinstatement, licensure lapse, licensure retirement, licensure voluntary surrender, Pharmacist Preceptor registration, in-state and out-of-state volunteer Pharmacist, and Nuclear Pharmacist. General responsibilities, confidentiality responsibilities, duty to report responsibilities, training responsibilities, Drug Utilization Review (DUR), Counseling, PIC qualifications, limitations and duties. Services such as Pharmacist consulting practice, administration of vaccines, drugs or devices, Clinical Pharmacy Agreements, Medication Therapy Management, prescribing practices, and naloxone. After the board permanently adopts and publishes Division 115, repeals Division 019 on the effective date of Division 115. Upon adoption of Division 115, the board will consider amending and or repealing the following rules at a future board meeting: OAR 855-041-1018, OAR 855-020-0105, OAR 855-020-0110, OAR 855-020-0120, OAR 855-020-0200, OAR 855-020-0300, OAR 855-041-1018, OAR 855-041-3000, OAR 855-041-3300, OAR 855-041-3305, OAR 855-041-3310, OAR 855- 041-3315, OAR 855-041-3320, OAR 855-041-3325, OAR 855-041-3330, OAR 855-041-0335, and OAR 855-041-3340.

The practice of pharmacy in Oregon requires a license. Counseling of an Oregon patient who is located in Oregon is the practice of pharmacy in Oregon. Other health care boards in Oregon and other states consider counseling to patients who are located in Oregon to require licensure. This would bring us in alignment with other boards and ensure that the Board is following statutory mandates regarding licensure requirements for those practicing pharmacy in Oregon.

Division 115
PHARMACISTS

855-115-0001
Applicability

(1) This Division applies to any Pharmacist who engages in the practice of pharmacy.

(2) Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance with statutes and rules unless exempt under ORS 689.225.

(3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a Pharmacist located in another state who is working for an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with the out-of-state pharmacy dispensing of a drug into Oregon, is not required to be licensed by the board.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, 689.155 & 689.255

855-115-0005
Definitions

(1) "Counseling" or “Counsel” means an interactive communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

(2) "Drug utilization review" or "DUR" means evaluation of a prescription to identify and resolve potential problems through the review of information provided to the Pharmacist by the patient, patient's agent, prescriber and the patient's record.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

855-115-0010
Licensure: Qualifications - General

(1) Before licensure as a Pharmacist, an applicant must meet the qualifications required that are applicable to their method of licensure;

(a) Examination or Score Transfer in OAR 855-115-0020; or

(b) Reciprocity in OAR 855-115-0025.

(2) If residing in the United States, proof of citizenship, legal permanent residency or qualifying visa, as required by 8 USC 1621.

(3) Foreign pharmacy graduates must also meet the requirements of OAR 855-115-0015 prior to applying for a Pharmacist license.

Statutes/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 2021 HB 2078

855-115-0015
Licensure: Qualifications - Foreign Pharmacy Graduate Education

(1) An applicant for pharmacist licensure who graduated from a foreign school, college, or program of pharmacy must meet the following educational requirements:

(a) Obtain certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC); and

(b) Submit evidence of 1440 hours in pharmacy practice as an intern or pharmacist in the United States or its jurisdiction.

(2) (1)(a) is not required for graduates of:

(a) A Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program located in Canada or its jurisdiction with a curriculum taught in English and who graduated between 1993 and June 30, 2004.

(b) The ACPE-accredited program at the Lebanese American University in Byblos, Lebanon with a Doctor of Pharmacy degree and graduated after 2002.

(3) If (1)(a) is required, an applicant must not count internship hours or practice as a pharmacist towards the requirement in (1)(b) that was completed before achieving the FPGEC certification.

(4) Once the educational qualifications in this rule are met, an applicant must also comply with the requirements for licensure in OAR 855-115-0020 for examination or score transfer or OAR 855-115-0025 for reciprocity.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 689.255

855-115-0020
Licensure: Qualifications - Examination or Score Transfer

(1) To receive licensure as a Pharmacist by examination or score transfer, an applicant must meet the following requirements:

(a) Provide evidence in the form of an official transcript from an Accreditation Council for Pharmacy Education (ACPE) accredited college or school of pharmacy or compliance with OAR 855-115-0015 that:

(A) A degree has been conferred; and

(B) The applicant has completed a minimum of 1440 hours in an Internship Program as that term is defined in OAR 855-031-0005.

(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;

(c) Pass the Oregon Multistate Pharmacy Jurisprudence Examination (MPJE) exam. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts; and

(d) Complete one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority.

(2) An applicant who has obtained their professional degree outside the United States is not eligible for licensure via examination or score transfer until they have met the requirements of OAR 855-115-0015.

(3) An applicant applying via score transfer must request the National Association of Boards of Pharmacy to transfer their NAPLEX score to Oregon.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 413.590, ORS 689.151,ORS 689.285

855-115-0025

Licensure: Qualifications - Reciprocity

(1) An applicant for licensure as a Pharmacist by reciprocity must meet the requirements of ORS 689.265 and provide evidence of the following requirements:

(a) Be a graduate, as shown by an official transcript, of an ACPE accredited college or school of pharmacy or compliance with OAR 855-115-0015;

(b) Have passed the NAPLEX;

(c) Have passed the Oregon MPJE. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;

(d) Proof that each Pharmacist license granted to the applicant is not suspended, revoked, canceled or otherwise completely restricted from the practice of pharmacy for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the practice of pharmacy; and

(e) Have either:

(A) Been engaged in the practice of pharmacy for period of at least 12 months including a minimum of 1440 hours of work experience as a licensed Pharmacist. Evidence supporting this work experience must be provided at time of application; or

(B) Completed 1440 hours in an Internship Program as that term is defined in OAR 855-031-0005 within the 12 month period immediately before the date of application. Evidence must be provided at time of application.

(2) An applicant who has obtained their professional degree outside the United States and jurisdiction is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-115-0015.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.265, ORS 689.405

855-115-0030

Licensure: Application

(1) An application for licensure as a Pharmacist may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of:

(a) Evidence of compliance with OAR 855-115-0020 or 855-115-0025;

(b) A completed application including:

(A) Payment of the fee prescribed in OAR 855-110;

(B) A current, passport regulation size photograph (full front, head to shoulders);

(C) Personal identification or proof of identity; and

(D) Certificate of completion for the one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority;

(c) A completed national fingerprint-based background check; and

(d) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application; and

(d) Any other grounds found in ORS 689.405.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of a Pharmacist expires June 30 in odd numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.225, ORS 689.285

855-115-0035
Licensure: Renewal or Reinstatement

(1) An applicant for renewal of a Pharmacist license must:

(a) Pay the biennial license fee required in OAR 855-110;

(b) Complete the continuing pharmacy education requirements as outlined in OAR 855-135;

(c) Be subject to a criminal background check; and

(d) Provide a written description and documentation regarding all conduct that is required to be disclosed.

(2) A Pharmacist who fails to renew their license by the expiration date and whose license has been lapsed for 12 months or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A person who fails to renew their license by the expiration date and whose license has been lapsed for greater than 12 months may apply to reinstate their Pharmacist license as follows:

(a) Apply per OAR 855-115-0030;

(b) Provide certification of completion of the continuing pharmacy education requirement in OAR 855-135 for all years in which the license was lapsed; and

(c) Meet the requirements below, if applicable.

(4) A person must take and pass the Oregon MPJE if their pharmacist license has been lapsed for more than three years. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts.

(5) If the Pharmacist license has been lapsed for more than five years and the person has not maintained an active pharmacist license in another US state or jurisdiction, a person must comply with (4) and take and pass the NAPLEX. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts.

(6) In lieu of reinstatement, a person may apply for licensure via reciprocity if the person has maintained an active pharmacist license in good standing in another US state or jurisdiction.

(7) A person whose Pharmacist license has been retired for more than 12 months need only pay the annual license fees for the year in which they seek a license, however they must also complete the requirements in (3).

(8) A person whose Pharmacist license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition to the board for reinstatement of such license pursuant to ORS 689.445 and in conjunction with the application process identified in OAR 855-115-0030.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.275, ORS 689.445

855-115-0040
Licensure: Lapse

(1) A Pharmacist may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person must not practice pharmacy if their license is lapsed.

(d) A person may apply for renewal or reinstatement of their license according to OAR 855-115-0035.

(2) If a Pharmacist requests to lapse their license prior to the expiration date, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board will not accept the lapse if an investigation of or disciplinary action against the licensee is pending.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0045
Licensure: Retire

(1) A Pharmacist may request that the board retire their license if the Pharmacist is in good standing, has been licensed as a Pharmacist for at least 20 years and is no longer practicing pharmacy.

(a) A retired license is not considered discipline.

(b) The board has continuing authority under ORS 689.153.

(c) A person must not practice pharmacy if the license is retired.

(d) A person may apply for renewal or reinstatement according to OAR 855-115-0035.

(2) If a Pharmacist requests to retire their license prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the request to retire the license.

(b) If the board accepts the request to retire the license, the board will notify the licensee of the date the license is no longer active.

(c) The board will not accept the request to retire the license if an investigation of or disciplinary action against the licensee is pending.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0050
Licensure: Voluntary Surrender

A Pharmacist may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date the order is signed by all parties and served on the licensee.

(4) The licensee must cease practicing pharmacy from the date the license terminates.

(5) A voluntarily surrendered license cannot be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-115-0035 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0060
Registration: In-State Volunteer

(1) A Pharmacist may register with the board for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services without compensation under the terms of the law.

(2) A no cost registration may be issued by the board upon receipt of a completed application. Registration requires submission of a signed form provided by the board in accordance with ORS 676.345(2).

(3) Registration will expire at the licensee's next license renewal date and may be renewed biennially. It is the licensee's responsibility to ensure his or her active registration in this program.

(4) Nothing in this section relieves licensee from the responsibility to comply with board regulations and still may be subject to disciplinary actions.

(5) Pharmacists providing care under the provisions of ORS 676.340 and ORS 676.345 remain subject to the board complaint investigation process articulated in ORS 676.175.

Statutory/Other Authority: ORS 676.340 & ORS 689.205
Statutes/Other Implemented: ORS 676.340 & ORS 676.345

855-115-0065
Notification: Out-of-State Volunteer

(1) A pharmacist who is not licensed in Oregon may, without compensation and in connection with a coordinating organization or other entity, practice pharmacy for 30 days each calendar year. The pharmacist is not required to apply for licensure or other authorization from the board to practice pharmacy under this section.

(2) To practice pharmacy under this section, the pharmacist who is not licensed in Oregon must submit on a form prescribed by the board, at least 10 days prior to commencing practice in this state, to the board:

(a) Proof that the pharmacist is in good standing and is not the subject of an active disciplinary action in any jurisdiction in which the Pharmacist is authorized to practice;

(b) An acknowledgement that the pharmacist must provide services only within the scope of practice of pharmacy and will provide services pursuant to the scope of practice of this state or the health care practitioner's licensing agency, whichever is more restrictive;

(c) An attestation that the pharmacist will not receive compensation for practice in this state;

(d) The name and contact information of the coordinating organization or other entity through which the Pharmacist will practice; and

(e) The dates on which the pharmacist will practice in this state.

(3) Except as otherwise provided, a pharmacist practicing under this section is subject to the laws and rules governing the pharmacy profession that the pharmacist is authorized to practice and to disciplinary action by the appropriate health professional regulatory board.

Statutory/Other Authority: ORS 689.205, ORS 689.315, 2022 HB 4096
Statutes/Other Implemented: ORS 689.151, 2022 HB 4096

855-115-0070
Notification: Nuclear Pharmacists

In order to qualify under these rules as a nuclear Pharmacist, a Pharmacist must :

(1) Meet minimum standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Protection Services of the Department of Human Services; and

(2) Be a Pharmacist licensed to practice in Oregon; and

(3) Submit to the Board of Pharmacy either:

(a) Evidence of current certification in nuclear pharmacy by the Board of Pharmacy Specialties; or

(b) Evidence that they meet both the following:

(A) Certification of a minimum of six month on-the-job training under the supervision of a qualified nuclear Pharmacist in a nuclear pharmacy providing radiopharmaceutical services; and

(B) Certification of completion of a nuclear pharmacy training program in a college of pharmacy or a nuclear pharmacy training program approved by the board.

(4) Receive a letter of notification from the board that the evidence submitted by the Pharmacist meets the above requirements and has been accepted by the board.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

855-115-0105
Responsibilities: General

When practicing pharmacy per ORS 689, each Pharmacist must:

(1) Use that degree of care, skill, diligence and reasonable professional judgment that is exercised by a careful and prudent Pharmacist in the same or similar circumstances;

(2) Be responsible for their own actions, however, this does not absolve the pharmacy from responsibility for the Pharmacist's actions;

(3) Be responsible for the actions of each Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician and non-licensed pharmacy personnel under their supervision;

(4) Ensure compliance with all state and federal laws and rules governing the practice of pharmacy;

(5) Control each aspect of the practice of pharmacy;

(6) Perform appropriately the duties of a Pharmacist;

(7) Ensure access to reference material and equipment needed based on the services provided;

(8) Ensure services are provided with required interpretation and translation per ORS 689.564;

(9) Ensure services occur in a sanitary, secure and confidential environment;

(10) Be clearly identified as a Pharmacist in all interactions and communications (e.g., nametag, phone interaction, chart notations);

(11) Display in plain sight the Pharmacist license within the pharmacy or place of business to which it applies;

(12) Engage in a continuous quality improvement program; and

(13) Review, adhere to and enforce written policies and procedures. The review must:

(a) Occur prior to engaging in the practice of pharmacy;

(b) Occur with each update; and

(c) Be documented and records retained according to OAR 855-104-0055.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.025, ORS 689.151, ORS 689.155, ORS 689.645, ORS 689.682, ORS 689.689 & 2022 HB 4034

855-115-0110
Responsibilities: Confidentiality

Each Pharmacist must comply with OAR 855-104-0015 regarding confidentiality.

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

855-115-0115
Responsibilities: Duty to Report

Each Pharmacist must report to the board as required by OAR 855-104-0010. In addition, unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, a Pharmacist must report to the board without undue delay, but within 1 business day of:

(1) Confirmed significant drug loss; or

(2) Any loss related to suspected drug theft of a controlled substance.

Statutory/Other Authority: ORS 689.205, ORS 689.455
Statutes/Other Implemented: ORS 676.150, ORS 689.151, ORS 689.155 & ORS 689.455

855-115-0120

Responsibilities: Personnel

(1) When practicing pharmacy per ORS 689, each Pharmacist must:

(a) Ensure personnel that require licensure have been granted and maintain licensure with the board;

(b) Ensure licensed personnel work within the duties permitted by their licensure;

(c) Ensure non-Pharmacist personnel only perform duties they are licensed and trained to perform;

(d) Know the identity of each Intern under their supervision, and Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction and control at all times;

(e) Ensure each Intern only practices pharmacy under the supervision of a Pharmacist as outlined in OAR 855-120 including any applicable ratios;

(f) Ensure each Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a Pharmacist as outlined in OAR 855-125;

(g) Ensure licensed personnel do not engage in prohibited practices as outlined for Interns in OAR 855-120-0150 and for Certified Oregon Pharmacy Technicians and Pharmacy Technicians in OAR 855-125-0150;

(h) Ensure non-licensed personnel do not practice or assist in the practice of pharmacy;

(i) Ensure initial and ongoing training is completed that is commensurate with the tasks that the Pharmacist and persons under their supervision will perform, prior to the performance of those tasks;

(j) Ensure continued competency in tasks that are performed by the Pharmacist and persons under their supervision; and

(k) Ensure that the supervision of non-Pharmacist personnel does not exceed their capacity to safely supervise based on the workload and services being provided.

(2) When engaging in the practice of pharmacy per ORS 689, each Pharmacist may delegate the practice of pharmacy to other health care providers who are appropriately trained and authorized to perform the delegated tasks.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

855-115-0125

Responsibilities: Drugs, Records and Security

When practicing pharmacy per ORS 689, each Pharmacist must:

(1) Ensure the security of prescription drugs, pharmacy and patient records including:

(a) Provide adequate safeguards against loss, theft, or diversion; and

(b) Ensure only persons authorized by the Pharmacist access the areas where prescription drugs, pharmacy and patient records are stored by restricting access;

(2) Ensure that all records are maintained in accordance with state and federal laws and rules;

(3) Only receive drugs from an Oregon Registered Drug Outlet (e.g., Wholesaler, Manufacturer or Pharmacy);

(4) Comply with the drug storage rules for pharmacies in OAR 855-041-1036;

(5) Ensure drugs and devices that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or identified as suspect or illegitimate, or otherwise unfit for dispensing or administration must be documented, quarantined and physically separated from other drugs and devices until they are destroyed or returned to the supplier;

(6) Ensure each compounded drug is prepared in compliance with OAR 855-045;

(7) Ensure all computer equipment used for the practice of pharmacy:

(a) Establishes and maintains a secure connection to patient information to which they have access;

(b) Prevents unauthorized access to patient information; and

(c) Is configured so information from any patient records are not duplicated, downloaded, or removed from the electronic database if accessed remotely;

(8) Document accurately and maintain records in the practice of pharmacy including, but not limited to:

(a) Services provided;

(b) The date, time and identification of the licensee and the specific activity or functions performed; and

(c) Maintain records pertaining to the acquisition, storage, dispensing or administration, and disposal of drugs and devices; and

(9) Ensure reporting of data as required by federal and state regulations, including but not limited to:

(a) ALERT Immunization Information System (ALERT-IIS) per ORS 433.090, ORS 433.092, ORS 433.094, ORS 433.095, ORS 433.096, ORS 433.098, ORS 433.100, ORS 433.102, ORS 433.103, and ORS 433.104;

(b) Communicable diseases per ORS 433.004; and

(c) Vaccine Adverse Event Reporting System (VAERS) per 21 CFR 600.80 (v. 04/01/2022).

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

855-115-0130
Responsibilities: Drug Outlet

(1) When practicing pharmacy per ORS 689 for a Drug Outlet, each Pharmacist must:

(a) Be responsible for the daily conduct, operation, management and control of the Drug Outlet pharmacy;

(b) Ensure that only a Pharmacist has access to the Drug Outlet pharmacy when the pharmacy is closed, except as permitted in OAR 855-041-6310;

(c) Ensure each prescription contains all the elements required in OAR 855-041 or OAR 855-139;

(d) Ensure the patient record contains the elements required in OAR 855-041 or OAR 855-139;

(e) Ensure prescriptions, prescription refills, and drug orders are dispensed:

(A) Accurately;

(B) To the correct party;

(C) Pursuant to a valid prescription;

(D) Pursuant to a valid patient-practitioner relationship; and

(E) For a legitimate medical purpose;

(f) Ensure the Drug Outlet pharmacy is operated in a professional manner at all times;

(g) Ensure the drug outlet reports data as required by federal and state regulations, including but not limited to:

(A) Prescription Drug Monitoring Program (PDMP) per ORS 413A.890, ORS 413A.895, ORS 413A.896, ORS 413A.898, and OAR 333-023;

(B) Death with Dignity per ORS 127.800, ORS 127.805, ORS 127.810, ORS 127.815, ORS 127.820, ORS 127.825, ORS 127.830, ORS 127.835, ORS 127.840, ORS 127.845, ORS 127.850, ORS 127.855, ORS 127.860, ORS 127.865, ORS 127.870, ORS 127.875, ORS 127.880, ORS 127.885, ORS 127.890, ORS 127.892, ORS 127.895, ORS 127.897, and OAR 333-009;

(C) Controlled substances per 21 CFR 1301.74 (v. 04/01/2022); and

(D) Listed chemicals per 21 CFR 1310.05 (v. 04/01/2022); and

(2) A Pharmacist who utilizes licensees remotely, must comply with OAR 855-041-3200 through OAR 855-041-3250.

(3) When engaging in the practice of pharmacy per ORS 689, each Pharmacist may delegate final verification of drug and dosage form, device, or product to a Certified Oregon Pharmacy Technician or Pharmacy Technician per ORS 689.005 when the following conditions are met:

(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;

(b) The Certified Oregon Pharmacy Technician or Pharmacy Technician does not use discretion in conducting final verification;

(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and

(d) Ensure the Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.

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

855-115-0140
Drug Utilization Review (DUR)

(1) A Pharmacist must complete a drug utilization review (DUR) by reviewing the patient record prior to dispensing each prescription drug or device for the purpose of identifying the following:

(a) Over-utilization or under-utilization;

(b) Therapeutic duplication;

(c) Drug-disease contraindications;

(d) Drug-drug interactions;

(e) Incorrect drug dosage or formulation;

(f) Inappropriate duration of treatment;

(g) Drug-allergy interactions; and

(h) Drug abuse or misuse.

(2) Upon recognizing a concern with any of the items in (1)(a)-(h), the Pharmacist must take steps to mitigate or resolve the problem and document the steps taken and outcome.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 689.155

855-115-0145
Counseling

(1) For each prescription, the pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(2) The pharmacist must counsel the patient or patient's agent on the use of a drug or device:

(a) Upon request;

(b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;

(c) When there has been a change in the dose, formulation, or directions;

(d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or

(e) For any refill that the pharmacist deems counseling is necessary.

(3) When communicating (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the pharmacist is proficient in the patient's preferred language.

(4) For a prescription delivered outside of a Drug Outlet Pharmacy to a patient for self-administration, the pharmacist must:

(a) Attempt to provide counseling prior to delivery as required in (1) and (2);

(b) Reattempt to provide counseling by end of the next business day if counseling does not occur prior to delivery to the patient; and

(c) Provide drug information in a format accessible by the patient, including information on how to contact the pharmacist with the delivery.

(5) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused,

(a) Only a pharmacist can accept a patient's or patient's agent's request not to be counseled, when counseling is required.

(b) The pharmacist may choose not to release the prescription until counseling has been completed.

(6) A pharmacist must initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

(7) The pharmacist that attempts counseling, provides counseling or accepts the request not to be counseled must document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction.

(8) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.

(9) Counseling on a new prescription may include, but is not limited to, the following elements:

(a) Name and description of the drug;

(b) Dosage form, dose, route of administration, and duration of drug therapy;

(c) Intended use of the drug and expected action;

(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) Techniques for adherence and self-monitoring drug therapy;

(g) Proper storage and appropriate disposal method(s) of unwanted or unused medication;

(h) Refill information;

(i) Action to be taken in the event of a missed dose; and

(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(10) Counseling on a refill prescription may include, but is not limited to, the following elements:

(a) Name and purpose of the medication;

(b) Directions for use, including technique;

(c) Perceived side effects; and

(d) Adherence.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 689.155

855-115-0150
Prohibited Practices

Pharmacists must not:

(1) Engage in the dispensing, distribution or delivery of drugs unless working for a registered Drug Outlet pharmacy.

(2) Possess personally or store drugs other than in a registered Drug Outlet pharmacy except for those drugs legally prescribed for the personal use of the Pharmacist or when the Pharmacist possesses or stores the drugs in the usual course of business and within the Pharmacist's scope of practice.

(3) Diagnose.

(4) Engage in any form of discrimination, harassment, intimidation, or assault.

(5) Permit any Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician to perform any task in which the supervising Pharmacist is not trained or qualified to perform.

(6) Permit any non-licensed pharmacy personnel to perform any function that constitutes the practice of pharmacy as defined in ORS 689 or the assistance of the practice of pharmacy. Non-licensed personnel may only perform functions permitted by the Pharmacist providing supervision.

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

855-115-0200
Pharmacist-in-Charge: Qualifications and Limitations

Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:

(1) Complete a board-provided PIC training course as described below:

(a) A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90-days after appointment.

(b) A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to the appointment.

(2) Complete a board-provided PIC training course at least every five years.

Statutory Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 689.155

855-115-0210
Pharmacist-in-Charge: Responsibilities

(1) In addition to the responsibilities of a Pharmacist outlined in OAR 855-115, a Pharmacist-in-Charge of a Drug Outlet pharmacy must:

(a) Be actively engaged in pharmacy activities at the Drug Outlet pharmacy;

(b) Be physically present at the Drug Outlet pharmacy on a regular basis for a sufficient amount of time as needed to ensure Drug Outlet pharmacy compliance;

(c) Be responsible for the ongoing conduct, operation, management and control of the Drug Outlet pharmacy;

(d) Establish, maintain, and enforce written policies and procedures governing the practice of pharmacy that are compliant with federal and state laws and rules;

(e) Ensure maintenance of complete and accurate records;

(f) Establish, maintain and enforce a continuous quality improvement program;

(g) Develop, implement and submit a plan of correction for observations noted on an inspection within the time allowed by the board;

(h) Complete an annual self-inspection of the pharmacy using the Self-Inspection Form provided by the board, by July 1 each year and within 15 days of becoming PIC. The completed self-inspection forms must be signed and dated by the PIC and retained for three years from the date of completion;

(i) Ensure a controlled substance inventory with discrepancy reconciliation is accurately completed and documented; and

(j) For all controlled drugs either prior to the opening or after the close of business on the inventory date:

(A) Within 15 days of a change in PIC; and

(B) At least every 367 days; and

(i) For all Schedule II controlled drugs:

(ii) At least every 93 days in a Retail Drug Outlet Pharmacy; and

(iii) At least every 31 days in an Institutional Drug Outlet Pharmacy.

(2) The PIC of a Drug Outlet pharmacy affiliated with the following Drug Outlet types must also comply with the PIC responsibilities as outlined in:

(a) Pharmacy Prescription Kiosk in OAR 855-141;

(b) Pharmacy Prescription Locker in OAR 855-143; and

(c) Remote Dispensing Site Pharmacy in OAR 855-139.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 689.155

855-115-0300
Services: Consulting Practice

(1) A Pharmacist who provides services to an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure as well as by any relevant federal and state laws and rules.

(2) A Pharmacist who provides services to a correctional facility, long term care facility, community-based care facility, hospital drug room, or charitable pharmacy that does not have additional Pharmacist service requirements under the terms of its licensure with any other state agency, must provide services that include but are not limited to the following:

(a) Provide the facility with policies and procedure relating to security, storage and distribution of drugs within the facility;

(b) Provide guidance on the proper documentation of drug administration or dispensing; and

(c) Provide educational materials or programs as requested.

(3) A Pharmacist who provides services to an Oregon licensed healthcare provider must follow all state and federal laws and rules related to the practice of pharmacy.

(4) A Pharmacist must maintain appropriate records of their services in (2) - (4) for three years and make them available to the board for inspection.

(5) A Pharmacist may store health protected records outside an Oregon licensed facility as permitted in OAR 855-104-0055.

(6) Records and documents must be retained according to OAR 855-104-0055.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 689.155

855-115-0305
Services: Administration of Vaccines, Drugs, or Devices

(1) In accordance with ORS 689.645 and ORS 689.655, a Pharmacist may administer a vaccine, drug or device as specified in this rule.

(2) A Pharmacist who administers a vaccine, drug or device must:

(a) Prior to administration of an injectable drug or device, receive practical training on the injection site and administration technique that is utilized;

(A) For vaccines, the training:

(i) May include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board; and

(ii) Must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

(B) For orally administered drugs, training is not required; and

(C) Records of training must be retained according to OAR 855-104-0055.

(b) Hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years. The most current CPR certification record must be retained according to OAR 855-104-0055;

(c) Ensure that any drug administered to a patient was stored in accordance with the drug storage rules for pharmacies in ORS 855-041-1036;

(d) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the vaccine, drug or device;

(e) Ensure that vaccine, drug or device administration is documented in the patient's permanent record; and

(f) Ensure records and documents are retained according to OAR 855-104-0055. Records of administration must include but are not limited to:

(A) Patient identifier;

(B) Vaccine, drug or device and strength;

(C) Route and site of administration;

(D) Date and time of administration; and

(E) Pharmacist identifier.

(3) For vaccines only, the requirements in (2) and the following apply, the Pharmacist must:

(a) Follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022);

(b) Have access to a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);

(c) Give the appropriate Vaccine Information Statement (VIS) to the patient or patient's agent with each dose of vaccine covered by these forms. The Pharmacist must ensure that the patient or patient's agent is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine;

(d) Report all vaccinations administered to the ALERT IIS in accordance with OAR 333-049-0050, and for COVID-19 immunizations, in accordance with OAR 333-047-1000; and

(e) Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.

(4) The Pharmacist must be acting:

(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; or

(b) In accordance with a statewide drug therapy management protocol per OAR 855-115-0345 or clinical pharmacy agreement or collaborative drug therapy management agreement per OAR 855-115-0315; or

(c) In accordance with a written administration protocol issued by the Oregon Health Authority and approved by the board.

(5) The Pharmacist may administer a drug or device in conjunction with training the patient or the patient's agent how to administer or self-administer the drug or device.

(6) Except as required in (2), records and documents must be retained according to OAR 855-104-0055.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.655

855-115-0310
Services: Laboratory

(1) A Pharmacist must only order and receive laboratory test when:

(a) Managing drug therapy pursuant to the terms of a clinical pharmacy agreement or collaborative drug therapy management agreement with a provider under OAR 855-115-0315;

(b) Providing patient care services pursuant to the terms of the post diagnostic formulary listed in OAR 855-115-0340 that is developed under ORS 689.645 and adopted by the board under ORS 689.649;

(c) Providing patient care services pursuant to and as allowed by the terms of a protocol listed in OAR 855-115-0345 that is developed under ORS 689.645 and adopted by the board under ORS 689.649;

(d) Permitted under a Health Screen Testing Permit pursuant to ORS 438.010(8); ORS 438.060; ORS 438.130(2); ORS 438.150(5), (6) and (7); OAR 333-024-0370, OAR 333-024-0375, OAR 333-024-0380, OAR 333-024-0385, OAR 333-024-0390, OAR 333-024-0395 and OAR 333-024-0400; or

(e) Monitoring a therapeutic response or adverse effect to drug therapy under ORS 689.005.

(2) A pharmacy may perform a laboratory test as permitted under ORS 689.661.

(3) Records and documents must be retained according to OAR 855-104-0055.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

855-115-0315
Services: Collaborative Drug Therapy Management

(1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a Pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one practitioner and one Pharmacist; or

(b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more Pharmacists.

(2) A Pharmacist shall engage in collaborative drug therapy management with a practitioner only under a written arrangement that includes:

(a) The identification, either by name or by description, of each of the participating Pharmacists;

(b) The identification, by name or description, of each of the participating practitioners or group of practitioners;

(c) The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement;

(d) The types of decisions that the pharmacist is allowed to make, which may include:

(A) A detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case;

(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;

(C) A detailed description of the activities the pharmacist is to follow including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system; and

(D) Circumstances which will cause the pharmacist to initiate communication with the practitioner, including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect.

(e) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary;

(f) Quality assurance and periodic review by a panel of the participating Pharmacists and practitioners;

(g) Authorization by the practitioner for the pharmacist to participate in collaborative drug therapy; and

(h) A requirement for the collaborative drug therapy arrangement to be reviewed and updated, or discontinued at least every two years.

(3) The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request.

(4) Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

855-115-0320

Services: Medication Therapy Management

(1) Medication Therapy Management (MTM) is a distinct service or group of services that is intended to optimize the therapeutic outcomes of a patient. Medication Therapy Management can be an independent service provided by a Pharmacist or can be in conjunction with the provision of a medication product with the objectives of:

(a) Enhancing appropriate medication use;

(b) Improving medication adherence;

(c) Increasing detection of adverse drug events;

(d) Improving collaboration between practitioner and Pharmacist; and

(e) Improving outcomes.

(2) A Pharmacist that provides MTM services must ensure that they are provided according to the individual needs of the patient and may include but are not limited to the following:

(a) Performing or otherwise obtaining the patient's health status assessment;

(b) Developing a medication treatment plan for monitoring and evaluating the patient's response to therapy;

(c) Monitoring the safety and effectiveness of the medication therapy;

(d) Selecting, initiating, modifying or administering medication therapy in consultation with the practitioner where appropriate;

(e) Performing a medication review to identify, prevent or resolve medication related problems;

(f) Monitoring the patient for adverse drug events;

(g) Providing education and training to the patient or the patient's agent on the use or administration of the medication where appropriate;

(h) Documenting the delivery of care, communications with other involved healthcare providers and other appropriate documentation and records as required. Such records must:

(A) Be accurate;

(B) Identify the person who completed each action;

(C) Records and documents must be retained according to OAR 855-104-0055.

(i) Providing necessary services to enhance the patient's adherence with the therapeutic regimen; and

(j) Integrating the medication therapy management services within the overall health management plan for the patient.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

855-115-0330
Services: Prescribing - Formulary or Protocol Compendia

(1) A Pharmacist located and licensed in Oregon may prescribe and dispense a FDA-approved drug and device included on either the Formulary or Protocol Compendia, set forth in this Division.

(2) A Pharmacist may submit a concept, on a form prescribed by the board to the Public Health and Pharmacy Formulary Advisory Committee for consideration, for the addition of a drug or device to the Formulary Compendia or the development of a protocol for the Protocol Compendia. A Pharmacist may provide feedback on the Formulary or Protocol Compendia on a board prescribed form and located on the board website.

(3) A Pharmacist must only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.

(4) The Pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.

(5) For each drug or device the Pharmacist prescribes via the Formulary or Protocol Compendia, the Pharmacist must:

(a) Ensure training and education requirements have been met prior to engaging in prescribing activities. A copy of all required training and education must be retained according to OAR 855-104-0055;

(b) Collect subjective and objective information about the patient's health history and clinical status. If prescribing pursuant to the Formulary Compendia in OAR 855-115-0340, a diagnosis from the patient's healthcare provider is required.

(c) Assess the information collected in (b). Any physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means.

(d) Create an individualized patient-centered care plan that utilizes information obtained in the assessment to evaluate and develop a care plan;

(e) Implement the care plan, to include:

(A) Addressing medication and health-related problems and engaging in preventive care strategies;

(B) Initiating, modifying, discontinuing, or administering medication therapy as permitted by the Formulary or Protocol Compendia;

(C) Providing education and self-management training to the patient or caregiver;

(D) Contributing to coordination of care, including the referral or transition of the patient to another health care professional; and

(E) Scheduling follow-up care as needed to achieve goals of therapy.

(f) Monitor and evaluate the effectiveness of the care plan and make modifications to the plan; and

(g) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a Formulary or Protocol Compendia drug or device.

(6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.

(7) All records and documents must be retained according to OAR 855-104-0055 and must be made available to the patient and provider upon request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645 & ORS 689.649

855-115-0335
Services: Prescribing - Prohibited Practices

(1) A Pharmacist must not prescribe a drug or device via the Formulary or Protocol Compendia:

(a) To self; or

(b) When the compendia requires referral to non-Pharmacist provider.

(2) A Pharmacist must not require, but may allow, a patient to schedule an appointment with the Pharmacist for the prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645 & ORS 689.649

855-115-0340

Services: Prescribing - Formulary Compendium

A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, a FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented. Devices and supplies:

(1) Diabetic blood sugar testing supplies;

(2) Injection supplies;

(3) Nebulizers and associated supplies;

(4) Inhalation spacers;

(5) Peak flow meters;

(6) International Normalized Ratio (INR) testing supplies;

(7) Enteral nutrition supplies;

(8) Ostomy products and supplies; and

(9) Non-invasive blood pressure monitors.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645 & ORS 689.649

855-115-0345

Services: Prescribing - Protocol Compendium

A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, FDA-approved drugs and devices listed in the following compendium, pursuant to a statewide drug therapy management protocol.

(1) Continuation of therapy including emergency refills of insulin (v. 06/2023)

(2) Conditions

(a) Cough and cold symptom management

(A) Pseudoephedrine (v. 06/2021);

(B) Benzonatate (v. 06/2021);

(C) Short-acting beta agonists (v. 06/2021);

(D) Intranasal corticosteroids (v. 06/2021);

(b) Vulvovaginal candidiasis (VVC) (v. 06/2021);

(c) COVID-19 Antigen Self-Test (v. 12/2021);

(3) Preventative care

(a) Emergency Contraception (v. 06/2021);

(b) Male and female condoms (v. 06/2021);

(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT (v. 06/2022);

(d) Travel Medications (v. 06/2023);

(e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);

(f) HIV Pre-exposure Prophylaxis (PrEP) (v.06/2023); and

(g) Contraception (v. 06/2023).

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649 & ORS 689.689

855-115-0350
Services: Prescribing Practices - Naloxone

(1) A Pharmacist, having determined that there is an identified medical need, can prescribe naloxone and the necessary medical supplies to administer naloxone for opiate overdose:

(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME);

(b) To an individual seeking naloxone;

(c) To an entity seeking naloxone.

(2) The Pharmacist must determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.

(3) The Pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.

(4) The Pharmacist must dispense the naloxone product in a properly labeled container.

(5) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.

(6) The Pharmacist must document the encounter and the prescription, and maintain records for three years.

(7) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682, ORS 689.684

Division 120: Interns and Preceptors (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 120 for Interns and Preceptors

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates a new Division 120 for Interns and Preceptors. Proposes relocating and reorganizing existing Intern rules from Division 031. After the board permanently adopts and publishes Division 120, repeals Division 031 on the effective date of Division 120.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

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): None anticipated.

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, small businesses or members of the public.

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): Relocates rules from Division 031 to newly created Division 120 Interns. The proposed rule amendments include adding requirements for Interns for applicability, licensure qualification, application, renewal and reinstatement applications, license lapse, voluntary surrender of a license, general responsibilities, confidentiality, duty to report, permitted practices, grounds for discipline, internship program and out-of-state experience. Adds proposed rule requirements for Preceptors including licensure qualification, application, licensure lapse, voluntary surrender of a license, general responsibilities, confidentiality, duty to report, ratio and supervision, prohibited practices, grounds for discipline, qualifications and responsibilities for Internship Program supervisor.

Rule revisions are in alignment with the board's strategy to systematically organize all Divisions. After the board permanently adopts and publishes Division 120, repeals Division 031 on the effective date of Division 120. Upon adoption of Division 120 the board will consider amending OAR 855-006-0005 and relocating relevant definitions related to Interns and Preceptors to Division 120 as well as consider amending OAR 855-019-0200 at a future board meeting.

Division 120
INTERNS AND PRECEPTORS

855-120-0001
Applicability

This Division applies to any individual who is:

(1) Enrolled in or has completed a Bachelor or Doctor of Pharmacy at a College of Pharmacy or School of Pharmacy (COP or SOP) or is certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC), and who acts as Intern; or

(2) Licensed by the board as a Preceptor to supervise an Intern.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225

855-120-0005
Definitions

(1) "ACPE accredited" means a college or school of pharmacy that is accredited, accredited with probation, pre-candidate or candidate status by Accreditation Council for Pharmacy Education (v. 5/2023) including the Lebanese American University school in Byblos, Lebanon after 2002.

(2) "College of Pharmacy or School of Pharmacy (COP or SOP)" means an ACPE accredited college or school of pharmacy.

(3) "Healthcare Preceptor" means a pharmacist, or person with an active healthcare license in good standing that can independently practice pharmacy within the scope of their licensure and is licensed by the board to supervise the internship training of a licensed Intern.

(4) "Intern" means a person who is enrolled in or has completed a course of study at a board approved college or school of pharmacy and who is licensed with the board as an Intern.

(5) "Internship Program" means a professional experiential program that is approved by the board.

(6) "Internship Program Supervisor " is a Pharmacist licensed with the board as a Preceptor who supervises the Internship Program for a COP or SOP located in Oregon.

(7) "Other Preceptor" means a person who is not licensed as a pharmacist or other healthcare provider in Oregon and is licensed by the board to supervise the internship training of a licensed Intern.

(8) "Preceptor" means a Pharmacist or a person licensed by the board to supervise the internship training of a licensed Intern.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

855-120-0010
Licensure: Qualifications - Intern

(1) To qualify for licensure as an Intern, an applicant must provide proof that they:

(a) Are enrolled in a Doctor of Pharmacy program at a COP or SOP; or

(b) Have graduated with a Bachelor or Doctor of Pharmacy degree from a COP or SOP for the purpose of obtaining the qualifications to apply for a Pharmacist license; or

(c) Have graduated with a Bachelor, Master or Doctor of Pharmacy degree from a foreign college or school of pharmacy and are:

(A) Pursuing an Intern license for the purpose of obtaining the qualifications to apply for a Pharmacist license; and

(B) Certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC). Graduates between 1993 and June 30, 2004 of a Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program located in Canada or its jurisdiction with a curriculum taught in English do not have to submit certification from the FPGEC but must meet all other requirements under this rule for an FPGEC certified intern.

(2) If residing in the United States, an applicant must provide proof of citizenship, legal permanent residency or qualifying visa as required by 8 USC 1621.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 689.255

855-120-0030
Licensure: Application- Intern

(1) An application for licensure as an Intern may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of:

(a) Documentation required in OAR 855-120-0030 and for FPGEC certified documentation required in OAR 855-120-0015; and

(b) A completed application including:

(A) Payment of the fee prescribed in OAR 855-110;

(B) A current, passport regulation size photograph (full front, head to shoulders);

(C) Personal identification or proof of identity;

(D) A completed national fingerprint-based background check; and

(E) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of an Intern expires November 30 and may be renewed as follows:

(a) Biennially prior to graduation from a COP or SOP.

(b) Once after graduation from a COP or SOP.

(c) Once if FPGEC certified or a graduate of a CCAPP program between 1993 and June 30, 2004.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

855-120-0035
Licensure: Renewal or Reinstatement - Intern

(1) When applying for renewal of an Intern license, an applicant must:

(a) Pay the biennial license fee required in OAR 855-110;

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-135;

(c) Be subject to a criminal background check; and

(d) Provide a written description and documentation regarding all conduct that is required to be disclosed.

(2) An Intern who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license.

(3) An Intern or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate per OAR 855-120-0010; and

(4) A person whose Intern license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition to the board in writing for reinstatement of such license pursuant to ORS 689.445 may apply to reinstate per OAR 855-120-0010.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.275, ORS 689.445

855-120-0040
Licensure: Lapse - Intern

(1) An Intern may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date:

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not practice as an Intern if the license is lapsed.

(d) A person may apply for renewal according to OAR 855-120-0035.

(2) If a person requests lapse prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board may not accept the lapse if an investigation of or disciplinary action against the licensee is pending.

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-0050

Licensure: Voluntary Surrender - Intern

An Intern may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date is signed by all parties and served on the licensee.

(4) The licensee must cease practicing as an Intern from the date the license terminates.

(5) A voluntarily surrendered license may not be renewed. A former licensee who wants to obtain a license must apply for a license per OAR 855-120-0030 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-0105

Responsibilities: General - Intern

(1) Each Intern is responsible for their own actions; however, this does not absolve the supervising Pharmacist or Preceptor and the pharmacy from responsibility for the Intern's actions.

(2) An Intern is responsible for recognizing the limits of their knowledge and experience and for resolving situations beyond their expertise by consulting with the supervising Pharmacist or Preceptor.

(3) An Intern must:

(a) Comply with all state and federal laws and rules governing the practice of pharmacy;

(b) Only engage in the practice of pharmacy under the supervision of a Pharmacist or Healthcare Preceptor:

(A) After successful completion of academic coursework corresponding to those tasks; and

(B) When permitted by the supervising Pharmacist or Healthcare Preceptor;

(c) Only work within the scope of duties permitted by their license and by the supervising Pharmacist or Healthcare Preceptor;

(d) Know the identity of the supervising Pharmacist or Preceptor at all times;

(e) Only perform tasks they are trained and competent to perform;

(f) Appropriately perform the tasks permitted;

(g) Only access the pharmacy area when a Pharmacist is physically present;

(h) Be clearly identified as an Intern in all interactions and communications (e.g., nametag, phone interaction, chart notations);

(i) Display in plain sight the Intern license within the pharmacy or place of business to which it applies;

(j) Review and adhere to written policies and procedures. The review must:

(A) Occur prior to engaging in the practice of pharmacy as an Intern;

(B) Occur with each update to the policies and procedures; and

(C) Be documented and records retained according to OAR 855-104-0055;

(k) Dispense and deliver prescriptions accurately and to the correct party; and

(l) For hours earned in an Internship Program, must verify that their Preceptor is currently licensed with the board as a Preceptor.

(4) An Intern may not work more than 50 hours per week in an Internship Program and must comply with all supervision and ratio requirements.

(5) An Intern may perform the duties of a pharmacy technician under the supervision of a Pharmacist so long as they adhere to the rules in OAR 855-125. When solely performing technician duties under the supervision of a Pharmacist the ratios in OAR 855-120-1122 do not apply.

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

855-120-0110
Responsibilities: Confidentiality - Intern

Each Intern must comply with OAR 855-104-0015 regarding confidentiality.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-120-0115
Responsibilities: Duty to Report - Intern

Each Intern must report to the board as required by OAR 855-104-0010. In addition, unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each Intern must report to the board without undue delay, but within 10 working days if they:

(1) Have been removed from an Internship Program site for reasons including but not limited to patient safety, unprofessional conduct or suspected violation of ORS 475, ORS 689 or OAR 855; or

(2) Have been dismissed from the Doctor of Pharmacy degree program.

(3) For (1) and (2) the Intern must report the date and reason for the removal or dismissal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.150, ORS 689.151, ORS 689.155 & ORS 689.455

855-120-0135
Responsibilities: Permitted Practices - Intern

Interns must only practice pharmacy as authorized by the rules of the board and as permitted by the supervising Pharmacist or Healthcare Preceptor with the practice of pharmacy in their scope. When practicing pharmacy, an Intern must adhere to all the applicable rules in OAR 855-115 for Pharmacists.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.155 & 2022 HB 4034

855-120-0150
Prohibited Practices - Intern

(1) An Intern must not:

(a) Practice pharmacy as defined in ORS 689.005 except as permitted by the Pharmacist or Healthcare Preceptor who is supervising the Intern;

(b) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace;

(c) Communicate (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, unless the Intern is a health care interpreter registered by the Oregon Health Authority under ORS 413.558 or the supervising Preceptor is also fluent in the language being interpreted; or

(d) Engage in patient care services when the supervising Pharmacist is not trained and qualified to perform the service.

(2) Until an Intern has successfully completed their first academic year, an Intern may observe, but must not:

(a) Conduct a Drug Utilization Review or Drug Regimen Review;

(b) Counsel a patient or the patient's agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in the patient's record or chart;

(c) Advise on therapeutic values, content, hazards and use of drugs and devices;

(d) Conduct Medication Therapy Management;

(e) Practice pursuant to a Clinical Pharmacy Agreement or engage in Collaborative Drug Therapy Management;

(f) Practice pursuant to Statewide Drug Therapy Management Protocols;

(g) Prescribe a vaccine, drug or device; or

(h) Perform verification as defined in OAR 855-006-0005.

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

855-120-0155
Grounds for Discipline - Intern

The following are grounds for discipline:

(1) Continuing to practice as an Intern when one of the following has occurred:

(a) Dismissal from the Doctor of Pharmacy degree program enrolled in to obtain the Intern license; or

(b) Failure to maintain an active Intern license; or

(2) Any other grounds found in ORS 689.405.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.405

855-120-0190
Internship Programs

(1) Interns must complete 1440 hours of internship in an Internship Program to qualify for licensure as a Pharmacist in OAR 855-115-0010 and 855-115-0015.

(2) For obtaining internship hours necessary to apply for a Pharmacist license, the board approves programs:

(a) Administered by an COP or SOP;

(b) Administered for a foreign graduate with FPGEC certification by a Pharmacist registered with the board as a Preceptor;

(c) Administered by another Board of Pharmacy or equivalent in any US state or jurisdiction.

(3) The Internship Program for:

(a) Students enrolled in a COP or SOP located in Oregon must be supervised by an Internship Program Supervisor; or

(b) Foreign graduates with FPGEC certification located in Oregon must be supervised by a licensed Preceptor.

(4) Foreign graduates with FPGEC certification located in Oregon must document the hours obtained on a board approved form.

(5) All Internship Programs must include, but are not limited to:

(a) Direct patient care;

(b) Interprofessional interaction and practice;

(c) Medication dispensing, distribution, administration, and systems management; and

(d) Professional development.

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

855-120-0195
Out-of-State Internship Experience

(1) In order for an Intern to obtain credit for experience obtained outside of Oregon as part of an COP or SOP with an Internship Program based in Oregon, an Intern must be licensed as required by state laws and rules in the state in which they practice.

(2) In order for an out-of-state intern to engage in the practice of pharmacy in the State of Oregon, the intern must:

(a) Be licensed as an Intern by the State of Oregon; and

(b) Comply with ORS 475, ORS 689 and OAR 855.

Statutory/Other Authority: ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.255

855-120-1010
Licensure: Qualifications - Preceptor

To qualify for licensure as a Preceptor, an applicant who is:

(1) A pharmacist must have been actively practicing as a pharmacist in any state for at least one year immediately prior to applying for a Preceptor license unless the pharmacist has been licensed for at least 6 months and is actively participating in an ASHP-accredited, pre-candidate, candidate or conditional accredited PGY1 residency program. The pharmacist license must be in good standing.

(2) A licensed healthcare professional must possess a license in good standing.

(3) Not a licensed healthcare professional must possess a Master or Doctorate degree in the academic discipline for which they are precepting.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 689.255

855-120-1030
Licensure: Application - Preceptor

(1) An application for licensure as a Preceptor may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of:

(a) Attestation to the requirements in OAR 855-120-1010;

(b) A completed application; and

(c) Personal identification that includes a photograph.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of a Preceptor expires June 30 in odd numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

855-120-1040
Licensure: Lapse - Preceptor

(1) A Preceptor may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not practice as a Preceptor if the license is lapsed.

(d) A person may apply to reinstate a Preceptor license according to OAR 855-120-1035.

(2) If a person requests to lapse the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board may not accept the lapse if an investigation of or disciplinary action against the licensee is pending.

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-1050
Licensure: Voluntary Surrender - Preceptor

A Preceptor may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date the licensee is sent the executed final order.

(4) The licensee must cease acting as a Preceptor from the date the license terminates.

(5) A voluntarily surrendered license may not be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-120-1035 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-1070
Responsibilities: General - Preceptor

(1) Each Preceptor is responsible for their own actions.

(2) Each Preceptor is responsible for supervising the actions of each Intern.

(3) A Preceptor must:

(a) Display in plain sight the Preceptor license within the pharmacy or place of business to which it applies;

(b) Provide the Intern with experiences, which in the Preceptor's judgment will increase the Intern's competency in the practice of pharmacy or as a member of the healthcare team; and

(c) Verify that each Intern being supervised by the Preceptor is currently licensed with the board as an Intern.

Statutory/Other Authority: ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.255

855-120-1110
Responsibilities: Confidentiality - Preceptor

Preceptors must follow all applicable confidentiality laws.

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

855-120-1115

Responsibilities: Duty to Report - Preceptor

Within 10 working days, unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each:

(1) Preceptor at an Internship Program site must report if they have dismissed an Intern from an Internship Program site for reasons including but not limited to patient safety, unprofessional conduct or suspected violation of ORS 475, ORS 689 or OAR 855.

(2) Internship Program Supervisor must report the following on behalf of a COP or SOP if it:

(a) Has removed a Preceptor or Internship Program site from the Internship Program for reasons including but not limited to patient safety, unprofessional conduct or suspected violation of ORS 475, ORS 689 or OAR 855; or

(b) Has dismissed an Intern from a Doctor of Pharmacy degree program.

(3) For (1) and (2) the Preceptor and Internship Program Supervisor must report the date and reason for the removal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.150, ORS 689.151, ORS 689.155 & ORS 689.455

855-120-1122

Responsibilities: Supervision - Preceptor

(1) For direct patient care activities, a Pharmacist or Preceptor may supervise no more than four Interns.

(2) For non-direct patient care activities, a Pharmacist or Preceptor may supervise as many Interns as they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare.

(3) The majority of an Intern's overall experience in an Internship Program must be under the supervision of a licensed Pharmacist Preceptor.

Statutory/Other Authority: ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.255

855-120-1150

Prohibited Practices - Preceptor

(1) A Preceptor must not engage in any form of discrimination, harassment, intimidation, or assault in the workplace.

(2) A Preceptor, who is not a Pharmacist, must not supervise an Intern in the practice of pharmacy as defined in ORS 689.005 unless the:

(a) Practice is within the scope of the Healthcare Preceptor's professional license;

(b) Intern is practicing as a part of an Internship Program at a COP or SOP; and

(c) Intern has successfully completed their first academic year.

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

855-120-1155
Grounds for Discipline - Preceptor

The board may suspend, revoke, or restrict the license of a Preceptor or may impose a civil penalty upon the Preceptor upon the following grounds:

(1) Continuing to supervise an Intern in an Internship Program when one of the following has occurred:

(a) School has removed the Preceptor or Internship Program site from the Internship Program for reasons including but not limited to patient safety, unprofessional conduct or suspected violation of ORS 475, ORS 689 or OAR 855.

(b) Licensee is not permitted to supervise an Intern per Board order.

(c) Registrant is not permitted to utilize Interns per Board order.

(2) Any other grounds found in ORS 689.405.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.405

855-120-1205
Qualifications and Responsibilities: Internship Program Supervisor

(1) The Internship Program Supervisor for a COP or SOP located in Oregon must:

(a) Be licensed as a Pharmacist

(b) Be licensed as a Preceptor;

(c) Maintain a record of each internship completed as part of the Internship Program. This record must be made available to the board upon request;

(d) Submit a report on the Internship Program to the board at the end of each academic year. This report must include the names of students who have:

(A) Successfully completed the degree program including:

(i) Date of graduation; and

(ii) Hours earned in Internship Program; and

(B) Extended their course of study; and

(e) Maintain a list of preceptors and Internship Program sites, in and out-of-state, approved by the school and must make this list available to the board upon request.

(2) The Pharmacist who supervises the Internship Program for a FPGEC certified Intern located in Oregon must:

(a) Be licensed as a Pharmacist;

(b) Be licensed as a Preceptor; and

(c) Certify hours completed for internship credit in the Internship Program on a board-approved form. This record must be made available to the board upon request.

(3) The Internship Program Supervisor in (1) and the supervising Preceptor in (2) must ensure the Internship Program includes the following components:

(a) Direct patient care;

(b) Interprofessional interaction and practice;

(c) Medication dispensing, distribution, administration, and systems management; and

(d) Professional development.

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

Division 125: Pharmacy Technicians (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 125 for Pharmacy Technicians

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 125 for Certified Oregon Pharmacy Technicians (COPT) and Pharmacy Technicians (PT). Proposes relocating and reorganizing existing COPT and PT rules from Division 025. Adds new requirements related to general responsibilities, licensure, and prohibited practices. After the board permanently adopts and publishes Division 125, repeals Division 025 on the effective date of Division 125.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

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): None anticipated.

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, small businesses or members of the public.

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. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Relocates existing rules from Division 025 to newly created Division 125 Certified Oregon Pharmacy Technicians and Pharmacy Technicians. The proposed new language includes adding requirements for lapsing a license, voluntary surrender of a license, general responsibilities, confidentiality, duty to report and prohibited practices. Rule revisions are in alignment with the board's strategy to systematically organize all Divisions. After the board permanently adopts and publishes Division 125, repeals Division 025 on the effective date of Division 125.

Division 125
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-125-0001
Applicability

(1) This Division applies to any individual who assists a Pharmacist in the practice of pharmacy.

(2) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may assist a Pharmacist in the practice of pharmacy and must act in compliance with statutes and rules under the supervision, direction, and control of a Pharmacist.

(3) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification when delegated to do so by a Pharmacist and done in compliance with all applicable statutes and rules and under the supervision, direction, and control of that Pharmacist.

(4) Only a person licensed as a Certified Oregon Pharmacy Technician may use the titles "Certified Oregon Pharmacy Technician" and "COPT."

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.225,ORS 689.486

855-125-0005
Definitions

Placeholder

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

855-125-0010
Licensure: Qualifications – Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) To qualify for licensure as a Certified Oregon Pharmacy Technician or Pharmacy Technician, an applicant must demonstrate that the applicant is at least 18 years of age and has completed high school (or equivalent).

(2) To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must also demonstrate that the applicant has taken and passed a national pharmacy technician certification examination offered by:

(a) Pharmacy Technician Certification Board (PTCB); or

(b) National Healthcareer Association (NHA).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-125-0030

Licensure: Application - Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) An application for licensure as a Certified Oregon Pharmacy Technician or Pharmacy Technician may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of a completed application including:

(a) Payment of the fee prescribed in OAR 855-110;

(b) A current, passport regulation size photograph (full front, head to shoulders);

(c) Personal identification or proof of identity;

(d) A completed national fingerprint-based background check; and

(e) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(3) An applicant for a Certified Oregon Pharmacy Technician license, must provide a passing result from PTCB or NHA on a national pharmacy technician certification examination.

(4) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application or requests resulting from the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405 or ORS 689.490.

(5) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(6) The license of a Certified Oregon Pharmacy Technician or Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-125-0035

Licensure: Renewal or Reinstatement Applications - Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) An applicant for renewal of a Certified Oregon Pharmacy Technician or Pharmacy Technician license must:

(a) Pay the biennial license fee required in OAR 855-110;

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-021;

(c) Be subject to an annual criminal background check; and

(d) Provide a written description and documentation regarding all conduct that is required to be disclosed.

(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A Certified Oregon Pharmacy Technician or Pharmacy Technician or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-125-0020; and

(b) Provide certification of completion of 10 continuing education hours earned in the prior 12 months. These hours may not be counted toward a future renewal; and must include:

(A) One hour of continuing pharmacy education in pharmacy law;

(B) One hour of continuing pharmacy education in patient safety or error prevention;

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

(4) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405 or ORS 689.490.

(5) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.

(6) Any person whose Certified Oregon Pharmacy Technician or Pharmacy Technician license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition the board for reinstatement of such license pursuant to ORS 689.445 and in conjunction with the application process identified in OAR 855-125-0020.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, ORS 689.445, ORS 689.486 & ORS 413.450

855-125-0040
Licensure: Lapse

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not assist in the practice of pharmacy if the license is lapsed.

(d) A person may apply for renewal or reinstatement according to OAR 855-125-0030.

(2) If a person requests lapse prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board may not accept the lapse if an investigation of, or disciplinary action against the licensee is pending.

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-125-0050
Licensure: Voluntary Surrender

A Certified Oregon Pharmacy Technician or Pharmacy Technician may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date is the order is signed by all parties and served on the licensee.

(4) The licensee must cease assisting in the practice of pharmacy from the date the license terminates.

(5) A voluntarily surrendered license may not be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-125-0030 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation, action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-125-0105
Responsibilities: General - Certified Oregon Pharmacy Technician and Pharmacy Technician

(1) Each Certified Oregon Pharmacy Technician and Pharmacy Technician is responsible for their own actions; however, this does not absolve the Pharmacist and the pharmacy from responsibility for the Certified Oregon Pharmacy Technician or Pharmacy Technician's actions.

(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician may not engage in the practice of pharmacy as defined in ORS 689.005.

(3) A Certified Oregon Pharmacy Technician and Pharmacy Technician must:

(a) Comply with all state and federal laws and rules governing the practice of pharmacy;

(b) Only assist in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;

(c) Know the identity of the Pharmacist who is providing supervision, direction and control at all times;

(d) Only work within the scope of duties permitted by their license;

(e) Only work within the scope of duties permitted by the Pharmacist providing supervision, direction and control;

(f) Only perform duties they are trained to perform;

(g) Appropriately perform the duties permitted;

(h) Only access the pharmacy area when a Pharmacist is physically present at the Drug Outlet Pharmacy or when the Drug Outlet Pharmacy is operating under a Remote Dispensing Site Pharmacy (RDSP) registration and following the requirements in OAR 855-139;

(i) Be clearly identified as a Certified Oregon Pharmacy Technician or Pharmacy Technician in all interactions and communications (e.g., nametag, phone interaction, chart notations);

(j) Display in plain sight the Certified Oregon Pharmacy Technician or Pharmacy Technician license within the pharmacy or place of business to which it applies;

(k) Ensure initial and ongoing training is completed that is commensurate with the tasks that the Certified Oregon Pharmacy Technician or Pharmacy Technician will perform, prior to the performance of those tasks and with each update to the written policies and procedures;

(l) Review and adhere to written policies and procedures. The review must:

(A) Occur prior to assisting in the practice of pharmacy;

(B) Occur with each update; and

(C) Be documented and records retained according to OAR 855-104-0055; and

(m) Dispense and deliver prescriptions accurately and to the correct party.

(4) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification of the drug and dosage, device or product when:

(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;

(b) No discretion is needed;

(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and

(d) The Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.

Statutory/Other Authority: ORS 689.205, 2022 HB 4034
Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

855-125-0110
Responsibilities: Confidentiality

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must comply with OAR 855-104-0015 regarding confidentiality.

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

855-125-0115
Responsibilities: Duty to Report

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must comply with OAR 855-104-0010 regarding duty to report.

Statutory /Other Authority: ORS 689.455
Statutes/Other Implemented: ORS 689.455

855-125-0135
Responsibilities: Permitted Practices

Certified Oregon Pharmacy Technicians or Pharmacy Technicians:

(1) Must only assist in the practice of pharmacy as authorized by the rules of the board and as permitted by the Pharmacist providing supervision, direction, and control.

(2) Must ensure that work is verified by a Pharmacist if judgment is utilized when assisting in the practice of pharmacy.

(3) May perform final verification as permitted under OAR 855-125-0105(4).

Statutory /Other Authority: ORS 689.005, ORS 689.225
Statutes/Other Implemented: ORS 689.151, 2022 HB 4034

855-125-0150
Prohibited Practices

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:

(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0105(4), including but not limited to the following tasks:

(a) Evaluate and interpret a prescription;

(b) Conduct a Drug Utilization Review or Drug Regimen Review;

(c) Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription;

(d) Counsel a patient or the patient's agent regarding a prescription;

(e) Accept a patient or patient's agent's request to decline counseling;

(f) Advise on therapeutic values, content, hazards and use of drugs and devices;

(g) Interpret the clinical data in a patient record system or patient chart;

(h) Conduct Medication Therapy Management;

(i) Practice pursuant to a Clinical Pharmacy Agreement or Collaborative Drug Therapy Management;

(j) Practice pursuant to Statewide Drug Therapy Management Protocols;

(k) Prescribe a vaccine, drug or device;

(l) Administer a vaccine, drug or device;

(m) Order, interpret or monitor a laboratory test;

(n) Receive or provide a new or transferred prescription orally;

(o) Supervise, direct, or control another licensee in the licensee practicing or assisting in the practice of pharmacy;

(p) Delegate tasks to healthcare providers; and

(q) Deny the patient or the patient's agent request to speak to the Pharmacist.

(2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.

(3) Perform any task while assisting in the practice of pharmacy that requires judgment unless it is verified by a Pharmacist.

(4) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace.

(5) Refuse a request from a patient, patient's agent, or practitioner to interact with a Pharmacist.

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.155

Division 7: Compliance with the Oregon Health Authority's COVID-19 Requirements

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals COVID-19 related rule no longer in effect

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals rule that required licensees and registrants to comply with the Oregon Health Authority's (OHA) requirements that were issued to control COVID-19.

Documents Relied Upon per ORS 183.335(2)(b)(D): OAR 333-019-1011, OAR 333-019-1025, OHA Public Health Order Rescinding Health Care Masking

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed repeal provides clarity for licensees and registrants. It is anticipated that repeal of this rule will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommend repealing the rule for clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals rule that is no longer necessary. The OHA rescinded provisions in OAR 333-019-1011 which required workers in health care settings to wear masks on 4/3/2023 and repealed OAR 333-019-1010 requiring workers in health care settings to be COVID-19 vaccinated on 5/11/2023.

Division 7
PUBLIC HEALTH EMERGENCY

~~855-007-0088~~
~~Compliance with the Oregon Health Authority's COVID-19 Requirements~~

~~(1) The Oregon Health Authority (OHA) has adopted certain rules to control the communicable disease COVID-19. Unprofessional conduct includes failing to comply with any applicable provision of an OHA COVID-19-related rule or any provision of this rule.~~

~~(2) Failing to comply as described in subsection (1) includes, but is not limited to:~~

~~(a) Failing to comply with OHA's rules requiring masks, face coverings or face shields, including OAR 333-019-1011 and OAR 333-019-1025.~~

~~(b) Failing to comply with OHA's rules requiring vaccinations, including OAR 333-019-1010.~~

~~(3) No disciplinary action or penalty action will be taken under this rule if the rule alleged to have been violated is not in effect at the time of the alleged violation.~~

~~(4) Imposition of discipline for violating this rule is as authorized by ORS 689.405 and ORS 689.445. Any such discipline will be imposed in accordance with ORS Ch. 183.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

Divisions: 006/041/043/045/183: 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; Repeals Division 45 and creates new Division 183 for Drug Compounding

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 45 and creates a new Division 183 for Drug Compounding. Adds additional general requirements for Drug Outlet Pharmacies, Dispensing Practitioner Drug Outlets (DPDO), Correctional Facilities (CF) and Community Health Clinics (CHC) related to dispensing compounded drugs in Divisions 041 and 043. These rules apply to the preparation and dispensing of compounded drugs from a Drug Outlet. These rules do not apply to the preparation and direct administration of compounded drugs by a healthcare provider. Proposed amendments are a result of the board's 2022-2026 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

Documents Relied Upon per ORS 183.335(2)(b)(D):

USP Chapters: USP Compounding Compendium; State Compliance with USP Chapters (v. 2021)

Designated Person Responsibilities: ASHP List

Sterile Compounding Technology:

- ISMP Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology (2016 and 2022)

- Pedersen CA, Schneider PJ, Ganio MC, Scheckelhoff DJ. ASHP National Survey of Pharmacy Practice in Hospital Settings: Dispensing and Administration-2020. Am J Health Syst Pharm. 2021 Jun 7;78(12):1074-1093. DOI: 10.1093/ajhp/zxab120. PMID: 33754638; PMCID: PMC8083667.

- Moniz TT, Chu S, Tom C, Lutz P, Arnold A, Gura KM, Patterson A. Sterile Product Compounding Using an I.V. Compounding Workflow Management System at a Pediatric Hospital. Am J Health Syst Pharm. 2014 Aug 1;71(15):1311-7. DOI: 10.2146/ajhp130649. PMID: 25027539.

- Speth SL, Fields DB, Schlemmer CB, Harrison C. Optimizing I.V. Work-Flow. Am J Health Syst Pharm. 2013; 70(23):2076,2078-80. DOI: 10.2146/ajhp120738

- Deng Y, Lin AC, Hingl J, Huang G, Altaye M, Maynard H, Mayhaus D, Penm J. Risk factors for I.V. Compounding Errors When Using an Automated Workflow Management System. Am J Health Syst Pharm. 2016 Jun 15;73(12):887-93. DOI: 10.2146/ajhp150278. PMID: 27261239.

- NV: NAC 639.67017 Use of automated compounding devices.

Sterile Compounding Accreditation: PCAB/ACHC, NABP, TJC

Standard Operating Procedures: ASHP List 795 797

Compounded Drug Recalls: CA Law 4126.9. Recall of Nonsterile Compounded Drugs; 4127.8. Pharmacies that Compound Sterile Drug Products; Recalls; Requirements

Requirements For Use by a Veterinarian: Compounding Animal Drugs from Bulk Drug Substances Guidance for Industry (August 2022), Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

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 registration and compliance requirements will positively impact all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): To be determined.

Related to sterile compounding technology- Compounding Workgroup members stated that in their experience, barcoding and imaging technology procurement, implementation, ongoing maintenance, and training is estimated to cost between $30,000 - $130,000 initially and $50,000 annually. This type of technology is typically customized, requires specialized training and requires extra staff to operate.

Related to sterile compounding accreditation/certification through PCAB/ACHC, NABP and TJC- Compounding Workgroup members stated in their experience, the estimated cost is between $4,500 to $17,500 depending on the vendor for a three-year accreditation/certification.

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 clarifying that all Drug Outlets that compound drugs must comply with OAR 855-183; amending the definition of "Compounding" in Division 006 to match the definition in the USP standards adopted by reference; creating a new Division 183 by revising and relocating existing rules from Division 045. In OAR 855-183, creating proposed rules related to requirements for Compounding in the areas of "Applicability", "Definitions", "Designation", "Personnel", "General Requirements", "Compounding Technology", "Delivery", "Compounding Labeling" for both compounded sterile preparations (CSPs) and compounded non-sterile preparations (CNSPs) 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 general requirements to comply with OAR 855-183 for DPDOs, Community Health Clinics and Correctional Facilities. Will repeal Division 045 upon adoption of new Division 183.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the August 2023 board meeting.
  - The rules were sent to rulemaking at the June 2023 board meeting for the July 2023 rulemaking hearing for public comment only.

- Highlights/Markup
  - Rule language highlighted in yellow denote staff proposed amendments made since the rule package was sent to rulemaking for public comment only at the June 2023 board meeting.
  - **Mark**~~up~~ in this package is in comparison to the current rules for Div 006, 041, 043, 045, and 183

Division 6
DEFINITIONS

855-006-0005
Definitions
As used in OAR Chapter 855:

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. 03/21/2023).

(2) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.

(3) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.

(4) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

(5) "Biosimilar" product means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (v. 12/28/2022).

(6) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(7) “Certified health care interpreter” has the meaning given that term in ORS 413.550.

(8) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the Pharmacist are not considered Certified Oregon Pharmacy Technicians or Pharmacy Technicians.

(9) “Clinical Pharmacy Agreement” means an agreement between a Pharmacist or pharmacy and a health care organization, or a ~~p~~**P**hysician as defined in ORS 677.010 or a ~~n~~**N**aturopathic ~~p~~**P**hysician as defined in ORS 685.010 that permits the Pharmacist to engage in the practice of clinical pharmacy pharmacy **as defined in ORS 689.005** for the benefit of the patients of the health care organization, or ~~p~~**P**hysician or ~~n~~**N**aturopathic ~~p~~**P**hysician.
Note: This is in rulemaking package #D6

(10) "Collaborative Drug Therapy Management" means **the process in which a Pharmacist or pharmacy and a health care provider or group of health care providers** ~~participation by a Pharmacist in the management of drug therapy pursuant to a written~~ **agree to a pre-specified drug therapy management** protocol that ~~includes information specific to the dosage, frequency, duration, and route of administration of the drug, authorized by a practitioner and~~ **is** initiated **for an individual patient on the** ~~upon a~~ prescription **or prescription drug** order of **a participating provider.** ~~for an individual patient and:~~

~~(a) Is agreed to by one Pharmacist and one practitioner; or~~

~~(b) Is agreed to by one or more Pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic, or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.~~

Note: This is in rulemaking package #D6

(11) "Compounding" means the **process of combining, admixing, diluting, pooling, reconstituting, or otherwise altering a drug product or bulk drug substance to create a new preparation.** ~~preparation, mixing, assembling, packaging, or labeling of a drug or device:~~

(a) **For non-sterile preparations, compounding does not include reconstituting according to the manufacturers labeling.** ~~As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the Pharmacist and the patient, in the course of professional practice; or~~

(b) **For sterile preparations, compounding includes repackaging.** ~~For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or~~

~~(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.~~

(12) "Confidential Information" means any patient information obtained by a Pharmacist or pharmacy.

(13) "Consulting Pharmacist" means a Pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.

(14) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(15) “Custodian of pharmacy records” means a board licensee or registrant who is responsible for the maintenance, care or keeping of pharmacy records based on the services provided by the pharmacy, regardless of whether the records are in that person's actual physical custody and control.

(16) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(17) "Drug Regimen Review” or “DRR" means the process conducted by a Pharmacist who is consulting for a long-term-care facility or other institution, either prior to dispensing or at a later time, with the goal of ensuring that optimal patient outcomes are achieved from the drug therapy.

(18) “Entry system” enables control of access to a secured area.

(19) “Final verification” means after prescription information is entered into a pharmacy’s electronic system and reviewed by a Pharmacist for accuracy, a physical verification that the drug and drug dosage, device or product selected from a pharmacy’s inventory pursuant to the electronic system entry is the prescribed drug and drug dosage, device, or product.

(20) "Good standing" means a license or registration that is not suspended, revoked, or otherwise restricted from the practice of pharmacy or subject to a current disciplinary order.

(21) “Health care interpreter” has the meaning given that term in ORS 413.550.

(22) “Health care interpreter registry” means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.

(23) “Individual with limited English proficiency” means a person who, by reason of place of birth or culture, communicates in a language other than English and does not communicate in English with adequate ability to communicate effectively with a health care provider.

(24) “Interchangeable” means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 USC 262(k)(4) (v. 12/28/2022).

(25) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose,

contains all information required by federal and state law, and is within the practitioner's scope of practice.

(26) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.

(27) “Misbranded” has the same definition as set forth in 21 USC 352 (v. 12/28/2022).

(28) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.

(29) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.

(30) "Nationally Certified Exam" means an exam that is approved by the board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible, and valid.

(31) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(32) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:

(a) The creation and retention of accurate and complete patient records;

(b) Assuming authority and responsibility for product selection of drugs and devices;

(c) Developing and maintaining a safe practice setting for the Pharmacist, for pharmacy staff and for the general public;

(d) Maintaining confidentiality of patient information.

(33) “Official compendium” means the official United States Pharmacopeia <USP>, official National Formulary <NF> (v. USP NF 2023, Issue 1), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2023), or any supplement to any of these.

(34) "Oral Counseling" means an oral communication process between a Pharmacist and a patient or a patient’s agent in which the Pharmacist obtains information from the patient (or agent) and the patient's pharmacy records, assesses that information, and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.

(35) Participation in Drug Selection and Drug Utilization Review:

(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.

(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the Pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review include, but are not limited to:

(A) Over-utilization or under-utilization;

(B) Therapeutic duplication;

(C) Drug-disease contraindications;

(D) Drug-drug interactions;

(E) Incorrect drug dosage;

(F) Incorrect duration of treatment;

(G) Drug-allergy interactions; and

(H) Clinical drug abuse or misuse.

(36) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:

(a) Cure of a disease;

(b) Elimination or reduction of a patient's symptomatology;

(c) Arrest or slowing of a disease process; or

(d) Prevention of a disease or symptomatology.

(37) “Pharmacist” means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.

(38) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board but has not completed the specialized education program pursuant to OAR 855-025-0012.

(39) “Practice of clinical pharmacy” means:

(a) The health science discipline in which, in conjunction with the patient's other practitioners, a Pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;

(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and

(c) The practice of pharmacy by a Pharmacist pursuant to a clinical pharmacy agreement.

(40) "Practice of pharmacy" is as defined in ORS 689.005.

(41) "Prescription drug" or "legend drug" is as defined in ORS 689.005 and:

(a) Required by federal law, prior to being dispensed or delivered, to be labeled with "Rx only"; or

(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

(42) "Prescription released by the Pharmacist" means, a prescription which has been reviewed by the Pharmacist that does not require further Pharmacist intervention such as reconstitution or counseling.

(43) "Prohibited conduct" means conduct by a licensee that:

(a) Constitutes a criminal act against a patient or client; or

(b) Constitutes a criminal act that creates a risk of harm to a patient or client.

(44) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:

(a) Assure retention of their purity and potency;

(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;

(c) Assure security and minimize the risk of their loss through accident or theft;

(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;

(e) Protect the health, safety and welfare of the Pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.

(45) "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.

(46) "Reasonable professional judgment" means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities, qualifications, and competencies, after careful review, analysis and consideration of the relevant subject

matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion, or conclusion.

(47) “Reference biological product” means the biological product licensed pursuant to 42 USC 262(a) (v. 12/28/2022) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

(48) “Repackage” means the act of taking a drug from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug.

(49) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication, the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.

(50) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as Certified Oregon Pharmacy Technicians or Pharmacy Technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or

(b) A structured program approved by the board and designed to educate Certified Oregon Pharmacy Technicians or Pharmacy Technicians in one or more specific issues of patient health and safety that is offered by:

(A) An organization recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians;

(B) An employer recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians; or

(C) A trade association recognized by the board as representing pharmacies.

(51) “Still image capture” means a specific image captured electronically from a video or other image capture device.

(52) “Store and forward” means a video or still image record which is saved electronically for future review.

(53) "Supervision by a Pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician being supervised, coupled with the ability to control and be responsible for the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician's action.

(54) “Surveillance system” means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

(55) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.

(56) "Verification" means the confirmation by the Pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an Intern, a Certified Oregon Pharmacy Technician, or a Pharmacy Technician.
[Publications: Publications referenced are available for review at the agency or from United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & 2022 HB 4034

Division 41
OPERATION OF PHARMACIES

855-041-1018
Outlet: General Requirements

A ~~d~~**D**rug ~~o~~**O**utlet ~~p~~**P**harmacy 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 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

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

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

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

(a) Proper drug storage conditions are maintained; and

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

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

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

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

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

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.305

855-043-0630
Correctional Facility **(CF)** - Drug Delivery and Control
NOTE: This rule is also in mailing #D2- Short-acting opioid antagonist

(1) Policies and Procedures: The ~~p~~**P**harmacist and the practitioner representing the facility ~~shall be~~ **are** responsible for establishing written policies and procedures for medication management including, but not limited to, drug procurement, dispensing, administration, labeling, medication counseling, drug utilization review, medication records, parenterals, emergency and nonroutine dispensing procedures, stop orders, over-the-counter drugs, security, storage and disposal of drugs withing the facility. Policies and procedures ~~shall~~ **must** be reviewed and updated annually by the ~~p~~**P**harmacist and the practitioner, maintained in the facility; and be made available to the ~~B~~**b**oard for inspection. The facility ~~shall~~ **must** submit to the ~~B~~**b**oard for approval, the name of any employee ~~p~~**P**harmacist or a written agreement between the ~~p~~**P**harmacist and the facility regarding drug policies and procedures. The facility ~~shall~~ **must** notify the ~~B~~**b**oard of any change of ~~p~~**P**harmacist within 15 days of the change.

(2) Dispensing: Prescription drugs ~~shall~~ **must** be dispensed by a ~~p~~**P**harmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system. **The Correctional Facility (CF) must ensure that compounded preparations are dispensed in compliance with OAR 855-183.**

(3) Unit Dose Dispensing System. The "Unit Dose Dispensing System" is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stock from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled:

(a) A unit dose dispensing system ~~shall~~ **must**:

(A) By nature of the system;

(i) Provide for separation of medications by patient name and location; and

(ii) Provide for separating medications by day of administration.

(B) By means of an individual patient medication record:

(i) Record the drug and dosing regimen of those drugs dispensed by the pharmacy;

(ii) Record the actual doses dispensed and returned to the pharmacy;

(iii) Record the date of the original order and the date the order is discontinued;

(iv) Provide a means for the ~~p~~**P**harmacist to verify the prescriber's original order;

(v) Provide a means for the ~~p~~**P**harmacist 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~~ **CF** utilizing a unit dose dispensing system ~~shall~~ **must** establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies ~~shall~~ **must** be available in the pharmacy for inspection by the ~~B~~**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 ~~O~~AR 855-041-~~0177~~(4).

(c) The ~~p~~**P**harmacist ~~shall~~ **must** certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.

(d) All medication ~~shall~~ **must** be stored in a locked area or locked cart.

(4) Labeling: Prescription drugs dispensed in individual containers or medication cards ~~shall~~ **must** be labeled with the following information:

NOTE: This rule is also in mailing #D2- Short-acting opioid antagonist

(a) Name and identifying number of the patient/inmate;

(b) Name, strength, and quantity of the drug dispensed. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(c) Name of the prescriber;

(d) Initials of the dispenser and the date of dispensing;

(e) Directions for use;

(f) Auxiliary labels and cautionary statements as required;

(g) Manufacturer's expiration date, or an earlier date if preferable; and

(h) Name of the pharmacy.

(5) Patient counseling:

(a) Upon receipt of a prescription drug order and following review by the ~~p~~**P**harmacist of the patient's record, the ~~p~~**P**harmacist ~~shall~~ **must** initiate and provide oral counseling to the patient or to the patient's agent or care giver in all ambulatory care settings and for discharge medications in institutions:

(A) Upon request; or

(B) On matters which a reasonable and prudent ~~p~~**P**harmacist would deem significant; or

(C) Whenever the drug prescribed has not previously been dispensed to the patient; or

(D) Whenever the patient's medication record shows the drug has not been previously dispensed to the patient in the same dosage, form, strength or with the same written directions.

(b) When counseling is provided it ~~shall~~ **must** include information that a reasonable and prudent ~~p~~**P**harmacist would deem necessary to provide for the safe and effective use of the drug. Such information may include the following:

(A) The name and description of the drug;

(B) The dosage form, dose, route of administration, and duration of drug therapy;

(C) The intended use of the drug and expected actions;

(D) Special directions and precautions for preparation, administration, and use by the patient;

(E) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(F) The possible dangers of taking the drug with alcohol, or taking the drug and then operating a motor vehicle or other hazardous machinery;

(G) Techniques for self-monitoring drug therapy;

(H) Proper storage;

(I) Prescription refill information;

(J) Action to be taken in the event of a missed dose; and

(K) Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Patient counseling ~~shall~~ **must** be in person whenever practicable. Whenever the prescription is delivered outside the confines of the pharmacy by mail or other third party delivery, counseling ~~shall~~ **must** be in writing and by free access to the ~~p~~**P**harmacist by phone.

(d) Subsections (a) and (b) of this section ~~shall~~ **must** not apply to those prescription drug orders for inpatients in hospitals or institutions where the drug is to be administered by a nurse or other individual authorized to administer drugs.

(e) Notwithstanding the requirements set forth in subsection (a), a ~~p~~**P**harmacist is not required to provide oral counseling when a patient refuses the ~~p~~**P**harmacist 's attempt to counsel, or when the ~~p~~**P**harmacist, 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~~ **CF**.

(6) Administration: Drugs ~~shall~~ **must** be administered to inmate/ patients by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined ~~in~~ by the **Oregon State Board of Nursing in** ~~Board administrative rule 851-047-0020~~ **OAR 851-045-0060**. Drugs selected by registered nurses from manufacturer's or ~~p~~**P**harmacist's bulk drug containers ~~shall~~ **must** not be administered by unlicensed persons, except under certain emergency and nonroutine situations as described in the facility's policies and procedures.

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

855-043-0740

Community Health Clinic (CHC) - Dispensing and Drug Delivery

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

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

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

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

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

(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

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

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

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

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

(a) Proper drug storage conditions are maintained; and

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

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

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

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

(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.
[Publications: Publications referenced are available for review at the agency.]

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

Division ~~45~~ **183**
DRUG COMPOUNDING

~~855-045-0200~~ **855-183-0001**
~~Application~~ **Applicability**

(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for ~~use or~~ **dispensing, delivery or** distribution in Oregon must register with the board as a drug outlet and comply with board regulations.

(2) These rules apply to sterile and non-sterile compounding of a drug **for humans and animals**.

(3) Entities that are registered with FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act in 21 USC 353b (04/10/2023) must register with the board as a manufacturer in OAR 855-060.

~~(3) 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 (05/01/2020 v. 2014);~~

~~(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (05/01/2020 v. 2008);~~

~~(c) USP <800> Hazardous Drugs—Handling in Healthcare Settings (07/01/2020 v. 2020);~~

~~(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging (12/01/2020 v. 2020); and~~

~~(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151~~

~~(05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2016), 1231 (12/01/2021), and 1821 (05/01/2017).~~

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

~~855-045-0210~~ **855-183-0010**
~~Registration~~ **Designation**

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

~~(1) A non-resident drug outlet that distributes a non-patient specific compounded drug into Oregon must be registered with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.~~

~~(2) A resident drug outlet that distributes a non-patient specific human compounded drug within or outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.~~

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

~~855-045-0220~~ **855-183-0050**
Personnel ~~and Responsibilities~~

(1) All personnel who prepare and supervise the preparation of a compound must **obtain the education,** ~~complete appropriate~~ 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**.

(2) Training must be conducted by qualified individuals on a continuing basis and with sufficient frequency required by applicable USP standards to ensure that compounding personnel remain familiar with operations and policies and procedures.

(3) The training must be documented and records retained according to OAR 855-183-0550.

(4) Each Drug Outlet must ensure:

(a) For non-sterile compounding, personnel in the compounding area are authorized to be in the area by the person providing supervision when compounding activities are occurring.

(b) For sterile compounding, personnel in the compounding area are authorized by the person providing supervision to be in the area.

(c) The annual self-inspection is completed using the board's Compounding Self-Inspection Form by July 1 and retained for board inspection.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

~~(2) The Pharmacist-in-Charge (PIC) and the drug outlet must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR 855-045-0200(3) for all aspects of the compounding operation according to the type of compounding performed and must include written procedures for:~~

~~(a) Personnel qualifications, to include training, evaluation and requalification;~~

~~(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, handling, and storage;~~

~~(g) Creating master formulation records, with documented pharmacist approval;~~

~~(h) Creating compounding records;~~

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

~~(j) Continuous quality assurance program and quality controls, to include release testing, end-product evaluation, and quantitative/qualitative testing;~~

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

~~(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug.~~

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

855-183-0200
Requirements: General

~~855-045-0200~~
~~Application~~

(~~3~~**1**)All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:

(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations **(11/01/2022) and all chapters referenced therein, including but not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 659 (04/01/2021), 797 (11/01/2022), 800 (07/01/2020), 1112 (2013), 1163 (12/01/2020), and 1231 (12/01/2021)** ~~(05/01/2020 v. 2014)~~;

(b) USP <797> Pharmaceutical Compounding—Sterile Preparations **(11/01/2022) and all chapters referenced therein, including but not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018), 659 (04/01/2021), 788 (05/01/2013), 789 (08/01/2015), 800 (07/01/2020), 825 (12/01/2020), 1066 (08/01/2015), 1085 (12/01/2020), 1113 (2013), 1116 (2013), 1163 (12/01/2020), 1197 (05/01/2021), 1207 (08/01/2016), 1223 (05/01/2018), 1225 (08/01/2017), 1228.1 (08/01/2016), 1228.4 (11/01/2019), 1229 (08/01/2022), 1229.1 (2013), 1229.4 (05/01/2018), 1229.5 (08/01/2022), 1229.8 (05/01/2018), and 1229.9 (08/01/2016)** ~~(05/01/2020 v. 2008)~~;

(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)** ~~(07/01/2020 v. 2020)~~;

(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging **(12/01/2020) and all chapters referenced therein, including but not limited to Chapters 71 (2013), 85 (05/01/2018), 659 (04/01/2021), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1113 (2013), 1116 (2013), and 1163 (12/01/2020)** ~~(12/01/2020 v. 2020)~~; and

~~(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2016), 1231 (12/01/2021), and 1821 (05/01/2017).~~

(2) A drug must only be compounded and dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs except as provided in OAR 855-183-0730. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

NOTE: Remove 'except as provided in OAR 855-183-0730 if board does not send OAR 855-183-0730 to rulemaking.

(3) A drug may be compounded for a commercially available product according to OAR 855-183-0710.

NOTE: Remove (3) if board does not send OAR 855-183-0710 to rulemaking.

(4-1-1) Beginning July 1, 2025, verification of compounded non-sterile preparations (CNSPs) and compounded sterile preparations (CSPs) must utilize a system that incorporates barcoding to verify ingredients.

(4-1-2) Verification of compounded sterile preparations (CSPs) may use a system that incorporates imaging or gravimetrics to verify ingredient quantity and finished CSP volumes.

(4-2) Verification of compounded non-sterile preparations (CNSPs) and compounded sterile preparations (CSPs) may utilize a system that incorporates:

(a) Barcoding to verify ingredients; and

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

(4-3) Verification of compounded sterile preparations (CSPs) may utilize a system that incorporates:

(a) Barcoding to verify ingredients; and

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

POLICY DISCUSSION: May vs. must with implementation dates

(5) It is recommended that verification of CNSPs and CSPs 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.

POLICY DISCUSSION: Recommendation vs. must (prohibited practice) with implementation dates

(6) Beginning July 1, 2025, a Drug Outlet that prepares CSPs from 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.

POLICY DISCUSSION: May vs. must with implementation dates

(7) For CNSPs, the compounding area must have a visible line of demarcation to designate the area used for compounding. Other activities may not occur in this area when compounding is occurring.

POLICY DISCUSSION: May vs. must with implementation dates

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

855-183-0205
Technology: Automated Compounding Devices (ACDs)

(1) For the purposes of this rule, an "automated compounding device" is a device that compounds, measures, and/or packages a specified quantity of individual components in a predetermined sequence for a sterile preparation.

(2) A Drug Outlet Pharmacy, DPDO, CF or CHC may use an Automated Compounding Device (ACD) to:

(a) Assist with the compounding of a CSP; or

(b) Produce a final CSP.

(3) If a Drug Outlet Pharmacy, DPDO, CF or CHC uses an ACD as described in (1), the outlet must establish and maintain written policies and procedures, in addition to the policies and procedures established and maintained pursuant to OAR 855-183-0500, that address:

(a) The qualifications and training that a person must have to operate the ACD;

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

(c) The testing required to be performed on the ACD to ensure that the ACD is measuring and dispensing the components of the compounded drug product and preparing the final compounded drug product within tolerances of not more than plus or minus 5 percent.

(4) If a Drug Outlet Pharmacy, DPDO, CF or CHC uses an ACD to assist with the compounding of a drug product for parenteral nutrition, the Drug Outlet Pharmacy, DPDO, CF or CHC must establish safe maximum limits for each additive that may be used in compounding such a drug product. The outlet must ensure that:

(a) The ACD will not allow compounding the drug product for parenteral nutrition if a maximum limit for an additive will be exceeded until a Pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order; or
(b) If an ACD cannot be programmed to not allow the compounding process as described in (a):

(A) The ACD is equipped with an audible alarm or some other mechanism that will alert the Pharmacist if a maximum limit for an additive has been exceeded; and

(B) The Drug Outlet Pharmacy, DPDO, CF 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.

(5) If the Drug Outlet Pharmacy, DPDO, CF or CHC uses a computerized order entry system in conjunction with the ACD, the pharmacy must ensure that the computerized order entry system will cease processing the order if a maximum limit for an additive will be exceeded until a Pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

(6) A Drug Outlet Pharmacy, DPDO, CF 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, CF 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

~~855-045-0240~~ **855-183-0400**

Labeling: ~~of~~ Compounded ~~Drugs~~ 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 ~~drug dispensed or distributed~~ **preparation** must **prominently and legibly** contain the following, at a minimum:

~~(1) The generic or official name of each active ingredient;~~

(~~2~~**1**) The strength ~~or concentration~~ of each active ingredient~~, to include primary solution for a sterile parenteral preparation~~;

(~~3~~**2**) The ~~dosage form and~~ route of administration;

~~(4) Rate of infusion, for a sterile parenteral preparation;~~

~~(5) The total quantity of the drug product;~~

~~(6) A beyond-use date (BUD), compliant with standards required in OAR 855-045-0200(3); and~~

(3) Indication that the preparation is compounded.

(~~7~~**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

~~855-045-0240~~ **855-183-0410**

Labeling: ~~of~~ Compounded ~~Drugs~~ Sterile Preparations (CSPs)

In addition to the labeling requirements specified in **in USP <797> (11/01/2022),** OAR 855-041, **OAR 855-043 and 855-139,** the label of a compounded drug dispensed or distributed must contain the following, at a minimum:

~~(1) The generic or official name of each active ingredient;~~

(~~2~~**1**) The strength ~~or concentration~~ of each active ingredient, to include **the identity of the** ~~primary~~ **base** solution for a sterile parenteral preparation;

(~~3~~**2**) The ~~dosage form and~~ route of administration;

(~~4~~**3**) Rate of infusion **or titration parameters**, for a sterile parenteral preparation;

~~(5) The total quantity of the drug product;~~

~~(6) A beyond-use date (BUD), compliant with standards required in OAR 855-045-0200(3); and~~

(4) Indication that the preparation is compounded.

(~~7~~**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: Batch Preparation

The label of a CNSP and CSP that is prepared in anticipation of a patient-specific prescription must contain the following:

(1) The name, strength or concentration, and quantity of each active ingredient used in the compounded drug preparation;

(2) The total quantity or volume of the compounded drug preparation;

(3) Internal lot number;

(4) The assigned beyond-use date (BUD);

(5) Indication that the preparation is compounded; and

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

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

855-183-0450
Disposal

The Drug Outlet Pharmacy, DPDO, CF and CHC must ensure the disposal of hazardous pharmaceutical waste is 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

~~855-045-0220~~
~~Personnel and Responsibilities~~

~~(2) The Pharmacist-in-Charge (PIC) and the~~ **Each** ~~d~~**D**rug ~~o~~**O**utlet **Pharmacy, DPDO, CF and CHC** must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR **855-183-0200** ~~855-045-0200(3)~~ 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~~**1**) Personnel qualifications, to include training~~, evaluation and requalification~~ **and ongoing competency assessment**;

(~~b~~**2**) Hand hygiene;

(~~c~~**3**) Garbing;

(~~d~~**4**) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;

(~~e~~**5**) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;

(~~f~~**6**) Components, to include selection, **receipt,** handling, ~~and~~ storage **and disposal**;

(~~g~~**7**) Creating master formulation records, with documented ~~pharmacist~~ approval **by a Pharmacist for a Drug Outlet Pharmacy or prescriber with prescribing and dispensing privileges for a DPDO, CF or CHC**;

(~~h~~**8**) Creating compounding records;

(~~i~~**9**) Establishing ~~beyond-use dates (~~BUDs~~)~~;

(10) Labeling;

(~~j~~**11**) Continuous quality assurance program and quality controls, to include**:**

(a) ~~r~~**R**elease testing, end-product evaluation, and quantitative/qualitative testing;

(b) Complaint handling process;

(c) Adverse event and error reporting process; and

(d) Recall procedure; and

(~~k~~**12**) Completed compounded preparations, to include handling, packaging, storage and transport**.**~~;~~

~~(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug.~~

NOTE: *Consider adding 'The recall procedure must include notification to the board within 10 business days in the event of a patient-level recall of a compounded drug.' to (11)(d) if board does not send OAR 855-183-0520 to rulemaking.*

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

855-183-0520
Recalls

(1) Each Drug Outlet Pharmacy, DPDO, CF and CHC that determines a recall is warranted must immediately issue a recall and immediately initiate communication with each recipient Drug Outlet, prescriber and patient receiving the recalled drug that was dispensed or intended for use in this state and document each attempt. Initial communication must be completed:

(a) Within 12 hours of the recall if use or exposure to the recalled compounded drug will cause serious adverse health consequences or death. If confirmation that the recipient received the communication cannot be established within this timeframe, the outlet must make two additional attempts to provide communication 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 temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. If confirmation that the recipient received the communication cannot be established within this timeframe, the outlet must make two additional attempts to provide communication within 24 hours of the initial attempt.

(2) If the recalled drug is not likely to cause adverse health consequences, the recipient Drug Outlet, prescriber or patient receiving the recalled drug that was dispensed or intended for use in this state, must be notified within 72 hours of the recall and the outlet must document the notification.

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

(4) A Drug Outlet Pharmacy, DPDO, CF or CHC that has been advised that a patient has been harmed by using a compounded product potentially attributable to the outlet must report the event to MedWatch within 72 hours of the outlet being advised.

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

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

~~855-045-0270~~ **855-183-0550**
Records: General Requirements

~~(1) All records must be maintained in written or electronic format, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if then retrievable within three business days. Required records include, but are not limited to:~~

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~~ **and** corrective actions for any failures~~, including gloved fingertip and thumb sampling test and aseptic manipulation validation~~. The ~~pharmacy~~ **outlet** 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; and

(d) Cleaning**, sanitizing** and disinfecting of all compounding areas and equipment.

(e) Receipt, handling, storage and disposal of components;

(~~2~~**f**) Master formulation records **for all**~~, including as appropriate~~:

(A) CNSPs;

(B) CSPs prepared for more than one patient;

(C) CSPs prepared from a non-sterile ingredient;

(g) Compounding records for all:

(A) CNSPs;

(B) CSPs; and

(C) Immediate-use CSPs prepared for more than one patient; and

(h) Release testing, end-product evaluation and quantitative/qualitative testing.

(4) Information related to complaints and adverse events including corrective actions taken.

(5) Results of investigations including corrective actions taken and recalls.

~~(a) The name, strength and dosage form of the preparation;~~

~~(b) Physical description of the final preparation;~~

~~(c) Ingredient identities and amounts;~~

~~(d) Complete instructions for preparing the product, including equipment, supplies, and a description of the compounding steps;~~

~~(e) Calculations needed to determine and verify quantities of components and doses of ingredients;~~

~~(f) Compatibility and stability information, including references;~~

~~(g) Beyond-use date (BUD) assignment and storage requirements, including reference source;~~

~~(h) Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration;~~

~~(i) Quality control procedures and expected results; and~~

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

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~
~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

~~(l) Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used;~~

~~(m) Total quantity compounded;~~

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

~~(o) 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;~~

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

~~(q) Any other information required by the pharmacy's policies and procedures.~~

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

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

In addition to the MFR requirements specified in USP <795> (11/01/2022), the MFR for a CNSP must contain the following, at a minimum:

(1) Appropriate calculations to determine and verify quantities and concentrations of components and strength or activity of the Active Pharmaceutical Ingredients (APIs);

(2) Compatibility and stability information, including USP or other available references;

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

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

(5) Any other information required by the outlet'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: Master Formulation Records (MFR) for CSP

If a MFR is required for a CSP in USP <797> (11/01/2022), the MFR for a CSP must contain the requirements specified in the standard and the following, at a minimum:

(1) Appropriate calculations to determine and verify quantities and concentrations of components, and if performing non-sterile to sterile compounding the strength or activity of the APIs;

(2) Compatibility and stability information, including USP or other available references;

(3) Quality control procedures that include the expected results and limits of tolerability for quantitative results;

(4) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(5) Any other information required by the outlet'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: Compounding Records (CR) for CNSP

~~855-045-0270~~
~~Records~~
~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

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:

(~~l~~**1**) Pharmacist **or prescriber with prescribing and dispensing privileges performance and** documented verification **that each of the following are correct:** ~~of compounded product accuracy including the correct~~

(a) ~~f~~**F**ormula~~;~~**;**

(b) ~~c~~**C**alculations **to determine and verify quantities and/or concentrations of components and strength or activity of each API;**~~;~~

(c) ~~q~~**Q**uantities ~~and the correct measurements and drugs used~~;

(d) Compounding technique; and

(e) Accurate preparation of the CNSP.

(~~m~~**2**) **Final yield** ~~Total quantity compounded~~;

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

(~~o~~**3**) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;

(~~p~~**4**) Records of dispensing or transfer of all compounded preparations; and

(~~q~~**5**) Any other information required by the ~~pharmacy~~ **outlet**'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: Compounding Records (CR) for CSP

~~855-045-0270~~

~~Records~~

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

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:

(~~l~~**1**) Pharmacist **or prescriber with prescribing and dispensing privileges performance and** documented verification **that each of the following are correct:** ~~of compounded product accuracy including the correct~~

(a) ~~f~~**F**ormula~~;~~;

(b) ~~c~~**C**alculations **to determine and verify quantities and/or concentrations of components and strength or activity of each API**~~;~~;

(c) ~~q~~**Q**uantities ~~and the correct measurements and drugs used~~;

(d) Compounding technique; and

(e) Accurate preparation of the CNSP.

(~~m~~**2**) **Final yield** ~~Total quantity compounded~~;

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

(~~o~~**3**) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;

(~~p~~**4**) Records of dispensing or transfer of all compounded preparations; and

(~~q~~**5**) Any other information required by the ~~pharmacy~~ **outlet**'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) Carpet in compounding area; and

(2) Animals in the compounding area.

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

855-183-0700
Preparation According to FDA Labeling

Compounding does not include:

(1) 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 when the:

(a) Product is prepared as a single dose for an individual patient; and

(b) Labeling includes information for the diluent, the resultant strength, the container closure system and BUD.

(3) Docking and activation of a proprietary bag and vial system in accordance with the FDA-approved labeling for immediate administration to an individual patient.

[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
Service: Copies of an Approved Drug

A Drug Outlet Pharmacy, DPDO, CF, 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 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) shortages database published on the ASHP website, www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages.

(3) The Drug Outlet is unable to obtain the approved drug from a Wholesale Distributor Drug Outlet. Documentation of good faith effort must be retained by the Drug Outlet.

POLICY DISCUSSION: FDA Guidance Essential Copies

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

855-183-0730

Service: For Use by a Veterinarian

(1) This rule only applies to drugs compounded by a Drug Outlet Pharmacy intended for non-food producing animal use by licensed veterinarians.

(2) A Drug Outlet Pharmacy may compound drugs intended for non-food producing animal use:

(a) Based on a patient-specific prescription from a licensed veterinarian.

(b) For in-office use (e.g., office stock) by a licensed veterinarian, specifically for a single treatment episode, not to exceed 120-hour supply.

(3) The compounded preparations must not be distributed by an entity other than the Drug Outlet Pharmacy that compounded such veterinary drug preparations.

POLICY DISCUSSION: FDA Guidance Compounding Animal Drugs Section III-B.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

Divisions 019/041/043/044/139: Short-acting Opioid Antagonist (naloxone/nalmefene); DPDO, CF, CHC, Charitable Pharmacy Labeling; Minimum Equipment Requirements

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Short-acting Opioid Antagonist; DPDO, CF, CHC, and Charitable Pharmacy labeling exemption

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amends existing rules related to naloxone by utilizing the newly defined term "short-acting opioid antagonist" from 2023 HB 2395. Amends existing rules for Dispensing Practitioner Drug Outlet (DPDO), Correctional Facility (CF) Community Health Clinic (CHC) and Charitable Pharmacies by incorporating labeling exemption requirements from 2023 SB 450. Repeals OAR 855-041-2340 Naloxone and OAR 855-139-0720 Naloxone General Requirements.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 SB 450, 2023 HB 2395, Narcan (naloxone) package insert, Opvee (nalfemene) package insert

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed amendments and repeals provide clarity for licensees and registrants. It is anticipated that amending or repealing these rules will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Proposed amendments are legislative mandates of 2023 SB 450 and 2023 HB 2395.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments in OAR 855-019-0460 include striking "naloxone" and utilizing "short-acting opioid antagonist" as defined in 2023 HB 2395, adds labeling exemptions when dispensing an FDA approved short-acting opioid antagonist in the form of a nasal spray as mandated in 2023 SB 450 and repeals language that is no longer necessary.

Proposes repealing OAR 855-041-2340 and OAR 855-139-0720 as they are no longer necessary and amends OAR 855-041-1035 and OAR 855-139-0155 by striking outdated citations.

Proposes amending OAR 855-041-1130, OAR 855-043-0540, OAR 855-043-0630, OAR 855-043-0735 and OAR 855-044-0060 by incorporating statutory reference "2023 SB 450" labeling exemptions for DPDOs, CHCs and Charitable Pharmacies when dispensing an FDA approved short-acting opioid antagonist in the form of a nasal spray.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the August 2023 board meeting.

- Highlights/Markup
  - Rule language highlighted in yellow denote staff proposed amendments made since the rule package was first noticed for the August 2023 board meeting.
  - **Mark~~up~~** in this package is in comparison to the current rules for Div 019, 041, 043, 044, and 139

Division 19
PHARMACISTS

855-019-0460
Short-acting Opioid Antagonist (Naloxone/**Nalmefene)** ~~Delivery of Care and Prescribing~~

(1) A ~~p~~**P**harmacist, ~~having determined that there is an identified medical need, can~~ **may** prescribe **any FDA-approved short-acting opioid antagonist (e.g.,** naloxone, **nalmefene)** and the necessary medical supplies to administer ~~naloxone~~ **a short-acting opioid antagonist** for opiate overdose:

(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME);

(b) To an individual seeking ~~naloxone~~ **a short-acting opioid antagonist**;

(c) To an entity seeking ~~naloxone~~ **a short-acting opioid antagonist**.

~~(2) The pharmacist shall determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.~~

~~(3) The pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer the naloxone.~~

(~~4~~**2**) ~~The~~ **A** ~~p~~**P**harmacist **is not required to label the prescription according to OAR 855-041-1130** ~~shall~~ **if** dispens**ing**~~e the naloxone~~ **a FDA-approved short-acting opioid antagonist in the form of a nasal spray** ~~product in a properly labeled container~~.

~~(5) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.~~

(~~6~~**3**) The ~~p~~**P**harmacist must document the encounter**,** the prescription and maintain records for three years.

~~(7) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682, ORS 689.684, & ~~2019 OL Ch. 470,~~ **2023 HB 2395, 2023 SB 450**

Division 41
OPERATION OF PHARMACIES

855-041-1035
Minimum Equipment Requirements

(1) Each retail drug outlet and institutional drug outlet must have the following:

(a) Appropriate and current pharmaceutical references (e.g., pharmacology, injectables, and veterinary drugs) based on services offered by the outlet;

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g., USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;

(c) Access to appropriate electronic reporting databases (e.g., PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(d) Appropriate equipment to maintain the proper storage of drugs;

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g., USP) based on services offered by the outlet;

(f) A sink with running hot and cold water;

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for

patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up pharmacy per OAR 855-041-2100;

(D) Providing written notice in a conspicuous manner that ~~naloxone~~ **short-acting opioid antagonists (e.g., naloxone, nalmefene)** and the necessary medical supplies to administer ~~naloxone~~ **short-acting opioid antagonists** are available at the pharmacy if ~~naloxone~~ **short-acting opioid antagonist** services are provided by the pharmacy ~~per OAR 855-041-2340~~; and

(E) Providing notification of accurate hours of operation at each pharmacy entrance; and

(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g.~~,~~ website, social media, mobile applications).

(i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508, ORS 689.515, ORS 689.564~~,~~ ~~&~~ ORS 689.686, **2023 HB 2395**

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling

Except as described in SB 450 (2023), ~~P~~**p**rescriptions must be labeled with the following information:

(1) Name, address and telephone number of the pharmacy;

(2) Date of fill;

(3) Identifying number;

(4) Name of patient;

(5) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(6) Directions for use by the patient;

(7) Name of practitioner;

(8) Required precautionary information regarding controlled substances;

(9) Such other and further accessory cautionary information as required for patient safety;

(10) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must not exceed:

(a) That on the manufacturer's container if dispensed in the manufacturer's container; or

(b) The earliest date of either:

(A) The manufacturer's expiration date; or

(B) One year from the date the drug was repackaged and dispensed.

(11) Any drug expiring before the expected length of time for the course of therapy must not be dispensed.

(12) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505~~, &~~ ORS 689.515, **2023 SB 450**

~~855-041-2340~~
~~Naloxone~~

~~Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:~~

~~(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction;~~

~~(2) Documentation and recordkeeping: and~~

~~(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682 & 2019 OL Ch. 470~~

Division 43
PRACTITIONER DISPENSING

855-043-0540
Dispensing Practitioner Drug Outlet - Labeling

(1) **Except as described in SB 450 (2023),** ~~A~~**a** prescription must be labeled with the following information:

(a) Name of patient;

(b) Name of prescriber;

(c) Name, address, and phone number of the clinic;

(d) Date of dispensing;

(e) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(f) Quantity dispensed;

(g) Directions for use;

(h) Cautionary statements, if any, as required by law; and

(i) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier. Any drug expiring before the expected length of time for course of therapy must not be dispensed.

(j) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules.

(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-043-0004, the name of the patient may be omitted.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305, **2023 SB 450**

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

(1) Policies and Procedures: The ~~p~~**P**harmacist and the practitioner representing the facility ~~shall be~~ **are** responsible for establishing written policies and procedures for medication management including, but not limited to, drug procurement, dispensing, administration, labeling, medication counseling, drug utilization review, medication records, parenterals, emergency and nonroutine dispensing procedures, stop orders, over-the-counter drugs, security, storage and disposal of drugs withing the facility. Policies and procedures ~~shall~~ **must** be reviewed and updated annually by the ~~p~~**P**harmacist and the practitioner, maintained in the facility; and be made available to the ~~B~~**b**oard for inspection. The facility ~~shall~~ **must** submit to the ~~B~~**b**oard for approval, the name of any employee ~~p~~**P**harmacist or a written agreement between the ~~p~~**P**harmacist and the facility regarding drug policies and procedures. The facility ~~shall~~ **must** notify the ~~B~~**b**oard of any change of ~~p~~**P**harmacist within 15 days of the change.

(2) Dispensing: Prescription drugs ~~shall~~ **must** be dispensed by a ~~p~~**P**harmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system. **The Correctional Facility (CF) must ensure that compounded preparations are dispensed in compliance with OAR 855-183.**
NOTE: This rule amendment is also in mailing #D1- Drug Compounding

(3) Unit Dose Dispensing System. The "Unit Dose Dispensing System" is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stock from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled:

(a) A unit dose dispensing system ~~shall~~ **must**:

(A) By nature of the system;

(i) Provide for separation of medications by patient name and location; and

(ii) Provide for separating medications by day of administration.

(B) By means of an individual patient medication record:

(i) Record the drug and dosing regimen of those drugs dispensed by the pharmacy;

(ii) Record the actual doses dispensed and returned to the pharmacy;

(iii) Record the date of the original order and the date the order is discontinued;

(iv) Provide a means for the ~~p~~**P**harmacist to verify the prescriber's original order;

(v) Provide a means for the ~~p~~**P**harmacist 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~~ **CF** utilizing a unit dose dispensing system ~~shall~~ **must** establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies ~~shall~~ **must** be available in the pharmacy for inspection by the ~~B~~**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 ~~p~~**P**harmacist ~~shall~~ **must** certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.

(d) All medication ~~shall~~ **must** be stored in a locked area or locked cart.

(4) Labeling: **Except as described in SB 450 (2023),** ~~P~~**p**rescription drugs dispensed in individual containers or medication cards ~~shall~~ **must** be labeled with the following information:

(a) Name and identifying number of the patient/inmate;

(b) Name, strength, and quantity of the drug dispensed. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(c) Name of the prescriber;

(d) Initials of the dispenser and the date of dispensing;

(e) Directions for use;

(f) Auxiliary labels and cautionary statements as required;

(g) Manufacturer's expiration date, or an earlier date if preferable; and

(h) Name of the pharmacy.

(5) Patient counseling:

(a) Upon receipt of a prescription drug order and following review by the ~~p~~**P**harmacist of the patient's record, the ~~p~~**P**harmacist ~~shall~~ **must** initiate and provide oral counseling to the patient or to the patient's agent or care giver in all ambulatory care settings and for discharge medications in institutions:

(A) Upon request; or

(B) On matters which a reasonable and prudent ~~p~~**P**harmacist would deem significant; or

(C) Whenever the drug prescribed has not previously been dispensed to the patient; or

(D) Whenever the patient's medication record shows the drug has not been previously dispensed to the patient in the same dosage, form, strength or with the same written directions.

(b) When counseling is provided it ~~shall~~ **must** include information that a reasonable and prudent ~~p~~**P**harmacist would deem necessary to provide for the safe and effective use of the drug. Such information may include the following:

(A) The name and description of the drug;

(B) The dosage form, dose, route of administration, and duration of drug therapy;

(C) The intended use of the drug and expected actions;

(D) Special directions and precautions for preparation, administration, and use by the patient;

(E) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(F) The possible dangers of taking the drug with alcohol, or taking the drug and then operating a motor vehicle or other hazardous machinery;

(G) Techniques for self-monitoring drug therapy;

(H) Proper storage;

(I) Prescription refill information;

(J) Action to be taken in the event of a missed dose; and

(K) Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Patient counseling ~~shall~~ **must** be in person whenever practicable. Whenever the prescription is delivered outside the confines of the pharmacy by mail or other third party delivery, counseling ~~shall~~ **must** be in writing and by free access to the ~~p~~**P**harmacist by phone.

(d) Subsections (a) and (b) of this section ~~shall~~ **must** not apply to those prescription drug orders for inpatients in hospitals or institutions where the drug is to be administered by a nurse or other individual authorized to administer drugs.

(e) Notwithstanding the requirements set forth in subsection (a), a ~~p~~**P**harmacist is not required to provide oral counseling when a patient refuses the ~~p~~**P**harmacist 's attempt to counsel, or when the ~~p~~**P**harmacist, 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~~ **CF**.

(6) Administration: Drugs ~~shall~~ **must** be administered to inmate/ patients by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined ~~in~~ by the **Oregon State Board of Nursing in** ~~Board administrative rule 851-047-0020~~ **OAR 851-045-0060**. Drugs selected by registered nurses from manufacturer's or ~~p~~**P**harmacist's bulk drug containers ~~shall~~ **must** not be administered by unlicensed persons, except under certain emergency and nonroutine situations as described in the facility's policies and procedures.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155**, 2023 SB 450**

855-043-0735
Community Health Clinic (CHC) - Labeling

(1) **Except as described in SB 450 (2023),** ~~A~~**a** prescription must be labeled with the following information:

(a) Unique identifier (i.e.**,** prescription number);

(b) Name of patient;

(c) Name of prescriber;

(d) Name, address, and phone number of the clinic;

(e) Date of dispensing;

(f) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(g) Quantity dispensed;

(h) Directions for use;

(i) Initials of the practitioner who has been given dispensing privileges by their licensing ~~B~~**b**oard or the Registered Nurse;

(j) Cautionary statements, if any, as required by law; and

(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.

(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from the label, the patient's name may be omitted from the records and a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, **2023 SB 450**

Division 44
CHARITABLE PHARMACIES

855-044-0060
Labeling

(1) **Except as described in SB 450 (2023),** ~~T~~the label on a drug dispensed or distributed from a charitable pharmacy must meet all federal rules and laws and must contain:

(a) The name, address and telephone number of the pharmacy;

(b) The name of the prescribing practitioner;

(c) The initials of the dispensing practitioner;

(d) Date dispensed;

(e) The name of the patient;

(f) Name and manufacturer of drug, drug strength, the quantity dispensed;

(g) Directions for use;

(i) The expiration date;

(j) A unique identifier; and

(k) Any further cautionary information required for patient safety.

(2) All original patient identification must be removed.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.774, **2023 SB 450**

Division 139
REMOTE DISPENSING SITE PHARMACY

~~855-139-0720~~
~~Service: Naloxone- General Requirements~~

~~Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:~~

~~(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction;~~

~~(2) Documentation and recordkeeping: and~~

~~(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.305, ORS 689.681 & ORS 689.682~~

855-139-0155

Outlet: Minimum Equipment Requirements

(1) Each Oregon Retail Drug Outlet RDSP must have the following:

(a) Appropriate and current pharmaceutical references (e.g., pharmacology, injectables, and veterinary drugs) services offered by the outlet;

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g., USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;

(c) Access to appropriate electronic reporting databases (e.g., PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(d) Appropriate equipment to maintain the proper storage of drugs;

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g., USP) based on services offered by the outlet;

(f) A sink with running hot and cold water;

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating “This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve.” The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-139-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing written notice in a conspicuous manner that ~~naloxone~~ **short-acting opioid antagonists (e.g., naloxone, nalmefene)** and the necessary medical supplies to administer ~~naloxone~~ **short-acting opioid antagonists** are available at the pharmacy if ~~naloxone~~ **short-acting opioid antagonist** services are provided by the pharmacy ~~per OAR 855-139-0720~~;

(D) Stating "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed Pharmacist from (insert name of RDSP Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and

(E) Providing notification of accurate hours of operation at each pharmacy entrance; and

(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).

(i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

Statutory/Other Authority: ORS 689.205, ORS 689.686, ORS 689.515 & 2021 SB 629,
Statutes/Other Implemented: ORS 689.155, **2023 HB 2395**

Divisions 019/025/041/139: Immunizations

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Pharmacist and pharmacy technician administration of vaccines

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Beginning 1/1/2024, proposed rule amendments will permit a Pharmacist to administer an influenza vaccine to persons who are six months of age or older and permits a Certified Oregon Pharmacy Technician (COPT) or Pharmacy Technician (PT) to administer a vaccine under the supervision of a Pharmacist.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 HB 2486, 2023 HB 2278

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): The adoption of the proposed rules are not expected to have any negative impact on any group of people. The new and amended rules may have a positive impact by making it easier for Black, Indigenous, and American Indian/Alaska Native people (BIPOC-AI/AN) to access vaccines by pharmacy technicians to administer them and pharmacists to administer influenza vaccine to patients aged 6 months and older. This may contribute to closing disparities in vaccination rates between white persons and BIPOC-AI/AN. Pharmacies are often located in communities where BIPOC-AI/AN live and are more accessible than other healthcare settings. Pharmacists and pharmacy technicians are also trained to provide culturally competent care.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated as the new rules do not require a Pharmacist, COPT or PT to provide vaccinations.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not convened. The board has the expertise and experience necessary to draft the proposed amendments and new rule on its own. The rulemaking process will be open to public comment, and the board will consider all rulemaking hearing comments received and make adjustments as needed.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Due to recently adopted legislation, 2023 HB 2486 and 2023 HB 2278 related to immunizations, it is necessary to amend and adopt rules for Pharmacists, COPTs and PTs, Drug Outlet Pharmacies and Remote Dispensing Site Pharmacies to comply with the directives of the legislation.

Amends OAR 855-019-0270 by moving rules related to protocols and to whom a pharmacist can administer vaccines to 855-019-0280.

Amends OAR 855-019-0280 by incorporating language moved from OAR 855-019-0270; Adds that a Pharmacist may administer to a person who is six months of age or older if the vaccine administered is an influenza vaccine per 2023 HB 2278 beginning 1/1/2024; Moves requirements for a pharmacy to 855-041-1040; Adds rules related to the Pharmacist duties for administration or supervision of vaccination;

Removes requirement for Pharmacist to 'give' Vaccine Information Statement (VIS) to patient and ensure it was read by/to patient and alternatively requires Pharmacist to 'ensure' patient receives VIS; Adds pharmacist requirements for supervising Interns, COPTs and PTs who administer a vaccine, which includes the Pharmacist being immediately available to the vaccinator.

Amends OAR 855-019-0290 by adding the phrase "or supervises each administration of" to OAR 855-019-0290(1).

Adopts new rule OAR 855-025-0024 Services: Vaccine Administration which permits an appropriately trained and qualified COPT and PT to perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist pursuant to 2023 HB 2486 beginning 1/1/2024.

Amends OAR 855-041-1040(2)(i) by adding requirements for the outlet to have policies and procedures for COPT/PT vaccination; Adds (2)(l) "Disposal of drugs and/or devices including hazardous and pharmaceutical waste" which is relocated from OAR 855-019-0270.

Proposes amending Remote Dispensing Site Pharmacy Prohibited Practices: General in OAR 855-139-0600(1) by adding (b) which prohibits a COPT/PT at a RDSP to "Administer a vaccine."

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the August 2023 board meeting.

- Highlights/Markup
  - None- 1st review
  - **Mark**~~up~~ in this package is in comparison to the current rules for Div 019, 025, 041 and 139

Division 019
PHARMACISTS

855-019-0270
Vaccination: Qualifications

~~(1) In this rule and in OAR 855-019-0280, an intern who is appropriately trained and qualified in accordance with Section (3) of this rule may perform the same duties as a pharmacist, provided that the intern is supervised by an appropriately trained and qualified pharmacist.~~

~~(2) A pharmacist may administer vaccines to persons who are at least 7 years of age as provided by these rules. For the purposes of this rule, a person is at least 7 years of age on the day of the person's seventh birthday.~~

(~~3~~**1**) A ~~p~~**P**harmacist may administer vaccines ~~under section (1) or section (2) of this rule only~~ if the Pharmacist:

(a) ~~The pharmacist h~~**H**as completed a course of training approved by the Board and maintained competency~~;~~

~~(b) The pharmacist training~~ **that** includes, injection site, and Cardiopulmonary Resuscitation (CPR) specific to the age and population **of patients being vaccinated by the ~~p~~P**harmacist ~~treats~~;

(~~c~~**b**) ~~The pharmacist h~~**H**olds active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that contains a hands-on training component and is valid for not more than three years~~, and documentation of the certification is placed on file in the pharmacy~~;

~~(d) The vaccines are Prescribes, administered in accordance with an administration protocol written and approved by the Oregon Health Authority (OHA); and~~

(~~e~~**c**) ~~The pharmacist h~~**H**as **access to the** ~~a~~ current ~~copy~~ **edition** of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."

~~(4) A pharmacist otherwise in compliance with section three of this rule may, during a declared emergency, administer a vaccine to a person who is at least three (3) years of age when;~~

~~(a) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or~~

~~(b) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.~~

~~(5) A pharmacist may not delegate the administration of vaccines to another person.~~

Statutory/Other Authority: ORS 689.205 **ORS 689.645**, **ORS** 433.441, **ORS** 433.443 & ~~2015 OL Ch 295,~~**2023 HB 2278, 2023 HB 2486**
Statutes/Other Implemented: ORS 689.151, 689.155, 689.645 & ~~2015 OL Ch 295,~~ **2023 HB 2278, 2023 HB 2486**

855-019-0280
~~Immunization~~ **Vaccination:** Protocols, Policies and Procedures

(1) Prior to **prescribing,** administering **or dispensing** a vaccine, ~~to a person who is at least 7 years of age~~ a ~~p~~**P**harmacist must follow protocols written and approved by the Oregon Health Authority (OHA) for ~~administration of~~ vaccines and the treatment of severe adverse events following administration of a vaccine.

(2) A Pharmacist may administer vaccines:

(a) To a person who is seven years of age or older;

(b) To a person who is six months of age or older if the vaccine administered is an influenza vaccine; and

(~~2~~**c**) ~~A pharmacist during a declared emergency may administer a vaccine t~~To a person who is at least three ~~(3)~~ years of age when;

(~~a~~**A**) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or

(~~b~~**B**) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.

~~(3) The pharmacy must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.~~

(3) A Pharmacist who administers or supervises administration of any vaccine must:

(a) Make vaccine recommendations;

(b) Select each vaccine to be administered;

(c) Prescribe each vaccine per OHA protocol in (1);

(4**d**) ~~The pharmacist must give~~ **Ensure** the appropriate Vaccine Information Statement (VIS) **is provided** to the patient or legal representative ~~with~~ **prior to** each dose of vaccine ~~covered by these forms. The pharmacist must ensure that the patient or legal representative is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine.~~

(e) Perform verification prior to administration that includes but is not limited to:

(A) Prescription order accuracy verification; and

(B) Vaccine product accuracy review;

(f) Advise or counsel on therapeutic values, content, hazards and use of each vaccine;

(g) Manage adverse events;

(~~5~~**h**) ~~The pharmacist must report~~ **Report** adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient~~.~~**;**

(i) Verify accuracy and completeness of documentation for vaccine administration; and

(j) Ensure all persons administering vaccinations under their supervision are appropriately trained and qualified.

~~(6) The pharmacist may prescribe, administer or dispense immunizations, including oral vaccines, as established by written protocols approved by OHA.~~

(4) An appropriately trained and qualified Pharmacist may permit an appropriately trained and qualified:

(a) Intern to perform the same duties as a Pharmacist except as prohibited in OAR 855-019-0200(6).

(b) Certified Oregon Pharmacy Technician or Pharmacy Technician to conduct the physical act of administering a vaccine in accordance with OAR 855-025-0024.

(5) The appropriately trained and qualified Pharmacist who supervises an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician to vaccinate must be immediately available to the vaccinator.

Statutory/Other Authority: ORS 689.205, **ORS 689.645,** 433.441, 433.443 & ~~2015 OL Ch 295~~ **2023 HB 2278, 2023 HB 2486**
Statutes/Other Implemented: ORS 689.151, 689.155, 689.645 & ~~2015 OL Ch 295~~, **2023 HB 2278, 2023 HB 2486**

855-019-0290
Vaccination: Record Keeping and Reporting

~~(1)~~ A ~~p~~**P**harmacist who administers **or supervises each administration of** a vaccine to a patient must**:**

(1) ~~f~~**F**ully document the administration in the patient's permanent record.

(2) ~~A pharmacist who administers any vaccine must r~~**R**eport the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A ~~p~~**P**harmacist is not required to notify the primary health care provider.

(~~a~~) The name, address, gender and date of birth of the patient;

(b) The date of administration of the vaccine;

(c) The NDC number of the vaccine, or other acceptable standardized vaccine code set;

(d) The address of the pharmacy where vaccine was administered unless automatically embedded in the electronic report provided to the OHA ALERT Immunization System;

(e) The phone number of the patient when available;

(f) The dose amount, manufacturer, site of administration, lot number and expiration date of the vaccine when available;

(3) ~~A pharmacist who administers any vaccine will k~~**K**eep documentation of current CPR training. This documentation will be kept on site and available for inspection.

(4) ~~A pharmacist who administers any vaccine will~~ ~~f~~**F**ollow storage and handling guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC).

(5) For the purpose of participation in the Oregon Vaccines for Children program,

(a) The vaccine eligibility code for each dose must be reported to the ALERT Immunization Information System in the manner prescribed by OHA, and

(b) The ~~p~~**P**harmacist is recognized as a prescriber.

(6**c**) If providing state or federal vaccines during a pandemic as determined by the CDC, the event and priority code as specified by OHA must be provided upon request in the manner prescribed by OHA.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, 689.155 & 689.645, **2023 HB 2278, 2023 HB 2486**

Division 025
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-025-0024
Services: Vaccine Administration

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist:

(a) To a person who is seven years of age or older;

(b) To a person who is at least three years of age when;

(A) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or

(B) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.

(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician must:

(a) Prior to administration of a vaccine, receive practical training that includes infection control, recognition of anatomical landmarks and competency in hands-on administration technique.

(b) Prior to administration of a vaccine, hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program that is specific to the age and population receiving the vaccine, contains a hands-on training component, and is valid for not more than three years.

(3) Document the vaccine administration including but not limited to the vaccine administered, dose, expiration date, lot number, and injection site.

(4) Notify the supervising Pharmacist immediately in the event of a suspected adverse reaction to a vaccine.

(5) The training required in (2) may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board.

(6) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

Statutory/Other Authority: ORS 689.205, 2023 HB 2278, 2023 HB 2486
Statutes/Other Implemented: ORS 689.151, 2023 HB 2278, 2023 HB 2486

Division 041
OPERATION OF PHARMACIES

855-041-1040
Outlet: Policies and Procedures

(1) The drug outlet pharmacy and its Pharmacist in Charge is accountable for establishing, maintaining, and enforcing written policies and procedures for the drug outlet pharmacy. The written policies and procedures must be maintained at the drug outlet pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the responsibilities of the drug outlet pharmacy including;

(a) Security;

(b) Operation, testing and maintenance of pharmacy systems and equipment;

(c) Sanitation;

(d) Storage of drugs;

(e) Dispensing;

(f) Pharmacist supervision, direction and control of non-Pharmacists;

(g) Documenting the date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(h) Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians;

(i) Certified Oregon Pharmacy Technician or Pharmacy Technician final verification **and/or vaccination**, if utilized;

(j) Drug and/or device procurement;

(k) Receiving of drugs and/or devices;

(l) Disposal of drugs and/or devices including hazardous and pharmaceutical waste;

(~~l~~**m**) Delivery of drugs and/or devices;

(~~m~~**n**) Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling);

(~~n~~**o**) Recordkeeping;

(~~o~~**p**) Patient confidentiality;

(~~p~~**q**) Continuous quality improvement;

(~~q~~**r**) Plan for discontinuing and recovering services in the event of a pharmacy closure;

(~~r~~**s**) Training: initial and ongoing; and

(~~s~~**t**) Interpretation, translation and prescription reader services.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034, **2023 HB 2278, 2023 HB 2486**
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508 & 2022 HB 4034, **2023 HB 2278, 2023 HB 2486**

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet RDSP must not:

(1) Allow a Certified Oregon Pharmacy Technician or Pharmacy Technician to:

(a) ~~ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist~~**. Refuse a request from a patient, patient's agent, or practitioner to interact with a Pharmacist**; **and**

(b) Administer a vaccine.

(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the board pursuant to ORS 689.305;

(3) Compound sterile preparations; or

(4) Repackage drugs.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315 & **ORS 689.700** ~~2022 HB 4034~~

Statutes/Other Implemented: ORS 689.155, **ORS 689.700** & ~~2022 HB 4034~~, **2023 HB 2486**

Division 115: Short-acting Opioid Antagonist (naloxone/nalmefene)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Short-acting Opioid Antagonist; Labeling exemption

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments include incorporating the newly defined term "short-acting opioid antagonist" from 2023 HB 2395 and adds labeling exemption requirements from 2023 SB 450.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 SB 450, 2023 HB 2395, Narcan (naloxone) package insert, Opvee (nalfemene) package insert

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed amendments provide clarity for licensees and registrants. It is anticipated that amending these rules will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Proposed rules are legislative mandates of 2023 SB 450 and 2023 HB 2395.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments in OAR 855-115-0350 include striking "naloxone" and utilizing "short-acting opioid antagonist" as defined in 2023 HB 2395, adds labeling exemptions when dispensing an FDA approved short-acting opioid antagonist in the form of a nasal spray as mandated in 2023 SB 450 and repeals language that is no longer necessary.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the August 2023 board meeting.

- Highlights
  - None- 1st review
  - **Mark~~up~~** in this package is in comparison to the Div 115 rules filed for rulemaking in June 2023.

Division 115
PHARMACISTS

855-115-0350

Services: Prescribing Practices – **Short-acting Opioid Antagonists (**Naloxone **/ Nalmefene)**

(1) A Pharmacist~~, having determined that there is an identified medical need, can~~ **may** prescribe **any FDA approved short-acting opioid antagonist (e.g.,** naloxone**, nalmefene)** and the necessary medical supplies to administer ~~naloxone~~ **a short-acting opioid antagonist** for opiate overdose:

(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME);

(b) To an individual seeking ~~naloxone~~ **a short-acting opioid antagonist**;

(c) To an entity seeking **a short-acting opioid antagonist** ~~naloxone~~.

~~(2) The Pharmacist must determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.~~

~~(3) The Pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.~~

(4**2**) ~~The~~ **A** Pharmacist **is not required to label the prescription according to OAR 855-041-1130 if** ~~must~~ dispens**ing**~~e~~ **a FDA approved short-acting opioid antagonist** ~~the naloxone product in a properly labeled container~~.

~~(5) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.~~

(~~6~~**3**) The Pharmacist must document the encounter, ~~and~~ the prescription and maintain records ~~for three years~~ **according to OAR 855-104-0055**.

~~(7) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.~~

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682, ORS 689.684**, 2023 HB 2395, 2023 SB 450**

Divisions 115/125: Immunizations

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Pharmacist and pharmacy technician administration of vaccines

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Beginning 1/1/2024, proposed new rules will permit a Pharmacist to administer an influenza vaccine to persons who are six months of age or older and permits a Certified Oregon Pharmacy Technician (COPT) or Pharmacy Technician (PT) to administer a vaccine under the supervision of a Pharmacist.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 HB 2486, 2023 HB 2278

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): The adoption of the proposed rules are not expected to have any negative impact on any group of people. The new and amended rules may have a positive impact by making it easier for Black, Indigenous, and people of color Black, Indigenous, people of color and American Indian/Alaska Native people (BIPOC-AI/AN) to access vaccines by allowing pharmacy technicians to administer them and pharmacists to administer influenza vaccine to patients aged 6 months and older. This may contribute to closing disparities in vaccination rates between white persons and BIPOC-AI/AN. Pharmacies are often located in communities where BIPOC-AI/AN live and are more accessible than other healthcare settings. Pharmacists and pharmacy technicians are also trained to provide culturally competent care.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated as the new rules do not require a Pharmacist, COPT or PT to provide vaccinations.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, A RAC was not convened. The board has the expertise and experience necessary to draft the rule on its own. The rulemaking process will be open to public comment, and the board will consider all rulemaking hearing comments received and make adjustments as needed.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Due to recently adopted legislation, 2023 HB 2486 and 2023 HB 2278 related to immunizations, it is necessary to adopt new rules for Pharmacists, COPTs and PTs to comply with the directives of the legislation.

Proposed new rule OAR 855-115-0305 adds vaccine administration requirements for Pharmacists who provide or supervise the administration of a vaccine, including training, verification and documentation requirements; Permits an Intern to perform the same duties as a Pharmacist except as prohibited in OAR 855-120-0150; Permits a COPT or PT to perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist pursuant to 2023 HB 2486 beginning 1/1/2024. Removes proposed rule language that is no longer necessary due to the new legislation.

Proposed new rule OAR 855-125-0305 adds vaccine administration requirements for COPTs or PTs, permits an appropriately trained and qualified COPT and PT to perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist pursuant to 2023 HB 2486 beginning 1/1/2024, adds training and certification requirements prior to administering vaccines, adds documentation requirements, adds notification and record retention requirements.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the August 2023 board meeting.

- Highlights/Markup
  - Rule language highlighted in green denote rules moved within the package
  - Rule language highlighted in yellow denote staff proposed amendments to rules moved within the package.
  - **Mark~~up~~** in this package is in comparison to the Div 115 and 125 rules filed for rulemaking in June 2023.

Division 115
PHARMACISTS

855-115-0305
Services: Administration of Vaccines, Drugs, or Devices

(1) In accordance with ORS 689.645 and ORS 689.655, a Pharmacist may administer a vaccine, drug or device as specified in this rule. **The Pharmacist must be acting:**

(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; or

(b) In accordance with a statewide drug therapy management protocol per OAR 855-115-0345 or clinical pharmacy agreement or collaborative drug therapy management agreement per OAR 855-115-0315; or

(c) In accordance with a written administration protocol issued by the Oregon Health Authority and approved by the board.

(2) A Pharmacist who administers a vaccine, drug or device must:

(a) Prior to administration of an injectable drug or device, receive practical training on the injection site and administration technique that is utilized~~;~~**.**

~~(A) For vaccines, the training:~~

~~(i) May include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board; and~~

~~(ii) Must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.~~

~~(B)~~ For orally administered drugs, training is not required~~; and~~**.**

~~(C) Records of training must be retained according to OAR 855-104-0055.~~

(b) Hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years. The most current CPR certification record must be retained according to OAR 855-104-0055;

(c) Ensure that any drug administered to a patient was stored in accordance with the drug storage rules for pharmacies in ORS 855-041-1036;

(d) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the vaccine, drug or device;

(e) Ensure that vaccine, drug or device administration is documented in the patient's permanent record; and

(f) Ensure records and documents are retained according to OAR 855-104-0055. Records of administration must include but are not limited to:

(A) Patient identifier;

(B) Vaccine, drug or device and strength;

(C) Route and site of administration;

(D) Date and time of administration; and

(E) Pharmacist identifier.

(3) For vaccines only, the requirements in (2) and the following apply, **and** the Pharmacist **who administers or supervises each administration of a vaccine to a patient** must:

(a) Complete training that includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. The training may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board; and

(b) Make vaccine recommendations;

(c) Select each vaccine to be administered;

(d) Prescribe each vaccine pursuant to (1);

(e) Ensure the appropriate Vaccine Information Statement (VIS) is provided to the patient or patient's agent prior to each dose of vaccine.

(f) Perform verification prior to administration that includes but is not limited to:

(A) Prescription order accuracy verification; and

(B) Vaccine product accuracy review;

(g) Advise or counsel on therapeutic values, content, hazards and use of each vaccine;

(h) Manage adverse events;

~~(a) Follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022);~~

~~(b) Have access to a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);~~

~~(c) Give the appropriate Vaccine Information Statement (VIS) to the patient or patient's agent with each dose of vaccine covered by these forms. The Pharmacist must ensure that the patient or patient's agent is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine;~~

~~(d) Report all vaccinations administered to the ALERT IIS in accordance with OAR 333-049-0050, and for COVID-19 immunizations, in accordance with OAR 333-047-1000; and~~

(~~e~~**i**) Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient**;**

(j) Verify accuracy and completeness of documentation for vaccine administration;

(k) Ensure all persons administering vaccinations under their supervision are appropriately trained and qualified;

(m) Follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022); and

(n) Have access to a current edition of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);

~~(4) The Pharmacist must be acting:~~

~~(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; or~~

~~(b) In accordance with a statewide drug therapy management protocol per OAR 855-115-0345 or clinical pharmacy agreement or collaborative drug therapy management agreement per OAR 855-115-0315; or~~

~~(c) In accordance with a written administration protocol issued by the Oregon Health Authority and approved by the board.~~

(5) The Pharmacist may administer a drug or device in conjunction with training the patient or the patient's agent how to administer or self-administer the drug or device.

(6) ~~Except as required in (2), r~~**R**ecords and documents must be retained according to OAR 855-104-0055.

(7) An appropriately trained and qualified Pharmacist may permit an appropriately trained and qualified:

(a) Intern to perform the same duties as a Pharmacist except as prohibited in OAR 855-120-0150.

(b) Certified Oregon Pharmacy Technician or Pharmacy Technician to conduct the physical act of administering a vaccine in accordance with OAR 855-120-0305.

(8) The appropriately trained and qualified Pharmacist who is supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician providing vaccinations must be immediately available to the vaccinator.

Statutory/Other Authority: ORS 689.205, **2023 HB 2486, 2023 HB 2278**
Statutes/Other Implemented: ORS 689.655, 2**023 HB 2486, 2023 HB 2278**

Division 125
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-125-0305
Services: Vaccine Administration

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist:

(a) To a person who is seven years of age or older;

(b) To a person who is at least three years of age when;

(A) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or

(B) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.

(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician must:

(a) Prior to administration of a vaccine, receive practical training that includes infection control, recognition of anatomical landmarks and competency in hands-on administration technique.

(b) Prior to administration of a vaccine, hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program that is specific to the age and population receiving the vaccine, contains a hands-on training component, and is valid for not more than three years.

(3) Document the vaccine administration including but not limited to the vaccine administered, dose, expiration date, lot number, and injection site.

(4) Notify the supervising Pharmacist immediately in the event of a suspected adverse reaction to a vaccine.

(5) The training required in (2) may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board.

(6) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

Statutory/Other Authority: ORS 689.205, 2023 HB 2486, 2023 HB 2278
Statutes/Other Implemented: ORS 689.151, 2023 HB 2486, 2023 HB 2278

Division 006/115: Clinical Pharmacy Agreement (CPA) & Collaborative Drug Therapy Management (CDTM) Definitions

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Clinical Pharmacy Agreement; Collaborative Drug Therapy Management Definitions

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Revises existing definitions for Clinical Pharmacy Agreement (CPA) and Collaborative Drug Therapy Management (CDTM). Relocates and revises existing CDTM rules from Division 019 into Division 115.

Documents Relied Upon per ORS 183.335(2)(b)(D): None available.

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed amendments provide clarity for licensees and registrants. It is anticipated that repeal of this rule will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

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): Proposed amendments are necessary to ensure clarity for licensees and registrants. Amendments include adding statutory reference ORS 689.005 to OAR 855-006-0005(9) "Clinical Pharmacy Agreement". Proposes revising the definition of "Collaborative Drug Therapy Management" in OAR 855-006-0005(10) by adding descriptive language related to the process in which a Pharmacist or pharmacy and a health care provider or group of health care providers agree to a pre-specified drug therapy management protocol is initiated for an individual patient on the prescription or prescription drug order of a participating provider. Proposes to strike existing language that is no longer necessary.

Proposed new rule OAR 855-115-0315 adds requirements for Pharmacists who provide Clinical Pharmacy Agreement under a written protocol and modifies requirements from OAR 855-019-0260 for Pharmacists who provide Collaborative Drug Therapy Management services under a written protocol; relocates and revises existing language from OAR 855-019-0260 and proposes repealing OAR 855-019-0260 upon the effective date of OAR 855-115-0315.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the August 2023 board meeting.

- Highlights/Markup
  - Rule language highlighted in yellow denote staff proposed amendments made since the rule package was first noticed for the August 2023 board meeting.
  - **Mark~~up~~** in this package is in comparison to current rules in Div 006 and Div 019.

Division 006
DEFINITIONS

855-006-0005
Definitions
NOTE: This rule is also in rule package #D1 Compounding

(9) "Clinical Pharmacy Agreement" means an agreement between a Pharmacist or pharmacy and a health care organization, or a ~~p~~**P**hysician as defined in ORS 677.010 or a ~~n~~**N**aturopathic ~~p~~**P**hysician as defined in ORS 685.010 that permits the Pharmacist to engage in the practice of clinical pharmacy pharmacy **as defined in ORS 689.005** for the benefit of the patients of the health care organization, or ~~p~~**P**hysician or ~~n~~**N**aturopathic ~~p~~**P**hysician.

(10) "Collaborative Drug Therapy Management" means **the process in which a Pharmacist or pharmacy and a health care provider or group of health care providers** ~~participation by a Pharmacist in the management of drug therapy pursuant to a written~~ **agree to a pre-specified drug therapy management** protocol that ~~includes information specific to the dosage, frequency, duration, and route of administration of the drug, authorized by a practitioner and~~ **is** initiated **for an individual patient on the** ~~upon a~~ prescription **or prescription drug** order of **a participating provider.** ~~for an individual patient and:~~

~~(a) Is agreed to by one Pharmacist and one practitioner; or~~

~~(b) Is agreed to by one or more Pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic, or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.~~

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: **ORS 689.005**, ORS 689.151, ORS 689.155 & 2022 HB 4034

Division 115
PHARMACISTS

~~855-019-0260~~ **855-115-0315**
Services: Clinical Pharmacy Agreement & Collaborative Drug Therapy Management

(1) A Pharmacist or pharmacy may engage in the practice of clinical pharmacy under a written Clinical Pharmacy Agreement with health care organization, Physician or Naturopathic Physician.

(2) If the agreement in (1) is made with a health care organization, the organization is responsible for ensuring that each protocol utilized by a Pharmacist or pharmacy to provide clinical pharmacy services:

(a) Is developed and overseen by a Physician or Naturopathic Physician acting within their scope.

(b) Is reviewed by each participating health care provider.

(c) Cannot allow any act that is prohibited by ORS 475, ORS 689 and OAR 855.

(3) Each protocol developed under the agreement in (1) must include:

(a) The name of the principal Pharmacist and principal Physician or Naturopathic Physician who is responsible for:

(A) Initial training and ongoing competency assessment for participating Pharmacists; if necessary;

(B) Development, quality assurance and updating or discontinuing each protocol;

(b) The identification, either by name or by description, of each participating Pharmacist;

(c) The identification, either by name or description, of each participating physician, naturopathic physician or health care providers within a health care organization. These persons must have scope to independently treat patients.

(d) The disease state or patient panel for which the Pharmacist may provide clinical pharmacy services;

(e) Types of clinical pharmacy services provided;

(f) Communication to the patient's Physician, Naturopathic Physician or health care provider within the health care organization concerning:

(A) Information collected;

(B) Patient assessment;

(C) Plan of care including follow-up;

(D) Services provided; and

(E) Circumstances requiring urgent communication with the patient's health care provider; and

(g) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary.

~~(1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:~~
~~(a) Is agreed to by one practitioner and one pharmacist; or~~

~~(b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more pharmacists.~~

(~~2~~**4**) A ~~p~~**P**harmacist ~~shall~~ **may** engage in ~~c~~**C**ollaborative ~~d~~**D**rug ~~t~~**T**herapy ~~m~~**M**anagement **under a written protocol** with a ~~practitioner~~ **health care provider who is acting within their scope.** ~~only under a written arrangement that includes:~~

(5) Each protocol developed under the agreement in (4) must include:

(a) The name of the principal Pharmacist and health care provider who are responsible for:

(A) Initial training and ongoing competency assessment for participating Pharmacists, if necessary; and

(B) Development, quality assurance and updating or discontinuance of each protocol;

(~~a~~**b**) The identification, either by name or by description, of each ~~of the~~ participating ~~p~~**P**harmacist~~s~~;

(~~b~~**c**) The identification, by name or description, of each of the participating **health care provider** ~~practitioners~~ or group of **health care providers** ~~practitioners~~;

~~(c) The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement;~~

~~(d) The types of decisions that the pharmacist is allowed to make, which may include:~~

(A**d**) A detailed description of the: ~~types of diseases, drugs, or drug categories involved, and the activities allowed in each case;~~

(A) Indications;

(B) Drugs including dosage, frequency, duration and route of administration;

(C) Methods;

(D) Procedures;

(E) Decision criteria; and

(F) Plan the Pharmacist is to follow;

~~(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;~~

(~~C~~**f**) ~~A detailed description of the activities the pharmacist is to follow including~~ ~~d~~**D**ocumentation ~~of~~ **the Pharmacist is to complete concerning** ~~decisions made~~ **actions taken** and a plan or appropriate mechanism for communication, feedback, and reporting to the ~~practitioner~~ **health care provider** concerning specific ~~decisions made~~ **actions taken**. ~~In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system~~;

(~~D~~**g**) Circumstances which will cause the ~~p~~**P**harmacist to initiate communication with the ~~practitioner~~ **health care provider;** ~~including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect.~~

(e) Training requirement for ~~p~~**P**harmacist participation and ongoing assessment of competency, if necessary;

~~(f) Quality assurance and periodic review by a panel of the participating pharmacists and practitioners;~~

~~(g) Authorization by the practitioner for the pharmacist to participate in collaborative drug therapy; and~~

(~~h~~**6**) ~~A requirement for the collaborative drug therapy arrangement to~~ **Each protocol developed in (1) and (4) must** be reviewed and updated~~,~~ or discontinued at least every two years;

(7) The Pharmacist must document the protocol version and all clinical pharmacy activities in the prescription record, patient profile, electronic health record or in some other appropriate system.

(~~3~~**8**) ~~The collaborative drug therapy arrangement and associated r~~**R**ecords **and documents** must ~~be kept on file in the pharmacy and made available to any appropriate health licensing board upon request~~ **retained according to OAR 855-104-0055.**

~~(4) Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151~~,~~ ~~&~~ **ORS** 689.155

Division 045: Drug Compounding (USP <795> and USP <797>)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Incorporates additional USP <795> and USP <797> standards adopted by reference

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Permits Drug Outlet pharmacies to implement USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (v. 11/01/2022) and <797> Pharmaceutical Compounding—Sterile Preparations (v. 11/01/2022) as an alternative to USP <795> (05/01/2020 v. 2014) and USP <797> (05/01/2020 v. 2008).

Documents Relied Upon per ORS 183.335(2)(b)(D):

- USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (v. 11/01/2022) – Publication Announcement

- USP <797> Pharmaceutical Compounding—Sterile Preparations (v. 11/01/2022)- Publication Announcement

OAR 855-045-0205 Temporary Rule

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. This is currently a temporary rule that needs to be permanently adopted prior to the temporary rule 10/31/2023 expiration date in order to facilitate timely compliance with USP standards.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Permanently adopts the current temporary rule that allows Drug Outlet pharmacies to implement USP <795> Pharmaceutical Compounding Non-Sterile Preparations (v. 11/01/2022) and <797> Pharmaceutical Compounding – Sterile Preparations (v. 11/01/2022).

The United States Pharmacopeia (USP) published its revised standards for USP General Chapters <795> and <797> on November 1, 2022. These new USP standards will be effective on November 1, 2023. In addition, USP <800> will become enforceable on November 1, 2023. The board anticipates adopting these updated USP Chapters (<795> and <797>) by reference effective November 1, 2023. USP <800> issued July 1, 2020 is already required in rule. Due to the numerous and complex process changes required for compliance, registrants may implement the revised USP Chapters <795> and <797> prior to that date.

DIVISION 45
DRUG COMPOUNDING

855-045-0205
Compliance with New Standards

As an alternative to the requirements in OAR 855-045-0200(3)(a) and (3)(b) registrants may comply with any or all standards contained in:

(a) USP <795> Pharmaceutical Compounding—Non-Sterile Preparations (11/1/2022).

(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (11/1/2022).

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

Title: Board Meeting Recording and Summary

S	**Situation:** Board staff spend several hours per month drafting and editing meeting minutes after each board, committee and workgroup meeting.
B	**Background:** **AG Manual 2019** **7. Minutes and Recordkeeping** A governing body must provide for written minutes of its meetings and executive sessions, or sound, video, or digital recording.[671] The written minutes or recording must include at least the following information: • members present; • motions, proposals, resolutions, orders, ordinances and measures proposed and their disposition; • results of all votes; and, the vote of each member by name, except for public bodies consisting of more than 25 members unless recording by name is requested by a member of that body; • the substance of any discussion on any matter; and • a reference to any document discussed at the meeting, unless even a reference to the document is exempt under Public Records Law.[672] Written minutes need not be a verbatim transcript, and a sound, video, or digital recording is not required to contain a full recording of the meeting, except as otherwise provided by law. However, the minutes or recording must contain the above information and must give "a true reflection of the matters discussed at the meeting and the views of the participants." Public bodies must keep a record of their public meetings. Written minutes, audio and video recordings are acceptable. Minutes must include the members present, all motions, resolutions, votes taken and the substance of any discussion. **ORS Chapter 192 — Records; Public Reports and Meetings** **ORS 192.650 Recording or written minutes required; content; fees.** (1) The governing body of a public body shall provide for the sound, video or digital recording **or** the taking of written minutes of all its meetings. Neither a full transcript nor a full recording of the meeting is required, except as otherwise provided by law, but the written minutes or recording must give a true reflection of the matters discussed at the meeting and the views of the participants. All minutes or recordings shall be available to the public within a reasonable time after the meeting, and shall include at least the following information: (a) All members of the governing body present; (b) All motions, proposals, resolutions, orders, ordinances and measures proposed and their disposition; (c) The results of all votes and, except for public bodies consisting of more than 25 members unless requested by a member of that body, the vote of each member by name; (d) The substance of any discussion on any matter; and

	(e) Subject to ORS 192.311 (*Definitions for ORS 192.311 to 192.478*) to 192.478 (*Exemption for Judicial Department*) relating to public records, a reference to any document discussed at the meeting. (2) Minutes of executive sessions shall be kept in accordance with subsection (1) of this section. However, the minutes of a hearing held under ORS 332.061 (*Hearing to expel minor students or to examine confidential records*) shall contain only the material not excluded under ORS 332.061 (*Hearing to expel minor students or to examine confidential records*) (2). Instead of written minutes, a record of any executive session may be kept in the form of a sound or video tape or digital recording, which need not be transcribed unless otherwise provided by law. If the disclosure of certain material is inconsistent with the purpose for which a meeting under ORS 192.660 (*Executive sessions permitted on certain matters*) is authorized to be held, that material may be excluded from disclosure. However, excluded materials are authorized to be examined privately by a court in any legal action and the court shall determine their admissibility. **OAR 166-350-0010 Board and Commission Records (4)** (4) Board and Commission Meeting Minutes: Series documents the official proceedings of the board or commission meetings. Records may include agendas; minutes; meeting notices; items for board action; contested case hearings schedules; committee reports; exhibits; and related correspondence and documentation. Records may also include audio recordings of meetings used to prepare summaries. (Retention: Minutes: Permanent, transfer to State Archives after 10 years; Audio recordings: one year after transcribed, destroy; Other records: five years, destroy).
A	**Assessment:** Written minutes of board, committee and workgroup meetings are not required to be produced if the meeting is recorded and the recording is available. Several hours of staff time per month will be saved and a meeting summary with timestamps can serve as a more complete record of the meeting discussion.
R	**Recommendation:** Board direction to staff to: 1. Discontinue drafting written meeting minutes and instead, post a “meeting summary” with roll calls, meeting agenda items with timestamp of the meeting recording, and all motions with votes. 2. Retain meeting audio recording as official record of meeting consistent with ORS 192.650 and post on board’s website with meeting summary.

Oregon Board of Pharmacy

Budget Report: May 2023 (Month 23)

Revenue:

Through May, revenue is $8,578,717 (-1.5%) **under** budget

Expenditures:

Through May, **total expenditures** are $8,590,741 (7.5%) **under** budget

Personal services are $6,194,106 (3.7%) **under** budget

Services and Supplies are $2,396,635 (18.7%) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: ($12,024)

Cash Balance:

Cash balance through May is $4,031,535 which represents (9.98) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through May 2023. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,951,281, which represents (13.23) months of operating expense*)

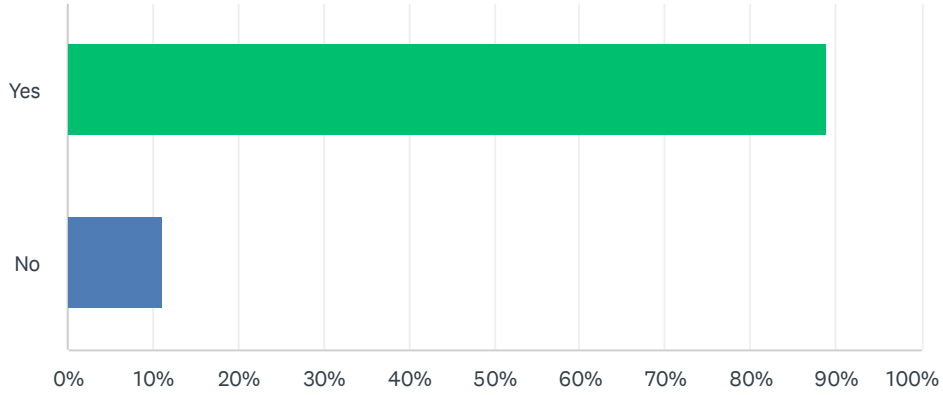
Cash balance target is $2,244,921, (6.0 months of operating expense)

*Note: The end of biennium projected cash balance is calculated based on the biennium to date plus the remaining months projections for 2021-23.

Oregon Board of Pharmacy				
Total All Funds - LAB 2021-2023				
Actuals through May 2023				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**3,679,852**	**4,714,145**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	8,716,500.00	8,650,361.99	66,138.01
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	291,124.75	(98,129.75)
505	FINES AND FORFEITS	410,000.00	332,490.23	77,509.77
605	INTEREST AND INVESTMENTS	131,250.00	140,590.04	(9,340.04)
975	OTHER REVENUE	84,335.00	63,266.63	21,068.37
	TOTAL REVENUE	**9,535,080.00**	**9,477,833.64**	**57,246.36**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	443,120.00	261,014.00	182,106.00
	TOTAL TRANSFER OUT	**443,120.00**	**261,014.00**	**182,106.00**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,283,003.00	4,179,398.85	103,604.15
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	12,825.57	(12,825.57)
3180	SHIFT DIFFERENTIAL	-	18.50	(18.50)
3190	ALL OTHER DIFFERENTIAL	198,616.00	173,647.43	24,968.57
3210	ERB ASSESSMENT	1,276.00	1,238.40	37.60
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	757,047.54	3,689.46
3221	PENSION BOND CONTRIBUTION	236,241.00	233,440.51	2,800.49
3230	SOCIAL SECURITY TAX	334,236.00	311,576.13	22,659.87
3240	UNEMPLOYMENT ASSESSMENT	-	219.10	(219.10)
3241	PAID LEAVE OREGON-EMPLOYER	-	5,023.50	(5,023.50)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	866.69	145.31
3260	MASS TRANSIT	27,053.00	25,842.98	1,210.02
3270	FLEXIBLE BENEFITS	841,104.00	779,260.66	61,843.34
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,482,605.42**	**227,978.58**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	67,340.06	48,553.94
4125	OUT-OF-STATE TRAVEL	17,024.00	2,725.77	14,298.23
4150	EMPLOYEE TRAINING	22,320.00	25,873.75	(3,553.75)
4175	OFFICE EXPENSES	134,566.00	52,449.09	82,116.91
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	56,666.04	(5,736.04)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	204,352.10	(1,811.10)
4250	DATA PROCESSING	318,678.00	351,240.03	(32,562.03)
4275	PUBLICITY & PUBLICATIONS	43,329.00	23,017.06	20,311.94
4300	PROFESSIONAL SERVICES	339,713.00	241,654.03	98,058.97
4315	IT PROFESSIONAL SERVICES	134,467.00	5,530.00	128,937.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	532,726.36	89,108.64
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,706.63	1,711.37
4425	FACILITIES RENT & TAXES	229,042.00	285,485.83	(56,443.83)
4475	FACILITIES MAINTENANCE	55.00	1,851.13	(1,796.13)
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	500.00	702.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	221,795.75	28,683.25
4650	OTHER SERVICES AND SUPPLIES	411,285.00	409,604.90	1,680.10
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	5,423.49	8,684.51
4715	IT EXPENDABLE PROPERTY	45,228.00	5,136.87	40,091.13
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,497,078.89**	**461,716.11**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,691,342.00**	**8,979,684.31**	**711,657.69**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**4,951,281**	
	End of biennium projected cash balance in months		13.23	
	Cash balance target of 6.0 months (working capital)		2,244,921	

Q1 Executive Director's performance expectations are current.

Answered: 9 Skipped: 0

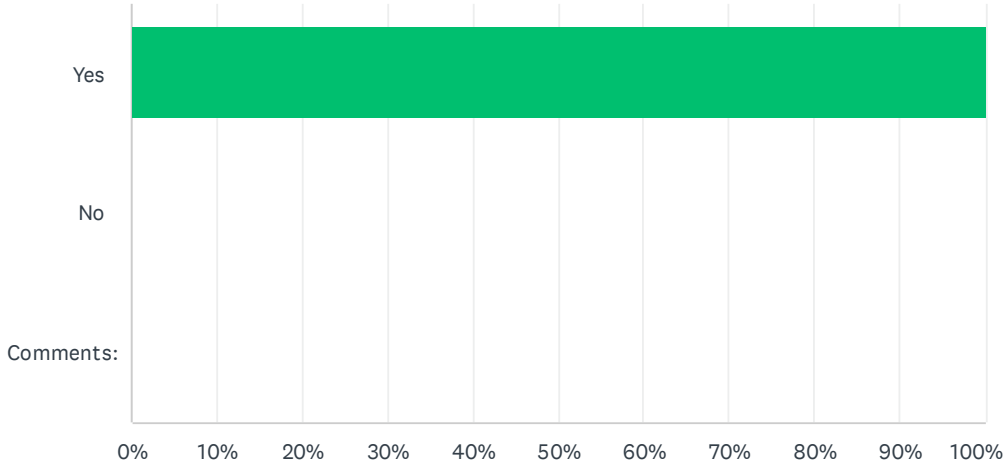


ANSWER CHOICES	RESPONSES	
Yes	88.89%	8
No	11.11%	1
TOTAL		9

#	COMMENTS:	DATE
1	Question is somewhat unclear to me, however, Executive Director's performance has not met the expectations set forth for the position.	7/14/2023 3:53 PM

Q2 Executive Director receives annual performance feedback.

Answered: 9 Skipped: 0

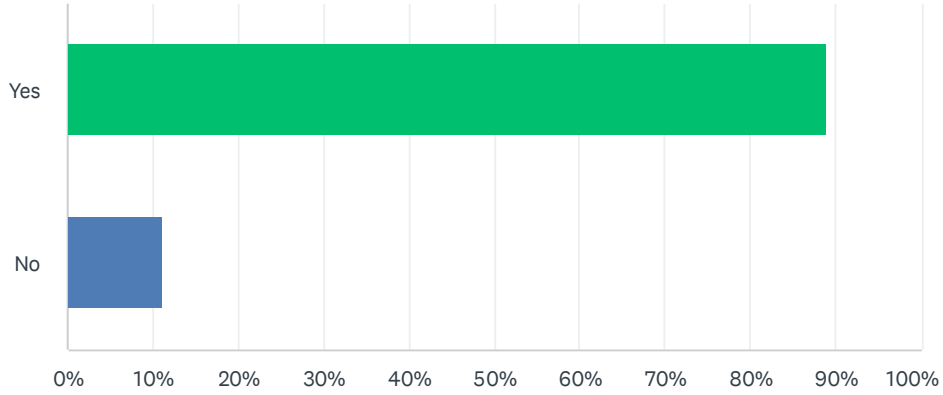


ANSWER CHOICES	RESPONSES	
Yes	100.00%	9
No	0.00%	0
Comments:	0.00%	0
TOTAL		9

#	COMMENTS:	DATE
	There are no responses.	

Q3 The agency's mission and high-level goals are current and applicable.

Answered: 9 Skipped: 0

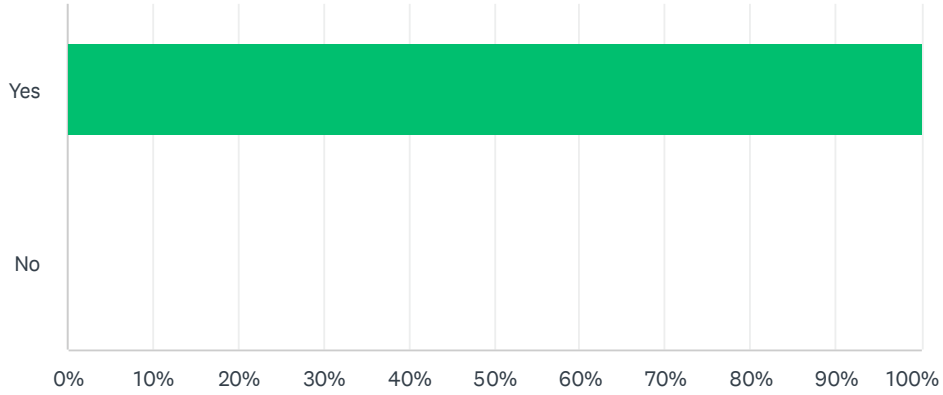


ANSWER CHOICES	RESPONSES	
Yes	88.89%	8
No	11.11%	1
TOTAL		9

#	COMMENTS:	DATE
1	The agency's mission and high-level goals require an update to ensure their relevance and applicability in the current context. It is crucial to realign our objectives with the evolving needs and challenges of the present time. By revisiting and refining our mission, we can aim to maximize our impact, optimize resource allocation, and effectively serve the needs of our stakeholders and the broader community.	7/14/2023 3:53 PM

Q4 The board reviews the Annual Performance Progress Report.

Answered: 9 Skipped: 0

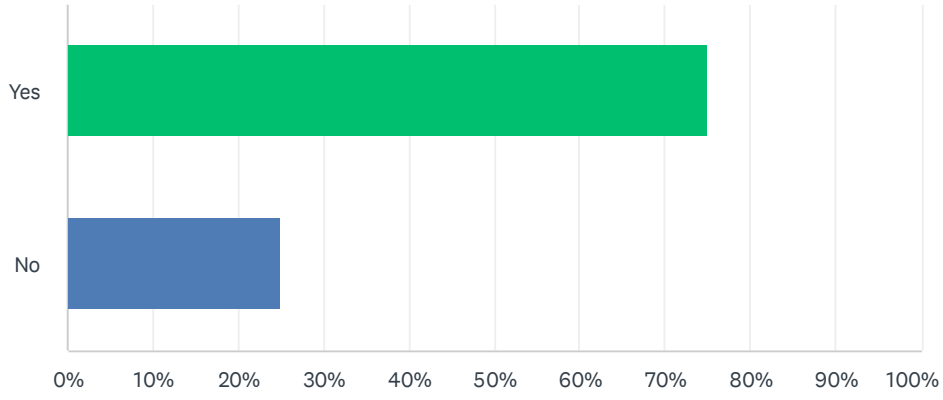


ANSWER CHOICES	RESPONSES	
Yes	100.00%	9
No	0.00%	0
TOTAL		9

#	COMMENTS:	DATE
1	Would like to see this at beginning of a meeting day	7/14/2023 10:25 AM

Q5 The board is appropriately involved in review of the agency's key communications.

Answered: 8 Skipped: 1

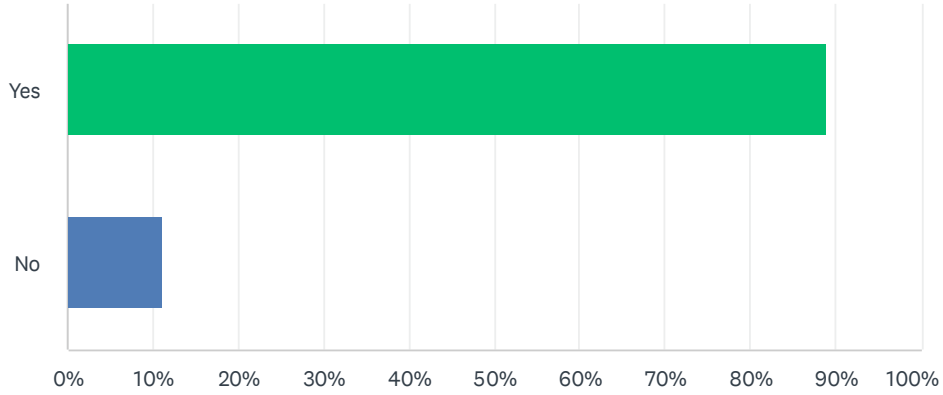


ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

#	COMMENTS:	DATE
1	BUT-When its talked about its not talked about much and I wonder sometimes if the appropriate licensees are getting communications. Just ask the new Board members if they know.	7/15/2023 5:01 PM
2	There are concerns regarding the transparency of key communications, particularly in the context of board member engagement and effective communication channels. There is a need for improved communication with board members.	7/14/2023 3:53 PM
3	Not sure	6/29/2023 5:50 PM

Q6 The board is appropriately involved with policy making activities.

Answered: 9 Skipped: 0

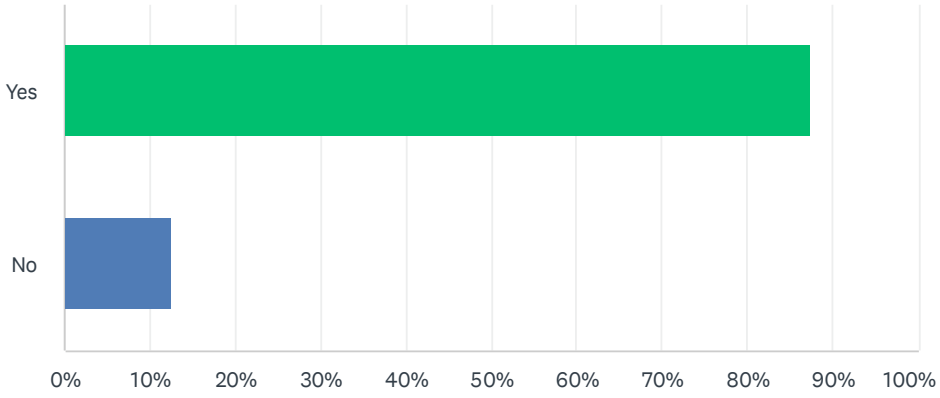


ANSWER CHOICES	RESPONSES	
Yes	88.89%	8
No	11.11%	1
TOTAL		9

#	COMMENTS:	DATE
1	BUT-We are having a discussion about the inspection that we were not involve in (if that is policy making)	7/15/2023 5:01 PM
2	Policy making activities are primarily directed by the board of staff, with limited input from board members.	7/14/2023 3:53 PM
3	The board is involved but not always heard.	7/14/2023 11:38 AM

Q7 The agency's policy option packages are aligned with their mission and goals.

Answered: 8 Skipped: 1

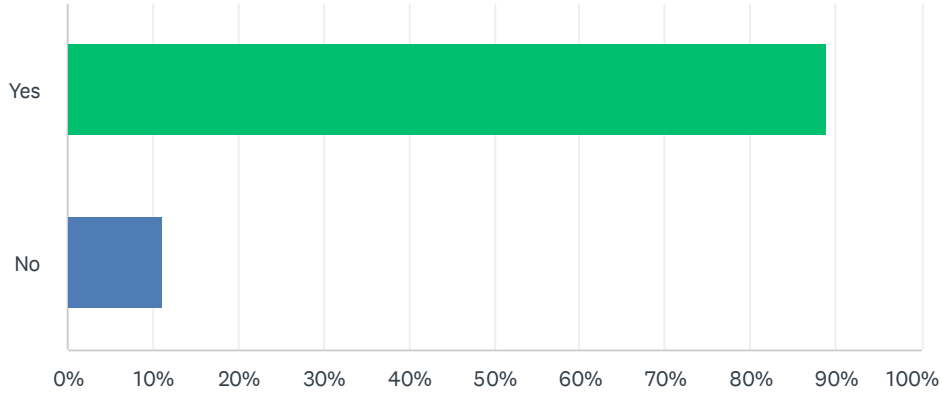


ANSWER CHOICES	RESPONSES	
Yes	87.50%	7
No	12.50%	1
TOTAL		8

#	COMMENTS:	DATE
1	Not sure	6/29/2023 5:50 PM

Q8 The board reviews all proposed budgets.

Answered: 9 Skipped: 0

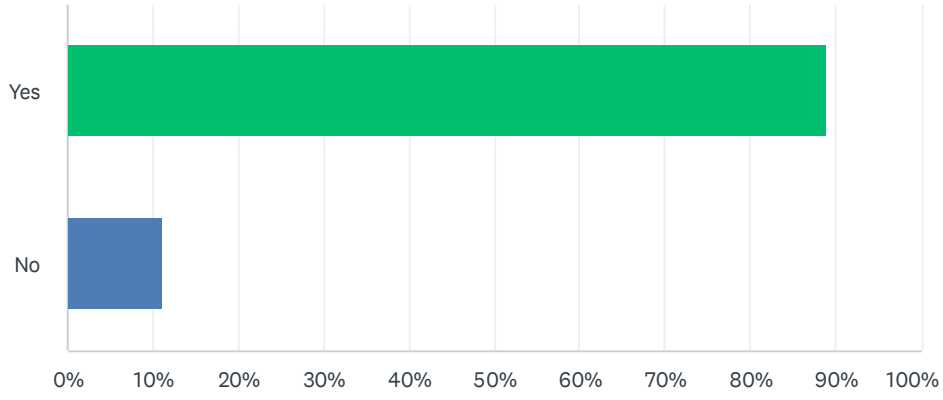


ANSWER CHOICES	RESPONSES	
Yes	88.89%	8
No	11.11%	1
TOTAL		9

#	COMMENTS:	DATE
1	Yes, in less then 10 minutes	7/14/2023 3:53 PM

Q9 The board periodically reviews key financial information and audit findings.

Answered: 9 Skipped: 0

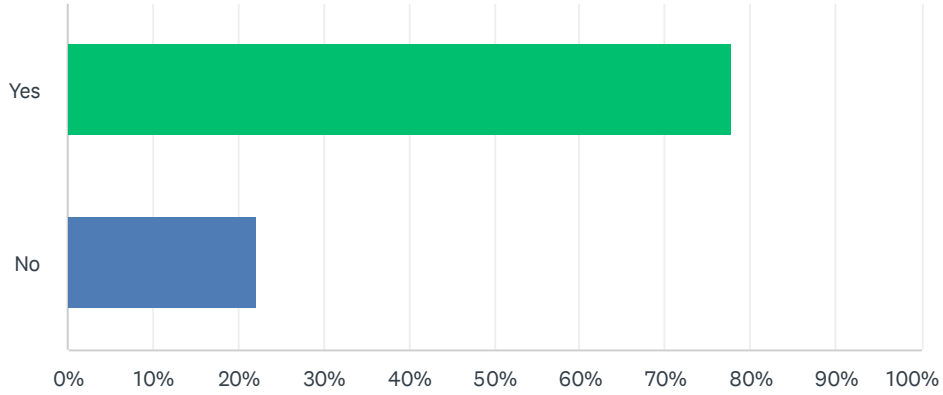


ANSWER CHOICES	RESPONSES	
Yes	88.89%	8
No	11.11%	1
TOTAL		9

#	COMMENTS:	DATE
1	Yes, In less then 10 minutes	7/14/2023 3:53 PM

Q10 The board is appropriately accounting for resources.

Answered: 9 Skipped: 0

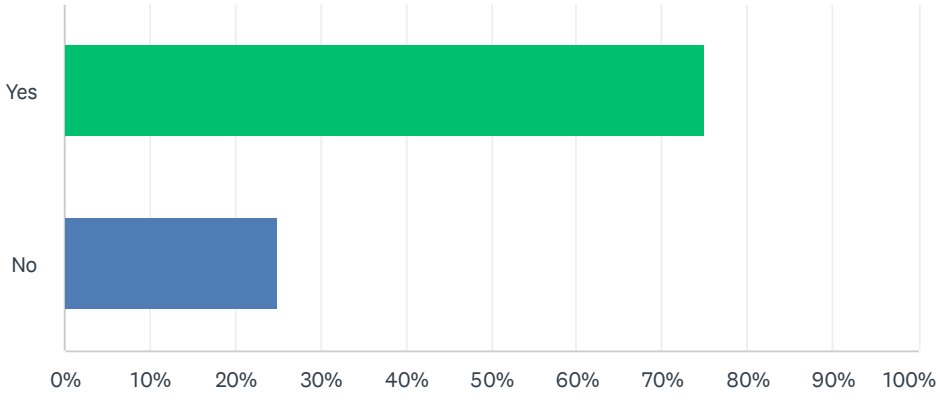


ANSWER CHOICES	RESPONSES	
Yes	77.78%	7
No	22.22%	2
TOTAL		9

#	COMMENTS:	DATE
	There are no responses.	

Q11 The agency adheres to accounting rules and other relevant financial controls.

Answered: 8 Skipped: 1

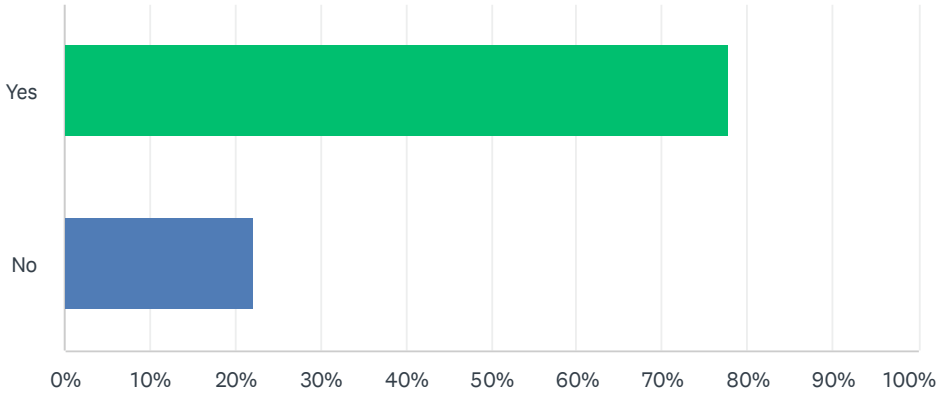


ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

#	COMMENTS:	DATE
1	As a board member, I am unable to locate the accounting rules and participate in direct financial control.	7/14/2023 3:53 PM
2	We do not have visualization of this	7/14/2023 10:25 AM
3	I guess	6/29/2023 5:50 PM

Q12 Board members act in accordance with their roles as public representatives.

Answered: 9 Skipped: 0

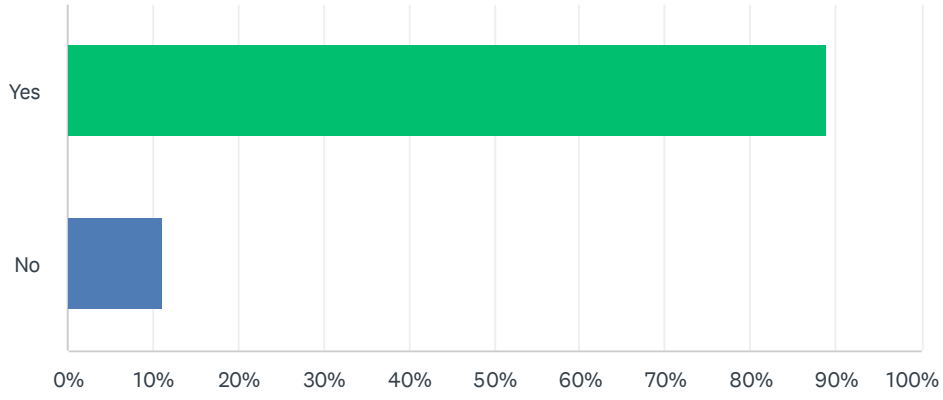


ANSWER CHOICES	RESPONSES	
Yes	77.78%	7
No	22.22%	2
TOTAL		9

#	COMMENTS:	DATE
1	Question is somewhat unclear to me however, The board of staff advises board members to refrain from engaging with the public.	7/14/2023 3:53 PM
2	The role is to protect the public. It is my opinion that there are a few statements made in each meeting to alter proposed rule which are motivated by business or other conflicting interests.	6/30/2023 9:03 AM

Q13 The board coordinates with others where responsibilities and interests overlap.

Answered: 9 Skipped: 0

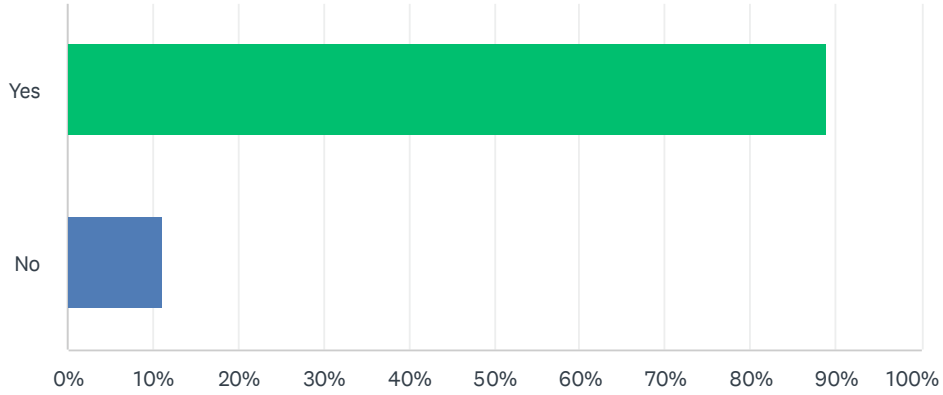


ANSWER CHOICES	RESPONSES	
Yes	88.89%	8
No	11.11%	1
TOTAL		9

#	COMMENTS:	DATE
1	Question is somewhat unclear.	7/14/2023 3:53 PM

Q14 The board members identify and attend appropriate training sessions.

Answered: 9 Skipped: 0

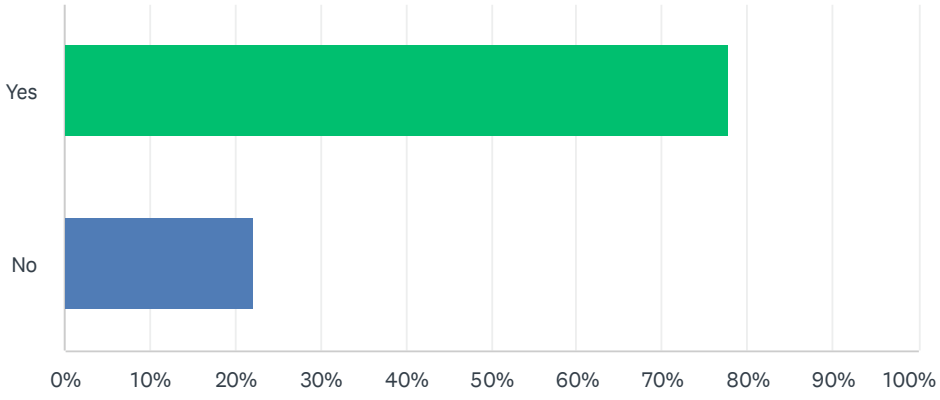


ANSWER CHOICES	RESPONSES	
Yes	88.89%	8
No	11.11%	1
TOTAL		9

#	COMMENTS:	DATE
1	Question is unclear. I did not attend any training sessions on a specific subject	7/14/2023 3:53 PM
2	Not sure about identifying	7/14/2023 10:25 AM
3	It is unknown to me if all board members complete DAS trainings, and what the ramifications would be if not completed.	6/30/2023 9:03 AM

Q15 The board reviews its management practices to ensure best practices are utilized.

Answered: 9 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	77.78%	7
No	22.22%	2
TOTAL		9

#	COMMENTS:	DATE
1	I am answering this question with the understanding that “management practices” means operation of board proceedings and other related office activities.	6/30/2023 9:03 AM

Q16 General comments, observations or questions to discuss at the August 2023 Annual Board Business Meeting:

Answered: 2 Skipped: 7

#	RESPONSES	DATE
1	We are on track with our strategic plan. Board members come from a variety backgrounds that contribute appropriately to policy discussion.	7/6/2023 4:09 PM
2	How can we help the board meetings operate more efficiently, with possible goal to decrease length of some meetings back to 2 days? This might include speaking time limits, not talking out of turn, or other management opportunities.	6/30/2023 9:03 AM

From: Oregon Board of Pharmacy
To: MELVIN Rachel * BOP
Subject: Pharmacist Volunteer Opportunity - apply now
Date: Monday, June 26, 2023 5:46:02 PM

June 26, 2023 - Pharmacist Volunteer Opportunity - apply now

The Oregon Board of Pharmacy is seeking applicants for 3 volunteer pharmacist positions for 2-year terms. Applicants must live in Oregon. Please click on the following links for more information:

1 appointment/reappointment to the Rural Health Coordinating Council

2 appointments/reappointments to the Council on Naturopathic Physicians Formulary

To be considered, please send the following to: Karen.S.MacLean@bop.oregon.gov by **July 15, 2023** for consideration at the August 10-11, 2023 Board meeting.

1. A letter of Interest specifying which Council you're interested in and why.
2. List any specific experience you have to support this work.
3. A current CV.

Thank you,

Board Staff

Date: 6/8/23
Name: Natalie Gustafson

List the board, committee or commission to which appointed:
Oregon Board of Naturopathic Medicine Formulary Council

Please provide a brief summary of contribution to the council in the last year:

I have been on the OBNM Formulary Council since August 2011, with my current term ending June 2023. In 2021, I was appointed chair of the formulary council, and have remained chair until present. We meet every six months, typically in March and September. I would like to express my interest at remaining on this Council for another term and provide a summary of my activity on the council over the last year.

In the March 2022 meeting, the formulary council was advised on the status of the new psilocybin advisory board updates, and reviewed a request from a naturopathic physician to update ketamine prescribing rules. Naturopathic physicians had limited ketamine prescribing rights due to a statutory restriction against general anesthesia, but requested prescribing access to injectable ketamine for purposes other than general anesthesia.

We formed a Ketamine Rule Advisory subcommittee that reviewed the current rules, conducted research, and discussed parameters, such as continuing education requirements, for prescribing rights to better advise the council. As a compounding pharmacist, I had previously done extensive research in ketamine, and was asked to be a member of the subcommittee. The subcommittee met three times in May and June of 2022. We reviewed safety information, clinical application, received feedback from prescribers utilizing ketamine injectables, and discussed suggested pharmacology and ethical education requirements. The subcommittee presented our findings and recommendations at the September formulary council meeting. The formulary council voted to move forward with presenting these recommendations to the Oregon Board of Naturopathic Medicine (OBNM). I then attended the October 10, 2022 OBNM meeting to help answer questions and present information gathered by the subcommittee, who voted to adopt these recommendations.

As a result of the formulary council's work and recommendations, there were updates made to 850-060-0223 Formulary Compendium Exclusions and a new rule 850-060-0210 Education and Reporting Requirements for Ketamine Therapy added for naturopathic physicians that went into effect January 1, 2023.

At the March 2023 meeting, I was asked to provide an update on the current regulatory situation with desiccated thyroid extract, availability and compounding status. We reviewed the status of Oregon Psilocybin Services, status of suboxone and X-waiver and had a discussion on criteria for pharmacy CE credit approval for naturopathic physicians. We also reviewed the applications by Carmen Ionescu and Adam Alani for reappointment to the council, but did not have the quorum required to vote. Thus, we will need to review and vote in the next formulary council meeting.

I have enjoyed my time on the council and as chair, and believe I still bring value as chair. Being a member for twelve years means I have knowledge of the history and formulary changes that have occurred over that time. I also bring valuable knowledge in the area of compounding. The updated USP Chapters <795> and <797> regarding nonsterile and sterile compounding practice requirements go into

effect November 1, 2023 and I can advise the council on how these changes may impact naturopathic physicians and continue to provide updates.

Thank you for your consideration.

Sincerely,

Natalie Gustafson, PharmD

Natalie Gustafson, PharmD

Education

PharmD — Doctor of Pharmacy (S*umma Cum Laude*)
Northeastern University, Boston, MA

Current Positions

Director of Pharmacy, Lloyd Central Compounding Pharmacy, Portland, OR
Jan 2012 – Present

Director of Pharmacy, Pacific Compounds Pharmacy, Hillsboro, OR
July 2009 – September 2017

CE Courses and Presentations Given

2023 Autoimmune Thyroid Conditions: Overview & Therapy
Invited Speaker for NUNM Autoimmune Conference

2023 Hormones: Expanding your Delivery Options
Invited Speaker for IWHIM Women's Health Symposium Portland, OR

2023 Overview of Compounding in Autoimmune Conditions
Guest Lecturer for NUNM Rheumatology Group Students Portland, OR

2022 Hormones: Expanding your Delivery Options
Invited Speaker for IWHIM Women's Health Symposium Portland, OR

2021 Compounding for Autoimmune Disorders: LDN, Topicals and More
Invited Speaker for NUNM Autoimmune Conference

2021 Impact of Thyroid and Hormone Replacement Therapy on the Cardiovascular System
Invited Speaker for Nurse Practitioners of OR 2021 Pharmacology Conference Portland, OR

2021 The Impact of Delivery Methods in HRT
Invited Speaker for IWHIM Women's Health Symposium Portland, OR

2021 Oncology Compounding
Guest Lecturer for NUNM Students Portland, OR

2020 The Impact of Delivery Methods in HRT
Invited Speaker for IWHIM Women's Health Symposium Portland, OR

2020 Introduction to Compounding

Guest Lecturer for NUNM Students Portland, OR

2020 Specialty Compounded Medications in Pediatrics
Invited Speaker for IWHIM Pediatric/Adolescent Medicine Portland, OR

2019 How to Integrate Compounding into Your Practice
Invited Speaker for Integrative Dermatology Symposium San Diego, CA

2019 The Impact of Delivery Methods in HRT
Invited Speaker for IWHIM Women's Health Symposium Portland, OR

2019 Introduction to Compounding
Invited Speaker for NUNM Residents Portland, OR

2018 Topical Pain Medications
Invited Speaker for NUNM Pain Conference Portland, OR

2018 The Impact of Delivery Methods in HRT
Invited Speaker for IWHIM Women's Health Symposium Portland, OR

2018 Low Dose Naltrexone & Autoimmune Conditions
Invited Speaker for NUNM Autoimmune Conference Portland, OR

2018 Specialty Compounded Medications in Pediatrics
Invited Speaker for IWHIM Pediatric/Adolescent Medicine Portland, OR

2017 Non-Opiate Medication Options: Compounding, Topicals, and More
Invited Speaker for COHC Chronic Non-Cancer Pain 101: Provider Workshop Bend, OR

2017 Low Dose Naltrexone
Invited Speaker for IWHIM Primary Care for Women Portland, OR

2017 Use of Low Dose Naltrexone and Erythromycin in SIBO
Invited Speaker for NUNM SIBO Conference Portland, OR

2017 Introduction to Compounding
Invited Speaker for NUNM Residents Portland, OR

2017 The Impact of Delivery Methods in HRT
Invited Speaker for IWHIM Women's Health Symposium Portland, OR

2016 Low Dose Naltrexone for Pain Management
Invited Speaker for NUNM Pain Management Conference Portland, OR

2016 Topical Pain Management
Invited Speaker for OANP's Pain Management Course Portland, OR

2016 The Impact of Delivery Methods in HRT
Invited Speaker for IWHIM Women's Health Symposium Portland, OR

2016 The Missing Link Between Cholesterol and Glucose
Low Dose Naltrexone: Endorphins Impact on the Gut
Invited Speaker for Hawaii Doc Talks, Hawaii

2015 Compounded alternatives in Wound Healing and Scar Prevention
Invited Speaker for Columbia Wound Care Consortium, Portland, OR

2014 Managing Treatment of Hypogonadism
Invited Speaker for OANP 19th Annual Pharmacy and Ethics Conference

2014 Use and Considerations of Low Dose Naltrexone & Topical Pain Medications
Speaker for several naturopathic physicians, Portland, OR

2014 Use and Considerations of Low Dose Naltrexone
Invited Speaker for British Columbia Naturopathic Association, Vancouver, BC

2014 Pharmacodynamics of Hormone Replacement Therapy
Invited Speaker for WIBI Women's Health Symposium, Portland, OR

2014 The Impact of Delivery Methods in HRT
Invited Speaker for IWHIM Conference, Portland, OR

2013 Holistic Management of Depression and Anxiety
Invited Speaker for NWNPC 57th Annual Convention, Portland, OR

2012 Low Dose Naltrexone and the Importance of Endorphin Regulation
Invited Speaker for OANP 17th Annual Pharmacy and Ethics Conference

2012 Topical Pain Medications
Speaker for CE course. Location: Portland and Beaverton

2012 Management of Asthma & COPD
Speaker for CE course. Location: Beaverton

2012 CE Course: Pharmacotherapy of Diabetes Mellitus, Hyperlipidemia and Hypertension agents.
Speaker for CE course. Location: Portland

2012 Dermatology Treatment Alternatives
Speaker for CE course. Location: Portland and Beaverton

2012 Topical Pain Medications
Invited Speaker for Pain Society of Oregon

2012 Polypharmacy in the Aging Woman
Invited Speaker at Institute of Women's Health and Integrative Medicine Conference

2011 Management of Asthma & COPD
Invited Speaker for OANP 16th Annual Pharmacy and Ethics Conference
Location: Portland

2011 Dermatology Treatment Alternatives
Speaker for CE course. Location: Portland

2011 Depression, Anxiety & GI Medications
Speaker for CE course. Location: Portland

2011 Pain Management- Traditional and Compounded Options
Speaker for CE course. Location: Portland

2011 CE Course: Pharmacotherapy of Diabetes Mellitus, Hyperlipidemia and Hypertension agents.
Speaker for CE course. Location: Portland

2011 CE Course: Low Dose Naltrexone (LDN): Regulating Immune Function Using Endorphins
Speaker for CE Course. Location: Beaverton (spring) & Portland (fall)

2010 CE Course: Managing Drugs, Disease & Herbal Interactions in Diabetes Therapy
Invited Speaker for OANP 15th Annual Pharmacy and Ethics Conference
Location: Portland

Publications

Seibert, Jan and Gustafson, Natalie. Understanding and Treating the Imbalanced Neuroendoimmune System of Hashimoto's Thyroiditis. Naturopathic Doctor News & Review. August 10, 2011.

Awards

National College of Naturopathic Medicine Unsung Heroes award 2015

Leadership

Oregon Board of Pharmacy Compounding Workgroup appointed member (2023)
Formulary Council Ketamine Advisory Committee member, Oregon Board of Naturopathic Medicine (2022)
Formulary Council appointed chair, Oregon Board of Naturopathic Medicine (2021-present)
Formulary Council appointed member, Oregon Board of Naturopathic Medicine (2011-2020)
Oregon Board of Pharmacy Compounding Rules Advisory Committee (RAC) member (2019)

Professional Development

2023 APC Educon 2023

2022 OANP 27th Annual Pharmacy and Ethics Conference

2020 PCCA International Seminar

2019 IACP 25th Annual Compounders on Capitol Hill

2018 OANP 23rd Annual Pharmacy and Ethics Conference

2017 OANP 22nd Annual Pharmacy and Ethics Conference
2017 WIBI's 5th Annual Women in Balance Symposium

2016 OANP 21st Annual Pharmacy and Ethics Conference
2016 ACHC USP <800> Workshop

2015 OANP 20th Annual Pharmacy and Ethics Conference

2014 OANP 19th Annual Pharmacy and Ethics Conference

2013 OANP 18th Annual Pharmacy and Ethics Conference

2012 OANP 17th Annual Pharmacy and Ethics Conference

2011 OANP 16th Annual Pharmacy and Ethics Conference

2010 OANP 15th Annual Pharmacy and Ethics Conference
2010 The Spectrum of BHRT and Wellness (ZRT Conference)

2008 Primary compounding training at Professional Compounding Centers of America

Professional Memberships

Alliance of Pharmacy Compounding (ACP)
National Community Pharmacists Association (NCPA)
Oregon State Pharmacy Association (OSPA)

Sammi Molvi

Date: July 7, 2023

To: Karen MacLean

Orson Board of Pharmacy

Re: Letter of Interest

I am writing to apply for the Volunteer Opportunity for Council on Naturopathic Physicians Formulary.

Throughout my work at Professional Compounding Pharmacy in Corvallis, I have been working with Medical Doctors and Naturopathic Medical doctors to provide prescription services that include formulating customized medications for their patients to meet their medications needs that are not available through current manufactured drugs.

My experience as part of PRN Health Solutions Staffing Company offered me the opportunity to travel around the state from Ashland to Portland, Eastern Oregon to Southern Oregon. It also created the opportunity to work in various pharmacy settings.

My interactions with Naturopathic physicians over the years has been very beneficial to have a good understanding of the Profession of Naturopathy as I wish to serve on the Council on Naturopathic Physicians Formulary. Early in my career, I had been one of the instructors for the Pharmacy Technician at Linn Benton Community College. The teaching experience helped me tremendously to develop good listening and communicating skills. As I have worked in many different settings over the years, it will be very helpful to work with other members of the Formulary Council.

Sincerely,
Sammi Molvi

References: available upon request

Sammi Molvi

I am driven by passion for bringing positive changes to healthcare services through improved community education, and working with health care professionals.

EDUCATION

B.S. in Pharmacy, Oregon State University (OSU)

B.S. in Business Administration, OSU

CCN, Certified Clinical Nutrition

Special Training in Women's Health

Certified Diabetes Educator

Compounder training, PCCA

EXPERIENCE

Health Solutions Pharmacy Inc. — Director

2000 - 2021

Founded the company with the principle to help our community to provide custom made medications that were not available through current manufactured products. We acquired Professional compounding Pharmacy in 2000 to provide service to:

Hospice Palliative care team, Work alongside Doctors and Nurses to come up with unique ways to deliver Pain Meds, Nausea Meds, and other related Palliative Care treatments.

Worked with Physicians (**M.D., D.O, and Naturopathic Doctors**) to provide custom made medications for Women's health like HRT. Progesterone suppositories for women needed during pregnancy, customized non-commercial thyroid and related chronic conditions.

Worked with local pediatricians to provide custom medications for certain chronic conditions that were not available commercially.

Worked with Samaritan Radiation Cancer Center to formulate topical burn treatment for Radiation.

Offered patients access to hormone testing via Diagnos Tech lab before NMD, MD, and DO started offering HRT testing regularly, 2000-2015.

PRN Health Solutions Inc.

2002-2010

Founded the Pharmacist Staffing Company to provide properly trained quality pharmacists to Retail chains, Independent pharmacies, Hospitals, and Nursing home pharmacies. All our pharmacists had to go through a background check, and initial training with each computer system prior to assignment. All pharmacists were company employees.

Negative Incidence under PRN Health Solutions Inc. 2005

Only a single incident where a patient received incorrect medication at a Rite Aid store while working at Corvallis, OR, location in 2004-05 period. This store at that time used SCRIPT PRO 200 to fill drugs. The drug in question was one of the drugs in the machine. It was not researched to see where the error occurred. Since I was the final check Pharmacist, It shows as my error. As an agency pharmacist, I did not have access and cooperation of the Retail chain company to look into it further. In summary, I took responsibility for having my final check.

Current Employment / Professional Activities

Consultant and part-time pharmacist at Pet Pharmacy, NW. Corvallis, OR

Volunteer Preceptor with OSU College of Pharmacy.
2019-current
Community outreach Program for P1 and P2 OSU students. We Perform Blood sugar screening and Blood pressure screening.

Karma Bio Health., Formulation Consultant
2022-current
Provide scientific and CDMO relations for FDA 505(b) 2 pathway.

SKILLS

Problem-Solving, Verbal and Written, Communication, Multi-Tasking, Team building.

Technical Skills

Windows-Word Excel PowerPoint, Google suite

AUGUST 2023/ Kc

July 7, 2023

Dear Rural Health Coordinating Council Members,

I am writing to express my sincere interest in serving an additional term as the pharmacist representative on the Rural Health Coordinating Council. Care for rural and underserved patients continues to be my primary area of focus in my practice and what I spend a large amount of my time committed to at Pacific University. These past two years on the council seem to have flown by and following each meeting I am hopeful for the future of advancing and improving health care in rural Oregon and impressed by the individuals I get to connect with. I hope to continue my involvement with the council to be a sounding board of pharmacists and the profession.

Over the years much of what I wrote about myself in my first letter of intent still holds true today. I am still with Virginia Garcia Memorial Health Center in Cornelius Oregon and an ambulatory care pharmacist focusing on team-based care and advancing the pharmacists scope of practice while improving patient outcomes. I am also involved with the Area Health Education Centers (AHEC) program at the School of Pharmacy, mentoring students and leading courses for those who have a passion for care of rural and underserved populations. Additionally, I have taken on the director of introductory pharmacy practice experiences (IPPE) role at the school and have tried to continue to expose students to rural healthcare by placing most in at least one rural health system/hospital experience during one of their 4-week summer rotations. I take great pride in these endeavors and I am hopeful that my efforts are helping to advance rural healthcare and expand the pharmacist's impact. In reflecting on the past two years though, I do feel that I have missed out on providing a valuable learning opportunity to my students particularly our AHEC scholars through this position. So often in pharmacy school legal and regulatory affairs curriculum is skimmed over and forgotten about by students as they focus on the therapeutics and application. I understand, I was a student myself, however that does not mean it cannot be corrected or improved upon. No matter if I am reappointed to the council or not, I would like to incorporate some level of attendance requirements to the RHCC and/or Oregon Board of Pharmacy meetings for our AHEC scholar students. It would be beneficial for the AHEC students to hear from the Office of Rural Health and what they doing for the state and to learn from other healthcare professions about the trials and tribulations they encounter and how being in rural Oregon impacts them. My hope is that this truly emphasizes the importance of advocacy for their profession, the importance of team-based care and helping one another.

Regardless if I am reappointed I would like to thank the rural health coordinating council for giving me the opportunity to serve and I would welcome the opportunity to continue. Thank you for your consideration and please don't hesitate to reach out with any questions the council may have.

Sincerely,

John Begert PharmD BCACP
Associate Professor
Director of Introductory Pharmacy Practice Experiences
Pacific University School of Pharmacy

SCHOOL OF PHARMACY
222 SE 8th Avenue, Suite 451
Hillsboro, OR 97123

John Begert PharmD BCACP

Education

Oregon State University, *Corvallis, OR* and
Oregon Health & Science University, *Portland OR*
Doctor of Pharmacy — June 2013

Oregon State University, *Corvallis OR*
Bachelor of General Science - *Cum Laude*, Pre-Pharmacy option, Chemistry Minor — June 2009

Employment

Associate Professor of Clinical Practice
Pacific University Oregon School of Pharmacy
Hillsboro OR. 97123 — July 2015 - Present

Adjunct Faculty
University of Portland School of Nursing
Portland OR. 971 — March 2017 – 2021

Pharmacy Intern
Bi-Mart Corporation
Community Pharmacy
Forest Grove, Junction City, Woodburn Oregon — June 2010 – July 2013

Post-Graduate Training

Pacific University Oregon School of Pharmacy/VGMHC
Post-Graduate Year 2 Residency
Director: Melanie P. Foeppel, RPh, PharmD BCACP — July 2014 – July 2015

Pacific University Oregon School of Pharmacy/VGMHC
Academic Fellowship
ASHP PGY1 equivalent experience
Director: Melanie P. Foeppel, RPh, PharmD BCACP — July 2013 – June 2014

Licensure & Certification

Board Certified Ambulatory Care Pharmacist (BCACP)
Credential #6151619 — Oct. 2018 - Present

State of Oregon Pharmacist License
License Number: RPH-0013721 — Aug. 2013 - Present

State of Oregon Preceptor License
License Number: RPH-0013721-P — Aug. 2014 - Present

Pharmacist-in-Charge Certified — May 2013 - Present

APhA Pharmacy-Based Immunization Certification — June 2010 - Present

American Red Cross CPR and AED-Adult Certified — Sept. 2009 - Present

Teaching

Pacific University School of Pharmacy

Required Courses – School of Pharmacy									
Course #	**Course Title**	**Academic Year**							
		AY1516	*AY1617*	*AY1718*	*AY1819*	*AY1920*	*AY2021*	*AY2122*	*AY2223*
PHRM 532	Personal & Prof Development								X
PHRM 538	Integ Sci & Therapeutics I								X
PHRM 541	Pharm Skills & Application II								X*
PHRM 542	Personal & Prof Development								X
PHRM 620	Community Pharmacy IPPE								X*
PHRM 622	Health System IPPE								X*
PHRM 633	Pharm Skills & Application III								X*
PHRM 649	Pharm Skills & Application IV								X
PHRM 637	Community Pharm Outreach IPPE								X*
PHRM 641	CS: Intro to Patient-Centered Care	X	X	X					
PHRM 642	CS: Cardiovascular I				X*	X*	X*	X*	
PHRM 643	CS: Neuropsych I	X	X	X					
PHRM 644	CS: Neuropsych II	X*	X	X					
PHRM 646	CS: Endocrine	X	X*	X*	X*	X*	X*	X*	
PHRM 680	CS: Immunology	X*							
PHRM 590	Pharmacy Practice 1 (longitudinal)	X‡			X‡				
PHRM 592	Pharmacy Practice 2 (longitudinal)		X‡	X‡	X	X	X		
PHRM 690	Pharmacy Practice 3 (longitudinal)	X	X*	X*	X*	X*	X*	X*	
PHRM 692	Pharmacy Practice 4 (longitudinal)	X	X	X	X	X	X		
PHRM 694	Social and Administrative Sciences (longitudinal)		X						
Elective Courses – School of Pharmacy									
PHRM 709	CS: Comprehensive Curricular Review	X				X			
PHRM 766	CS: Literature Evaluation: Beyond the Basics (elective)	X							

	Care for Underserved Populations Learning Track (AHEC Scholars Program)		X	X	X	X	X	X	X
PHRM 771	CS: Underserved Healthcare Seminar			X*		X*	X*	X*	X*
PHRM 778	Evidence Based Medicine				X	X	X		
Interprofessional Courses – College of Health Professions									
GPSY 851	Psychopharmacology	X							
DHS	Cardiovascular Medications	X	X	X	X	X	X	X	
PA 520	Behavioral Health: Mental Health Medications			X	X	X	X	X	
HPE 390	Managing the Graduate School Application Process				X				
CHP 560	Interprofessional International Experience: Nicaragua I	X							
CHP 561	Interprofessional International Experience: Nicaragua II	X							
ICC	Illness Anxiety Disorder	X							
						* Course Coordinator ‡ Preceptor (alternate)			

EXPERIENTIAL TEACHING

Role	**# of Students**							
	AY1516	*AY1617*	*AY1718*	*AY1819*	*AY1920*	*AY2021*	*AY2122*	*AY 2223*
IPPE Preceptor					N/A			
APPE Preceptor		2	3	4	4	2	1	3
Student Scholarship		1	2	2	2	1	2	1

ADVISING

Graduating Class	**# of Students**							
	AY1516	*AY1617*	*AY1718*	*AY1819*	*AY1920*	*AY2021*	*AY2122*	*AY2223*
Class of 2016	4							
Class of 2017	4	4						
Class of 2018	5	5	7					
Class of 2019		5	3	3				
Class of 2020			4	6	6			
Class of 2021				5	4	4		
Class of 2022					4	4	4	

Class of 2023						4	4	3
Class of 2024							4	6
Class of 2025								2

University of Portland School of Nursing

CLASSROOM TEACHING						
Required Courses – Doctor of Nursing Practice						
Course #	**Course Title**	**Academic Year**				
		AY1516	*AY1617*	*AY1718*	*AY1819*	*AY1920*
NRS 608A	Advanced Pharmacotherapeutics		X*	X*	X*	X*
						* Co-Coordinator

Post-Graduate Training Programs

Learning Experience	**Role**	**# of Residents/Fellows**						
		AY1516	*AY1617*	*AY1718*	*AY1819*	*AY1920*	*AY2021*	*AY 2223*
Post-Graduate Year One (PGY1) Residency Program – Virginia Garcia memorial Health Center								
Teaching Rotation	Primary Preceptor	1				1		
Research	Primary Preceptor		1	1				
Clinical	Co-Preceptor						1	1
Post-Graduate Year Two (PGY2) Residency Program – Pacific University School of Pharmacy								
Teaching Rotation	Primary Preceptor	1	1	1	1	1	1	
Research	Primary Preceptor		1		1			
Clinical	Co-Preceptor	1	1	1	1	1	1	

Scholarship

Peer-Reviewed Publications

Bzowyckyl AS, **Begert J.** Diabetes, Therapeutic Inertia, and Patient' Medication Experience. Diabetes Spectrum. 2020 Feb; 33(1): 31-37

Begert J, Bridget B. Literature Review: Off-label Use of Mirtazapine for Anxiety. Mental Health Clinician. 2015; 5(6):265-70.

Book Chapters

Saito E, **Begert J,** Nuziale B, Chau V, Steinkopf M. Chapter 25: Sweetening the deal: Improving health outcomes for patients with diabetes mellitus. In: Covvey JR, Arya V, DiPietro Mager N, Gilman N, Herring M, Ochs L, Waddington L, eds. Public health in pharmacy practice: a casebook. 2nd ed. Geneseo, NY: Milne Open Textbooks; 2021.

Saito E, **Begert J.** Chapter: peripheral artery disease, In Ambulatory Care Self-Assessment Program 2020 Book 1: Cardiology Care. Dixon, Harris (Editors), Board of Pharmacy Specialties, Washington DC, 2020: 105-123.

Peer-Reviewed Abstracts, Posters and Presentations

Begert J. Investigating the impact of racial health disparities on patients with peripheral artery disease. Presented for the Academy of managed care pharmacy CPE credit webinar series. Sept. 2021.

Ofuasia-Koroleva A, Albiar O, Bradley B, **Begert J**. Evaluation of the prescribing practices of z-drugs used at a federally qualified health center. Presented at the College of Psychiatric and Neurologic Pharmacists annual meeting 2021.

Mortensen G, Bradley B, **Begert J**. An evaluation of antipsychotic indication use in adult patients at a federally qualified health center. Presented at the American Society of Health System Pharmacists Mid-Year Annual Meeting 2020

Roberts S, Saito E, **Begert J,** Carter N, Backus D, Doyle I. Preparing the next generation of providers: expanding pharmacists' impact on caring for underserved population. Presented during the AACP Annual Meeting, Virtual Pharmacy Education 2020.

Maratita W, **Begert J.** Chamorros with diabetes: developing a culturally-appropriate resource for healthcare providers. Presented during the Legacy Health Literacy Conference 2019. Portland OR.

Laursen T, **Begert J.** Retrospective review of combination therapy comprising GLP-1 receptor agonists and bolus insulin for type-2 diabetes mellitus. Presented during the Northwestern States Residency Conference 2019. Portland OR.

Nguyen J, Bradley B, **Begert J.** Evaluation of the prescribing practices of prazosin used at a federally qualified health center. Presented at the American Society of Health System Pharmacists Mid-Year Annual Meeting 2019. Las Vegas NV.

Begert J, Backus D, Nuziale B, Fry M, Cox P, Stillwell S. Utilizing clinical pharmacists to teach pharmacotherapeutics for a family nurse practitioner program. Presented during the 7th International Nurse Education Conference 2018. Banff, Canada.

Stanislaw J, **Begert J**. Evaluation of monitoring of appropriate potassium and creatinine in patients on spironolactone in a federally qualified health center. Presented at the American Society of Health System Pharmacists Mid-Year Annual Meeting 2018. Anaheim CA.

Kawaguchi-Suzuki M, Backus D, Low P, Cleven AJ, Nuziale B, Stamper B, Fry M, Marcus K, **Begert J**, Harrelson J, Rao D, Fuentes D. Fall semester pharmacotherapy capstone presentation: building a patient case with a comorbidity. Presented during the American Association of Colleges of Pharmacy Annual Meeting 2017. Nashville, TN.

Fedler S, **Begert J**, Sherwood E, Suchsland E. Evaluation of clonidine prescribing practices and appropriate treatment of hypertension and anxiety in adults 18 years and older and a FQHC. Presented at the American Society of Health System Pharmacists Mid-Year Annual Meeting 2017. Orlando FL.

McIlwain M, Davis-Risen S, Boggis T, Zuniga R, Reisch R, Van Atta J, Hacker N, Saito E, **Begert J**, Parker K, Corvus T. Promoting Interprofessional Team-based Care Competencies through Simulation-based Learning: A Global Aging Initiative. Presented at the Annual Meeting of the Association for Gerontology in Higher Education (AGHE) 2017. Miami, FL

Davis-Risen S, Boggis T, Hacker N, Van Atta J, Reisch R, Marshall T, Saito E, **Begert J**, Parker K. Simulation-based learning to promote interprofessional collaborative practice competencies. Presented at the Physicians Assistant Western Consortium Conference. 2016. Hillsboro OR.

Mcelravey J, Wegrzyn N, **Begert J**, Deines S. Outcomes Analysis of a Clinical Pharmacy Spirometry Service within a Federally Qualified Health Center. Presented at the Oregon Society of Health System Pharmacists Annual Meeting 2016. Sunriver OR.

Steele K., **Begert J**., McElravey J, Turner RB, Marcus K. Impact of clinical pharmacy spirometry service for COPD management on patient outcomes compared to usual care. Presented at the American Society of Health System Pharmacists Mid-Year Meeting 2016. Las Vegas NV.

Plechot K, **Begert J,** Deines S. Evaluation of appropriate monitoring of diabetic patients on ACE-I or ARB therapy within a federally qualified health center. Presented at the American Society of Health System Pharmacists Mid-Year Annual Meeting 2016. Las Vegas NV.

Begert J, Saito E, Deines S, Foeppel M. Team Based Approach to Medicare Annual Wellness Visits Within a Federally Qualified Health Center. Presented at the American Society of Health System Pharmacists Mid-Year Annual Meeting 2015, New Orleans LA.

Begert J, Saito E, Deines S, Foeppel M. Medicare annual wellness visits as a method to promote referrals for disease state management by clinical pharmacists**.** Presented at the mid-year annual meeting for the American Society of Health System Pharmacists 2014. Anaheim CA.

Begert J, Deines S, Foeppel M. Needs assessment in the development of a community-retail pharmacy experiential manual**.** Presented at the Western State Residency Meeting 2014. San Diego.

Invited Presentations

Begert J. Literature you might have missed. The ANTLER trial. Presented at the Oregon Society of Health System Pharmacists Annual Seminar. April. 2023. *

Begert J. Updates in heart failure management. Presented at the Oregon State Pharmacy Association Annual Meeting. Oct. 2021. Portland OR.

Begert J. Technology in online learning. Oregon Pharmacy Teaching Certificate Resident Program. 2021 Portland OR.

Begert J. How to write an abstract and present a poster. Oregon Pharmacy Teaching Certificate Resident Program 2021. Portland OR.

Begert J. Age matters: type 2 diabetes management in older adults vs. pediatric populations. Presented for Oregon extension for community healthcare outcomes (ECHO) network. Team-based approached to diabetes care management. Mar. 2020. Portland OR

Begert J. Balancing evidence and dose: use of newer diabetes agents. Presented for Oregon extension for community healthcare outcomes (ECHO) network. Team-based approached to diabetes care management. Nov. 2020. Portland OR

Begert J. How to write an abstract and present a poster. Oregon Pharmacy Teaching Certificate Resident Program 2020. Portland OR.

Begert J, Potter A. Utilizing virtual campus tours, digital brochures and ad redirection for pharmacy school recruitment. Accepted for presentation at Leadership in Enrollment Management Workshop at American Association of College of Pharmacy Annual Meeting 2020 (*Postponed due to COVID-19).* Long Beach CA.

Gibbard R, **Begert J**. Clinical Pearl: Management of euglycemic diabetic ketoacidosis secondary to SGLT-2 Inhibitor use. Accepted for presentation at Oregon Society of Health System Pharmacists Annual Meeting 2020 (*Postposed due to COVID-19).* Sunriver OR.

Begert J, Tallman G. How to write an abstract and present a poster. Oregon Pharmacy Teaching Certificate Resident Program 2019. Portland OR.

Backus D, **Begert J**. Clinical considerations for cannabis use. Presented at the Forum for Aging in Rural Oregon 2019. Lincoln City OR.

Begert J. Utilizing a simulated electronic health record in a pharmacy practice skills curriculum. Presented to the Oregon Technology in Education Network Annual Conference 2019. Forest Grove OR.

Begert J, Hughes J, Fuentes D, Foley C, Backus D, Hogan A. Co-curricular interprofessional activities foster team-based readiness, professionalism, and development of self-awareness. Presented during the American Association of Colleges of Pharmacy Annual Meeting 2018. Special interest group. Boston, MA

Complex diabetic patient case with physician assistant studies and pharmacy – day 2. Interprofessional experience pop-up case day. Presented at Pacific University 2018. Hillsboro OR.

Hughes J, Turner C, Fuentes D, Davis-Risen S, Hogan A, **Begert J**, Nguyen J, Nuziale B, Boyle P, Pestka B, Low P, Backus D. Developing interprofessional collaboration across physician assistant, audiology and pharmacy students through case-based activities. Presented during the Association of Schools of Allied Health Professions Annual Conference 2017. San Antonio, TX.

Fuentes D, **Begert J,** Gibbard R, Kraus C, Foley C. The safe classroom: Pairing team-based learning with accessory notes sheets to enhance deeper learning. Presented during the American Association of Colleges of Pharmacy. Special interest group. Annual Meeting 2017. Nashville, TN.

Hughes J, Fuentes D, Turner C, Crawford E, Nuziale B, **Begert J**. ICC conferences develop collaboration between pharmacy & physician assistant students. Is there collaboration at your clinic? Presented during the CHP 10th anniversary event 2017. Hillsboro OR.

Fuentes D, **Begert J,** Gibbard R, Kraus C, Foley C. Team-based learning and accessory note content, use, and assessment in a graduate psychopharmacology course. Presented to the Oregon Technology in Education Network Annual Conference 2017. Forest Grove OR.

Begert J. Diabetes medications and pearls. Registered nurse training series for Virginia Garcia Memorial Health Center. 2017.

Complex diabetic patient case with dental hygiene and pharmacy – day 1. Interprofessional experience pop-up case day. Presented at Pacific University 2017. Hillsboro OR.

Complex diabetic patient case with physician assistant studies and pharmacy. Interprofessional experience pop-up case day. Presented at Pacific University 2017. Hillsboro OR.

Specific topics in sexual and reproductive health and infectious disease. Interprofessional experience pop-up case day. Presented at Pacific University 2016. Hillsboro OR.

Begert J. Evidence for the use of niacin for cardiovascular risk reduction. Drug Information Series **-** presented to Virginia Garcia Memorial Health Center staff and providers 2015. Hillsboro OR.

Begert J. Bisphosphonates: When to start them and how long to use them. Drug Information Series **-** presented to Virginia Garcia Memorial Health Center staff and providers 2015. Hillsboro OR.

Begert J. Spironolactone and heart failure. Drug Information Series **-** presented to Virginia Garcia Memorial Health Center staff and providers 2015. Hillsboro OR.

Begert J. Spironolactone and heart failure. Drug Information Series **-** presented to Virginia Garcia Memorial Health Center staff and providers 2015. Hillsboro OR.

Begert J. Cardiovascular risk with glyburide, glipizide and glimepiride**.** Drug Information Series **-** presented to Virginia Garcia Memorial Health Center staff and providers 2015. Hillsboro OR.

Begert J. Understanding Bipolar Disorder. Presented to the Professional Society of Pharmacists meeting 2014. Hillsboro OR.

Non-Peer Reviewed Abstracts, Posters and Publications

Tannouri S, Tran D, **Begert J**. American Diabetes Association Standards of Care 2023 Updates. Virgnia Garcia Memorial Health Center Monthly Newsletter. May 2023

Tannouri S, Carter N, **Begert J**., Relevant Precision Medicine Applications to Statins: Implications for Pharmacy Practice. Presented at the Oregon Society of Health System Pharmacists poster session. April 2023.

Waters T, **Begert J.** Rasey K. Spatial Analysis of Diabetes Outcomes, Income, and Residence in Low Food Access Areas. Presented during the School of Pharmacy Virtual Track Capstone presentations 2022.

Nguyen U, **Begert J.** Hormonal Contraception Prescribing and Dispensing: Comparing Access and Barriers to Care in Rural and Non-Rural Areas. Presented during the School of Pharmacy Virtual Track Capstone presentations 2022.

Kawaguchi-Suzuki M, Merlo JR, White D, Gibbard R, Ly L, Bzowyckyj A, Bojorquez D, **Begert J**, Saito E,Marcus K. Health-System Introductory Pharmacy Practice Experience as an online course in the United States. Pharmacy Education. 2020; 20(2) 11 – 12. https://doi.org/10.46542/pe.2020.202.1112

Rasey K, **Begert J**. Spatial analysis of diabetes outcomes and residence in low food access areas. Presented during the School of Pharmacy Virtual Track Capstone presentations 2020.

Pasqualone B, Thurman K, **Begert J.** Naloxone prescribing and dispensing: comparing access and barriers to care in rural and non-rural areas alike: data and analysis. Presented during the School of Pharmacy Track Capstone Poster Presentations 2020. Hillsboro OR.

Thurman K, **Begert J.** Naloxone prescribing and dispensing: comparing access and barriers to care in rural and non-rural areas alike. Presented during the School of Pharmacy Track Capstone Poster Presentations 2019. Hillsboro OR.

Begert J, Saito E, Deines S, Foeppel M. Medicare annual wellness visits as a method to promote referrals for disease state management by clinical pharmacists. Poster presented at the Western State Residency Meeting 2015, San Diego CA.

Begert J. Osteoporosis and bisphosphonates. Virginia Garcia Memorial Health Center monthly newsletter. 2015.

Grants

Bradley B, Cawley P, Begert J, Merlo J, Fortner J, Nuziale B, Bzowyckyj A. Development of pharmacy student encounter videos as examples to be utilized in redesigned pharmacy skills and application series. TARGET Grant. Submitted March 2021 for $3,352. Awarded.

Elbarby F, **Begert J,** Karimi R, Cleven A, Hoang H. National Association of Chain Drug Stores (NACDS) Diversity Grant: Development of An Integrative Elective Course and Health Fair to Reduce Diabetes Disparities Among the Underserved Population. Submitted March 2020 for $20,000. Not accepted.

Roberts S, **Begert J,** Fortner J, Low P. National Association of Chain Drug Stores (NACDS) Diversity Grant: Pharmaceutical research as pipeline (PReP) to pharmacy school for students with diverse backgrounds. Submitted March 2018 for $18,800. Not accepted.

Hughes J, Roberts S, Fuentes D, Malhotra A, **Begert J.** National Association of Chain Drug Stores (NACDS) Diversity Grant: Enhancing diversity in pharmacy education: recruitment and engagement of diverse populations into the profession of pharmacy through scholarly research. Submitted March 2017 for $15,000. Not accepted.

Academic Service and Involvement

Pacific University School of Pharmacy

Director of Introductory Pharmacy Practice Experiences

2022 – Present Member

Admissions Committee

2021 – 2022 Past Chair

2019 – 2021 Chair

2017 – 2019 Vice Chair
2015 – 2017 Member
2013 - 2014 Member

Alumni and Recruitment Committee
2019 – 2021 Ad-hoc Member
2018 – 2019 Member
2017 – 2018 Past Chair
2016 – 2017 Chair, Alumni and Recruitment Committee
2015 – 2016 Vice Chair, Alumni and Recruitment Committee

Alumni Advisory Board
2016 – 2021 Member

PGY2 Ambulatory Care Residency Program
2015 – Present Preceptor, Didactic and Longitudinal Teaching Experiences
2015 – Present Co-Preceptor, Longitudinal Primary Care Clinic Learning Experience
2015 – 2019 Preceptor, Longitudinal Research Project Experience
2015 – Present Member, Residency Advisory Committee

PGY1 Pharmacy Practice Residency Program, Virginia Garcia Memorial Health Center
2015 – Present Preceptor, Didactic and Longitudinal Teaching Experiences
2016 – 2018 Preceptor, Longitudinal Research Project Experience

Curriculum Committee

2022 – Present Member
2014 – 2015 Member

Research Incentive Grant Review Committee
2019 Peer Reviewer

Academic Fellowship Advisory Counsel
2013 – 2014 Member

Pacific University Service Day
2019 – 2020 Forest Grove Senior Center
2018 – 2019 Jackson Bottom Wetland Trail Repair
2017 – 2018 Hillsboro Parks and Rec. Trail Repair
2015 – 2017 Shute Public Library

Community Service and Outreach
2017 – 2019 Presenter, Hillsboro Chamber and Pacific University School to Career Health Professions Day
2019 Advisory Committee Member, Beaverton Health and Science High School
2019 Panelist, Forest Grove High School Career Expo
2019 Presenter, Pacific University Pre-Pharmacy Club Meet and Greet
2018 Presenter, Pacific University Health Professions Lunch and Learn
2017 – 2019 Preceptor, Diving Deep Into Diabetes – Diabetes Health Fair

2014 Preceptor, Operation Diabetes – American Diabetes Association Expo

College of Health Professions

CHP Interprofessional Education and Practice Committee
2022 – Present

Interprofessional Observed Structures Clinical Examination Program
2019 – 2022 Evaluator

Interprofessional Education and Practice Committee
2018 – 2019 Member

Interprofessional Nicaragua Experience
2014 – 2015 Faculty Advisor

Interprofessional Experience Pop-Up Cases
2015 – 2018 Faculty Advisor

Interprofessional Diabetes Clinic (IDC)
2013 – 2015 Faculty Advisor

Professional Service and Involvement

Oregon Office of Rural Health: Rural Health Coordinating Council – Oregon Board of Pharmacy Position
2021 – Present Member

Oregon Extension for Community Health Outcomes (ECHO) Network
2020 – 2021 Faculty Planner

Oregon Pharmacy Teaching Certificate (OPTC) Resident Program
2018 – Present Co-Coordinator

Area Health Education Centers Scholars Program (AHEC)
2019 – Present Alternate Member, Steering committee

American Association of Colleges of Pharmacy (AACP)
2018 – Present Pharmacy Brand Ambassador

American College of Clinical Pharmacy (ACCP)
2019 Proctor, Clinical Research Challenge

American Society of Health System Pharmacists (ASHP)
2018 – Present Evaluator, Local Clinical Skills Competition

Academy of Managed Care Pharmacy (AMCP)
2015 – Present Faculty Liaison
2017 – Present Judge, Regional Pharmacy & Therapeutics Competition

Virginia Garcia Memorial Health Center
2016 – Present Preceptor, Virginia Garcia Migrant Camp Outreach Clinic
2016 – Present Preceptor, Virginia Garcia Intern Program
2017 Facilitator, Virginia Garcia Professions Careers in Health Care Workshop

2015 Reviewer, Standards of Care Hypertension
2013 – 2014 Lead Pharmacist, Choosing Health: Clinical Pharmacy and Behavioral Health Integrated Smoking Cessation Program

Health and Interprofessional Practice Journal
2016 – Present Peer Reviewer

Western Association of Advisors for the Health Professions
2016 Invited panelist

Professional Memberships

Academy of Managed Care Pharmacy (AMCP)
American Society of Health System Pharmacists (ASHP)
American College of Clinical Pharmacy (ACCP)
American Association of Colleges of Pharmacy (AACP)
Oregon Society of Health System Pharmacists (OSHP)

Honors and Awards

P2 Teacher of the year. Pacific University School of Pharmacy. Academic year 2018-2019
Teacher of the year 2nd runner up. Pacific University School of Pharmacy. Academic year 2017-2018
Teacher of the year 1st runner up. Pacific University School of Pharmacy: Academic year 2016-2017
Nominee for the 2017-2018 Albert E. Rosica Jr. Memorial Award. Not awarded
2016 Oregon Society of Health System Pharmacists Annual Seminar Professional Poster Session: Best Poster Runner Up

References

Available upon request

From: Bruce Carlson
To: MACLEAN Karen S * BOP
Subject: Fwd: Pharmacist Volunteer Opportunity - apply now
Date: Tuesday, July 4, 2023 5:53:01 PM

Dear Ms MacLean:

I am writing to express my interest again in representing rural pharmacy on the Rural Health Coordinating Council. I believe that I am uniquely qualified because not only have I practiced pharmacy in rural Oregon in the communities of Coos Bay, Maupin and Madras, I have also practiced medicine in rural communities that are pharmacy deserts. I have retired as a physician but still maintain my pharmacy license. I also have experience with the Rural Health Coordinating Council by having served as the Oregon Medical Association representative to the body for over twenty five years. I am aware of many of the challenges affecting pharmacists and especially rural pharmacists. If appointed, I plan on being very proactive in supporting rural pharmacy at the Rural Health Coordinating Council and soliciting input from rural pharmacists.

Sincerely,

Bruce Carlson, RPh, MD

Enclosure:Resume

Bruce Carlson, BPharm,RPh, MD Umatilla, Oregon

CURRICULUM VITAE

BRUCE D. CARLSON, RPh, MD, DABFM

Undergraduate Education

Oregon State University, Corvallis, Oregon
September 1957 - June 1962
Degree: B.S. in Pharmacy - June 1962

Medical Education

Marquette School of Medicine, Milwaukee, Wisconsin
September 1965 - June 1969
Degree: M.D. - June 1969
Honors: Alpha Omega Alpha
Graduated #8 in class of 96

Internship

University of Oregon Medical School Hospitals and Clinics
June 1969 - June 1970
Type: Rotating

Residency

University of Oregon Medical School Hospitals and Clinics
July 1970 - July 1971
Type: Internal Medicine

Professional Experience

July 1971 - March 1979	Family Practice, John Day, OR
September 1971 - June 1972	Medical Investigator, Grant County, OR
September 1971 - April 1979 January 1987 - December 1989	County Health Officer, Grant County, OR
December 1974 - December 1987	Aviation Medical Examiner & Accident Investigator
1975 - March 1979	Medical Advisor, Respiratory Therapy Service, Blue Mt. Hospital, John Day, OR
August 1976 - December 1979	Medical Director, Family Planning Clinic, Grant County, OR
August 1977 - June 1980	Emergency Physician, Good Shepherd Hospital, Hermiston, OR

Professional Experience (cont)

August 1978 - November 1980	Part-time general practice, Condon, OR
January 1979 - June 1980	Director, Emergency Department Good Shepherd Hospital, Hermiston, OR
April 1979 – August 2000	Health Officer, Wasco-Sherman County, The Dalles, OR
July 1979 - June 1980	Medical Advisor, Hermiston Fire Dept/Ambulance, Hermiston, OR
August 1979 - December 1989	Emergency Physician, Mid-Columbia Medical Center, The Dalles, OR
May 1980 - May 1988	Director, Emergency Services, Mid-Columbia Medical Center, The Dalles, OR
October 1980 - May 1988	Medical Advisor, The Dalles Fire Department, The Dalles, OR
November 1980 – December 2012	Supervising Physician, Gilliam County Medical Center, Condon, OR
November 1980 – December 2018	Medical Investigator, Gilliam County, OR
December 1980 - December 1984	Physician Advisor, Arlington Ambulance Service, Arlington, OR
April 1981 - April 1983	Chairman, Risk Management Committee, Mid-Columbia Medical Center, The Dalles, OR
May 1981 - December 1984	Physician Advisor, EMT IIs, Southern Wasco County Ambulance Service, OR
August 1981 - December 1984	Physician Advisor, Rufus Volunteer Ambulance Service, Rufus, OR
August 1981 – December 2020	Oregon Medical Association Representative to Oregon Rural Health Coordinating Council
October 1982 - December 1982	Member, Emergency Medical Services Task Force, OR State Health Division
August 1984 - December 1986	Member, Mid-Columbia Health Planning Council
October 1984 - October 1986	Member, Board of Directors, OR Primary Care Association
January 1985 - May 1988	Supervising Physician, Rescue Unit, Wasco Rural Fire Protection District

Professional Experience (cont)

January 1985 – July 2014	Supervising Physician, South Gilliam County Ambulance, Condon, OR
January 1985 - October 1987	Chairman, State Rural Health Coordinating Council
January 1986 - June 1988	Rural Clinic Practitioner, Part-time, Maupin, OR
February 1988 - November 1991	Supervising Physician, Asher Clinic, Fossil, OR
May 1988 - November 1988	Staff Physician, St. Anthony Health Care Center, Hermiston, OR
December 1988 - May 1991	Medical Director, St. Anthony Umatilla Clinic, Umatilla, OR
June 1991 - January 1992	Medical Director, St. Anthony Health Care Center, Hermiston, OR
February 1992 –February 2021	Physician Owner, Urgent Health Care Center (formerly St. Anthony Health Care Center), Hermiston, OR
March 1992 –February 2021	Assistant Medical Investigator, Umatilla County, OR
September 1994- 2014	Member, Physician Assistant Committee, Oregon Board of Medical Examiners
August 1998 – July 2000	Supervising Physician, Arlington Medical Clinic, Arlington, OR
August 1998 – July 2000	Supervising Physician, Moro Medical Clinic, Moro, OR
September 2000 - 2004	Part-time Correctional Physician, Two Rivers Correctional Institution, Umatilla, OR
January 2001 – August 2015	Supervising Physician, North Lake Clinic, Christmas Valley, OR
February 2013 –February 2021	Physician Owner, Pendleton Primary Care Clinic, Pendleton, Oregon (Medicaid only clinic)

Hospital Staff Privileges

Blue Mountain Hospital John Day, OR	Active Staff, July 1971 - February 1979
Mid-Columbia Medical Center The Dalles, OR	Active Staff, August 1979 - August 1988 Emergency Services Staff, August 1988 - January 1990
Good Shepherd Hospital Hermiston, OR	Courtesy Staff, May 1988 Emergency Staff, July 1977 - June 1980
St. Anthony Hospital	Courtesy Staff, May 1988 - 1992 Pendleton, OR

Bruce D. Carlson, RPh, MD,

Professional Licenses Held

Pharmacy - Oregon #4763	Issued 1963 Active
Medicine - Oregon #7786	Issued 1971 Inactive, retired
Medicine - Washington #11806	Issued 1971 inactive

Memberships

Oregon Medical Association
Oregon Rural Health Association
National Association of Rural Health Clinics
National Rural Health Association
Oregon Academy of Family Physicians
American Academy of Family Physicians

Other

Diplomate, American Board of Family Practice, certified 1979, recertified 1985, 1991, 1997, 2003,2010 & 2017.

Formerly Certified, Advanced Cardiac Life Support (OHA)

Former Instructor & Course Director Advanced Cardiac Life Support

Advanced Trauma Life Support 1983

E.M.T. Instructor since 1972

Supervising Physician for rural physician assistants since 1980

Established rural clinic in Maupin, OR 1986

Awards

Outstanding Individual Contribution to Rural Health Care, Oregon Primary Care Association 1984 and 1998.

Rural Health Practitioner of the Year 2001, National Rural Health Association

Military Experience

U.S. Army - September 25, 1963 - August 25, 1965
1st Lt, Medical Service Corp
Honorable Discharge July 1984

Assignments

Chief, Medical Training Branch, G-3 U.S. Army Training Center, Armor, Fort Knox, Kentucky

Commanding Officer, Hospital Holding Company, Ireland Army Hospital, Fort Knox, Kentucky

Assistant Pharmacy Officer, Ireland Army Hospital, Fort Knox, Kentucky

Chief, Sanitation Section, Preventive Medicine Office, Fort Knox, KY

Interest & Hobbies

Photography, Computers, Automobile restoration, Flying. Currently hold private pilots license with single, multi-engine, and instrument ratings.

1) A Letter of Interest for Rural Health Coordinating Council

Priyal Patel

7/14/2023

Rural Health Coordinating Council

Oregon Health Sciences University

Office of Rural Health - L593

3181 SW Sam Jackson Park Road

Portland, Oregon 97239-3011.

Subject: Letter of Intent for Rural Health Coordinating Council Representational Member Position

I am writing to express my sincere interest in the Rural Health Coordinating Council Member position within the esteemed Rural Health Coordinating Council. With a deep-rooted connection to rural communities and a comprehensive understanding of the unique challenges faced by these areas, I am eager to contribute my expertise and commitment to improving healthcare services for rural residents.

Living in a rural area myself, I have personally witnessed the disparities in access to quality healthcare and the specific needs of rural populations. Through my personal encounters and interactions with fellow community members, I have developed a deep understanding of the various barriers and limitations that often hinder effective healthcare delivery in rural areas. This firsthand experience has fueled my passion for advocating and implementing effective solutions to bridge these gaps and ensure equitable healthcare delivery to all individuals, regardless of their geographic location.

I strongly believe that my dedication, combined with my professional experience and personal understanding of rural health challenges, would enable me to make meaningful contributions as a Rural Health Coordinating Council member. I am committed to fostering collaboration among various stakeholders, advocating for sustainable healthcare solutions, and ensuring that the unique needs of rural communities are recognized and prioritized.

Thank you for considering my application. I welcome the opportunity to discuss my qualifications further and contribute to the vital work of the Rural Health Coordinating Council. I have attached my resume for your review. Please feel free to contact me at your convenience via email or phone.

Sincerely,

Priyal Patel

2) List of specific experience to support this work.

With a diverse and extensive professional background in the field of pharmacy, I bring a unique set of qualifications to the role of a member of the RHCC. I have actively engaged with local healthcare providers, community organizations, and government agencies to advocate for improved healthcare access and address the specific needs of rural populations. These experiences have honed my ability to collaborate effectively with diverse stakeholders and find innovative solutions to healthcare challenges.

As an ambulatory care pharmacist, I have honed my skills in providing patient-centered care in outpatient settings. This experience has equipped me with comprehensive knowledge of chronic disease management, patient education and promoting positive health outcomes.
Additionally, as a co-owner of an independent pharmacy, I have acquired a deep understanding of the business aspect of pharmacy practice. This experience has honed my entrepreneurial mindset, strategic planning abilities, and financial acumen, enabling me to contribute to the development and growth of the pharmacy while ensuring the highest quality of patient care.

Furthermore, my time as a clinical pharmacist in a critical access hospital has provided me with extensive knowledge and expertise in managing complex medication regimens and optimizing medication use in acutely ill patients. Working in a fast-paced and dynamic environment, I have become adept at making critical decisions, collaborating with healthcare teams, and implementing evidence-based practices to enhance patient safety and outcomes.

In addition to my professional background and experience, I have also had the privilege of serving as a board member of the Oregon Board of Pharmacy. This esteemed position has provided me with a unique perspective on regulatory matters, policy development, and the enforcement of pharmacy practice standards.

Priyal Patel

ACADEMIC BACKGROUND

Graduated May 2015 **Doctor of Pharmacy**
Idaho State University
Meridian, Idaho
Four –year curriculum focused on the profession of pharmacy practice.

Attended 2009-2011 **Pre-Pharmacy**
North Dakota State University
Fargo, North Dakota

Graduated May 2005 **Bachelor in Pharmaceutical Science**
Al-Ameen College of Pharmacy
Bangalore, India
Four - year curriculum with emphasis on Pharmaceutical Sciences and Medicinal Chemistry

EMPLOYMENT HISTORY

Key Responsibilities:

Clinical Pharmacist
North Bend Medical Center November 2021- Present

- Develop and implement Clinical Pharmacy Agreement and chronic disease state protocols.
- Act as a provider in specialty care and responsible for monitoring compliance, ordering lab, and initiating and adjusting medication per protocol to optimize clinical outcomes.
- Assist with quality improvement projects under direct supervision of CMO to improve patient care.
- Responsible for the promotion of rational, safe, and cost-effective drug therapy in collaboration with primary care providers and specialists
- Provide Comprehensive Medication Management (CMM) and medication reconciliation to patient and/or caregivers.
- Perform chronic disease state management for better population health outcomes.
- Develop care plans for the patient, provider and/or payor.
- Document clinical interventions appropriately in EHR. Track, analyze and report program metrics and progress annually or as requested by leadership.
- Maintains professional and personal competency and complies with educational requirements.

Clinical Pharmacist *August 2019-Present*
Bay Area Hospital

- Perform all job duties and functions within the scope of practice for a registered Pharmacist to support centralized and decentralized pharmacy workflow.
- Responsible for providing quality pharmaceutical care and clinical pharmacy services to Bay Area hospitals including but not limited to medication preparation, distribution, and monitoring.
- Responsible for IV admixture preparation, Chemotherapy preparation, total parenteral nutrition in addition to standard unit dose preparation and dispensing.
- Responsible for medication reconciliation and engage in patient care; to educate patient and families on medication safety, increase medication and disease state understanding, and encourage continuity of care following hospital discharge.
- Working with Interdisciplinary team to assess and resolve all medication needs at discharge.

- Review medication orders for therapeutic appropriateness, duplications, interactions, overall effectiveness, and safety during inpatient stay and at discharge.

Pharmacy Site Manager *June 2016-August 2019*
Genoa Healthcare Company

- Implement sustainable workflow strategies, eliminate waste, meet store metrics, and improve customer and provider satisfaction.
- Implemented and sustained a compliant 340B pharmacy program.
- Initiated med synchronization, refills, and cycle fill programs as part pharmacy's clinical services to improve medication compliance.
- Developed the first policy and procedure for Medication Drop Boxes for both Genoa and Clackamas County Health Center to support safe disposable of unused and unwanted medication in Oregon.
- Nationally recognized by OutcomesMTM a top performing pharmacy in the nation for medication therapy management services.
- Created the first immunizations program in Genoa Region 1. That is now part of the standard of care for a company.
- Share pharmaceutical expertise by providing Continuing Education (CE) presentation and in-services for providers and clinic staff on psychotropic drugs and Long-Acting Injectable Antipsychotics.

Pharmacy Manager *September 2015-June 2016*
Rite Aid Pharmacy

- Plan, organize and supervise all pharmacy functionalities and activities.
  Set priorities to make pharmacy activities more proactive and qualitative.
- Manage pharmacy staff inclusive but not restricted to training and interviewing.
  Interact and maintain positive customer relations.
- Resolve problems arising in pharmacy administration.
- Monitor and manage financial activities of the pharmacy department.
- Supervise entire inventory management and initiate innovative inventory control functions in the pharmacy department.
- Ensure compliance of all state and federal laws in delivery of pharmacy services.

Volunteer Work:

Advance Health CCO – Voting member for P & T committee

- Participate in P & T committee. January 2022- Present

Board Member of Oregon Board of Pharmacy August 2022 to Present
Participate in Workgroup as A Board member 2022-2023

- Compounding Workgroup
- Safe Pharmacy Practice Conditions

CERTIFICATION

- Board Certified Geriatric Specialties
- APEXUS 340B University
- Pharmacy Immunization Certification
- First aid and CPR for healthcare professional
- PCCA Compounding Certificate
- Crucial Conversation Certificate
- Annual HIPPA Certification
- Annual Bloodborne Pathogen Training

Licenses

- Registered Pharmacist License -Idaho
- Registered Pharmacist License -Oregon

Membership of organization

- American Society of Health-Systems Pharmacists
- Professional Pharmacy Student Alliance, Idaho State University
- Idaho State Pharmacists Association
- Oregon State Pharmacy Association

Reference: Available upon request.