Oregon Board of Pharmacy
BOARD MEETING AGENDA
February 7-9, 2024

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: 994 805 198#**
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, February 7, 2024 @ 8:30AM
Thursday, February 8, 2024 @ 8:30AM
Friday, February 9, 2024 @ 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 to provide Public Comment, email your request to pharmacy.board@bop.oregon.gov by **12:00PM on 2/9/2024**

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, FEBRUARY 7, 2024

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. Public Comment Reminder
c. Housekeeping Items
d. Introduction of Board Counsel
e. 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. Written 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*

Oregon Board of Pharmacy
BOARD MEETING AGENDA
February 7-9, 2024

THURSDAY, FEBRUARY 8, 2024

I. **OPEN SESSION, Ian Doyle RPh, Presiding**
***Please note that the board will meet in Executive Session all day and anticipates resuming Open Session between 4:30-5:00PM.**
   a. Roll Call
   b. Public Comment Reminder
   c. Housekeeping Items

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. Deliberation on Disciplinary Cases and Investigations
   b. 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.

IV. **MATTERS TO BE DISCUSSED BY THE BOARD** *If time permits

Adjourn *Action Necessary*

FRIDAY, FEBRUARY 9, 2024

I. **OPEN SESSION, Ian Doyle RPh, Presiding**
   a. Roll Call
   b. Public Comment Reminder
   c. Housekeeping Items

II. **MOTIONS RELATED TO DISCIPLINARY ACTIONS** *Action Necessary*
**At this time the board will vote on cases, including proposed disciplinary actions against licensees/registrants.*

III. **GENERAL ADMINISTRATION**
   a. Discussion Items
      i. Rules
         1. Review Rulemaking Hearing Report & Comments **#A** *Action Necessary*
      ii. Consider Adoption of Temporary Rules
         1. Div 115 – Services: Prescribing – Protocol Compendium **#B** *Action Necessary*
         2. Div 020 – Pharmacist Prescriptive Authority *Suspend **#B1** *Action Necessary*
      iii. Consider Adoption of Rules
         1. Div 001 – Procedural Rules *REPEAL **#C** *Action Necessary*
         2. Div 006 – Definitions **#C1** *Action Necessary*
         3. Div 010 – Board Administration & Policies *REPEAL **#C2** *Action Necessary*

4. Div 019 – Pharmacists *REPEAL **#C3** *Action Necessary*
5. Div 020 – Pharmacist Prescriptive Authority *REPEAL **#C4** *Action Necessary*
6. Div 025 – Pharmacy Technicians *REPEAL **#C5** *Action Necessary*
7. Div 031 – Interns *REPEAL **#C6** *Action Necessary*
8. Div 041/110 – Consulting Drugless Pharmacies **#C7** *Action Necessary*
9. Div 041 – Institutional Drug Outlet Labeling – Short-acting Opioid Antagonist **#C8** *Action Necessary*
10. Div 115 – Pharmacists: Applicability **#C9** *Action Necessary*
11. Div 115 – Pharmacists: Collaborative Drug Therapy Management (CDTM) **#C10** *Action Necessary*
12. Div 115 – Pharmacists: Prohibited Practices **#C11** *Action Necessary*
13. Div 120 – Preceptor License Renewal or Reinstatement **#C12** *Action Necessary*

iv. Rules in Development
v. Rulemaking Policy Discussion Items
   1. Div 006/041/043/045/183 - Drug Compounding **#D**
   2. Div 115 PIC Qualifications & Limitations *REPEAL **#D1**
   3. Div 115 Services: Prescribing – Protocol Compendium **#D2**
   4. Div 115 Services: Prescribing Practices - Short-acting Opioid Antagonists **#D3**
   5. Div 120 Prohibited Practices – Intern **#D4**
   6. Div 020 Pharmacist Prescriptive Authority -Protocol Compendium *REPEAL **#D5**

vi. Recognition of Outgoing Board Member & Board Member Appointment Update
vii. Safe Pharmacy Practice Conditions
viii. NABP Member Forum Report **#E**
ix. Legislative Update **#F**

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

2024 Board Meeting Dates

- April 10-12, 2024 Portland
- June 12-14, 2024 Portland
- August 7-9, 2024 Portland
- October 9-11, 2024 Portland
- November 7, 2024 TBD
- December 11-13, 2024 Portland

Proposed 2025 Board Meeting Dates *Action Necessary*

- February 5-7, 2025 Portland
- April 9-11, 2025 Portland
- June 11-13, 2025 Portland
- August 6-8, 2025 Portland
- October 8-10, 2025 Portland
- November 5-6, 2025 TBD
- December 10-12, 2025 Portland

2024 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.)

- February 22, 2024
- May 28, 2024
- November 26, 2024

Conferences/Meetings

- 120th NABP Annual Meeting – May 14-17, 2024 Fort Worth, TX
- NABP District 6, 7, 8 Meeting – October 20-24, 2024 Albuquerque, NM

IV. 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 11.28.2023 – 1.24.2024 - **# CONSENT-1**
b. Board Meeting Summary - December 2023 - **# CONSENT-2**

V. PUBLIC COMMENT

VI. MATTERS TO BE DISCUSSED BY THE BOARD

Adjourn *Action Necessary*

Oregon
Tina Kotek, Governor

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR, 97232
Phone: 971-673-0001
Fax: 971-673-0002
pharmacy.rulemaking@bop.oregon.gov
www.oregon.gov/pharmacy

Date: January 25, 2024

To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: January 25, 2024

Hearing Location: Virtual Hearing via Teams

Proposed Rules:

- Division 001 related to Procedural Rules *REPEAL
- Division 006 related to Definitions
- Division 010 related to Board Administration and Policies *REPEAL
- Division 019 related to Pharmacists *REPEAL
- Division 020 related to Pharmacists Prescriptive Authority *REPEAL
- Division 025 related to Pharmacy Technicians *REPEAL
- Division 031 related to Interns *REPEAL
- Divisions 041/110 related to Consulting Drugless Pharmacies *Rule Amendments and REPEAL
- Division 041 related to Institutional Drug Outlet Labeling Requirements for Short-acting Opioid Antagonists
- Division 115 related to Pharmacists - Applicability
- Division 115 related to Pharmacists - Collaborative Drug Therapy Management (CDTM)
- Division 115 related to Pharmacist - Prohibited Practices
- Division 120 related to Preceptor License Renewal or Reinstatement

On December 22, 2023, the January 24, 2024 Rulemaking Hearing public notice was sent out via GovDelivery to 4,353 rulemaking/adopted rules subscribers and 22,739 licensees/registrants (27,092 total).

Interested parties 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 9:32AM and adjourned at 9:46AM. #8 people joined the public call to listen to the hearing. #1 person signed up to provide oral testimony, and #1 person provided testimony during the hearing. #7 written comments were received during the open comment period from 12/22/2023 through 4:30PM on 1/24/2024. The hearing was recorded, and the notice of proposed rulemaking filings were available on our website.

Oregon
Tina Kotek, Governor

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www.oregon.gov/pharmacy

The following board and staff members participated:

Board Member Hemmings
Board Member Vipperman
Staff Member Davis
Staff Member Melvin

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Repeals Division 001; Procedural Rules
REPEAL: OAR 855-001-0000, OAR 855-001-0005, OAR 855-001-0012, OAR 855-001-0016, OAR 855-001-0017, OAR 855-001-0035, and OAR 855-001-0040.

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Amends Definitions; Repeals Additional Definitions
AMEND: OAR 855-006-0005

REPEAL: OAR 855-006-0015

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Repeals Division 010; Board Administration and Policies
REPEAL: OAR 855-010-0005, OAR 855-010-0015, OAR 855-010-0016, OAR 855-010-0018, OAR 855-010-0021, OAR 855-010-0035, OAR 855-010-0100, OAR 855-010-0110, OAR 855-010-0120, and OAR 855-010-0130.

- No oral testimony was provided.

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SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Repeals rules in Division 019; Pharmacists
REPEAL: OAR 855-019-0100, OAR 855-019-0110, OAR 855-019-0120, OAR 855-019-0122, OAR 855-019-0123, OAR 855-019-0124, OAR 855-019-0125, OAR 855-019-0130, OAR 855-019-0140, OAR 855-019-0150, OAR 855-019-0160, OAR 855-019-0170, OAR 855-019-0171, OAR 855-019-0200, OAR 855-019-0205, OAR 855-019-0210, OAR 855-019-0220, OAR 855-019-0230, OAR 855-019-0240, OAR 855-019-0250, OAR 855-019-0260, OAR 855-019-0265, OAR 855-019-0300, OAR 855-019-0310, and OAR 855-019-0460.

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Repeals rules in Division 020; Pharmacist Prescriptive Authority
REPEAL: OAR 855-020-0110, OAR 855-020-0120, and OAR 855-020-0200.

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Repeals rules in Division 025; Certified Oregon Pharmacy Technicians and Pharmacy Technicians
REPEAL: OAR 855-025-0001, OAR 855-025-0005, OAR 855-025-0010, OAR 855-025-0011, OAR 855-025-0012, OAR 855-025-0015, OAR 855-025-0020, OAR 855-025-0023, OAR 855-025-0025, OAR 855-025-0030, OAR 855-025-0035, OAR 855-025-0040, and OAR 855-025-0050.

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Repeals Division 031; Interns
REPEAL: OAR 855-031-0005, OAR 855-031-0010, OAR 855-031-0016, OAR 855-031-0020, OAR 855-031-0026, OAR 855-031-0030, OAR 855-031-0045, OAR 855-031-0050, and OAR 855-031-0055.

- No oral testimony was provided.

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SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Consulting Drugless Pharmacy rule amendments and rule repeals
AMEND: OAR 855-041-3000 and OAR 855-110-0007.

REPEAL: 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 855-041-3335, and OAR 855-041-3340.

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Institutional Drug Outlet Labeling Requirements for Short-acting Opioid Antagonists
AMEND: OAR 855-041-6270, and OAR 855-041-6410.

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Applicability of Pharmacy Practice Regulations and Licensing Requirements for Pharmacists
ADOPT: OAR 855-115-0001.

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Pharmacists; Collaborative Drug Therapy Management (CDTM)
ADOPT: OAR 855-115-0315.

- No oral testimony was provided.

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SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Amends Pharmacist Prohibited Practices
AMEND: OAR 855-115-0150

- Brian Mayo from OSPA – Stated that he received a letter from Executive Director Fox regarding the next steps of the rulemaking process. He stated that board members made comments at the December 2023 board meeting that they cannot remember details of public comments. He will submit a pdf to be included with the written comments provided to the board which will include the OSPA letter, legal correspondence and the public comments already provided to the board when this rule was open for comment during the petition comment period.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Preceptor License Renewal or Reinstatement
ADOPT: OAR 855-120-1035

- No oral testimony was provided.

All written comments received by the public comment deadline date of 1/24/2024 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 12/22/2023 Notice of Proposed Rulemaking.

January 23, 2024

Jamal T. Fox
Executive Director
Oregon State Board of Pharmacy
800 N.E. Oregon Street, Suite 150
Portland, OR 97232

Re: Proposed Rules 855-006-0005, 855-115-0001, and 855-115-0315

Dear Executive Director Fox:

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 1726 pharmacies across 34 states and the District of Columbia.

We appreciate the Board's continued collaboration with stakeholders in refining and reforming the Oregon Administrative Rules. We're encouraged by the improvements made to the Division 006 Definitions section and the new Division 115 Applicability section, particularly the improvement from the previous language impacting out-of-state pharmacist licensure during central processing. This letter requests minor amendments to clarify the counseling definition and out-of-state pharmacist licensure as well as consider new patient access opportunities within the current Collaborative Drug Therapy Management (CDTM) statute framework.

855-006-0005: Definition of Counseling

ACI supports the revised and clarified definition of counseling in this section. We believe it hearkens back to the way counseling has been defined historically in Oregon and does not create any unnecessary conflict that could limit patient access. Thank you for reacting to the feedback provided in previous public comment periods. In September 2023, APhA, ASHP, and NABP unveiled strategies to bolster the pharmacy workforce in the report, "Implementing Solutions Summit: Building a Sustainable, Healthy, Pharmacy Workforce and Workplace." [1] One action solution recommended to Boards of Pharmacy in the report is to appropriately leverage artificial intelligence to help manage order verification and prescription review to free up time for pharmacy personnel to provide other value-added services. This rulemaking provides an opportunity for the board to simplify the definition of counseling to reflect future opportunities for pharmacists to use tools such as artificial intelligence in the delivery of information to patients. Removing the reference to types of communication as suggested below will allow for innovation within the practice of pharmacy without revisiting the language of this definition at a future date. We recommend the following edits:

> 855-006-0005 Definitions
> As used in OAR Chapter 855:
> (14) "Counseling" or "Counsel" means a~~n oral, electronic or 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.

[1] American Pharmacists Association, American Society of Health-System Pharmacists, National Association of Boards of Pharmacy. "Implementing Solutions Summit: Building a Sustainable, Healthy, Pharmacy Workforce and Workplace." Report issued September 27, 2023 and available from: https://nabp.pharmacy/wp-content/uploads/2023/09/Implementing-Solutions-Report.pdf (Accessed January 11, 2024).

OAR 855-115-0001: Out-of-State Pharmacist Licensure Requirements

We support the Board's decision in the September 2023 rulemaking hearing and December 2023 Board meeting to leave subpart (3) in OAR 855-115-0001. We support the language and intent to allow pharmacists and other personnel working for an out-of-state pharmacy to support pharmacies and patients within the state of Oregon without requiring licensure in Oregon, with the exception of the pharmacist-in-charge (PIC) of that out-of-state facility.

As care models and patient needs have evolved, the practice of pharmacy provided by an out-of-state pharmacy in many pharmacy settings may extend beyond the *"professional tasks…associated with dispensing a drug to a patient in Oregon."* The proposed rule creates ambiguity for the licensure requirements of pharmacists working for an out-of-state pharmacy providing clinical services to an Oregon patient that are not "dispensing" related. We contend that the allowance for exempting pharmacist licensure when providing dispensing services for a licensed out-of-state pharmacy should extend to all virtual care being provided by the pharmacist working for the out-of-state pharmacy. We recommend the following edits:

> 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 Page 2 of 3 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 working for 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).
> Statutory/Other Authority: ORS 689.205
> Statutes/Other Implemented: ORS 689.151, ORS 689.255

From a jurisdictional standpoint, the Board of Pharmacy has legal oversight over an out-of-state Oregon-licensed pharmacy/facility for whom the pharmacist is working unlike most other healthcare regulatory boards that oversee virtual care service providers. Virtual care is an umbrella term that encompasses terms associated with a wide variety of synchronous and asynchronous care delivery modalities enabled by technology, such as telemedicine, telehealth, m-health, e-consults, e-visits, video visits, remote patient monitoring, and similar technologies. Virtual care is not a separate form of pharmacy practice, but rather a delivery tool. The same standards of care must be met regardless of the delivery method (in-person or via virtual care). We would ask that the Board consider a parallel clarification in its future revisions of the appropriate rule sections including sections applicable to a pharmacy technician.

From a regulatory perspective, the Board continues to have strong accountability mechanisms for both the Oregon-licensed out-of-state pharmacy and the Oregon-licensed pharmacist-in-charge (PIC) with the minor amendments we recommend. In our January 23, 2023, comment letter, we provided detailed industry

challenges and pharmacist stressors impacting professional well-being and pharmacy working conditions. We are thankful for the Board's continued recognition that technology and shared services are important tools in balancing *dispensing* workforce needs. We are requesting the same licensure flexibility to create workforce support models for our *clinical services* provided to Oregon patients.

OAR 855-006-0005 and 855-115-0315: Collaborative Drug Therapy Management

ACI appreciates the continued effort of the Board since 2022 to address the nuances of your governing statutes surrounding clinical pharmacy agreements (CPAs) and collaborative drug therapy management (CDTM) protocols. Board member Patel demonstrated where clinical pharmacy agreements fit into the broader framework in Oregon in the December 2023 meeting. However, in most states, the term "CPA" refers to *collaborative* practice agreements and is simply a synonymous term with the historical use of collaborative drug therapy management (CDTM) protocols. As the Board continues to determine whether to further define clinical pharmacy agreements in the rules – please don't miss the opportunity before you to address the current reality that the CDTM definition in OAR 855-006-0005 and CDTM rules in OAR 855-115-0315 are suboptimal and impractical for almost all community pharmacy settings.

The successful decades of population-based CDTM in states like Washington State, Michigan, Wisconsin, and Nebraska, among others, is one of the core building blocks of pharmacist prescriptive authority moving forward on the continuum toward independent authority across the United States.[2] The plethora of published evidence of patient benefits and safety surrounding population-based CDTM in other states supplemented efforts for Oregon to pursue independent authority for hormonal contraceptives and HB 2397(2017) creating the Public Health and Pharmacist Formulary Advisory Committee. ACI requests amending CDTM rules to align with the recommendations of the National Alliance of State Pharmacy Associations (NASPA) and the American Pharmacists Association (APhA).[3-4] We are encouraged by the Board members willingness to reject the proposed changes in response to stakeholder feedback received in the November rulemaking hearing. We agree with Board member sentiments that a Rules Advisory Committee (RAC) convene experts on the topic who can guide the Board through this nuanced subject. This conversation should continue and as it does, we recommend the following edits as a basis to consider how Oregon can potentially move in a direction that will allow for innovative solutions to fill the gaps in health equity throughout the state:

855-006-0005 Definitions
As used in OAR Chapter 855:
(10) "Collaborative Drug Therapy Management" means the participation by a Pharmacist in the management of drug therapy pursuant to a written protocol ~~that includes information specific to 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 Pharmacist and one practitioner; or

(b) Is agreed to by one or more Pharmacists or pharmacies ~~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~~.

855-115-0315 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 or pharmacies registered by the board.

(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;

(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

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[2] Adams, Alex J., Krystalyn K. Weaver, and Jennifer Athay Adams. "Revisiting the continuum of pharmacist prescriptive authority." *Journal of the American Pharmacists Association* 63.5 (2023): 1508-1514.

[3] NASPA. 2015. Collaborative Practice Agreements: Key Elements of Legislative and Regulatory Change. Available from: https://naspa.us/wp-content/uploads/2017/01/CPA-Workgroup-Report-FINAL.pdf (Accessed January 11, 2024).

[4] American Pharmacists Association. 2019. APhA House of Delegates Policy Manual. Available from: https://www.pharmacist.com/apha-house-delegates?is_sso_called=1 (Accessed January 11, 2024).

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: Albertsons Comments 1/24/24
Date: Tuesday, January 23, 2024 12:13:34 PM
Attachments: Rulemaking comments 1-24-24 Hearing.pdf

> You don't often get email from rob.geddes@albertsons.com. Learn why this is important

Rachel,

Please accept the attached rulemaking comments for the 1/24/23 hearing.

Rob Geddes, PharmD, MBA
Director, Pharmacy Legislative and Regulatory Affairs
Albertsons Companies, Inc.
(M) 208.513.3470
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Rob.Geddes@albertsons.com

Book time with Rob Geddes

From: Andrew Hibbard
To: PHARMACY RULEMAKING * BOP
Subject: February Rule Making Hearing
Date: Wednesday, January 24, 2024 12:03:40 PM
Attachments: image001.png

Dear Members of the Oregon Board of Pharmacy,

I am writing to extend sincere appreciation to the Oregon Board of Pharmacy for the decision not to make any changes to many of the existing rules and, in particular, for retaining the current language governing Collaborative Drug Therapy Management (CDTM) and Clinical Pharmacy Agreements (CPA). Your decision reaffirms the adequacy of the current language and ensures that it aligns effectively with the legislative intent.

Clinical Pharmacy Agreements are synonymous with a health care provider professional service agreements and are in common use in Oregon with this purpose. It is a contract between a physician naturopathic physician, or a health care organization permitting the pharmacist or pharmacies to engage in the practice of clinical pharmacy and provider patient care services. HB 2028 permits health insurers and the Oregon Health Authority to provider payment or reimbursement for services pursuant to a clinical pharmacy or statewide drug therapy protocol.

I want to commend the Board for its prudent decision to maintain the status quo and refrain from making any unnecessary changes to the existing rules. This demonstrates your commitment to preserving the stability and effectiveness of the rules governing pharmacy practice in Oregon. We wholeheartedly agree with the Board's acknowledgment that the definition of CPA is entirely adequate to meet the legislative intent of HB 2028 (2015). This definition accurately reflects the essence

of CPAs as contracts between healthcare providers and pharmacists, enabling the practice of clinical pharmacy and the provision of patient care services.

By choosing to leave the current rules for CDTM intact, the Board has taken a significant step in ensuring that pharmacists can continue to provide valuable services without unnecessary administrative burdens or complications.

We are immensely grateful for your thoughtful consideration of the potential implications of rule changes and your dedication to maintaining a regulatory environment that promotes patient care, access to services, and positive patient outcomes. Your decision will undoubtedly have a positive impact on healthcare providers and patients across Oregon.

Andrew Hibbard, PharmD, BCACP, BCGP
Senior Pharmacy Clinical Coordinator
Work: 503-416-3395| Mobile:269-599-0857
careoregon.org

January 24, 2024

Oregon State Board of Pharmacy,

I hope this letter finds you well. I am writing to support the rules changes proposed in the January 24, 2024, rules hearing for collaborative drug therapy management (CDTM) 855-115-0315 and prohibitive practices 855-115-0150.

I would like to commend the members of the Board of Pharmacy and staff for their open and responsive review of the testimony and concerns shared by many across the profession and the resultant proposed rules at the January 24, 2024, hearing. I am gratified to see that currently enacted language for CDTM in OAR 855-019-0260 has been retained in the new Division 115 and the removal of "Diagnosis" from the list of prohibitive practices. As indicated in previous commentary submitted in writing or through verbal testimony over the past year regarding CDTM and prohibitive practices, these proposed rules will result in the continued ability for our highly trained and skilled pharmacists to collaborate with other healthcare providers to make a positive impact on patient care.

Professionally,

Ryan Wargo, PharmD, BCACP

From: Wargo, Ryan J :LSO Mgr Pharmacy
To: PHARMACY RULEMAKING * BOP
Subject: Comment on OAR 855-115-0315 and OAR 855-115-0150
Date: Wednesday, January 24, 2024 9:51:49 AM
Attachments: JanRulesComment_ORBOP.pdf

Oregon State Board of Pharmacy,

Please see the attached comment on OAR 855-115-0315 and OAR 855-115-0150. Thank you for your open and responsive review of previous testimony regarding these rules to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Professionally,

Ryan Wargo, PharmD, BCACP
Manager - Ambulatory Pharmacy Services
Legacy Health
2225 NW Northrup St, Room 317
Portland, OR 97210
Phone: 503-415-5865

January 23, 2024

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

Dear Oregon Board of Pharmacy Members -

We are writing in response to your invitation for public comment related to the proposed rule change for “Collaborative Drug Therapy Management” (CDTM), which is scheduled to be considered by the Board at the January 24, 2024 Rulemaking Hearing. We are grateful for the Board's ongoing efforts to advance the role of pharmacy services in improving health care for Oregonians and your commitment to providing clarity to legislative intent through the rulemaking process, including the thorough review of language related to CDTM. We greatly appreciate your work to convene the Collaborative Drug Therapy Management (CDTM) and Clinical Pharmacy Agreement (CPA) Workgroup, as well as how responsive the Board has been with regard to previous input provided on this issue.

Through the provision of primary care services in seven Community Health Centers and nine Student Health Centers, as well as dental services in seven locations and care tailored for people living with HIV in our Health Services Center, Multnomah County Community Health Centers are the largest public health federally qualified health center in Oregon. Pharmacy services are a critical component of the care that we provide, as our seven pharmacy locations and pharmacy staff serve patients across the most populous county in the state - dispensing approximately 350,000 prescriptions per year to health center patients (regardless of ability to pay). Our clinical pharmacists are vital members of our multidisciplinary health care team, ensuring that our patients have access to key services that improve health outcomes and help control health care costs - including medication therapy management, individualized adherence support, post-diagnostic collaborative drug therapy management and Medicare Wellness Visits.

We appreciate the continued efforts of the Board to provide clarity with respect to the intent and safety of CDTM through the rules that govern this practice, and support the decision to maintain the existing CDTM language in OAR 855-019-0260, and move what is currently outlined to OAR 855-115-0315. Additionally, we are supportive of maintaining the definition of Clinical Pharmacy Agreement (CPA) currently outlined in code, which is consistent with the legislative intent and achieving intended objectives.

Thank you again for the opportunity to provide comment on this proposed rule change, and please do not hesitate to contact Laura Blanke at laura.blanke@multco.us or 503-545-9576 if you have questions or if we can be of any further assistance.

Sincerely,

DJ Rhodes, DHA, MBA
Executive Director
Multnomah County Community Health Center

Adrienne Daniels, MPH
Deputy Director
Multnomah County Community Health Center

Michele Koder, PharmD, RPh
Pharmacy Director
Multnomah County Community Health Center

Ritchie Longoria, PharmD, RPh
Deputy Pharmacy Director
Multnomah County Community Health Center

Bernadette Thomas, APRN, DNP, MPH
Chief Clinical Officer
Multnomah County Community Health Center

From:	Laura Blanke
To:	PHARMACY RULEMAKING * BOP
Cc:	Michele Koder
Subject:	Written Comments on Oregon Board of Pharmacy CDTM Rule
Date:	Tuesday, January 23, 2024 4:17:36 PM
Attachments:	Multnomah County Health Center Comments to Board of Pharmacy-CDTM Rules.pdf

To The Members of the Oregon Board of Pharmacy -

Thank you for the opportunity to provide written comments on Division 115 related to Pharmacists - Collaborative Drug Therapy Management (CDTM). Please find the response from the Multnomah County Health Center attached, and please do not hesitate to contact me if you have questions or need additional information.

Thanks again!

Laura Blanke, MPH (*she/her*)
Strategy, Policy & Research Analyst
Community Health Center
Multnomah County Health Department

Oregon Society of Health-System Pharmacists
9600 SW Oak Street, Suite 565
Tigard, OR 97223
p 503.255.2973 | f 503.253.9172
mail@oshp.org | https://www.oshp.org/

Tuesday, January 23, 2024

Oregon State Board of Pharmacy,

On behalf of the 700 pharmacy practitioner members of OSHP, we would like to support the rules changes suggested in the proposed rules in the January 24, 2024, rules hearing.

OSHP has consistently provided testimony and input to the Board and staff regarding the ongoing process of rules revision and modernization over the past year. We would like to commend the members of the Board of Pharmacy and staff for their open and responsive review of our testimony and concerns and the resultant proposed rules proposed at the January 24, 2024, hearing. We are particularly gratified to see that the definition of collaborative drug therapy management has been retained {855-006-0005 (10)}and that the addition of "diagnose" to prohibited practices has been eliminated. {855-115-0150(3)}

As stated previously, OSHP believes that these proposed rules will result in the best practice of pharmacy in all settings, including health-systems, and will improve the quality and safety of medication use in Oregon.

OSHP looks forward to continuing collaboration with the Oregon Board of Pharmacy as pharmacy practice continues to change to meet the needs of our patients.

Professionally yours,

OSHP Legal and Regulatory Affairs Committee.

From: Millard, Michael
To: PHARMACY RULEMAKING * BOP
Subject: Revised comment on rulemaking
Date: Tuesday, January 23, 2024 8:17:36 PM
Attachments: Comment to OBOP for Jan 24 rules hearing.docx

Please replace this copy of the OSHP testimony for the Jan 24 hearing. I have replaced the error dispense with the proper word diagnose. Please excuse the error.

--

"A lie is not the truth because you believe it"
Michael Millard B.Pharm MS FOSHP
Professor Emeritus
Pacific University School of Pharmacy
millard@pacificu.edu | 971-998-8838

OREGON STATE PHARMACY ASSOCIATION
19363 Willamette Drive #260 • West Linn, Oregon 97068
(503) 582-9055 • www.oregonpharmacy.org • info@oregonpharmacy.org

January 18, 2024

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

Dear Board of Pharmacy members,

OSPA would like to thank the board members for voting "yes" at the December meeting to initiate proceedings to repeal to rule 855-115-0150 (3) for Prohibited Practices, which states "Pharmacists Must Not: Diagnose."

I received a letter from Director Fox which summarizes the outcome and provides details on the next steps. This include drafting formal rulemaking documents, holding a rulemaking hearing on January 24th, and then the Board meeting in February.

As noted in Director Fox's letter, the Board received valuable input from interested parties during the public comment period from October 23, 2023 – November 15, 2023, including a letter from OSPA's attorney with Tonkon Torp. Rather than asking our busy members to resubmit public comments again, I've taken the liberty to provide all the written comments from the December meeting in this letter. I hope this is helpful for the Board members and will also reduce requests for our busy pharmacists.

Thank you!

Sincerely,
Brian Mayo
Executive Director

OREGON STATE PHARMACY ASSOCIATION
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September 25, 2023

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

Dear Ian and Board of Pharmacy members,

We write today with grave concerns about a rule that was passed last month. Per OAR 137-001-0070 the Oregon State Pharmacy Association is formally requesting a **repeal** to rule 855-115-0150 for Prohibited Practices, that state "Pharmacists Must Not: Diagnose."

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
828 Statutes/Other Implemented: ORS 689.155
Oregon Secretary of State Administrative Rules

OREGON STATE PHARMACY ASSOCIATION
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Rapid rule changes are leading to patient harm

The Board's rapid rule changes and vague definitions have led to general confusion and an inability to be certain about what is expected of licensees. We have expressed concerns in public comments, along with meetings held with the Executive Director and his staff. Board staff continues to send an outlandishly large volume of rules into rulemaking hearings. We recognize some are sent for comment only, but **the high volume of rules makes it virtually impossible for anyone to fully review, digest, and provide thoughtful feedback in the limited amount of time given, let alone assure compliance.**

The most recent Board agenda contained proposed rules that were difficult to decipher. Rather than a straight-forward red line comparison, a confusing new division was created; even text formatting became a hindrance when comparing the changes to the previous rule version. This matters. Members of the public deserve ease and clarity when unraveling revisions to the rules.

The August Board packet was 386 pages long, yet contained a change to accepted standards regarding a pharmacist's ability to diagnose. **"Pharmacists Must Not;" diagnose on page 218, line 816, will create harm to patients. If implemented, it will create a substantial barrier in rural areas of Oregon.**

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country "conducted >42 million COVID-19 tests". Authors estimate that pharmacists "averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs." 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists

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to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

During the Board of Pharmacy meetings, board members verbally request public comments, so they have support on the optimal way to address staff-led rule proposals. It is not realistic to expect the public to be able read through 300+ page documents and make verbal or written comments in the short amount of time currently allowed. If there are no public comments due to the aforementioned reason, we are deeply concerned that Board members are pressured to approve the rules without discussion and perhaps a limited understanding. The Board members must be empowered to guide the staff on rules, not the reverse order.

Transparency is lacking in rule adoption. Board members are not prompted to discuss rules publicly, thus the public cannot understand their intent. During the latest rule hearing, there were serious concerns around proposed rules with Counseling and with Compounding that took the focus away from identifying the problem in the obscure new section: “Diagnose”. **Previously the rules comported with ORS Chapter 689** *"pursuant to a diagnosis by a health care practitioner who has prescriptive authority and is qualified to make the diagnosis.”* Our view is that a change to this language was not required, and with no discussion from the Board about the need for this change, our licensees are left to question what changes are required to stay compliant.

Thank you for reading this letter and considering our request. Please reach out to us with questions or if you need any further information in order to assist us with our concerns.

Sincerely,
Brian Mayo
Executive Director

November 14, 2023

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

Dear Board of Pharmacy members,

Thank you for providing us with the opportunity to request a **repeal** to rule 855-115-0150 (3) for Prohibited Practices, which states "Pharmacists Must Not: Diagnose." We appreciate the process being undertaken to work through fixing this new rule. If left unchanged it will impact every pharmacist and add another barrier to serving patients effectively.

Our formal request addresses why we feel the rule should be repealed. On behalf of all pharmacists in the state of Oregon, not just OSPA members, we further submit the attached legal memorandum to the Board regarding the Board's consideration of our request.

As you will see in the memo, per our counsel's legal analysis, very strong support exists for the Board to grant our petition.

We look forward to your discussion of this request at the December meeting. Thank you again for working with us to recognize pharmacist's current role in serving the citizens of Oregon.

Sincerely,

Brian Mayo
Executive Director

Maureen McGee
maureen.mcgee@tonkon.com

503.802.5726 direct
503.221.1440 main

November 15, 2023

VIA EMAIL

Ian Doyle, Chair
Mr. Jamal T. Fox, Executive Director
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Re: OAR 855-115-0150 (3) Should be Deleted by Amendment

Dear Chair Doyle, Director Fox and Members of the Oregon Board of Pharmacy:

Thank you for the opportunity to comment on the Oregon State Pharmacy Association's (OSPA) petition (the Petition) under ORS 183.390 and OAR 137-001-0070, requesting an amendment to the recently-adopted Oregon Administrative Rule 855-115-0150 to delete subsection (3) of that rule, which declares that a pharmacist must not "diagnose."

For the reasons further explained below, OAR 855-155-0150 (3) is unnecessary and has the potential to raise considerable confusion among pharmacists that is likely have a chilling effect on pharmacists engaging in activities that are clearly authorized by statute. This outcome will disincentivize those who hold a pharmacist license from practicing to the full extent of their licensure and training, having a negative impact on the businesses where licensees work and reducing access to care for Oregonians.

OAR 183.390 and OAR 137-001-0070 therefore dictate that the best option for reducing these negative impacts while still achieving the rule's substantive goals is to grant the OSPA's petition and amend OAR 855-115-0150 to delete subsection (3).

I. BACKGROUND

In August of 2023, the Oregon Board of Pharmacy (the Board) adopted, among a host of other significant regulatory changes, a new rule provision set to become effective on March 1, 2024 that, for the first time, explicitly states in law that a pharmacist may not diagnose. OAR 855-115-0150 (3). OSPA submitted the Petition at issue asking the Board to delete that provision.

When reviewing a petition requesting the adoption, amendment or repeal of a rule under ORS 183.390 and OAR 137-001-0070, the Board shall request public comment on whether options exist for achieving the rule's substantive goals in a way that reduces the negative economic impact on businesses and "shall consider," among other factors, the statutory citation or legal

basis for the rule, the continuing need for the rule, and the nature of complaints received. ORS 183.390; OAR 137-001-0070. For the reasons explained below, an analysis of those criteria dictates that the Petition should be granted.

II. ANALYSIS

A. OAR 855-155-0150 (3) is unnecessary in the context of existing, well-established statutory law.

The scope of practice for pharmacists in Oregon is governed by provisions in ORS Chapter 689, which also grant the State Board of Pharmacy with authority to enforce those provisions and exercise general supervision over the practice of pharmacy in Oregon. Statute recognizes two levels of scope of practice within the profession, the "practice of clinical pharmacy" and the "practice of pharmacy," both as defined in ORS 689.005.

The ability to "diagnose" as contemplated in the context of other health professions—such as in the practice of medicine—is not included in the statutory scope of the practice of clinical pharmacy or the practice of pharmacy. *Cf.* ORS 677.085 (providing that person engages in practice of medicine if person offers or undertakes to diagnose, cure or treat in any manner, any disease); ORS 677.010 (4) (defining "diagnose" for purposes of statutes governing practice of medicine); ORS 677.060 (clarifying that the practice of pharmacy does not fall within scope of ORS Chapter 677). For that reason, the legislature has not deemed it necessary to provide for an explicit prohibition against diagnosis by pharmacists.

Given this background, the Board relied solely on its general authority in ORS 689.155 (7) and ORS 689.205 to adopt rules "necessary" to carry out, administer and enforce ORS Chapter 689, and has indicated that it adopted the rule "because there is no authority in ORS Chapter 689 for pharmacists to diagnose and the Board wanted to make sure that pharmacists know this." *Notice for Invitation of Public Comment*, Oregon Board of Pharmacy Bulletin. In other words, the Board appears to have adopted OAR 855-155-0150 (3) simply in an attempt to provide education to licensees about the existing state of the law.

There is no need in carrying out proper administration and enforcement of law to restate in rule what the law already is. This is particularly true where the Board has a variety of other means at its disposal to educate pharmacists about the boundaries of their scope of practice, such as continuing education or enforcement, and could just as easily communicate scope of practice decisions through those means. *See* ORS 689.285 (requiring continuing education by means determined by the Board); ORS 689.145 (providing the Board with broad enforcement authority).

Because the extent of a pharmacist's scope of practice is clear in statute and because the Board has other, well-established means at its disposal to educate pharmacists, adopting OAR 855-155-0150 (3) as a means to educate pharmacists about what is *not* included in their scope of practice was unnecessary, and there is no continuing necessity for the rule.

B. The nature of comments received shows that the rule has the potential to raise considerable confusion, having a negative effect on businesses that employ licensed pharmacists.

As evidenced by the OSPA's letter, the prohibition against diagnosis in OAR 855-155-0150 (3) has already sown confusion and raised significant questions as to whether pharmacists may continue to carry out activities that they are clearly authorized by law to do and that require some level of diagnostic skill.

No applicable statutes exist that explicitly define what "diagnosis" or engaging in diagnostic activities would mean in the context of the practice of pharmacy. Where a term is not statutorily defined, dictionary definitions can help in discerning the term's plain, natural and ordinary meaning. *See State v. Gaines,* 346 Or. 160, 175 (2009). Here, the dictionary defines the term "diagnose" in its common usage as "to identify (as a disease or condition) by symptoms or distinguishing characteristics." *Webster's Third New Int'l Dictionary* 622 (unabridged ed 2022).

While the ability to "diagnose" as contemplated in other health professions is not included within a pharmacist's statutory scope of practice, pharmacists *are* clearly authorized by statute to apply their skill and knowledge, in particular cases and subject to certain protocols, to identify diseases or conditions by their symptoms or distinguishing characteristics. *See, e.g. Sutton v. Cook,* 254 Or. 116, 121-22 (1969) (practitioner of a particular school of the healing arts is entitled to have his conduct tested by the standards of their own school). These abilities generally apply in the context of the prescribing authorities that have been added to the practice of pharmacy by the legislature over time in order to expand access to public health services. ORS 689.005 (31)(L) (prescribing and administering of injectable hormonal contraceptives and the prescribing and dispensing of self-administered hormonal contraceptives pursuant to ORS 689.689; ORS 689.005 (31)(m) (prescribing and dispensing of emergency refills of insulin and associated insulin-related devices and supplies pursuant to ORS 689.696); ORS 689.005 (31)(n) (prescribing, dispensing and administering of preexposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies, pursuant to ORS 689.704 and rules adopted by the board under ORS 689.645 and 689.704); ORS 689.005 and ORS 689.295 (authorizing clinical pharmacy agreements).

Pharmacists have also long provided clinical advice to include over-the-counter relief that may aid in decreasing unnecessary emergency room visits for common conditions. Providing such advice also requires application of diagnostic skill that has traditionally been considered well within the scope of a pharmacist's practice and that arguably fits within the dictionary definition of "diagnose."

In adopting OAR 855-115-0150 (3), the Board gave no guidance to pharmacists as to what it intended the scope of the term "diagnose" to mean within the context of the rule. Because of this lack of clarity, pharmacists are now expressing fear that because exercising their prescribing authority under statute could be interpreted by some to constitute "diagnosis" under the plain meaning of the term, they may be putting themselves at enforcement risk by engaging in those activities.

That confusion clearly does not appear to have been the intent of the Board in adopting OAR 855-115-0115 (3), but it is a result that must be seriously considered when evaluating whether a better opportunity exists to achieve the rule's substantive goals. Further, because the rule as written presents a significant risk of encouraging pharmacists to cease practicing to the full extent of their licensure and training, it also presents the risk of having a negative effect on both businesses that employ licensed pharmacists and patients who have come to rely on their pharmacists. Businesses may see less income as pharmacists step back from engaging in lawful prescribing activities, and patients may see lowered access to care, particularly in rural communities and other communities where health care delivery challenges exist.

C. Better opportunities exist for achieving the substantive goals for adopting OAR 855-155-0150 (3).

The Board has indicated that the substantive goal in adopting OAR 855-115-0115 (3) was to better educate pharmacists about their scope of practice. *See Notice for Invitation of Public Comment*, Oregon Board of Pharmacy Bulletin, October 23, 2023 (Accessed November 15, 2023). However, given the lack of statutory necessity for the rule and other issues raised above, it becomes clear that the Board could have just as easily achieved its substantive goals by increasing educational opportunities like continuing education courses.

Finally, it bears mention that the rulemaking process itself could have provided an opportunity for education and engagement in this instance, and could do so in the future. Under OAR 183.333, agencies are encouraged to seek public input to the maximum extent possible before giving notice of intent to adopt a rule, and are authorized to appoint rulemaking advisory committees (RAC) to obtain public views that will help in rule drafting. The Board did not utilize a RAC in this instance, despite the fact that OAR 855-0155-0150 (3) was adopted as part of a wide-ranging reorganization of the regulatory regime applicable to pharmacists. Had the Board convened a RAC, it could have engaged in dialog with stakeholders to communicate its intent for this particular rule, hear stakeholder concerns, and identify solutions for a path forward that would have increased a shared understanding regarding scope of practice without raising confusion among licensees.

III. CONCLUSION

For the reasons set forth above, OAR 855-155-0150 (3) is unnecessary and much more likely to sow confusion than provide clarity for licensees—having a harmful impact on businesses employing licensees. In applying the standards for review of a rulemaking petition under ORS 183.390 and OAR 137-001-0070, the Board should grant the Petition and initiate rulemaking to amend OAR 855-115-0150 by deleting subsection (3).

In endeavoring to provide direction regarding diagnosis and the scope of a pharmacist's practice in the future, the Board should provide that direction in a way that, clearly accounts for the historic and lawful practice of pharmacists applying in diagnostic skill, utilizes clear definitions, is combined with a robust continuing education offering for pharmacists, encourages pharmacists to practice to the full extent of their licensure and training, and is adopted pursuant

to an open, transparent rulemaking process that utilizes a rulemaking advisory committee appointed under the provisions of ORS 183.333.

Sincerely,

s/

Maureen McGee

From:	Brian Mayo
To:	PHARMACY RULEMAKING * BOP
Subject:	Public Comments for Rule Repeal
Date:	Wednesday, November 15, 2023 12:14:54 PM
Attachments:	MAM draft cover letter.docx OSPA Submission.pdf

Hi Rachel,

I hope you are doing well! Please see the attached files for OSPA public comments on our rule repeal request.

Brian Mayo
Executive Director
Oregon State Pharmacy Association
Office: (503) 582-9055
brian@oregonpharmacy.org | www.oregonpharmacy.org
Leading Pharmacy, Advancing Healthcare!

From: Alison Reta, PharmD, CDE
To: PHARMACY RULEMAKING * BOP
Subject: Comment on new rule 855-115- 0150
Date: Tuesday, November 14, 2023 12:31:43 PM
Attachments: image001.png
image002.png
image003.png

Dear Members of the Oregon State Board of Pharmacy,

I am writing to express concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions (new rule 855-115- 0150). I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

First and foremost, I must emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patient access to care. It will hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements routinely order, interpret, and monitor laboratory values such as blood glucose levels, cholesterol levels, and urine albumin-creatinine ratio results for patients referred for diabetes management. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

This rule change may disrupt vital test-to-treat programs. The COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers; this causes delays in treatment and increases the burden on an already strained healthcare system.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon’s Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management for conditions such as hyperlipidemia, kidney protection, and cardiovascular risk when pharmacists are referred patients for the management of diabetes. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make

recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service in abundance and without issue for decades.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board considers these arguments carefully and takes steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve in the State of Oregon.

Sincerely,

Alison Reta

Alison Reta, PharmD, CDCES

Clinical Pharmacist, Diabetes Specialist

Virginia Garcia Memorial Health Center

Address 2725 SW Cedar Hills Blvd #200, Beaverton, OR 97005

Phone 503-352-8150 (Tu/Wed/Thu) | **Email** areta@vgmhc.org

Website VirginiaGarcia.org

From: Amanda M
To: PHARMACY RULEMAKING * BOP
Subject: Response to Notice for Invitation of Public Comment
Date: Thursday, November 9, 2023 1:52:34 PM

Dear Oregon Board of Pharmacy members,

I have a Doctorate of Pharmacy, not a Juris Doctorate, so I am not an expert in the law. However, I implore every board member to use their common sense when reviewing the petition to repeal a rule and public comments. Does it really make sense that if something is not in statute, it is prohibited? If that is the case, you have a lot of rules to strike, including all of the counseling rules. Counseling is not mentioned in ORS 689. Don't take my non-lawyer opinion on it, search for it yourself. Is it really in the interest of public safety to prohibit counseling? If the answer is no, the same answer applies to diagnosing.

Pharmacists daily are asked to recommend drugs. Some of the time, they have a diagnosis. Other times, they have to walk patients through key questions in order to ensure they are providing appropriate care and not harming the public. This practice, which is often not compensated, is sometimes the ONLY access point the public has to a healthcare provider. The thought of having to turn people away from this service because of the actions of your board makes it easy to understand why pharmacists give up on trying to work within the rules you constantly change to make their life harder. It goes against the reason most people become pharmacists in the first place. It goes against the very mission statement you purport to uphold. You will cause harm to the public if you do not change this rules.

The Board's lawyer is available to you to give you legal advice, but as a licensee and Oregonian, I do not believe she is giving you advice that is in the best interest of citizens of this state. Some of the advice you appear to be relying on defies logic and common sense. The medical board and nursing board does not refuse to engage with licensees and tell them to ask a lawyer if they have questions about the rules written and enforced by their board.

Board members are the ones who make decisions. Please use the power invested in you by the state of Oregon to make good choices that help advance the health and safety of Oregonians, not the agenda forced upon you by someone who is not in charge. Please start treating pharmacists with the respect they deserve as healthcare professionals who are doing the best with what they have before our profession disappears in this state.

I hesitate to make comments as there is fear of retribution from Board staff towards pharmacists who have made public comments recently, and like most licensees I value my license and do not wish to be threatened for simply doing what I feel is right. I am a lifelong Oregonian, but the current environment of the profession in this state has made me seriously question whether I want to continue living and making professional contributions here. I am somewhat encouraged by the discussion of this Board at the recent strategic planning session. I look forward to a better working relationship between the Board and the profession of pharmacists, starting with revisiting this rule which was not ever commented on by Board members during a Board meeting so we could have this dialogue in a different manner. Please do not dismiss this petition out of hand.

Sincerely,
Amanda Meeker

From:	Watson, Amy
To:	PHARMACY RULEMAKING * BOP
Subject:	Request to Repeal - 855-115-0150 Prohibited Practices
Date:	Monday, November 13, 2023 11:19:55 AM
Attachments:	2023 11 Board of Pharmacy RPH diagnose.pdf

Dear Board of Pharmacy,
I am writing to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose." This rule, it will disrupt pharmacy services in Oregon and will be clinically devastating to patient access to safe care.
Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care testing was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country "conducted >42 million COVID-19 tests". Authors estimate that pharmacists "averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs." 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription. This unnecessarily increases health care costs and delays or prevents appropriate care.

Perhaps one of the greatest disruptions to care is the conflict between rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

With limited access to health care across our state including rural healthcare deserts, we cannot allow restrictions on appropriate care including by pharmacists utilizing appropriate diagnostic information to prescribe medications at the point-of-care.

Sincerely,

Amy R. Watson PharmD, MBA, FACHE
Director Pharmacy Services & Chief Pharmacy Officer | Asante
Email: Amy.Watson@asante.org | Phone: 541-789-5031
Excellence | Respect | Honesty | Service | Teamwork

From: Andrew Gibler
To: PHARMACY RULEMAKING * BOP
Subject: Public Comment on Proposed OAR 855-115-0150
Date: Wednesday, November 15, 2023 1:52:22 PM

Dear Board of Pharmacy,

Today I write to you as a licensed Oregon pharmacist, and my public comments may not be reflective of any view held by my colleagues at the Oregon Health Authority or on the Public Health and Pharmacy Formulary Advisory Committee.

Please do not adopt amendment OAR 855-115-0150(3) as written, which states, "pharmacists must not: diagnose."

Diagnosis is not defined in Chapter 689 for pharmacists, but it is defined in Chapter 677 for those practicing medicine. ORS 677.010(4) states that, "*diagnose means to examine another person **in any manner** to determine the source or nature of a disease or other physical or mental condition, or to hold oneself out or represent that a person is so examining another person. It is not necessary that the examination be made in the presence of such other person; **it may be made on information supplied** either directly or indirectly by such other person*." [note that bolded language is mine]

I am concerned that if this OAR is adopted as amended, it will dissuade many pharmacists from:

1) Providing over the counter (OTC) counseling; and
2) Prescribing from the Oregon Board of Pharmacy-approved formulary and protocol compendia.

Pharmacists are trained and proficient to use clinical judgement about whether a specific OTC treatment or referral is appropriate based on patient interview of past medical and social history, basic physical examination, and review of current signs and symptoms. Pharmacists may interpret OTC counseling as diagnostic and dissuade them from providing care if this OAR is adopted as amended.

Pharmacists prescribing from the Oregon Board of Pharmacy-approved formulary and protocol compendia must also use clinical judgement to determine if the patient is a candidate for such treatment under the protocol. The Board of Pharmacy should adopt rules that clearly state that practicing under these protocols, including interpretation of laboratory values, is not making a diagnosis. The current conditions that are treated under the formulary and protocol compendia do not require a diagnosis, but the amended language OAR 855-115-0150(3) is ambiguous enough that it may dissuade pharmacists from practicing under these protocols.

I have concerns that if pharmacists are discouraged to practice clinical pharmacy, it will result in delayed care and patient harm in our communities. Public comment like this would not be necessary if Board of Pharmacy staff could help interpret ambiguous OARs for licensed pharmacists as was commonly done in the past. I strongly urge the Board to only adopt OARs that are explicit enough that every pharmacist would interpret them the same way and be confident enough to use their knowledge, expertise, and experience to provide clinical services. We need clinical pharmacists more than ever.

Sincerely,

Andrew Gibler, PharmD *(RPH #11081)*

From: Andrew Hibbard
To: PHARMACY RULEMAKING * BOP
Subject: Response to Notice For Invitation to Public Comment
Date: Tuesday, November 14, 2023 11:45:42 AM

Dear Members of the Oregon State Board of Pharmacy,

I hope this letter finds you well. I am writing to express my deep concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

First and foremost, I must emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patient access to care. It will hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements routinely order, interpret, and monitor laboratory values such as blood glucose levels, cholesterol levels, and urine albumin-creatinine ratio results for referred for diabetes management. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

This rule change may disrupt vital test-to-treat programs. The COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers, causing delays in treatment and increasing the burden on an already strained healthcare system.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon’s Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management for conditions such as hyperlipidemia, kidney protection, and cardiovascular risk when pharmacists are referred patients for the management of diabetes. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service, in abundance, and

without issue for decades.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Sincerely,

Andrew Hibbard Pharm.D., BCACP, BCGP

November 13, 2023

Dear Board of Pharmacy,

I am writing to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose." This rule, it will disrupt pharmacy services in Oregon and will be clinically devastating to patient access to safe care.

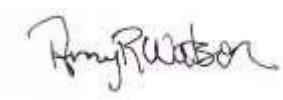
Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care testing was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country "conducted >42 million COVID-19 tests". Authors estimate that pharmacists "averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs." 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription. This unnecessarily increases health care costs and delays or prevents appropriate care.

Perhaps one of the greatest disruptions to care is the conflict between rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

With limited access to health care across our state including rural healthcare deserts, we cannot allow restrictions on appropriate care including by pharmacists utilizing appropriate diagnostic information to prescribe medications at the point-of-care.

Sincerely,



Amy R. Watson, PharmD, MBA, FACHE
Dir Pharmacy Services & Chief Pharmacy Officer, Asante

From:	Watson, Amy
To:	PHARMACY RULEMAKING * BOP
Subject:	Request to Repeal - 855-115-0150 Prohibited Practices
Date:	Monday, November 13, 2023 11:19:55 AM
Attachments:	2023 11 Board of Pharmacy RPH diagnose.pdf

Dear Board of Pharmacy,
I am writing to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose." This rule, it will disrupt pharmacy services in Oregon and will be clinically devastating to patient access to safe care.
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Sincerely,

Amy R. Watson PharmD, MBA, FACHE
Director Pharmacy Services & Chief Pharmacy Officer | Asante
Email: Amy.Watson@asante.org | Phone: 541-789-5031
Excellence | Respect | Honesty | Service | Teamwork

From:	Mosesman, Ashley
To:	PHARMACY RULEMAKING * BOP
Subject:	REPEAL - OAR 855-115-0150 Pharmacist: Prohibited Practices
Date:	Tuesday, November 7, 2023 5:23:43 PM

Dear Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose." If you don't fix this rule, it will up-end pharmacy services in Oregon and will be **clinically devastating to patient safety.**

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country "conducted >42 million COVID-19 tests". Authors estimate that pharmacists "averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs." 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Take Care,

Ashley Mosesman
PharmD Candidate | Class of 2026
Pacific University, School of Pharmacy
Email: mose9897@pacificu.edu | Tel: (925) 351-8698

From: Dan Kennedy
To: PHARMACY RULEMAKING * BOP
Subject: Letter in support of Repeal
Date: Thursday, November 16, 2023 3:58:53 PM

OAR 137-001-0070 (3) Prohibited Practice-Diagnosis

To whom it may Concern;

I am writing to you today to express my support for the repeal of Rule 137-991-0070 (3) "Prohibited Practices" Pharmacists may **not** diagnose. While I understand the intent of including prohibited practices, addition of this rule essentially creates confusion and limits pharmacist's ability to further the scope of future pharmacy practice.
As this is not stated in statute, it gives the appearance that the Board of Pharmacy is making rules out of whole cloth without regard to different practice settings.The needs of Pharmacists in Ambulatory Care, Community Pharmacy etc. need to be considered. Retention could have a chilling effect on Pharmacist/Patient consultations where a patient is looking for professional advice. Community Pharmacists have long assessed their patients who present with a multitude of concerns.Patients rely upon Pharmacist advice up to and including the need for referral to another healthcare provider.

I believe this rule further complicates and confuses pharmacy professionals, is unnecessary and appears to micromanage the profession of pharmacy. I strongly urge you to repeal this rule.

Sincerely,

Dan Kennedy RPh, FAPhA
President of the Oregon State Pharmacy Association
(speaking on behalf of myself)

From: Petley, David
To: PHARMACY RULEMAKING * BOP
Subject: Please reconsider 855-115- 0150 "Pharmacists Must Not: Diagnose."
Date: Wednesday, November 15, 2023 4:22:29 PM

David Thomas Petley, Pharm D, BCPS, BCCCP
61890 Ross Inlet Rd

Coos Bay, Oregon 97420

davidtpetley@gmail.com

541-870-6466

11/15/2023

Oregon State Board of Pharmacy 800 NE Oregon Street, Suite 150 Portland, OR 97232

Dear Members of the Oregon State Board of Pharmacy,

I hope this letter finds you well. I am writing to express my deep concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

First and foremost, I must emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patient access to care. It will hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements in ambulatory care and hospitals routinely order, interpret, and monitor laboratory values such as electrolyte levels, vancomycin levels, ANC, heparin anti Xa, aPTT, INR, blood glucose levels, cholesterol levels, and creatinine results for routine ambulatory and hospitalized care. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

This rule change may disrupt vital test-to-treat programs. The COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers, causing delays in treatment and increasing the burden on an already strained healthcare system.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon's Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts

patient access to timely care, contradicting the committee's purpose.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management for conditions such as infectious diseases, diabetic ketoacidosis, hyperglycemia, anticoagulation, hyperlipidemia, kidney protection, and cardiovascular risk when pharmacists are consulted by hospital physicians. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service, in abundance, and without issue for decades.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Sincerely,

David T Petley, Pharm D, BCPS, BCCCP

Lead Inpatient Clinical Pharmacist

Bay Area Hospital

Coos Bay Oregon

November 15, 2023

Jamal T. Fox, MPA
Executive Director Oregon State Board of Pharmacy
800 N.E. Oregon Street, Suite 150
Portland, OR 97232

Re: Proposed Amendment OAR 855-115-0150(3) Pharmacist: Prohibited Practices

Dear Mr. Fox,

Pharmacists are positioned to play a critical role in shifting who has access to tools for HIV prevention by making pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) more visible and accessible to those who stand to benefit the most. PrEP is an important piece of the Oregon Health Authority (OHA) End HIV Oregon Campaign. The *Oregon Board of Pharmacy Preventative Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Drug Therapy Management for the Oregon Pharmacist* allows Oregon pharmacists to participate in a vital role in reducing the number of new HIV diagnoses in Oregon by increasing access and lowering systemic barriers to people receiving HIV PrEP and/or HIV PEP.

The Preventative Care: HIV Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway follows the CDC PrEP Guidelines 2021 for pharmacists to assess patients for PrEP therapy. The laboratory tests included in the *Oregon Board of Pharmacy Preventative Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Drug Therapy Management for the Oregon Pharmacist* are interpreted by the pharmacist to determine if PrEP is safe to start or continue and if PrEP is expected to be effective to prevent a new HIV acquisition.

HIV is not diagnosed by the result of one HIV test as false positives may occur with some tests and in certain circumstances. When the interpretation of the HIV test(s) and any symptoms that may be present is that there are safety or effectiveness concerns with starting or continuing HIV PrEP, then the protocol requires that the pharmacist must refer the patient for further HIV tests and/or evaluation by a provider. When the interpretation of gonorrhea, chlamydia, syphilis, and Hepatitis C tests is that there may be a new infection, then the pharmacist must refer to a provider for further evaluation and treatment if the provider determines the treatment is indicated. The other tests included in the protocol are to monitor for potential contraindications and/or adverse effects of the PrEP medication regimen. None of the tests are included for the purpose of diagnosis.

In addition, The Oregon Board of Pharmacy October_2023_Bd_Mtg_Agenda.pdf (oregon.gov) Mailing F states, T*he lack of ability to diagnose does not deter pharmacists from participating in formulary and protocol prescribing under ORS 689.645, OAR 855-020 and the proposed OAR 855- 11*

Respectfully submitted,

Devon Flynn, PharmD, MPH, BCPS, AAHIVP*
Sharon Rask, RPh

*Please note the above comments reflect my personal, professional perspective and do not in any way represent the opinion or perspective of my employer(s).

From: Devon Flynn
To: PHARMACY RULEMAKING * BOP
Cc: Rask, Sharon
Subject: Public Comments OAR 855-115-0150(3)
Date: Wednesday, November 15, 2023 2:35:49 PM
Attachments: OBOP PrEP Comments_Nov 2023.docx

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To Oregon Board of Pharmacy,

Attached are comments regarding OAR 855-115-0150(3) that is on the agenda for the December 2023 Board meeting.

Thank you,
-Devon

11/15/2023

Dear Oregon Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.”
If you do not fix this rule, it will disrupt pharmacy services in Oregon. Additionally, patient safety will be seriously and devastatingly affected.
Pharmacists have been trained and are proficient in utilizing diagnostic information in their practice on a daily basis. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. Equipped with the knowledge of these values, pharmacists are able to make appropriate decisions and timely adjustments to medications to ensure patient health and safety.
They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary and preventing unnecessary drug use. The value of point-of-care tests was clearly established during the COVID-19 pandemic.
A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted >42 million COVID-19 tests”. Authors estimate that pharmacists “averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.” 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19."
Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.
Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to critical services they rely on, and current law will not be implemented.
Again, I earnestly appeal to you, as members of the Oregon Board of Pharmacy, to ask you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.”

Respectfully,

Irene C. Croswell, PharmD
RPH 0009231
Tualatin, OR

From: Irene Croswell
To: PHARMACY RULEMAKING * BOP
Subject: letter re: effects of prohibiting pharmacists from diagnosing
Date: Wednesday, November 15, 2023 2:20:09 PM
Attachments: Letter 11.15.23 Req repeal d.n diagnose.docx

Hello
Please see attached my letter addressing my concerns for the safety and health outcomes for patients that would be affected if pharmacists are prohibited to diagnose.
Thank you for your consideration,
Irene C Croswell PharmD

From: Melissa Netland
To: PHARMACY RULEMAKING * BOP
Subject: "not allowed to diagnose"
Date: Thursday, November 9, 2023 7:39:29 AM

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be clinically devastating to patient safety.

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted 42 million COVID-19 tests”. Authors estimate that pharmacists “averted 1 million deaths, 8 million hospitalizations, and $450 billion in health care costs.” The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19". Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Please do not take away our ability to provide immediate access to critical health care,

Sincerely,

James and Melissa Netland, Pharm BS, RPH's
Stayton Pharmacy and Sublimity Pharmacy owners

Your health.

Your clinic.

Your neighborhood.
NHCOregon.org

Jennifer McElravey, PharmD, BCACP, 340B ACE

7320 SW Hunziker Rd, Ste 102

Portland, OR 97223

mcelraveyj@nhcoregon.org 503-214-1075

11/15/2023

Oregon State Board of Pharmacy 800 NE Oregon Street, Suite 150 Portland, OR 97232

Dear Members of the Oregon State Board of Pharmacy,

I am writing to express my concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

There is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patients' access to care. It will hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and are proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements routinely order, interpret, and monitor laboratory values such as blood glucose levels, cholesterol levels, and urine albumin-creatinine ratio results for referred for diabetes management. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon's Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management for conditions such as hyperlipidemia, kidney protection, and cardiovascular risk when pharmacists are referred patients for the management of diabetes. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy

management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers, preventing effective implementation of team-based care models.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Sincerely,

Jennifer McElravey, Pharmacy Director and Oregon Licensed Pharmacist

From:	Jennifer McElravey
To:	PHARMACY RULEMAKING * BOP
Subject:	Public comment concerning the OSPA petition that challenged the recently approved pharmacy prohibited practice rules that state "pharmacist must not diagnose"
Date:	Wednesday, November 15, 2023 1:15:56 PM
Attachments:	image001.png 2023-11.14 NHC Pharmacy letter to Board of Pharmacy.pdf

Dear Oregon Board of Pharmacy,

I would like to submit my public comments in support of **repealing** the pharmacy prohibited practice rules that state that a pharmacist must not diagnose.

Thank you for your consideration,

Jennifer McElravey

Jennifer McElravey, PharmD, BCACP, 340B ACE *(she, her, hers)*
Director of Pharmacy
Cell: 503.926.4300 Direct: 503.214.1075 Fax 503.747.7013
7320 SW Hunziker Rd. Suite 102, Portland, OR 97223
mcelraveyj@nhcoregon.org | NHCOregon.org
Find us on Facebook, Instagram, and LinkedIn

From: DROLLINGER Kelly W * DOC
To: PHARMACY RULEMAKING * BOP
Subject: Prohibited practices
Date: Tuesday, November 14, 2023 12:46:53 PM

I remember being taught in pharmacy school that the BOP's specific role was to protect the public, not pharmacists. I recall being surprised by that statement (and wondering who supports and protects pharmacists) but can certainly appreciate your perspective as you serve in that role. I know that purpose is not taken lightly. I know the board's role in protecting the public was the intent of this rule, but I fear there are repercussions of the rule that could have a detrimental rather than positive impact.

In looking at the board's mission statement, "to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacturer and distribution of drugs." I share your mission statement to focus specifically on those words, "promote and protect public health."

My specific concern surrounds pharmacists' ability to use point-of-care (POC) testing, which may be considered a form of diagnosis in specific circumstances. I know as a pharmacist that we have not received the same training to diagnosis as physicians; however, the availability of certain labs or POC tests make certain disease states feasible to diagnose without expert training in physical exam.

For example, I have direct involvement in the development of a pending collaborative drug therapy management (CDTM) agreement for the OR Department of Corrections to have clinical pharmacists treat and monitor patients with hepatitis C. In the setting of this CDTM, if pharmacists are not allowed (and a provider is required) to make the diagnosis (a diagnosis made by simple labs), a significant number of patients will be lost to follow-up. I know this from experience and have witnessed this personally. Providers, especially in our setting, have a significant workload burden already placed on them because of staffing shortages. If these patients are lost to follow-up, fewer patients are treated and cured of HCV, which does not promote public health.

This law, without added clarity, has potential to interfere with the board's mission to promote public health. If my interpretation is correct, and we as pharmacists are not allowed to diagnose, even in the setting of a CDTM, our ability within ODOC to eradicate HCV will be weakened. More provider appointments will be required, which will result in treatment delays. In many cases, our setting is the most stable environment and the only opportunity for some of our patients to receive treatment prior to release.

Respectfully,

Kelly Drollinger, PharmD
Clinical Pharmacy Specialist

OR Dept of Corrections

Four Rivers Bldg.
88 SW 3rd Ave
Ontario, OR 97914
Office Phone: 503-986-6952
Mobile: 458-251-8543
Fax: 541-889-0027

From: LaceAnn Becker
To: PHARMACY RULEMAKING * BOP
Subject: Re: Rule 855-115- 0150
Date: Wednesday, November 8, 2023 3:28:34 PM

Dear Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be **clinically devastating to patient safety**.

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance,
a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted >42 million COVID-19 tests”. Authors estimate that pharmacists “averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.” 'The FDA recognized the capability of pharmacists during the pandemic and have
allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Thank you for your careful consideration in this matter and for keeping Oregonians safe.

Best,
LaceAnn Becker, RPh, PharmD

November 13th, 2023

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

Re: Request to repeal new rule 855-115-0150 for Prohibited Practices that states, "Pharmacists must not: Diagnose."

Dear Board Members and Staff of the Oregon State Board of Pharmacy,

It has come to my attention that the prohibited practices for pharmacists in the State of Oregon have recently changed to include the statement that pharmacists must not diagnose.

This is surprising to me as many of the board members are/were practicing pharmacists. I can't tell you how many times over my 14-year career as a pharmacist I've diagnosed and suggested treatment for conditions such as ringworm, eczema, postnasal drip, etc. Likewise, there are also plenty of times I've encountered patient questions about conditions that were out of my scope of practice and subsequently I've suggested the patient see their primary care doctor or go to the emergency room. As pharmacists are the most accessible healthcare providers, we encounter many different types of patient questions and I personally enjoy this role in the healthcare ecosystem.

We can argue the semantics of what defines "diagnosing" for payment purposes, but when patients come to my pharmacy, show/tell me their symptoms, and ask my opinion about what I would suggest to treat their current medical ailment what would you say I am doing? If a patient shows me a rash on her arm and I use my expertise to determine it is ringworm and suggest she apply OTC clotrimazole 1% to the affected area twice a day for two to four weeks, wouldn't a reasonable person consider this "diagnosing"?

Additionally, we are just scratching the surface on the value of point-of-care testing in pharmacies and how this could potentially be a win-win situation in which patients get more convenient and less expensive healthcare, while also helping pharmacies stay viable and keep their doors open.

I understand that your primary concern working on the board of pharmacy is the safety of the public and not trying to increase patient access by keeping pharmacies from closing. However, your role shouldn't be to throw barriers in front of pharmacies to block viable business

opportunities while simultaneously decreasing patient access for conditions that any pharmacist can easily diagnose and suggest treatment.

Thank you for your time and consideration. Let's work together to help Oregonians live safe and healthy lives.

Sincerely,

Dr. Levi J. Martin, Pharm.D., RPh

Bend, OR

From: Levi Martin
To: PHARMACY RULEMAKING * BOP
Subject: Public Comment
Date: Monday, November 13, 2023 11:52:48 AM
Attachments: Letter to OBOP.docx

Please find my attached comments for consideration.

Thank you,
Levi Martin

Sent from my iPhone

From: Molly Bloom
To: PHARMACY RULEMAKING * BOP
Subject: Request to repeal 855-115-0150
Date: Tuesday, November 14, 2023 2:27:04 PM

Dear Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.”

This change in language makes it seem as though a pharmacist is prohibited from even recommending over the counter medications to a patient. When assessing a patient during cough and cold or allergy season, pharmacists are essentially diagnosing a patient with rhinitis or seasonal allergies or common cold before recommending a product to use. Pharmacists have long been recognized as the most accessible health care professionals but if you take away our ability to recommend over the counter medications (for fear of it being seen as diagnosing), it will hugely impact the perception and utilization of our profession.

Furthermore, Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use. The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted 42 million COVID-19 tests”. Authors estimate that pharmacists “averted 1 million deaths, 8 million hospitalizations, and $450 billion in health care costs.” The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a diagnosis of COVID-19. **Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose.** As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor appointment to get a prescription.

Perhaps an even greater disruption to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Please consider rewording or revoking 855-115-0150 Prohibited Practices stating: Pharmacists Must Not: Diagnose”

Thank you,
Molly Bloom, PharmD

November 14, 2023

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

Dear Oregon Board of Pharmacy Members -

We are writing in response to your invitation for public comment related to the petition to repeal language in OAR 855-115-0150(3) Pharmacist: Prohibited Practices, a rule which was adopted by the Oregon Board of Pharmacy on August 11, 2023. We appreciate the opportunity to comment on the petitioner's September 25, 2023 request to the Board and agree with the petitioner that language which outlines that a pharmacist must not "diagnose" should be removed from OAR 855-115-0150(3) before the rule becomes effective on March 1, 2024.

The Board's stated rationale for adopting this language relates to the lack of authority in ORS Chapter 689 for pharmacists to diagnose, however, there is no language in statute that explicitly prohibits pharmacists from diagnosing. In fact, there are a variety of generally accepted expectations outlined for pharmacists which might be categorized as providing diagnostic services - and without specific legislative directive prompting the need for this prohibition to diagnose in rule, we are concerned this new language will conflict with existing practice and result in more confusion than clarity.

While "diagnose" is not defined in ORS Chapter 689 or in the adopted rule, it does appear in ORS Chapter 677 and is defined as, "to examine another person in any manner to determine the source or nature of a disease or other physical or mental condition, or to hold oneself out or represent that a person is so examining another person. It is not necessary that the examination be made in the presence of such other person; it may be made on information supplied either directly or indirectly by such other person."[1] While diagnosis is not the primary role of a pharmacist, there are certain functions within the current scope of practice for pharmacists that may fall within this definition.

The petitioner has enumerated several examples related to the pharmacists' role in interpreting diagnostic information and results from point of care testing, which outline ways in which this rule would conflict with existing care that is appropriate and crucial for pharmacists to deliver. The benefit of these services being available in the pharmacy setting is undeniable - in facilitating care that is necessary to improve health outcomes for individuals, minimizing contagion, and supporting cost and workforce efficiency within the larger health care system. Despite being critical services of great benefit to patients as well as other health care providers, the administration and interpretation of diagnostic tests by pharmacists will be subject to scrutiny under the new rule (jeopardizing equitable access).

Given the ambiguity in the definition of "diagnose", there are many situations in which a pharmacist may not be able to continue critical services. For example, pharmacists are explicitly authorized to provide immunizations to certain populations. Though uncommon, adverse reactions to vaccines are possible. As an example of the safety

[1] https://www.oregonlegislature.gov/bills_laws/ors/ors677.html

precautions put in place to ensure any adverse reaction can be appropriately managed in a pharmacy setting, administration of COVID-19 vaccination requires a 15-minute observation period. Pharmacists are trained to recognize the signs of an adverse reaction, and administer treatment or lifesaving intervention in the event of such a reaction. Doing so requires professional medical judgment that an adverse reaction is occurring, which might be considered "diagnosing" the patient. In this example, it is well within the scope of the pharmacist's practice to assess the situation ("diagnose" the adverse reaction and associated medical needs) and take steps necessary to act in the best interest of the patient. The FDA recognized the important role pharmacists have played in the pandemic and the need to grant federal authority to pharmacists to expand access to Paxlovid, which should be taken within 5 days of symptom onset. Our pharmacies were critical to dispensing Paxlovid and providing immediate access to high risk patients to prevent death and serious illness - as well as avert costs to the healthcare system associated with hospitalization. Without the ability to access these key services in the pharmacy setting, patients may encounter delays in life saving interventions or forgo them altogether due to the unwarranted barriers they face.

In addition to conflicting with current and appropriate practice, language prohibiting "diagnosis" may introduce hesitation from pharmacists in providing necessary and reasonable care. Rather than clarifying the pharmacist's role, this rule creates confusion. While the pharmacists' scope is well understood, it is unreasonable to anticipate every action that could be interpreted as falling under the umbrella of diagnosis - and the ambiguity as to what might be classified as "diagnosing" may prevent pharmacists from providing certain services due to liability concerns. Lack of access to services provided by pharmacists will be detrimental to health outcomes for patients, and disproportionately impact low-income individuals and residents of rural areas who rely on access to safety net services and community pharmacists to navigate their immediate health needs. Pharmacists are among the most accessible healthcare providers, with expertise in providing medical advice and interpreting medication responses and adverse reactions - resulting in improved outcomes. Removing their ability to perform the services for which they are trained will harm, not protect the public health, safety, and welfare outlined as central in the Board's mission statement - particularly in pharmacy deserts that most often disproportionately impact BIPOC communities.

Language referencing a prohibition of pharmacist to diagnose in OAR 855-115-0150(3) is narrowly constructed and unnecessarily restrictive, and has the potential to limit functions currently within the pharmacist's scope of practice - as "diagnose" may be interpreted broadly and encompass services which are appropriate for pharmacists to perform. If OAR 855-115-0150(3) becomes effective as currently written, language will not only conflict with provisions outlined within the pharmacist's responsibility, but will restrict patient access to critical services and unnecessarily raise liability concerns related to services which are within the pharmacists' scope.

We support the petition to repeal language in OAR 855-115-0150(3) that prohibits a pharmacist from diagnosing. The need for including this language in rule is unclear, and we look forward to further consideration of this matter when the Board convenes in December. Please do not hesitate to contact Laura Blanke at laura.blanke@multco.us or 503-545-9576 if you have questions or if we can be of any assistance.

Sincerely,

Michele Koder, PharmD, Pharmacy Director, Multnomah County Community Health Center
Bernadette Thomas, APRN, DNP, MPH, Chief Clinical Officer, Multnomah County Community Health Center
Amy Henninger, MD, Primary Care Medical Director, Multnomah County Community Health Center
Charlene Maxwell, FNP, DNP, Medical Director, Multnomah County Community Health Center

From: Laura Blanke
To: PHARMACY RULEMAKING * BOP
Subject: Public Comment on Oregon Board of Pharmacy Rule OAR 855-115-0150(3)
Date: Tuesday, November 14, 2023 8:47:29 AM
Attachments: Response to Oregon Board of Pharmacy Rule OAR 855-115-0150(3)_Multnomah County.pdf

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To The Members of the Oregon Board of Pharmacy -

Thank you for the opportunity to provide public comment related to the petition to repeal language in OAR 855-115-0150(3) Pharmacist: Prohibited Practices. Please find the response from the Multnomah County Health Center attached, and please do not hesitate to contact me if you have questions or need additional information.

Thanks again!

Laura Blanke, MPH (*she/her*)
Strategy, Policy & Research Analyst
Community Health Center
Multnomah County Health Department

 This email was encrypted for your privacy and security

From: Andrew Albanese
To: PHARMACY RULEMAKING * BOP
Subject: OSHP Testimony - Prohibitive Practices_New Rule 855_155_0150
Date: Wednesday, November 15, 2023 4:22:35 PM

November 15, 2023

Dear Members of the Oregon State Board of Pharmacy,

Thank you for your time considering OSHP's testimony.

OSHP would like to express our deep concerns regarding the recent rule change in 855-155-0150 that prohibits pharmacists from diagnosing medical conditions. We believe this rule change is detrimental to patient care, and want to emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

For more information please refer to Ryan Wargo’s letter that provides detail outlining the significant, negative impact this rule change will have on the practice of pharmacy in Oregon.

We urge the Board to reconsider this rule change and continue the status quo that allows pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Sincerely,

Andrew Albanese OSHP LRAC Chairman

From: Pamela Becker
To: PHARMACY RULEMAKING * BOP
Subject: Pharmacist diagnosing
Date: Monday, November 13, 2023 6:17:37 PM

Dear Board of Pharmacy members,
I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be **clinically devastating to patient safety.**

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted >42 million COVID-19 tests”. Authors estimate that pharmacists “averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.” 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Sent from my iPhone

From: PAT Hubbell
To: PHARMACY RULEMAKING * BOP
Subject: Diagnose repeal
Date: Wednesday, November 15, 2023 8:05:12 AM
Attachments: Outlook-bey450mn.png

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

Dear Board of Pharmacy members,

I am requesting a **repeal** to rule 855-115-0150(3) for Prohibited Practices, that state "Pharmacists Must Not: Diagnose." I appreciate the process to work through fixing this new rule. If left unchanged it will impact every pharmacist and add another barrier to serving patients effectively.

Pharmacists are the only front-line healthcare professionals that patients have direct access to without disturbingly long wait times for other healthcare providers. Pharmacists have been proven to demonstrate outstanding stewardship of all aspects of our professional abilities.

Let pharmacists continue to be an integral part of the healthcare team and serve Oregonians the best way possible.

We look forward to your discussion of this request at the December meeting. Thank you again for working with us to recognize pharmacist's current role in serving the citizens of Oregon.

Pat Hubbell, RPh, Owner
Oregon State Pharmacists Association President Elect
Portland Retail Druggist Association Spokesperson

Brooklyn Pharmacy
3131 SE Milwaukie Ave
Portland, OR 97202
P: 503-234-3488 - F: 503-235-0373
pat@brooklynpharmacyrx.com


BROOKLYN
PHARMACY

November 1, 2023

Members of the Oregon Board of Pharmacy
Cc: Mr. Jamal T. Fox - Executive Director
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Subject: Support for Repeal of OAR 137-001-0070(3) Pharmacist: Prohibited Practices

Dear Members of the Oregon Board of Pharmacy:

I'll be first to say, the term diagnose is a loaded term across healthcare. While simple on the surface, a diagnosis *can* have cascading impacts regarding billing, insurance, etc. That said, I write you to momentarily forget about your conceived notion of what defines a diagnosis – and let's talk about the practice of pharmacy.

For over 100 years, pharmacists have been the most accessible healthcare professionals across Oregon. Nearly every person in this state has walked up to a pharmacy and counter and asked, "I'm congested. Can the pharmacist help me find something?"

For over 100 years, that answer has been yes. Now, with OAR 137-001-0070(3), a reasonable pharmacists will conclude that helping that person appears to be a prohibited practice for pharmacists.

For over 100 years, pharmacists have been relied upon to ask the pertinent questions to determine if an over-the-counter (OTC) product would be indicated. In many cases, a pharmacist will recommend an OTC product. In other cases, the symptoms that they see, or the symptoms described by the patient, don't fit an OTC product causing them to refer them to their healthcare provider.

However – in order to make a conclusion about what product best suits their issue, we must come to a conclusion about what their problem is.

Merriam-Webster defines a diagnosis as "the art or act of identifying a disease from its signs and symptoms."[1] While we might split hairs on the definition of diagnose in healthcare, as described above, diagnosing has been an absolute core part of pharmacy for as long as there have been pharmacists.

With the implementation of OAR 137-001-0070(3), a pharmacist will violate administrative rule in Oregon by helping to figure out if someone has allergies or has a cold, by helping someone that has visible lice but hasn't been to their physician, or by helping hasn't had a bowel movement in three days for the first time in their life.

Pharmacists have been stewards of diagnosing over this entire period – understanding when they should say something definitive like "you have lice" (a diagnosis), something less definitive such as "I think you might have allergies, try cetirizine for a week, and contact your doctor if symptoms persist or get worse" (a diagnosis), and even definitive when the potential diagnosis is out of their scope by saying "you should probably seek medical attention right now" when a 70 year old male presents with shortness of breath & chest pain that radiates down their left arm (which.. they've likely made a preliminary diagnosis in their head while calmly telling that person that they probably aren't a candidate for an OTC therapy).

1- Merriam-Webster. (n.d.). Diagnose. In Merriam-Webster.com dictionary. Retrieved November 1, 2023, from https://www.merriam-webster.com/dictionary/diagnose

I get that there's nuance around the term diagnose. I also get that there isn't explicit direction that pharmacists can diagnose in Oregon statute. But, as described above, we have 100 years of precedent that states that diagnosing is within our scope and we need to acknowledge that, continue that, and celebrate the impacts on access that it's had on the state of Oregon.

Thank you,

Dr. Kevin Smith, PharmD, RPh

Portland, OR

From: Kevin Smith
To: PHARMACY RULEMAKING * BOP
Subject: Public Comment Submission: OAR 137-001-0070(3) Pharmacist: Prohibited Practices
Date: Thursday, November 2, 2023 12:58:50 PM
Attachments: image001.png
Request to Repeal OAR 137-001-0070.pdf

> You don't often get email from kevin.smith@prescryptive.com. Learn why this is important

Good afternoon Oregon Board of Pharmacy staff,

Please see attached letter for my public comment supporting the repeal of OAR 137-001-0070(3) Pharmacist: Prohibited Practices.
Please let me know if you have any issues with opening the letter, etc.

Thank you,
-Kevin Smith

--

Kevin Smith, PharmD | Principal Product Manager
Phone: (425) 655-2245
www.prescryptive.com

November 15, 2023

Dear Members of the Oregon State Board of Pharmacy,

I hope this letter finds you well. I am writing to express my deep concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is detrimental to patient care, and I would like to contest it on several grounds.

First and foremost, I must emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patient access to care and may disrupt vital test-to-treat programs and hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. As an example, the COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers, causing delays in treatment and increasing the burden on an already strained healthcare system.

Additionally, the prohibition of diagnosis via protocol is also at odds with the intent of Oregon's Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements routinely order, interpret, and monitor laboratory values such as blood glucose levels, cholesterol levels, and urine albumin-creatinine ratio results when referred for diabetes management. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management of comorbid complications such as hyperlipidemia, kidney disease, and cardiovascular disease when pharmacists are referred patients for the management of diabetes. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their, and the diagnostic providers, scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service, in abundance, and without issue for decades.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Professionally,

Ryan Wargo, PharmD, BCACP

From: Wargo, Ryan J :LSO Mgr Pharmacy
To: PHARMACY RULEMAKING * BOP
Subject: Regarding invitation for Public Comment on OAR 855-115-0150(3)
Date: Wednesday, November 15, 2023 2:44:01 PM
Attachments: Prohibitive Practices_New Rule 855_155_0150.pdf

Oregon State Board of Pharmacy,

Please the attached letter for comment on OAR 855-115-0150(3) Pharmacist: Prohibited Practices. Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Professionally,

Ryan Wargo, PharmD, BCACP
Manager - Ambulatory Pharmacy Services
Legacy Health
2225 NW Northrup St, Room 317
Portland, OR 97210
Phone: 503-415-5865

From: Santon Shagavah
To: PHARMACY RULEMAKING * BOP
Subject: Prohibiting Practice Diagnosing Letter.
Date: Wednesday, November 15, 2023 1:16:32 PM

Santon Shagavah

6907 SE 47TH AVE, PORTLAND, OR 97206. santon.shagavah@multco.us. 11/15/2023

Oregon State Board of Pharmacy 800 NE Oregon Street, Suite 150 Portland, OR 97232

Dear Members of the Oregon State Board of Pharmacy,

I hope this letter finds you well. I am writing to express my deep concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

First and foremost, I must emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patient access to care. It will hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements routinely order, interpret, and monitor laboratory values such as blood glucose levels, cholesterol levels, and urine albumin-creatinine ratio results for referred for diabetes management. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

This rule change may disrupt vital test-to-treat programs. The COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers, causing delays in treatment and increasing the burden on an already strained healthcare system.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon’s Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management for conditions such as hyperlipidemia, kidney protection, and cardiovascular risk when pharmacists are referred patients for the management of diabetes. These collaborative agreements

rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service, in abundance, and without issue for decades.

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Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Sincerely,

Santon Shagavah, Clinical Pharmacist, Oregon Licensed Pharmacist

 This email was encrypted for your privacy and security

From: Melissa Netland
To: PHARMACY RULEMAKING * BOP
Subject: "not allowed to diagnose"
Date: Thursday, November 9, 2023 7:39:29 AM

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be clinically devastating to patient safety.

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted 42 million COVID-19 tests”. Authors estimate that pharmacists “averted 1 million deaths, 8 million hospitalizations, and $450 billion in health care costs.” The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19". Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Please do not take away our ability to provide immediate access to critical health care,

Sincerely,

James and Melissa Netland, Pharm BS, RPH's
Stayton Pharmacy and Sublimity Pharmacy owners

November 10, 2023

To Whom It May Concern

Dear Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be **clinically devastating to patient safety.**

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted >42 million COVID-19 tests”. Authors estimate that pharmacists “averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.” 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

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Victor J Abreu

Victor Abreu, PharmD
Community-Based Pharmacy Resident
Oregon State University College of Pharmacy
Pronouns: he/him
abreuniv@oregonstate.edu 787.536.7788

From:	Abreu Nicolas, Victor J
To:	PHARMACY RULEMAKING * BOP
Subject:	Comments to repeal the rule that states, "Pharmacists must not: diagnose."
Date:	Friday, November 10, 2023 8:40:52 AM
Attachments:	lettert members to BOP.docx

Hello,

I'm attaching my thoughts regarding the rule-making in question

Best,
Victor

Victor Abreu, PharmD
Community-Based Pharmacy Resident
Oregon State University College of Pharmacy
Pronouns: he/him
abreuniv@oregonstate.edu 787.536.7788

From:	William Marais
To:	PHARMACY RULEMAKING * BOP
Subject:	Request to repeal the new rule 55-115-0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose"
Date:	Tuesday, November 14, 2023 6:10:29 PM

Dear Board of Pharmacy members, I am writing to you today to request a repeal to the new rule 55-115-0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose". If you don't X this rule, it will up-end pharmacy services in Oregon and it will be clinically devastating to patient safety. All pharmacists are proficient in utilizing diagnostic information in their practice . They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or INR's for patients on anticoagulants These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care test as valuable decisions support tools, For instance the pharmacist can quickly rule out a bacterial or viral infection helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use. The value of point of care tests was clearly established during the covid-19 pandemic. A recent study quantifying the contributions of Pharmacists during the pandemic found that pharmacists across the country conducted more than 42 million COVID- 19 tests. Authors estimate that pharmacist averted more than 1 million deaths, more than 8 million hospitalizations and $450 billion in healthcare costs . The FDA recognized the capability of Pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of covid-19 ". Now the board has revoked the state protocol on the grounds that pharmacist cannot diagnose. As a result patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription. Perhaps one of the greatest disruptions to care is the conflict in rule i and statute in order for pharmacist to participate in Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV / Syphilis / Treponemal / Chlamydia / Gonorrhea / Hepatitis B, and renal function, By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented

Kind Regards

William Marais RPh

From: Brian Mayo
To: PHARMACY RULEMAKING * BOP
Subject: Public comments for diagnose repeal
Date: Wednesday, January 24, 2024 9:32:08 AM
Attachments: 2024 January rulemaking letter with comments.pdf

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Hi Rachel,

Happy New Year! I hope you had a good holiday season!

I've attached a copy of our written comments to this email.

See you soon!

Brian

Brian Mayo
Executive Director
Oregon State Pharmacy Association
Office: (503) 582-9055
brian@oregonpharmacy.org | www.oregonpharmacy.org
Leading Pharmacy, Advancing Healthcare!

Lorri Walmsley, RPh., FAzPA
Director, Pharmacy Affairs
Walgreen Co.
5330 E. Washington St, Ste. 105
Phoenix, AZ 85034
p: 602-214-6618
lorri.walmsley@walgreens.com

November 20th, 2023
Oregon State Board of Pharmacy
Attention: Jamal Fox, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232
Via Email: pharmacy.rulemaking@bop.oregon.gov

RE: Divisions 115, and 125 – Pharmacists and Pharmacy Technicians

Dear Executive Director Fox 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 ability for licensees and registrants of the board, as well as the general public, to clearly understand the rules is paramount to ensuring public health and safety. We ask the board to review our comments, concerns, and suggested edits to the proposed rules.

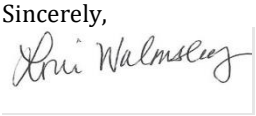
Walgreens again commends the board for its discussion in its previous meetings regarding OAR 855-115-0001(3) 'Applicability'. We thank the board members for continuing to review stakeholder feedback and ensure that quality services from pharmacists residing out of state can continue. However, Walgreens continues to have critical concerns that the proposed language could be interpreted to limit the ability of licensed pharmacists working in a non-resident pharmacy to serve patients in Oregon. There are qualified, licensed, and trained pharmacists nationwide providing specialized care to patients in Oregon, and without their expertise and availability, patients in Oregon will be left to navigate their complex disease states without them. Allowing licensed Oregon non-resident outlets with non-Oregon licensed pharmacists the ability to provide a patient's consultation and other remote pharmacy services whether or not they are part of the dispensing, delivering, or distribution process, is key to ensuring patients in Oregon continue to receive quality, safe, and timely pharmaceutical care. Additionally, there are licensed Oregon non-resident outlets that perform processing tasks (data entry, data review, DUR, and MTM services) without dispensing the final product to patients in Oregon. This rule remains unclear. We ask the board to provide clarity and ensure the public fully understands the intent of this rule. Would pharmacists be allowed to continue to provide services in non-resident licensed outlets without holding an individual Oregon pharmacist license?

If the rule is to be interpreted that there is a requirement that all non-resident pharmacists must be associated with the dispensing process to an Oregon patient or must hold an Oregon license, massive amounts of work would be forced back into Oregon-located pharmacies. Currently, many organizations, including community and health system pharmacies, have safely removed many aspects of prescription processing and patient care services to support the workload of in-state pharmacy teams and consequently have been able to increase access to local patient services like immunizations and health testing. Walgreens requests the board to review the stricken language below and ensure that there is no ambiguity on how this rule could be interpreted.

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 Page 2 of 3 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 working for 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).

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,



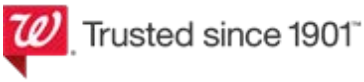
Lorri Walmsley, RPh, FAzPA

From:	Kroeger, Victoria
To:	PHARMACY RULEMAKING * BOP
Cc:	Walmsley, Lorri
Subject:	Walgreens Comments on Proposed Regulations
Date:	Wednesday, January 24, 2024 11:09:09 AM
Attachments:	image001.png Oregon Comment Letter January 2024 Div 115.pdf

Hello,

Please see attached comments on behalf of Walgreens.

Thank you,
Victoria Kroeger, PharmD, RPh
Manager, State Pharmacy Affairs
Walgreen Co.|7700 NE Ambassador Place #103|Portland|OR 97220
M:971-200-9158|F: 971 230 0559
Connect with me: www.linkedin.com/in/victoria-g-kroeger
She/Her why this matters



Division 115: Pharmacists (Protocol Compendium-Vaccines)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds Vaccine Protocols to Protocol Compendium

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Temporarily adds vaccine protocols to protocol compendium and adopts each protocol as a standard adopted by reference.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): OAR 855-115-0345 was adopted by the board in August 2023, to be effective 3/1/2024. Due to Oregon Administrative Rules Database (OARD) filing limitations, the board is unable to amend OAR 855-115-0345 until on/after 3/1/2024. A temporary rule filed and effective 3/1/2024 will permit the protocols to be effective on the same date as the rule becomes effective ensuring there is not a gap in the Pharmacists ability to provide vaccines to the public. Failure to implement immunization protocols in OAR 855-115-0345 may result in compromised patient access and care, posing a significant risk to public health by leaving individuals vulnerable to preventable diseases and potentially overwhelming other healthcare providers.

Documents Relied Upon per ORS 183.335(2)(b)(D):

Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway

Standard Protocol for All Vaccines: Managing Adverse Reactions

Cholera

Coronavirus 19

Haemophilus Influenzae type b

Hepatitis A containing vaccines

Hepatitis B containing vaccines

Human Papillomavirus

Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024

Influenza Live Attenuated Influenza Vaccine 2023-2024

Japanese Encephalitis

Measles, Mumps & Rubella containing vaccines

Meningococcal containing vaccines

Pneumococcal

Polio

Rabies

Respiratory Syncytial Virus

Tetanus, Diphtheria containing vaccines

Typhoid

Varicella containing vaccines

Yellow Fever

Zoster

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-115-0345: Proposed amendments add vaccine protocols to the compendium.

- History of rule package review
  - The board will complete a 1st review of this rule at the February 2024 board meeting.

- Highlights/Markup
  - Highlights- None, 1st review
  - **Mark~~up~~** – None, new rule

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)~~.~~**; and**

(h) Vaccines:

(A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 2/2024);

(B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 2/2024);

(C) Cholera (v. 2/2024);

(D) Coronavirus 2019 (v. 2/2024);

(E) Haemophilus Influenza type b (v. 2/2024);

(F) Hepatitis A containing vaccines (v. 2/2024);

(G) Hepatitis B containing vaccines (v. 2/2024);

(H) Human Papillomavirus (v. 2/2024);

(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 2/2024);

(J) Influenza - Live Attenuated Influenza Vaccine 2023-24 (v. 2/2024);

(K) Japanese Encephalitis (v. 2/2024);

(L) Meningococcal containing vaccines (v. 2/2024);

(M) Measles Mumps & Rubella containing vaccines (v. 2/2024);

(N) Pneumococcal (v. 2/2024);

(O) Polio (v. 2/2024);

(P) Rabies (v. 2/2024);

(Q) Respiratory Syncytial Virus (v. 2/2024);

(R) Tetanus Diphtheria containing vaccines (v. 2/2024);

(S) Typhoid (v. 2/2024);

(T) Varicella containing vaccines (v. 2/2024);

(U) Yellow fever (v. 2/2024); and

(V) Zoster (v. 2/2024).

[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

Division 020: Pharmacist Prescriptive Authority (Protocol Compendium)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Temporarily suspends Division 020 Protocol Compendium

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes to temporarily suspend OAR 855-020-0300 Protocol Compendium.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): To avoid a conflict with newly adopted OAR 855-115-0345 taking effect on 3/1/2024, the board must temporarily suspend OAR 855-020-0300, effective 2/29/2024 at 11:59PM. Due to Oregon Administrative Rules Database (OARD) filing limitations, the board was unable to send OAR 855-020-0300 to January 24, 2024 rulemaking because the newly added vaccine protocols weren't effective until 2/1/2024. A temporary suspension is necessary because this rule cannot be in effect at the same time as OAR 855-115-0345. All remaining Division 020 rules are currently in the process of being repealed.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 115 Pharmacists Permanent Administrative Order **https://www.oregon.gov/pharmacy/Documents/Div_115_Pharmacists_BP_16-2023TrackedChanges.pdf**

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Temporarily suspends OAR 855-020-0300 Protocol Compendium. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replaces Division 020. This rule needs to be suspended, effective 2/29/2024 to eliminate conflict with the Protocol Compendium permanently adopted in OAR 855-115-0345 effective 3/1/2024. In addition, OAR 855-020-0300 references other rules within Division 020. Since these supporting rules have already been repealed, keeping OAR 855-020-0300 in effect would leave it incomplete and potentially unenforceable.

- **History of rule package review**
  - The board will complete a 1st review of this rule at the February 2024 board meeting.

- **Highlights/Markup**
  - Highlights- None, 1st review
  - Markup – None, repeal

Division 020
PHARMACIST PRESCRIPTIVE AUTHORITY

~~855-020-0300~~
~~Protocol Compendium~~

~~A Pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium:~~

~~(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 (NRT) 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);~~

~~(g) Contraception (v. 06/2023); and~~

~~(h) Vaccinations:~~

~~(A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 2/2024);~~

~~(B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 2/2024);~~

~~(C) Cholera (v. 2/2024);~~

~~(D) Coronavirus 2019 (v. 2/2024);~~

~~(E) Haemophilus Influenza type b (v. 2/2024);~~

~~(F) Hepatitis A containing vaccines (v. 2/2024);~~

~~(G) Hepatitis B containing vaccines (v. 2/2024);~~

~~(H) Human Papillomavirus (v. 2/2024);~~

~~(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 2/2024);~~

~~(J) Influenza - Live Attenuated Influenza Vaccine 2023-24 (v. 2/2024);~~

~~(K) Japanese Encephalitis (v. 2/2024);~~

~~(L) Meningococcal containing vaccines (v. 2/2024);~~

~~(M) Measles Mumps & Rubella containing vaccines (v. 2/2024);~~

~~(N) Pneumococcal (v. 2/2024);~~

~~(O) Polio (v. 2/2024);~~

~~(P) Rabies (v. 2/2024);~~

~~(Q) Respiratory Syncytial Virus (v. 2/2024);~~

~~(R) Tetanus Diphtheria containing vaccines (v. 2/2024);~~

~~(S) Typhoid (v. 2/2024);~~

~~(T) Varicella containing vaccines (v. 2/2024);~~

~~(U) Yellow fever (v. 2/2024);~~

~~(V) Zoster (v. 2/2024).~~

~~[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, ORS 689.696~~

Division 001: Procedural Rules (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 001; Procedural Rules

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 001 Procedural Rules in its entirety, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Div 104 Universal Rules Permanent Administrative Order

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 proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s). The proposed rule repeal will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 104 Universal rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 001 Procedural Rules in its entirety. The board adopted Division 104 Universal Rules in August 2023, which replaces Division 001. Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.

~~Division 1~~
~~PROCEDURAL RULES~~

~~855-001-0000~~
~~Notice of Proposed Rule~~

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:

(1) In a manner established by rule adopted by the board under ORS183.341(4), which provides a reasonable opportunity for interested persons to be notified of the agency's proposed action;

(2) In the bulletin referred to in ORS 183.360 at least 21 days prior to the effective date;

(3) To persons who have requested notice pursuant to ORS183.335(8) at least 28 days before the effective date; and

(4) To persons specified in ORS 183.335(15) at least 49 days before the effective date; and

(5) 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; and

(a) Oregon State Pharmacy Association;

(b) Oregon Society of Health System Pharmacists;

(6) To the Associated Press and the Capitol Press Room.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 183.335

855-001-0005
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

855-001-0012
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~~

~~855-001-0016~~
~~Filing Exceptions and Argument to the Board~~

~~After a proposed order has been served on a party, the board must notify the party when written exceptions must be filed to be considered by the board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-001-0017~~
~~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~~

~~855-001-0035~~
~~Duty to Cooperate~~

~~(1) Applicants, licensees, and registrants must comply with all board requests, including responding 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~~

~~855-001-0040~~
~~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; and~~

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

~~(3) All records and documents required by ORS 475, ORS 689, and OAR 855:~~

~~(a) Must be stored on-site for 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 on-site storage and must be provided to the board upon request within three business days; and~~

~~(c) May be in written or electronic format.~~

~~(4) All licensees and employees must fully comply and cooperate with all questions and requests made by the Compliance Officer at the time of inspection.~~

~~(5) Refusal to allow inspection is grounds for discipline.~~

~~Statutory/Other Authority: ORS 475.125 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

Division 006: Definitions (COPT, CPA, CDTM, Compounding, Counseling, DUR, Intern, Pharmacy Technician, Additional Definitions- Electronically Transmitted Prescription, Tamper-resistant Prescription)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Definitions; Repeals Additional Definitions

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes to amend and revise existing definitions for Certified Oregon Pharmacy Technician (COPT), Counseling, Drug Utilization Review (DUR), Intern and Pharmacy Technician. Moves Tamper Resistant Prescription from OAR 855-006-0015 to OAR 855-006-0005. Proposes repeal of OAR 855-006-0015 including definition for Electronically Transmitted Prescription (ETP).

Documents Relied Upon per ORS 183.335(2)(b)(D):

OAR 855-041-0085 (2008) as referenced in the rule.
https://records.sos.state.or.us/ORSOSWebdrawer/Recordhtml/8158131

Medicaid Tamper-Resistant Prescription Information for State Health Policymakers v. 8/17/2007
https://www.cms.gov/Regulations-and-Guidance/Legislation/DeficitReductionAct/Downloads/Tamperproof.pdf

Division 115 Permanent Administrative Order
https://www.oregon.gov/pharmacy/Documents/Div_115_Pharmacists_BP_16-2023TrackedChanges.pdf

Division 120 Permanent Administrative Order
https://www.oregon.gov/pharmacy/Documents/Div_120_Interns_Preceptors_BP_17-2023TrackedChanges.pdf

Division 125 Permanent Administrative Order
https://www.oregon.gov/pharmacy/Documents/Div_125_Pharmacy_Technicians_BP_18-2023TrackedChanges.pdf

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 proposed rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed amendments have no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Proposed rule amendments have no additional economic impact on state agencies, units of local government, or the public.
(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.
(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.
(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No.

Intern- The board directed staff to convene a Workgroup for Intern rules consisting of Subject Matter Experts with expertise related to compounding to assist with the development of proposed rules/amendments. The new Intern rules in Division 120 were permanently adopted by the board in August 2023 to be effective 3/1/2024.

Certified Oregon Pharmacy Technicians / Pharmacy Technicians- The board did not direct staff to convene a workgroup or RAC for the proposed definitions. New rules for COPT/PT in Division 125 were permanently adopted by the board in August 2023 to be effective 3/1/2024.

Counseling, DUR, ETP, Tamper Resistant Prescription – The board did not direct staff to convene a workgroup or RAC. New rules for Pharmacist Counseling and DUR were adopted in Division 115 by the board in December 2023 and August 2023 respectively to be effective 3/1/2024. Tamper Resistant definition is being relocated to Definitions in OAR 855-006-0005. ETP is no longer needed.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-006-0005: Proposed amendments are necessary to ensure clarity for licensees and registrants. Proposes amending "Certified Oregon Pharmacy Technician" to remove requirements for a specialized education program and reference to clerical duties. Proposes adding definition for "Counseling" and "Drug Utilization Review or (DUR)". Proposes to repeal definitions for "Oral Counseling", "Participation in Drug Selection and Drug Utilization Review", "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices", and "specialized education program". Proposes amending "Pharmacy Technician" by removing reference to specialized education program. Proposes adding definition of "Intern" that was previously adopted in OAR 855-120-0005 effective 3/1/2024. Proposes moving Tamper Resistant Prescription from OAR 855-006-0015.
OAR 855-006-0015: To ensure clarity for licensees and registrants, moves Tamper-resistant Prescription to OAR 855-006-0005 and repeals definition for Electronically Transmitted Prescription from OAR 855-006-0015.

Division 006
DEFINITIONS

855-006-0005 *View current rule on SOS website *View 12/22/2023 Notice of Proposed Rulemaking
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 who has taken and passed a national pharmacy technician certification examination offered by the Pharmacy Technician Certification Board (PTCB) or National Healthcareer Association (NHA) and is licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board.

(9) “Clinical Pharmacy Agreement” means an agreement between a Pharmacist or pharmacy and a health care organization, or a physician as defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010 that permits the Pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization, or physician or naturopathic physician.

(10) "Collaborative Drug Therapy Management" means the participation by a Pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to 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 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.

(11) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(a) 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 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) "Counseling" or "Counsel" means an oral, electronic or 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.

(15) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(16) "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.

(17) "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.

(18) "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.

(19) "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.

(20) "Entry system" enables control of access to a secured area.

(21) “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.

(22) "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.

(23) “Health care interpreter” has the meaning given that term in ORS 413.550.

(24) “Health care interpreter registry” means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.

(25) “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.

(26) “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).

(27) "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.

(28) "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.

(29) "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.

(30) “Misbranded” has the same definition as set forth in 21 USC 352 (v. 12/28/2022).

(31) "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.

(32) "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.

(33) "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.

(34) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(35) "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.

(36) “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.

(37) "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.

(38) “Pharmacist” means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.

(39) "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.

(40) “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.

(41) “Practice of pharmacy” is as defined in ORS 689.005.

(42) “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.

(43) "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.

(44) “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.

(45) "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.

(46) “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.

(47) “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.

(48) “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.

(49) “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.

(50) “Still image capture” means a specific image captured electronically from a video or other image capture device.

(51) “Store and forward” means a video or still image record which is saved electronically for future review.

(52) "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.

(53) “Surveillance system” means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

(54) “Tamper-resistant Prescription” means a form for the purpose of issuing a handwritten or typed prescription, intended to be manually delivered to a pharmacy, which has been developed, and formatted to ensure security, integrity and authenticity using currently accepted technologies. Formatted features may include but are not limited to characteristics such as:

(a) The word “void” appears when photocopies are attempted;

(b) Background ink which reveals attempted alterations;

(c) Heat sensitive ink that changes colors;

(d) Penetrating ink to prevent chemical alterations;

(e) A watermark which cannot be photocopied;

(f) Coin reactive ink that reveals word when rubbed with a coin;

(g) Sequential numbering.

(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 689.005, ORS 689.151, ORS 689.155, 2022 HB 4034

~~855-006-0015~~
~~Additional Definitions~~

~~(1) Electronically Transmitted Prescription:~~

~~(a) Where used in this chapter, Electronically Transmitted Prescription (ETP) means a prescription for a drug or medical device issued by a practitioner, who is licensed and authorized to prescribe pursuant to the laws of this state and is acting within the scope of his or her practice, which has been transmitted by an electronic means that may include but is not limited to:~~

~~(A) Transmission by facsimile or hand held digital electronic device to a computer or facsimile;~~

~~(B) Transmission from a computer to another computer;~~

~~(C) Transmission by facsimile to computer; or~~

~~(D) Transmission from a computer to facsimile.~~

~~(b) ETP does not include an oral prescription that has been reduced to writing by a pharmacist pursuant to OAR 855-041-0085 and does not include prescriptions, or drug or device orders written for inpatient use in a hospital.~~

~~(c) For an ETP to be valid, it must contain the name and immediate contact information of the prescriber, and be electronically encrypted or in some manner protected by up-to-date technology from unauthorized access, alteration or use.~~

~~(2) Tamper-resistant Prescription:~~

~~(a) Where used in this chapter, Tamper-resistant Prescription means a form for the purpose of issuing a hand written or typed prescription, intended to be manually delivered to a pharmacy, which has been developed, produced and formatted to ensure security, integrity and authenticity using currently accepted technologies.~~

~~(b) Formatted features may include but are not limited to characteristics such as:~~

~~(A) The word "void" appears when photocopies are attempted;~~

~~(B) Background ink which reveals attempted alterations;~~

~~(C) Heat sensitive ink that changes colors;~~

~~(D) Penetrating ink to prevent chemical alterations;~~

~~(E) A watermark which cannot be photocopied;~~

~~(F) Coin reactive ink that reveals word when rubbed with a coin;~~

~~(G) Sequential numbering.~~

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

Division 010: Board Administration and Policies (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 010; Board Administration and Policies

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 010 Board Administration and Policies rules in its entirety, effective at 11:59PM on 2/29/20024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 102 Board Administration Rules Permanent Administrative Order

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 proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s). The proposed rule repeal will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing was sent to interested parties, some of whom may identify as a small business and had an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 102 Board Administration rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 010 Board Administration and Policies rules in its entirety. The board adopted Division 102 Board Administration rules in August 2023, which replaces Division 010. Division 010 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 102 rules to become effective at 12:00AM on 3/1/2024.

~~Division 10~~
~~BOARD ADMINISTRATION AND POLICIES~~

~~855-010-0005~~
~~Meetings~~

~~(1) The board meetings must be held not less than once every three months as designated by the board.~~

~~(2) The President of the board must have 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, which may include but is not limited to:~~

~~(a) Approval of providers of continuing pharmacy education accredited by the Accreditation Council for Pharmacy Education (ACPE);~~

~~(b) Approval of schools and colleges of pharmacy accredited, accredited with probation, pre-candidate or candidate status by ACPE; and~~

~~(c) Review and adopt standards by reference.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.135, ORS 689.151, ORS 689.185 & ORS 689.255~~

~~855-010-0015~~
~~Individual Commitments~~

~~(1) Board members must be governed by board action and must make no individual commitments or promises on matters of board policies.~~

~~(2) No declaration must be made or vote taken on any question, except at board meetings.~~

~~Statutory/Other Authority: ORS 689 & ORS 183~~
~~Statutes/Other Implemented: ORS 183~~

~~855-010-0016~~
~~Pharmacy Board Member and Public Health and Pharmacy Formulary Advisory Committee Member Compensation~~

~~(1) A board member and Public Health and Pharmacy Formulary Advisory Committee 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 member of the Public Health and Pharmacy Formulary Advisory Committee 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 Public Health and Pharmacy Formulary Advisory Committee 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~~

~~855-010-0018~~
~~Public Health and Pharmacy Formulary Advisory Committee~~

~~(1) The Public Health and Pharmacy Formulary Advisory Committee must consist of:~~

~~(a) Two physicians licensed to practice medicine under ORS 677.100 to 677.228;~~

~~(b) Two advanced practice registered nurses who have prescriptive authority and who are licensed by the Oregon State Board of Nursing; and~~

~~(c) Three Pharmacists licensed by the State Board of Pharmacy, at least one of whom is employed as a community Pharmacist and one of whom is employed as a health system Pharmacist.~~

~~(2) A Pharmacist may submit a concept, on a form prescribed by the board to the committee for consideration, for the development of a protocol or the addition of a drug or device to the formulary.~~

~~(3) The committee must recommend to the board, for adoption by rule, a protocol or 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.~~

~~(4) The committee must periodically review the formulary and protocol compendium and recommend the revisions to the board for adoption by rule.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.645, ORS 689.649 & ORS 689.155~~

~~855-010-0021~~
~~Adoption by Reference~~

~~(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~~

~~855-010-0035~~
~~Board Compliance Program~~

~~The board's Compliance Director and Compliance Officers must be pharmacists licensed in the State of Oregon.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.195~~

~~855-010-0100~~
~~State and Nationwide Criminal Background Checks for Licensure~~

~~(1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure; directors, officers and designated representatives of drug outlets applying for registration; 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; directors, officers and designated representatives of drug outlets applying for registration or renewal of a registration; 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.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205 ORS 181A.210, ORS 181A.215, ORS 670.280, ORS 676.303, OAR 125-007-0200, 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) The following are examples of crimes likely to result in denial unless there are significant mitigating circumstances:~~

~~(A) Aggravated murder;~~

~~(B) Murder;~~

~~(C) Rape I;~~

~~(D) Sodomy I;~~

~~(E) Unlawful sexual penetration I;~~

~~(F) Sexual abuse I~~

~~(j) 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.~~

~~(k) 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 183.413, ORS 183.415, ORS 183.417, ORS 183.425, ORS 183.430, ORS 183.435, ORS 183.440, ORS 183.445, ORS 183.450, ORS 183.452, ORS 183.453, ORS 183.457, ORS 183.458, ORS~~

~~183.459, ORS 183.460, ORS 183.462, ORS 183.464, and ORS 183.470 and in accordance with OAR 855-001-0005, OAR 855-001-0012, OAR 855-001-0016, and OAR 855-001-0017.~~

~~(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~~

~~855-010-0110~~
~~State and Nationwide 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.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205 ORS 181A.210, ORS 125-181A.215 and OAR 125-007-0200, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, and OAR 125-007-0310.~~

~~(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 181A.215 & ORS 676.303~~

~~855-010-0120~~
~~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~~

~~855-010-0130~~
~~Military Spouse or Domestic Partner~~

~~(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 Division 855-019 or OAR 855-025.~~

~~(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 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 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 019: Pharmacists (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 019; Pharmacists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 019 Pharmacist rules, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 115 Pharmacists Permanent Administrative Order

https://www.oregon.gov/pharmacy/Documents/Div_115_Supervision_Counseling_PIC_Qualifications_BP_31-2023TrackedChanges.pd

https://www.oregon.gov/pharmacy/Documents/Div_115_125_RPH_COPT_PT_Admin_Vaccines_BP_30-2023TrackedChanges.pdf

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 proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s). The proposed rule repeal will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.
Describe how small businesses were involved in the development of the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing was sent to interested parties, some of whom may identify as a small business and had an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 115 Pharmacists rules in August, October and December 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 019 Pharmacists rules. The board adopted Division 115 Pharmacists rules in August, October and December 2023 , which replaces Division 019. Division 019 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 115 rules to become effective at 12:00AM on 3/1/2024.

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Division 19

PHARMACISTS

855-019-0100

Application

(1) This Division applies to any pharmacist who is licensed to practice pharmacy in Oregon including any pharmacist located in another state who is consulting, or providing any other pharmacist service, for a patient, pharmacy or healthcare facility in Oregon.

(2) Where so indicated, these rules also apply to an intern who is licensed in Oregon.

(3) Any pharmacist who engages in the practice of pharmacy in Oregon must be licensed by the Board in accordance with the following rules.

(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).

(5) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, 689.155 & 689.255

855-019-0110

Definitions

In this Division of Rules: "Counseling" means an oral or other appropriate communication process between a pharmacist and a patient or a patient's agent in which the pharmacist obtains information from the patient or patient's agent, and, where appropriate, the patient's pharmacy records, assesses that information and provides the patient or patient's agent with professional advice regarding the safe and effective use of the drug or device for the purpose of assuring therapeutic appropriateness.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.005, ORS 689.151 & ORS 689.155

855-019-0120

Licensure

(1) Before licensure as a pharmacist, an applicant must meet the following requirements:

~~(a) Provide evidence from a school or college of pharmacy approved by the board that they have successfully completed all the requirements for graduation and, starting with the graduating class of 2011, including not less than 1440 hours of School-based Rotational Internships as that term is defined in OAR 855-031-0005, and that a degree will be conferred;~~

~~(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. This score is valid for only one year unless the board grants an extension. A candidate who does not attain this score 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 times;~~

~~(c) Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) exam with a score of not less than 75. The applicant may not take the MPJE until they have graduated from a school or college of pharmacy approved by the board. A candidate who does not attain this score 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 times. The MPJE score is valid for 6 months unless extended by the board;~~

~~(d) Complete an application for licensure, provide the board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check; and~~

~~(e) Complete one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority.~~

~~(2) A license, once obtained, will expire on June 30 in odd numbered years and must be renewed biennially.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 2021 HB 2078~~

~~855-019-0122~~
~~Renewal of Licensure as a Pharmacist~~

~~(1) An application for renewal of a pharmacist license must include documentation of:~~

~~(a) Completion of continuing pharmacy education requirements as outlined in OAR 855-135; and~~

~~(b) Payment of the biennial license fee required in OAR 855-110.~~

~~(2) A pharmacist will be subject to an annual criminal background check.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-019-0123~~
~~Liability Limitations for Volunteers~~

~~(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 676.345 remain subject to the Board complaint investigation process articulated in ORS 676.175.~~

~~Statutory/Other Authority: ORS 676.340 & 689.205~~
~~Statutes/Other Implemented: ORS 676.340 & 676.345~~

~~855-019-0124~~
~~Notification: Out-of-State Volunteer Pharmacist~~

~~(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, the 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~~

~~855-019-0125~~
~~Coaching from Board and Staff~~

~~No member or employee of the Board shall discuss the contents of an examination, its preparation or use with any candidate or other person. No member or employee of the Board shall coach a candidate or any other person on materials that may be used in the examination nor shall they accept any fees for any act of assistance that would bear on the examination.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-019-0130~~
~~Licensure by Reciprocity~~

~~(1) An applicant for licensure as a pharmacist by reciprocity must meet the requirements of ORS 689.265 and the following requirements:~~

~~(a) Be a graduate of a school or college of pharmacy approved by the Board;~~

~~(b) Have passed the NAPLEX or equivalent examination with a score of not less than 75;~~

~~(c) Have passed the MPJE with a score of not less than 75;~~

~~(d) Be licensed and in good standing in the state from which the applicant bases the reciprocity application;~~

~~(e) Have either:~~

~~(A) Been engaged in the practice of pharmacy for period of at least one year including a minimum of 1440 hours of work experience as a licensed pharmacist. Evidence supporting this work experience shall be provided at time of application; or~~

~~(B) Met the internship requirements of this state within the one-year period immediately before the date of this application. Evidence from the school or college of pharmacy supporting this internship shall be provided at time of application.~~

~~(2) Licensure as a pharmacist in another state precludes licensure to practice as an intern in the State of Oregon, except an applicant that has been accepted into an Oregon pharmacy residency program or for~~

licensure by examination or by reciprocity who must acquire internship hours to become eligible for licensure, and then only until the required hours have been acquired.

(3) An applicant who has obtained their professional degree outside the United States is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-019-0150.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 689.265

855-019-0140
NAPLEX Score Transfer

(1) An applicant for score transfer must be a graduate of a school or college of pharmacy approved by the Board and must have passed the NAPLEX or equivalent examination with a score of at least 75.

(2) Prior to taking the NAPLEX examination for their initial state of licensure, an applicant must have requested the National Association of Boards of Pharmacy to score transfer their NAPLEX score to Oregon.

(3) An applicant must provide the following documentation:

(a) Oregon Score Transfer Application;

(b) A passport regulation photograph;

(c) A copy of a birth certificate, US passport or naturalization documents, or a foreign passport endorsed with a US visa permitting full time employment;

(d) Evidence of successful completion of all graduation requirements from a school or college of pharmacy approved by the Board.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 689.265

855-019-0150
Foreign Pharmacy Graduates

(1) Foreign Pharmacy Graduates applying for licensure in Oregon must meet the following requirements:

(a) Provide a copy of a valid visa permitting full time employment;

(b) Provide a copy of the original certificate issued by the NABP Foreign Pharmacy Graduate Examination Committee (FPGEC); and

(c) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 91 days. This score shall only be valid for one year unless the Board grants an extension;

~~(d) After having completed the required number of intern hours, pass the MPJE with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 30 days. The MPJE score shall only be valid for 6 months unless extended by the Board.~~

~~(2) An applicant must complete 1440 hours in pharmacy practice as an intern that must be certified to the Board by the preceptors.~~

~~(3) An applicant may not count internship hours or practice as a pharmacist completed outside the United States toward Oregon's internship requirement.~~

~~(4) An applicant may not count internship hours or practice as a pharmacist that is completed before passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE), and either the TOEFL with TSE, or TOEFL (IBT) exams toward Oregon's internship requirement.~~

~~(5) The Board may waive any requirement of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & ORS 689.255~~

~~855-019-0160~~
~~Nuclear Pharmacists~~

~~In order to qualify under these rules as a nuclear pharmacist, a pharmacist shall:~~

~~(1) Meet minimal 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 Pharmaceutical 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~~

~~855-019-0170~~

~~Reinstatement of License~~

~~(1) A pharmacist who fails to renew their license by the deadline may reinstate their license as follows:~~
~~(a) By payment of the license fees and delinquency fees for all years during which the license was lapsed and for the current year; and~~

~~(b) By providing certification of completion of the continuing pharmacy education requirement in OAR 855-135 for all years in which the license was lapsed; and~~

~~(c) If their license has been lapsed for more than one year, pass the MPJE with a score of not less than 75; and~~

~~(d) Complete an application for licensure, provide the board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check.~~

~~(2) A pharmacist in good standing who retired from the practice of pharmacy after having been licensed for not less than 20 years need only pay the annual license fees for the year in which they seek a license, however they must provide certification of completion of continuing pharmacy education requirement in OAR 855-135 for all years since their retirement and pass the MPJE with a score of not less than 75.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & ORS 689.275~~

~~855-019-0171~~

~~Reinstatement of a Revoked or Surrendered License~~

~~A person whose pharmacist license has been revoked or surrendered shall have the right, at reasonable intervals, to petition to the Board in writing for reinstatement of such license. The written petition to the Board shall be made in conjunction with the application process identified in OAR 855-019-0120.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.275~~

~~855-019-0200~~

~~Pharmacist: General Responsibilities~~

~~ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A Pharmacist licensed to practice pharmacy by the board has the duty to use that degree of care, skill, diligence and reasonable professional judgment that is exercised by an ordinarily careful Pharmacist in the same or similar circumstances.~~

~~(1) A Pharmacist is responsible for their own actions; however, this does not absolve the pharmacy from responsibility for the Pharmacist's actions.~~

~~(2) A Pharmacist and pharmacy are responsible for the actions of Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians.~~

~~(3) Only a Pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require reasonable professional judgment of a Pharmacist include but are not limited to:~~

~~(a) Drug Utilization Review;~~

~~(b) Counseling;~~

~~(c) Drug Regimen Review;~~

~~(d) Medication Therapy Management;~~

~~(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;~~

~~(f) Practice pursuant to State Drug Therapy Management Protocols;~~

~~(g) Prescribing a drug or device, as authorized by statute;~~

~~(h) Ordering, interpreting and monitoring of a laboratory test;~~

~~(i) Oral receipt or transfer of a prescription; and~~

~~(j) Verification of the work performed by those under their supervision.~~

~~(4) A Pharmacist must:~~

~~(a) Comply with all state and federal laws and rules governing the practice of pharmacy;~~

~~(b) Control each aspect of the practice of pharmacy;~~

~~(c) Ensure each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;~~

~~(d) Ensure non-Pharmacist personnel only perform duties they are licensed and trained to perform.~~

~~(e) Know the identity of each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction and control at all times;~~

~~(f) Ensure that the supervision of non-Pharmacist personnel does not exceed their capacity to supervise based on the workload and services being provided.~~

~~(g) Conduct themselves in a professional manner at all times and not engage in any form of discrimination, harassment, intimidation, or assault in the workplace.~~

~~(h) Ensure and enforce the drug outlet written procedures for use of Certified Oregon Pharmacy Technicians and Pharmacy Technicians as required by OAR 855-025-0035;~~

~~(i) Ensure the security of the pharmacy area including:~~

~~(A) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;~~

~~(B) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;~~

~~(C) Ensuring that only a Pharmacist has access to the pharmacy when the pharmacy is closed.~~

~~(5) A 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.~~

~~(6) A Pharmacist may permit an Intern under their direction and supervision to perform any task listed in OAR 855-019-0200(3), except that an Intern must not:~~

~~(a) Perform the duties of a Pharmacist until after the Intern has successfully completed their first academic year, and only after successful completion of coursework corresponding to those duties;~~

~~(b) Prescribe a drug or device; or~~

~~(c) Perform final verification or verification as defined in OAR 855-006-0005.~~

~~(7) Each Pharmacist on duty and the PIC is responsible for the conduct, operation, management and control of the pharmacy;~~

~~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~~

~~855-019-0205~~
~~Duty to Report~~

~~(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.~~
~~(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(3) A pharmacist must report to the board within 10 days if they:~~

~~(a) Are convicted of a misdemeanor or a felony; or~~

~~(b) If they are arrested for a felony.~~

~~(4) A pharmacist who has reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting pharmacist must report the conduct without undue delay, but in no event later than 10 working days after the pharmacist learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.~~

~~(5) A pharmacist who reports to a board in good faith as required by section (4) of this rule is immune from civil liability for making the report.~~

~~(6) A pharmacist who has reasonable grounds to believe that any violation of these rules has occurred, must notify the board within 10 days. However, in the event of a significant drug loss or violation related to drug theft, the pharmacist must notify the board within one (1) business day.~~

~~(7) A pharmacist must notify the board in writing, within 15 days of any change in e-mail address, employment location or residence address.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.455~~

~~855-019-0210~~
~~Duties of the Pharmacist Receiving a Prescription~~

~~(1) A Pharmacist must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed or prepared for administration in accordance with the prescribing practitioner's authorization.~~

~~(2) A Pharmacist receiving a prescription is responsible for:~~

~~(a) Using professional judgment in dispensing only pursuant to a valid prescription. A Pharmacist must not dispense a prescription if the Pharmacist, in their professional judgment, believes that the prescription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner includes a clinical associate of the practitioner or any other practitioner acting in the~~

~~practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and issued pursuant to a valid patient-practitioner relationship; and~~

~~(b) Ensuring that the prescription contains all the information specified in Division 41 of this chapter of rules including the legible name and contact phone number of the prescribing practitioner for verification purposes.~~

~~(3) A Pharmacist may refuse to dispense a prescription to any person who lacks proper identification.~~

~~(4) Oral Prescription: Upon receipt of an oral prescription, the Pharmacist must promptly reduce the oral prescription to writing or create a permanent electronic record by recording:~~

~~(a) The date when the oral prescription was received;~~

~~(b) The name of the patient for whom, or the owner of the animal for which, the drug is to be dispensed;~~

~~(c) The full name and, in the case of controlled substances, the address and the DEA registration number, of the practitioner, or other number as authorized under rules adopted by reference under Division 80 of this chapter of rules;~~

~~(d) If the oral prescription is for an animal, the species of the animal for which the drug is prescribed;~~

~~(e) The name, strength, dosage form of the substance, quantity prescribed;~~

~~(f) The direction for use;~~

~~(g) The total number of refills authorized by the prescribing practitioner;~~

~~(h) The written signature or initials or electronic identifier of the receiving Pharmacist or Intern and the identity of the person transmitting the prescription;~~

~~(i) The written or electronic record of the oral prescription must be retained on file as required by Division 41 of this chapter of rules, and in the case of controlled substances, under rules adopted by reference in Division 80 of this chapter of rules.~~

~~(5) Facsimile Prescription: Upon receipt of a facsimile prescription, the Pharmacist must be confident that the prescription was sent by an authorized practitioner or practitioner's agent, and they must verify that:~~

~~(a) The facsimile contains all the information specified in Division 41 and Division 80 of this chapter of rules; and~~

~~(b) The facsimile prescription is not for a Schedule II controlled substance unless so permitted under federal regulations or Division 80 of this chapter of rules; and~~

~~(c) If the facsimile prescription is for a controlled substance, the prescription contains an original, manually signed signature of the prescriber. In this rule, manually signed specifically excludes a signature stamp or any form of digital signature unless permitted under federal regulations.~~

~~(6) Electronic Prescription: Before filling a prescription that has been received electronically, the Pharmacist must ensure that:~~
~~(a) The prescription was originated by an authorized practitioner or practitioner's agent;~~

~~(b) The prescription contains all the information specified in Division 41 of this chapter of rules.~~

~~(c) The prescription is not for a controlled substance unless permitted by federal regulations.~~

~~(7) The Pharmacist must ensure that a written prescription that is hand-carried or mailed into the pharmacy contains an original manually-signed signature of the prescribing practitioner or practitioner's agent.~~

~~(8) Computer Transfer of Prescription Information between Pharmacies: A Pharmacist that transmits or receives prescription information to or from another pharmacy electronically must ensure as appropriate:~~

~~(a) The accurate transfer of prescription information between pharmacies;~~

~~(b) The creation of an original prescription or image of an original prescription containing all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability and that the Pharmacist will use in verifying the prescription;~~

~~(c) The prescription is invalidated at the sending pharmacy; and~~

~~(d) Compliance with all relevant state and federal laws and rules regarding the transfer of controlled substance prescriptions.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508 & 2022 HB 4034~~

~~855-019-0220~~
~~Drug Utilization Review (DUR)~~

~~(1) A pharmacist shall maintain a record for each patient that contains easily retrievable information necessary for the pharmacist to perform a DUR and to identify previously dispensed drugs at the time a prescription or drug order is presented for dispensing or preparing for administration. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:~~

~~(a) Full name of the patient for whom the drug is prescribed;~~

~~(b) Address and telephone number of the patient;~~

~~(c) Patient's gender, age or date of birth;~~

(d) Chronic medical conditions and disease states of the patient;

(e) A list of all drugs or devices the patient is currently obtaining at that pharmacy showing the name of the drug or device, strength of the drug, the quantity and date received, and the name of the prescribing practitioner;
(f) Known allergies, adverse drug reactions, and drug idiosyncrasies;

(g) Pharmacist comments relevant to the individual's drug therapy, including any other information specific to that patient or drug; and

(h) Additional information, which may relate to DUR, or for the monitoring of the patient as appropriate.

(2) Patient records shall be maintained for at least three years.

(3) The pharmacist or intern shall perform a DUR prior to dispensing or preparing for administration any prescription or refill.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 689.155

855-019-0230
Counseling

(1) The Pharmacist or Intern must orally counsel the patient or patient's agent on the use of a drug or device as appropriate:

(a) The Pharmacist or Intern must counsel the patient on a new prescription and any changes in therapy, including but not limited to a change in directions or strength, or a prescription which is new to the pharmacy;

(b) Only the Pharmacist or Intern may accept a patient's or patient's agent's request not to be counseled. If, in their reasonable professional judgment, the Pharmacist or Intern believes that the patient's safety may be affected, the Pharmacist or Intern may choose not to release the prescription until counseling has been completed;

(c) The Pharmacist or Intern that provides counseling or accepts the request not to be counseled must document the interaction;

(d) A Pharmacist must not allow non-Pharmacist personnel to release a prescription that requires counseling, or accept the request not to be counseled;

(e) For a prescription delivered to a patient, except at a pharmacy or a pharmacy prescription locker, the Pharmacist must offer in writing, to provide direct counseling and information about the drug, including information on how to contact the Pharmacist;
(f) For each patient, the Pharmacist or Intern must determine the 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.

(g) 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 or Intern 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.

(2) Counseling on a refill prescription must be such as a reasonable and prudent Pharmacist would provide including but not limited to changes in strength or directions.

(3) A Pharmacist may provide counseling in a form other than oral counseling when, in their reasonable professional judgment, a form of counseling other than oral counseling would be more effective.

(4) A Pharmacist or Intern must initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

(5) For a discharge prescription from a hospital, the Pharmacist must ensure that the patient receives appropriate counseling.

Statutory/Other Authority: ORS 689.205 & 2021 HB 2359
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & 2021 HB 2359

855-019-0240
Consulting Pharmacist Practice

(1) Subject to the provisions of OAR 855-019-0100(4), a consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist.

(2) A consulting pharmacist for 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.

(3) A consulting pharmacist must maintain appropriate records of their consulting activities for three years, and make them available to the Board for inspection.

(4) A consulting pharmacist is responsible for the safe custody and security of all their records and must comply with all relevant federal and state laws and regulations concerning the security and privacy of patient information.

(5) A consulting pharmacist may store health protected records outside an Oregon licensed facility if registered as an Oregon Consulting or Drugless Pharmacy outlet as defined by OAR Chapter 855, division 41.

(6) A consulting pharmacist for a facility that is required by the Board to have a consultant pharmacist but which does not have additional consulting requirements under the terms of its licensure with any other state agency, shall 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;~~

~~(c) Provide educational materials or programs as requested.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.155~~

~~855-019-0250~~
~~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 provide 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 shall 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;~~

~~(h) Documenting the delivery of care, communications with other involved healthcare providers and other appropriate documentation and records as required. Such records shall:~~

(A) Provide accountability and an audit trail; and

(B) Be preserved for at least three years and be made available to the Board upon request except that when records are maintained by an outside contractor, the contract must specify that the records be retained by the contractor and made available to the Board for at least three years.

(i) Providing necessary services to enhance the patient's adherence with the therapeutic regimen;

(j) Integrating the medication therapy management services within the overall health management plan for the patient; and

(k) Providing for the safe custody and security of all records and compliance with all relevant federal and state laws and regulations concerning the security and privacy of patient information.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 689.155

855-019-0260
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;~~

~~(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 & 689.155~~

~~855-019-0265~~
~~Administration of Drugs~~

~~(1) In accordance with ORS 689.655, a pharmacist may administer a drug or device as specified in this rule.~~

~~(2) A pharmacist who administers a drug or device must:~~

~~(a) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device; and~~

~~(b) Ensure a record is kept for three years of such activities. This record shall include but is not limited to:~~

~~(A) Patient identifier;~~

~~(B) Drug or device and strength;~~

~~(C) Route and site of administration;~~

~~(D) Date and time of administration;~~

~~(E) Pharmacist identifier.~~

~~(3) 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 written protocol or collaborative drug therapy agreement with a licensed practitioner.~~

~~(4) The pharmacist must be able to document that they have received training on the drug or device to be administered and the route of administration. Such training may include a program 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.~~

~~(5) The pharmacist may administer a drug or device in conjunction with training the patient or the patient's caregiver how to administer or self-administer the drug or device.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.655~~

~~855-019-0300~~
~~Duties of a Pharmacist-in-Charge~~

~~(1) In accordance with OAR 855-041 and OAR 855-139, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) who is normally present in the pharmacy on a regular basis.~~

~~(2) In order to be a PIC, a Pharmacist must have:~~

~~(a) Completed at least one year of pharmacy practice; or~~

~~(b) Completed a board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the board, this course may be employer provided and may qualify for continuing education credit.~~

~~(3) A Pharmacist must not be designated PIC of more than three pharmacies without prior written approval by the board. If such approval is given, the Pharmacist must comply with the requirements in sub-section (4)(e) of this rule. Pharmacy Prescription Kiosks in OAR 855-141 and Pharmacy Prescription Lockers in OAR 855-143 do not count toward this limit.~~

~~(4) The PIC must perform the following the duties and responsibilities:~~

~~(a) When a change of PIC occurs, both the outgoing and incoming PICs must report the change to the board within 15 days of the occurrence, on a form provided by the board;~~

~~(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;~~

~~(c) The PIC must not authorize non-Pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;~~

~~(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a Pharmacist;~~

~~(e) A Pharmacist designated as PIC for more than one pharmacy must personally conduct and document a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit Form provided by the board;~~

~~(f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within the time allowed by the board.~~

~~(g) 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.~~

~~(5) The PIC is responsible for ensuring that the following activities are correctly completed:~~

~~(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;~~

~~(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the board;~~

~~(c) Conducting an annual self inspection of the pharmacy using the annual Self-Inspection Form provided by the board, by July 1 each year. The completed self-inspection forms must be signed and dated by the PIC and retained for three years from the date of completion;~~

~~(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;~~

~~(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.~~

~~(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Form;~~

~~(g) Implementing a quality assurance plan for the pharmacy.~~

~~(h) 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.~~

~~(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & ORS 689.155~~

~~855-019-0310~~
~~Grounds for Discipline~~

~~The State Board of Pharmacy may suspend, revoke, or restrict the license of a pharmacist or intern or may impose a civil penalty upon the pharmacist or intern upon the following grounds:~~

~~(1) Unprofessional conduct as defined in OAR 855-006-0020;~~

~~(2) Repeated or gross negligence;~~

~~(3) Impairment, which means an inability to practice with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;~~

~~(4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;~~

~~(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a license to practice pharmacy or a drug outlet registration;~~

~~(8) Permitting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;~~

~~(9) Aiding and abetting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;~~

~~(10) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto; or~~

~~(11) Failure to perform appropriately the duties of a pharmacist while engaging in the practice of pharmacy as defined in ORS 689.005.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, 689.155 & 689.405~~

~~855-019-0460~~

~~Short-acting Opioid Antagonist~~

~~(1) A Pharmacist may prescribe any FDA-approved short-acting opioid antagonist (e.g., naloxone, nalmefene) and the necessary medical supplies to administer 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 a short-acting opioid antagonist;~~

~~(c) To an entity seeking a short-acting opioid antagonist.~~

~~(2) A Pharmacist is not required to label the prescription according to OAR 855-041-1130 if dispensing a FDA-approved short-acting opioid antagonist in the form of a nasal spray.~~

~~(3) The Pharmacist must document the encounter, the prescription and maintain records for three years.~~

~~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~~

Division 020: Pharmacist Prescriptive Authority (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 20; Pharmacist Prescriptive Authority

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 020 Pharmacist Prescriptive Authority rules, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 115 Pharmacists Permanent Administrative Order

https://www.oregon.gov/pharmacy/Documents/Div_115_Supervision_Counseling_PIC_Qualifications_BP_31-2023TrackedChanges.pdf

https://www.oregon.gov/pharmacy/Documents/855-115-0350_Short-acting_Opioid_Antagonists_BP_26-2023TrackedChanges.pdf

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 proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s). The proposed rule repeal will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing was sent to interested parties, some of whom may identify as a small business and had an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 115 Pharmacists rules in August, October and December 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 020 Pharmacist Prescriptive Authority rules. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replaces Division 020. Division 020 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 115 rules to become effective at 12:00AM on 3/1/2024.

~~Division 20~~
~~PHARMACIST PRESCRIPTIVE AUTHORITY~~

~~855-020-0110~~
~~Prescribing Practices~~

~~(1) A Pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. 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.~~

~~(2) A Pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services pursuant to statewide drug therapy management protocols. The policies and procedures must describe current and referenced clinical guidelines, and include but not be limited to:~~

~~(a) Patient inclusion and exclusion criteria;~~

~~(b) Explicit medical referral criteria;~~

~~(c) Care plan preparation, implementation, and follow-up;~~

~~(d) Patient education; and~~

~~(e) Provider notification; and~~

~~(f) Maintaining confidentiality.~~

~~(3) 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.~~

~~(4) 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. An attestation of or certificate of completion of all required training and education must be retained for 6 years or uploaded into the Pharmacist's electronic licensing record with the board;~~

~~(b) Assess patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient's health history and clinical status. The Pharmacist's physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means;~~

~~(c) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the statewide drug therapy management protocol and policies and procedures;~~

~~(d) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and~~

~~(e) 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.~~

~~(5) The Pharmacist must maintain all records associated with prescribing and other related activities performed for a minimum of 7 years, and a copy must be made available to the patient and provider upon request. Pharmacy records must be retained and made available to the board for inspection upon request. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days. Records and documentation must be written, electronic or a combination of the two.~~

~~(6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.~~

~~Statutory/Other Authority: ORS 689.205 & ORS 689.689~~
~~Statutes/Other Implemented: ORS 689.645, ORS 689.649 & ORS 689.689~~

~~855-020-0120~~
~~Prescribing Prohibited Practices~~

~~A Pharmacist must not prescribe a drug or device:~~

~~(1) To self or a spouse, domestic partner, parent, guardian, sibling, child, aunt, uncle, grandchild and grandparent, including foster, in-law, and step relationships or other individual for whom a Pharmacist's personal or emotional involvement may render the Pharmacist unable to exercise detached professional judgment in prescribing pursuant to the Formulary and Protocol Compendia.~~

~~(2) An Intern must not prescribe a drug or device.~~

~~(3) 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 & ORS 689.689~~

~~855-020-0200~~
~~Formulary Compendium~~

~~A pharmacist may prescribe, according to rules in this Division, an 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~~

Division 025: Certified Oregon Pharmacy Technicians and Pharmacy Technicians (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 025; Certified Oregon Pharmacy Technicians and Pharmacy Technicians

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 025 Certified Oregon Pharmacy Technicians and Pharmacy Technicians rules, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 125 Pharmacy Technicians Permanent Administrative Order

https://www.oregon.gov/pharmacy/Documents/Div_125_Prohibited_Practices_BP_32-2023TrackedChanges.pdf

https://www.oregon.gov/pharmacy/Documents/Div_115_125_RPH_COPT_PT_Admin_Vaccines_BP_30-2023TrackedChanges.pdf

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 proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s). The proposed rule repeal will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing was sent to interested parties, some of whom may identify as a small business and had an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 125 Pharmacy Technicians rules in August 2023 and December 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 025 Certified Oregon Pharmacy Technician and Pharmacy Technicians rules in its entirety. The board adopted Division 125 Pharmacy Technicians rules in August 2023 and December 2023 which

replaces Division 025. Division 025 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 125 rules to become effective at 12:00AM on 3/1/2024.

~~Division 25~~
~~CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS~~

~~855-025-0001~~
~~Purpose and Scope~~

~~The purpose of the Pharmacy Technician (PT) license is to provide an opportunity for an individual to obtain competency in the role as a Pharmacy Technician. This license will allow an individual time to take and pass a national pharmacy technician certification examination, which is required to be eligible for licensure as a Certified Oregon Pharmacy Technician (CPT). These rules facilitate the initial licensure of a nationally certified Pharmacy Technician seeking licensure in Oregon.~~

~~Statutory/Other Authority: 689.205~~
~~Statutes/Other Implemented: 689.225 & 689.486~~

~~855-025-0005~~
~~Licensure: Qualifications - Pharmacy Technician or Certified Oregon Pharmacy Technician~~

~~(1) To qualify for licensure as a Pharmacy Technician or Certified Oregon 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).~~

~~(3) No person whose license has been denied, revoked, suspended or restricted by any healthcare professional regulatory board may be licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician unless the board determines that licensure will pose no danger to patients or to the public interest.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225 & ORS 689.486~~

~~855-025-0010~~
~~Licensure: Application- Pharmacy Technician~~

~~(1) An application for licensure as a Pharmacy Technician may be accessed on the board website.~~

~~(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline;~~

~~(3) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(4) The board may issue a license to a qualified applicant after the receipt of:~~

~~(a) A completed application;~~

~~(b) Payment of the fee prescribed in OAR 855-110;~~

~~(c) A current, passport regulation size photograph (full front, head to shoulders);~~

~~(d) Personal identification or proof of identity; and~~

~~(e) A completed national fingerprint-based background check.~~

~~(5) The license of a 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~~

~~855-025-0011~~
~~Licensure: Renewal or Reinstatement- Pharmacy Technician~~

~~(1) An applicant for renewal of a 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 855-135;~~

~~(c) Be subject to an annual criminal background check.~~

~~(2) A 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 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 855-025-0010; 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; and~~

~~(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.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225, ORS 689.486 & ORS 413.450~~

~~855-025-0012~~
~~Licensure: Application- Certified Oregon Pharmacy Technician~~

~~(1) An application for licensure as a Certified Oregon Pharmacy Technician may be accessed on the board website.~~

~~(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline.~~

~~(3) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(4) The board may issue a license to a qualified applicant after the receipt of:~~

~~(a) A completed application;~~

~~(b) Payment of the fee prescribed in OAR 855-110;~~

~~(c) A current, passport regulation size photograph (full front, head to shoulders);~~

~~(d) Personal identification or proof of identity;~~

~~(e) A completed national fingerprint-based background check; and~~

~~(f) Proof that the applicant has taken and passed a national pharmacy technician certification offered by the PTCB or the NHA.~~

~~(5) The license of a Certified Oregon 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~~

~~855-025-0015~~
~~Licensure: Renewal or Reinstatement- Certified Oregon Pharmacy Technician~~

~~(1) A person who has taken and passed a national pharmacy technician certification examination listed in OAR 855-025-0012(1)(a)–(b) may use the following title, and is referred to in these rules as, and is licensed as a "Certified Oregon Pharmacy Technician."~~

~~(2) An applicant for renewal of a Certified Oregon 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 855-135; and~~

~~(c) Be subject to an annual criminal background check.~~

~~(3) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.~~

~~(4) A Certified Oregon Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may renew their license and must pay a late fee required in OAR 855-110.~~

~~(5) A Certified Oregon Pharmacy Technician 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 855-025-0012; 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; and~~

~~(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.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225, ORS 689.486 & ORS 413.450~~

~~855-025-0020~~
~~Duty to Report~~

~~(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.~~

~~(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(3) A Pharmacy Technician or Certified Oregon Pharmacy Technician must report to the board within 10 days if they:~~

~~(a) Are convicted of a misdemeanor or a felony; or~~

~~(b) If they are arrested for a felony.~~

~~(4) A Pharmacy Technician or Certified Oregon Pharmacy Technician who has reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting Pharmacy Technician or Certified Oregon Pharmacy Technician must report the conduct without undue delay, but in no event later than 10 working days after the reporting Pharmacy Technician or Certified Oregon Pharmacy Technician learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.~~

~~(5) A Pharmacy Technician or Certified Oregon Pharmacy Technician who reports to a board in good faith as required by section (4) of this rule is immune from civil liability for making the report.~~

~~(6) A Pharmacy Technician or Certified Oregon Pharmacy Technician who has reasonable grounds to believe that prescription drugs or records have been lost or stolen, or any violation of these rules has occurred, must notify the board within 1 day.~~

~~(7) A Pharmacy Technician or Certified Oregon Pharmacy Technician must notify the board in writing, within 15 days, of any change in email address, employment location or residence address except that a Pharmacy Technician who is employed at more than one pharmacy need only report the name and address of the pharmacy at which the technician normally works the most hours.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155 & ORS 689.486~~

~~855-025-0023~~
~~Certified Oregon Pharmacy Technician and Pharmacy Technician: General Responsibilities~~

~~(1) A Certified Oregon Pharmacy Technician or 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 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 perform duties they are trained to perform; and~~

~~(f) Only access the pharmacy area when a Pharmacist is on duty.~~

~~(3) A Certified Oregon Pharmacy Technician or Pharmacy Technician may not engage in the practice of pharmacy as defined in ORS 689.005.~~

~~(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~~

~~855-025-0025~~
~~Use of Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~(1) A Pharmacist or pharmacy may use Pharmacy Technicians or Certified Oregon Pharmacy Technicians only as authorized by the rules of the Board.~~

~~(2) Pharmacy Technicians or Certified Oregon Pharmacy Technicians must be supervised by a Pharmacist.~~

~~(3) Pharmacists, Pharmacist Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians must be clearly identified as such to the public.~~

~~(4) Work performed by Pharmacy Technicians and Certified Oregon Pharmacy Technicians assisting the Pharmacist to prepare medications must be verified by a Pharmacist prior to release for patient use. Verification must be documented, available and consistent with the standard of practice.~~

~~(5) The pharmacist-in-charge must prepare and maintain in the pharmacy written procedures that describe the tasks performed by Pharmacy Technicians or Certified Oregon Pharmacy Technicians, and the methods of verification and documentation of work performed by Pharmacy Technicians or Certified Oregon Pharmacy Technicians. Written procedures must be available for inspection by the Board or its representatives. The pharmacist-in-charge must review written procedures annually and document that review on the annual pharmacist-in-charge inspection sheet.~~

~~(6) Training:~~

~~(a) The pharmacist-in-charge must outline, and each Pharmacy Technician or Certified Oregon Pharmacy Technician must complete initial training that includes on-the-job and related education that is commensurate with the tasks that the Pharmacy Technician or Certified Oregon Pharmacy Technician will perform, prior to the performance of those tasks.~~

~~(b) The pharmacist-in-charge must ensure the continuing competency of Pharmacy Technicians or Certified Oregon Pharmacy Technicians.~~

~~(c) The pharmacist-in-charge must document initial training of each Pharmacy Technician or Certified Oregon Pharmacy Technician and make that documentation available to the Board or its representatives upon request.~~

~~(7) Upon written request, the Board may waive any of the requirements of this rule upon a showing that a waiver will further public health or safety or the health or safety of a patient or other person. A waiver granted under this section is effective only when issued by the Board in writing.~~

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

~~855-025-0030~~
~~Confidentiality~~

~~(1) No licensee of the Board who obtains any patient information shall disclose that information to a third-party without the consent of the patient except as provided in section two of this rule.~~

~~(2) A licensee may disclose patient information:~~

~~(a) To the Board;~~

~~(b) To a practitioner, Pharmacist, Pharmacy Technician, or Certified Oregon Pharmacy Technician, if disclosure is authorized by a Pharmacist who reasonably believes that 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.~~

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

~~855-025-0035~~
~~Pharmacy and Pharmacist Responsibility for Supervising Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~(1) The supervising Pharmacist and the pharmacist-in-charge are responsible for the actions of Pharmacy Technicians or Certified Oregon Pharmacy Technicians. The use of Pharmacy Technicians or Certified Oregon Pharmacy Technicians to perform tasks not included in written procedures maintained by the~~

pharmacy constitutes unprofessional conduct on the part of the supervising Pharmacist and the pharmacist-in-charge.

(2) The pharmacy must maintain on file and post the current license of each Pharmacy Technician or Certified Oregon Pharmacy Technician.

(3) Before allowing any person to work as a Pharmacy Technician or Certified Oregon Pharmacy Technician, the pharmacy and Pharmacist shall verify that the person is currently licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician.

(4) Prior to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician, a person must provide to the Pharmacist or pharmacist-in-charge a copy of the person's current Pharmacy Technician license or current Certified Oregon Pharmacy Technician license.

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

855-025-0040
Certified Oregon Pharmacy Technician and Pharmacy Technician: Tasks and Guidelines

(1) Non-licensed pharmacy personnel may enter non-prescription information into a computer record system and may perform clerical duties such as filing prescriptions, delivery, housekeeping, and general record keeping, but the responsibility for the accuracy of the non-licensed pharmacy personnel's work lies with the Pharmacist.

(2) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician, acting in compliance with all applicable statutes and rules and under the supervision of a Pharmacist, may assist in the practice of pharmacy by the following:

(a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

(b) Reconstituting prescription medications. The supervising Pharmacist must verify the accuracy in all instances.

(c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.
(d) Entering information into the pharmacy computer. The Certified Oregon Pharmacy Technician or Pharmacy Technician shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising Pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.

(e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;

~~(f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The Pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.~~

~~(g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The Pharmacist must verify the accuracy of the finished task unless the requirements of OAR 855-025-0023(4) are met.~~

~~(h) Checking nursing units in a hospital or nursing home for nonjudgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a Pharmacist.~~

~~(i) Recording patient or medication information in computer systems for later verification by the Pharmacist.~~

~~(j) Bulk Compounding; Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(k) Preparation of parenteral products as follows:~~

~~(A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(l) Performing related activities approved in writing by the board.~~

~~(3) In order to protect the public, safety, health and welfare, Certified Oregon Pharmacy Technicians or Pharmacy Technicians shall not:~~

~~(a) Communicate or accept by oral communication a new or transferred prescription of any nature;~~

~~(b) Receive or transfer a prescription to another pharmacy without the prior verification of a Pharmacist.~~

~~(c) Provide a prescription or medication to a patient without a Pharmacist's verification of the accuracy of the dispensed prescription;~~

~~(d) Counsel a patient on medications or perform a drug utilization review;~~

~~(e) Perform any task that requires the professional judgment of a Pharmacist; or~~

~~(f) Engage in the practice of pharmacy as defined in ORS 689.~~

~~Statutory/Other Authority: ORS 689.205 & 2022 HB 4034~~
~~Statutes/Other Implemented: ORS 689.155 & 2022 HB 4034~~

~~855-025-0050~~

~~Grounds for Discipline of Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~The State Board of Pharmacy may refuse to issue or renew; or may suspend, revoke, or restrict the license of a Pharmacy Technician or Certified Oregon Pharmacy Technician; or may impose a civil penalty upon a Pharmacy Technician or Certified Oregon Pharmacy Technician upon the following grounds including but not limited to:~~

~~(1) Unprofessional conduct as defined in OAR 855-006-0020;~~

~~(2) Repeated or gross negligence in performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician;~~

~~(3) Impairment, which means an inability to assist in the practice of pharmacy with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;~~

~~(4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;~~

~~(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a Pharmacy Technician or Certified Oregon Pharmacy Technician license;~~

~~(8) Allowing an individual to engage in the duties of a Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician without a license or to use falsely the title of Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician;~~

~~(9) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto;~~

~~(10) Failure to appropriately perform the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician as outlined in OAR 855-025-0040 while assisting a Pharmacist in the practice of pharmacy as defined in ORS 689.005;~~

~~(11) Any act or practice relating to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician which is prohibited by state or federal law or regulation; or~~

~~(12) Any conduct or practice by a Pharmacy Technician, Certified Oregon Pharmacy Technician or pharmacy that the Board determines is contrary to the accepted standards of practice.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.151 & 689.405~~

Division 031: Interns (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 031; Interns

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 031 Intern rules in its entirety, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 120 Interns and Preceptors Permanent Administrative Order

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 proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s). The proposed rule repeal will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing was sent to interested parties, some of whom may identify as a small business and had an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 120 Interns and Preceptors rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 031 Interns rules in its entirety. The board adopted Division 120 Interns and Preceptors rules in August 2023, which replaces Division 031. Division 031 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 125 rules to become effective at 12:00AM on 3/1/2024.

~~Division 31~~
~~INTERNS~~

~~855-031-0005~~
~~Definitions~~

~~(1) An "intern" means any person who:~~

~~(a) Is enrolled in a course of study and is in good academic standing at a school or college of pharmacy that is approved by the Oregon Board of Pharmacy; or~~

~~(b) Is a graduate of a school or college of pharmacy that is approved by the board; or~~

~~(c) Is a foreign pharmacy graduate and holds a certificate from the Foreign Pharmacy Graduate Equivalency Committee (FPGEC); and~~

~~(d) Is licensed with the board as an intern.~~

~~(2) A "preceptor" means a pharmacist or a person licensed by the board to supervise the internship training of an intern.~~

~~(3) "Internship" means a professional experiential program or work experience.~~

~~(a) "Traditional Pharmacy-practice Internship (TPI)" means experience toward achieving competency in the practice of pharmacy for which no academic credit is granted to the intern.~~

~~(b) "School-based Rotational Internship (SRI)" means experience toward achieving competency in the practice of pharmacy in programs developed and administered by a school of pharmacy.~~

~~(c) "Other Internship" means experience toward achieving competency in the practice of pharmacy, other than in an internship as defined in (a) or (b), in a program approved by a school of pharmacy or the board.~~

~~(4) “School of pharmacy”: In this division of rules, “school of pharmacy” means a school or college of pharmacy that is approved by the board.~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.255~~

~~855-031-0010~~
~~Intern License Application~~

~~(1) Applications for licensure as an intern may be obtained from the board website.~~

~~(a) Failure to completely, accurately and honestly answer all questions on the application form for licensure or renewal of licensure is grounds for discipline;~~

~~(b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(2) The board may issue a license to a qualified intern after the receipt of:~~

~~(a) A completed application;~~

~~(b) Payment of the fee prescribed in OAR 855-110;~~

~~(c) A current, passport regulation size photograph (full front, head to shoulders);~~

~~(d) Furnish documentation required to conduct a national fingerprint-based background check; and~~

~~(e) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study, except for foreign pharmacy graduates who must:~~

~~(A) Provide a copy of a valid visa permitting full-time employment;~~

~~(B) Provide a copy of the original certificate issued by the Foreign Pharmacy Graduate Equivalency Examination Committee; and~~

~~(C) Provide evidence that they have passed the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT).~~

~~(3) The board may issue an intern license after processing the application, however unless the applicant is a foreign graduate or an applicant for licensure by reciprocity, it is not valid until the intern has started a course of study. The initial license is valid until the last day of November following the second anniversary of issue unless terminated automatically by any one of the following events. Renewed licenses are valid for two years unless terminated automatically by any one of the following events:~~

~~(a) Licensure to practice pharmacy is granted in any state; or~~

~~(b) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, fails to maintain enrollment or active registration in a pharmacy degree program for a period greater than one year; or~~

~~(c) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, has been graduated from a school of pharmacy for 12 months;~~

~~(d) The intern is dismissed, terminated or expelled by the school of pharmacy, or withdraws from the program.~~

~~(4) An intern must surrender their license to the board within 30 days of one of the above events.~~

~~(5) Notwithstanding the requirements of section (3) above, upon written request the board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section must only be effective when it is issued in writing.~~

~~[Publications: Publications referenced are available from the agency.]~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.207, ORS 689.255 & ORS 689.455~~

~~855-031-0016~~
~~Renewal of Licensure as an Intern~~
~~(1) An application for renewal of an intern license must include documentation of:~~

~~(a) Completion of continuing pharmacy education requirements as directed in OAR 855-135; and~~

~~(b) Payment of the license fee required in OAR 855-110.~~

~~(2) An intern will be subject to an annual criminal background check.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-031-0020~~
~~Intern Requirements and Responsibilities~~

~~(1) A licensed intern may practice in any one or a combination of the following approved internship experience areas:~~

~~(a) Traditional Pharmacy-practice Internship (TPI): an intern may not work in a TPI until after satisfactorily completing the first academic year in a school of pharmacy. An intern working in a TPI must be supervised by a licensed pharmacist or pharmacist preceptor;~~

~~(b) School-based Rotational Internship (SRI): an intern must be supervised by a licensed pharmacist or other person approved by a school of pharmacy to obtain credit for SRI hours;~~

~~(c) Other Internship.~~

~~(2) An intern may not work more than 48 hours per week in SRIs and must comply with all supervision and ratio requirements.~~

~~(3) An intern must verify that their preceptor is currently licensed with the board.~~

~~(4) An intern may not work in the practice of pharmacy unless supervised by a licensed pharmacist, except when an intern is working in a federal facility, however, to obtain credit for SRI experience in a federal facility located in Oregon, the intern must be licensed with the board.~~

~~(5) An intern who is working in a pharmacy or other place of business must conspicuously display their intern license in the pharmacy or place of business and must be clearly identified as an intern at all times.~~

~~(6) An intern may perform only the duties listed in Division 025 of this Chapter before completion of the first academic year in a school of pharmacy.~~

~~(7) An intern may, after successful completion of their first academic year, perform the duties of an intern listed in Division 019 of this Chapter, but only after successful completion of coursework corresponding to those duties at their school of pharmacy and only with the permission of their supervising pharmacist.~~

~~(8) An intern is responsible for his or her own actions and must comply with all board regulations.~~

(9) An intern must notify the board within 15 days of any change in their academic status that might affect their eligibility to work as an intern.

(10) An intern must notify the board in writing within 15 days of a change in permanent residence and TPI site.

(11) An intern must report to the board within 10 days if they are:

(a) Convicted of a misdemeanor or a felony; or

(b) Arrested for a felony.

(12) An intern who has reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The intern must report the conduct without undue delay, but in no event later than 10 working days after the intern learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.

(13) If needed by an intern for compliance with another board's requirement, an intern must maintain written or electronic records that support the number of TPI hours claimed by an intern and have those hours certified by a preceptor.

(14) An intern may make a voluntary report to the board on any preceptor's aptitude and professionalism in performing the duties of a preceptor. An intern must make such a report upon request by the board.

Statutory/Other Authority: ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.255 & ORS 689.455

855-031-0026
Ratio & Supervision

(1) A Pharmacist may not supervise more than one Intern at a time at a TPI site who performs the duties of an Intern as listed in OAR 855-019-0200(6). A Pharmacist may supervise more than one Intern if only one intern performs the duties of an Intern as listed in OAR 855-019-0200(6) and if other Interns supervised by the Pharmacist perform the duties listed in OAR 855-025-0040.

(2) A preceptor may not supervise more than two Interns simultaneously during a shift at an SRI site where patient specific recommendations for care or medications are provided without prior written authorization of the board.

(3) With the written approval of a school of pharmacy, and when in their reasonable professional judgment it is appropriate, a preceptor may supervise up to 10 Interns at public health outreach programs such as informational health fairs that provide general information but not direct patient care.
(4) For immunization clinics, an immunizing Pharmacist may supervise up to two immunizing Interns.

(5) A licensed preceptor may delegate the preceptor responsibilities to another licensed Pharmacist or preceptor.

(6) The majority of an Intern's overall experience must be with a licensed Pharmacist preceptor.

Statutory/Other Authority: ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.255

855-031-0030
Out-of-State Internship Experience

(1) In order for an Oregon intern to obtain credit for SRI experiences outside the State of Oregon, an intern must:

(a) Be licensed as required by state laws and rules in the state in which they will practice;

(b) Meet or exceed the minimum SRI requirements of the board;

(2) In order for an out-of-state intern to practice in the State of Oregon, the intern must meet all requirements of these rules.

Statutory/Other Authority: ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.255

855-031-0045
School and Preceptor Registration and Responsibilities

(1) A preceptor license may be issued by the board upon receipt of a completed application.

(2) A pharmacist preceptor must have been an actively practicing pharmacist for at least one year immediately prior to supervising an intern.

(3) A preceptor license must be renewed biennially and will expire on June 30 in odd numbered years.

(4) The preceptor may report to the board voluntarily, the progress and aptitude of an intern under the preceptor's supervision, or must do so upon request of the board.

(5) The preceptor must be responsible for supervision of the majority of the intern's SRI hours and must provide the intern with internship experiences, which in the preceptor's judgment will increase the intern's competency in the practice of pharmacy.

(6) Before supervising an intern in an SRI program, a preceptor must complete any training program required by the school of pharmacy.

(7) A preceptor must advise each school of pharmacy when they are supervising students from more than one school at the same time. This applies to both in-state and out-of-state schools or colleges of pharmacy.

(8) A preceptor must verify that their intern is currently licensed with the board.

(9) A pharmacist acting as a preceptor in a federal facility is not required to be licensed as a pharmacist in Oregon, but is required to be licensed as a preceptor with the board.

(10) The school of pharmacy must maintain a record of each intern's SRIs. This record must be made available to the board upon request.

(11) A school of pharmacy located in Oregon must submit a report on their experiential education program to the board at the end of each academic year. This report must include the names of students who successfully completed the program and graduated from the school. The school must maintain a list of preceptors and SRI sites, in and out-of-state, approved by the school and must make this list available to the board upon request.

(12) All records related to a student must be available for three years after the student graduates.

Statutory/Other Authority: ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.255

855-031-0050
Eligibility for Exams — Foreign Pharmacy Graduates

In addition to the other requirements of this Division, a foreign pharmacy graduate must complete 1440 internship hours before applying to take the Multistate Pharmacy Jurisprudence Examination (MPJE) and before applying for licensure as a pharmacist as specified in OAR 855-019-0150. Evidence of completing this requirement must be provided to the board by the applicant and must be authenticated by each preceptor.

Statutory/Other Authority: ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.255

855-031-0055
Eligibility for Exams and Pharmacist Licensure

(1) An intern is eligible to take the North American Pharmacist Licensure Examination (NAPLEX) and the MPJE, upon graduation and notification to the board by the school of pharmacy that their degree, with not less than 1440 hours of SRI, has been conferred.

(2) Upon meeting all requirements for pharmacist licensure, and before practicing pharmacy in the State of Oregon, a person must:

~~(a) Complete an application for licensure including providing any fingerprint card or other documentation required by the board to conduct a criminal background check;~~

~~(b) Pay the license fee as prescribed in OAR 855-110; and~~

~~(c) Obtain a license, which will expire on June 30 in odd numbered years.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.135, ORS 689.207, ORS 689.225 & ORS 689.275~~

Divisions 041/110 - Operation of Pharmacies & Fees

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Consulting Drugless Pharmacy rule amendments and rule repeals

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes striking Division 041 rules related to Consulting/Drugless Pharmacies and amending OAR 855-041-3000, effective at 12:00AM on 3/1/2024. Proposes amending OAR 855-110-0007(7)(a)(A) by striking Consulting "Drugless" Drug Outlet Pharmacy, effective at 12:00AM on 3/1/2024. Rules related to Consulting "Drugless" Pharmacies are no longer necessary as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 115 Pharmacists Permanent Administrative Order, Div 104 Universal Rules Permanent Administrative Order

Div 104 Universal Rules Permanent Administrative Order
https://www.oregon.gov/pharmacy/Documents/Div_104_Universal_Rules_BP_15-2023TrackedChanges.pdf

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 proposed rule amendments and rule repeals are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The agency estimates a reduction in revenue in the amount of $9900 in licensing fees for the 2023-2025 biennium by repealing Consulting/Drugless pharmacy rules.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s). The agency anticipates a reduction in revenue in the amount of $9900 for the 2023-2025 biennium by repealing Consulting/Drugless pharmacy rules. The proposed rule amendments and rule repeals have no additional economic impact on units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved in determining whether the rules should be amended or repealed. A notice of rulemaking hearing was sent to interested parties, some of whom may identify as a small business and had an opportunity to provide public comment on the proposed rule amendments and repeals.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The nature of the proposed rule amendments and rule repeals does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-041-3000 – Proposes to strike "Consulting/Drugless Pharmacy Outlets Purpose and Scope" from the rule title as well as strikes (4) as the rules referenced are being proposed to be repealed.

OAR 855-041-3300, OAR 855-041-3305, OAR 855-041-3310, OAR 855-041-3315, OAR 855-041-3315, OAR 855-041-3320, OAR 855-041-3325, OAR 855-041-3330, OAR 855-041-3335 and OAR 855-041-3340 are proposed to be repealed in their entirety effective at 11:59PM on 2/29/2024 due to Consulting/Drugless Pharmacy Outlets new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

OAR 855-110-0007 – : Proposes amending the rule by striking 7(a)(A) "Consulting/Drugless Pharmacy" as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

Division 41
OPERATION OF PHARMACIES

855-041-3000 ***View current rule on SOS website** ***View 12/22/2023 Notice of Proposed Rulemaking**
Central Fill and Remote Processing Outlet Designations

(1) The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of operation for centralized prescription drug filling by a pharmacy.

(2) The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription processing by a pharmacy.

(3) Prior to initiating one of the above drug outlet models, a description of how the model will be utilized must be submitted to the Board.

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

~~855-041-3300~~
~~Consulting/Drugless Pharmacy - Purpose and Scope~~

~~The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a single physical location. This location may be an office located in a home or other secure location. Registration is not required if records used or generated by a consulting pharmacist are stored in a location registered by the Board as a retail or institutional drug outlet or if the location is under the control of a practitioner who uses the services of the consulting pharmacist. The consulting pharmacist must be able to provide the Board with documentation of their pharmaceutical care activities. These rules are intended to ensure that a location where a pharmacist is engaged in Independent Pharmacy Practice may safely store records and protected health information. An applicant must submit to the Board for approval policies and procedures and a description of how their consulting or drugless pharmacy will be utilized to improve patient safety.~~

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

855-041-3305
Consulting/Drugless Pharmacy - Definitions

The following words and terms, when used OAR 855-041-3300 through 855-041-3340 shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the OAR chapter 855, division 6.

(1) "Consulting or Drugless Pharmacy" means any single physical location where pharmaceutical care services are performed or protected health information may be stored without the storage, possession, or ownership of any drug.

(2) "Consulting Pharmacist" means any pharmacist as defined by OAR chapter 855, division 6 and is described by chapter 855, division 19.

(3) "Independent Pharmacy Practice" means the provision of pharmaceutical services not related to physically handling or dispensing pharmaceuticals drugs or devices. This practice is characterized by the practice of an Oregon licensed pharmacist acting as an independent contractor whether or not directly employed or affiliated with an entity that is licensed by the Board. This service also does not include the provision of pharmaceutical care that is conducted within the physical confines or location of a licensed pharmacy registered with the Board.

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

855-041-3310
Consulting/Drugless Pharmacy - Registration

(1) The Consulting Pharmacy shall be registered as a retail or institutional drug outlet and comply with all the requirements of licensure as defined in OAR 855-041-1080 through 855-041-1100.

(2) The location must be available for inspection by the Board.

(3) A consulting pharmacist for an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure, as well as any applicable federal and state laws and rules.

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

855-041-3315
Consulting/Drugless Pharmacy - Personnel

~~(1) Each pharmacy must have a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the state in which the pharmacy is located if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;~~

~~(2) The pharmacy must comply with all applicable state and federal laws and rules governing the practice of pharmacy and maintain records in compliance with requirements of federal law and Board rules;~~

~~(3) A consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist 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; and~~

~~(4) Prospective drug utilization reviews, refill authorizations, interventions and patient counseling not associated with the dispensing of a drug for an Oregon patient must be performed by an Oregon licensed pharmacist.~~

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

~~855-041-3320~~
~~Consulting/Drugless Pharmacy - Confidentiality~~

~~(1) Each consulting pharmacy must comply with all applicable federal and state laws and rules regarding confidentiality, integrity and privacy of patient information.~~

~~(2) Each consulting pharmacy must ensure that electronic data systems are secure and comply with applicable federal and state laws and rules.~~

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

~~855-041-3325~~
~~Consulting/Drugless Pharmacy - General Provisions and Minimum Standards~~

~~(1) A consulting pharmacy shall:~~

~~(a) Maintain appropriate reference materials for drug information according to the scope of consulting services.~~

~~(b) Be located in a secure room with a door and suitable lock, and accessible only to persons authorized by the pharmacist-in-charge.~~

~~(c) Provide storage sufficient to secure confidential documents and any hardware necessary to access information.~~

~~(d) Be constructed in a manner of materials that make the space separate and distinct from the rest of the home or office building, and that protects the records from unauthorized access.~~

~~(2) A consulting pharmacy located in a residence must be approved by the Board.~~

~~(3) The consulting pharmacist must be able to provide the Board, upon request, with documentation of their pharmaceutical care activities.~~

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

~~855-041-3330~~
~~Consulting/Drugless Pharmacy - Security Requirements~~

~~(1) All consulting services must occur in a secure environment that includes but is not limited to:~~

~~(a) A closed system or other electronic storage device that is password protected;~~

~~(b) A secure room or safe that is locked to store records when the pharmacist is not directly monitoring them;~~

~~(c) Sufficient encryption for securing confidential documents and any hardware used in accessing authorized patient health information by electronic connection; and~~

~~(d) A data processing system that complies with all federal and state laws and rules to ensure compliant security software.~~

~~(2) Records stored at a practitioner's office must be kept secure either with other records at the facility or independently in a locked room where only the pharmacist, and physician and their agents have access;~~

~~(3) All records must be stored at the approved consulting or drugless pharmacy; and~~

~~(4) Any breach in the security of the system or breach of confidentiality must be documented and reported to the Board within seven days.~~

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

~~855-041-3335~~
~~Consulting/Drugless Pharmacy - Policies and Procedures~~

~~The consulting pharmacy must maintain a current policy and procedures manual that includes at a minimum:~~
~~(1) A policy on protecting confidentiality and integrity of patient information;~~

~~(2) An outline of responsibilities and scope of services;~~
~~(3) A policy on compliance with federal and state laws and rules;~~

~~(4) An operational Quality Assurance Program;~~

~~(5) A policy that describes use of computer systems.~~

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

~~855-041-3340~~
~~Consulting/Drugless Pharmacy - Records~~

~~(1) The recordkeeping and storage requirements in OAR 855-041-3300 through 855-041-3340 are in addition to the requirements of other recordkeeping and storage rules of the Board. Records and documentation may be written, electronic or a combination of the two.~~

~~(2) Each recordkeeping system must include quality improvement program documentation;~~

~~(3) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety, and welfare. Records must include but need not be limited to:~~

~~(a) Patient profiles and records;~~

~~(b) A list of current employees and their license numbers;~~

~~(A) Verification of each license and registration;~~

~~(B) The name of the individual responsible for verification of licensure and registration status.~~

~~(c) Copies of all contracts for consulting services and collaborative therapy agreements;~~

~~(d) Copies of all consultation reports submitted to practitioners and facilities.~~

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

Division 110
FEES

855-110-0007 ***View current rule on SOS website** ***View 12/22/2023 Notice of Proposed Rulemaking**
Fees for Registration, Renewal, and Reinspection of Drug Outlets

(1) Drug Distribution Agent. Expires September 30 annually - $400. Late renewal fee (received after September 30) - $100.

(2) Drug Room (including Correctional Facility). Expires March 31 annually - $100. Late renewal fee (received after March 31) - $75.

(3) Manufacturer (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually - $525. Late renewal fee (received after September 30) - $100.

(4) Nonprescription Drug Outlet. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.

(a) This includes the following categories of registration:

(A) Nonprescription Class A.

(B) Nonprescription Class B.

(C) Medical Device, Equipment & Gas Class C.

(b) Other nonprescription Drug Outlet registration category fees are as follows:

(A) Nonprescription Class D. Expires January 31 annually - $100. Late renewal fee (received after January 31) - $25.

(B) Nonprescription Class E. Expires January 31 annually - $0. Late renewal fee (received after January 31) - $0.

(5) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - $50. Expires December 31 annually.

(6) Re-inspection fee - $100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.

(7) Retail or Institutional Drug Outlet Pharmacy. Expires March 31 annually - $225. Late renewal fee (received after March 31) - $75.

(a) This includes the following categories of registration:

(A) Home Dialysis Retail Drug Outlet Pharmacy

(B) Institutional Drug Outlet Pharmacy

(C) Remote Dispensing Site Retail Drug Outlet Pharmacy

(D) Retail Drug Outlet Pharmacy

(b) Other Retail/Institutional Drug Outlet registration category fees are as follows:

(A) Charitable Retail Drug Outlet Pharmacy. Expires March 31 annually - $75. Late renewal fee (received after March 31) - $25.

(B) Community Health Clinic (CHC) Retail Drug Outlet Pharmacy. Expires March 31 annually - $100. Late renewal fee (received after March 31) - $25.
(C) Dispensing Practitioner Drug Outlet (DPDO) Retail Drug Outlet Pharmacy. Expires March 31 annually - $100. Late renewal fee (received after March 31) - $25.

(D) Prescription Kiosk Retail Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(E) Prescription Locker Retail Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(F) Remote Dispensing Machine Institutional Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(G) Remote Distribution Facility Institutional Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(8) Wholesaler (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually - $525. Late renewal fee (received after September 30) - $100.

Statutory/Other Authority: ORS 689.205, ORS 291.055
Statutes/Other Implemented: ORS 689.135, ORS 689.774, ORS 689.305

Division 041: Operation of Pharmacies (Short-acting Opioid Antagonist)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Institutional Drug Outlet Labeling Requirements for Short-acting Opioid Antagonists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes to amend Emergency Department labeling requirements related to short-acting opioid antagonist for practitioners with prescriptive authority in Oregon. Incorporates legislative mandates of 2023 HB 2395, 2023 SB 450, 2023 SB 1043 related to short-acting opioid antagonist.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 SB 450, 2023 SB 1043, 2023 HB 2395

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 proposed rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal anticipated. Licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): (1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) The proposed rule amendments will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule amendments apply to registrants of the Oregon Board of Pharmacy. Approximately 30 % of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and had an opportunity to provide public comment on the proposed rules for the board's consideration.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The resources involved in convening a RAC were not necessary to amend this rule. This rule enacts the mandates of 2023 SB 450, 2023 SB 1043, or 2023 HB 2395 and does not contain further decisions or requirements by the Board

beyond what is in the legislation itself.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-041-6270 - Proposes to amend rule by adding (8) that states that nothing in the rule is intended to restrict or conflict with the directives of 2023 SB 450, 2023 SB 1043, or 2023 HB 2395, effective upon filing.

OAR 855-041-6410 – Proposes amending (1)(d) and (e) by adding exemptions and incorporates a reference to 2023 SB450, effective upon filing

Division 041
OPERATION OF PHARMACIES

855-041-6270 ***View current rule on SOS website** ***View 12/22/2023 Notice of Proposed Rulemaking**
Institutional Drug Outlet Pharmacy Prescription Labeling

(1) Each pharmacy record keeping system must identify all pharmacy personnel involved in the repackaging including the pharmacist who verified the repackaged drug.

(2) Each repackaged drug, prepared by the pharmacy and intended for use within the facility must be in an appropriate container with a label that meets the requirements of OAR 855-041-1135 and includes:

(a) The brand or generic name and expiration date;

(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;

(c) The strength of the drug.

(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:

(a) Name and location of patient;

(b) Name and strength of drug;

(c) Route of administration, when necessary for clarification;

(d) Manufacturer and lot number, or internal pharmacy code;

(e) Auxiliary labels as needed, and

(f) Expiration date.

(4) A drug that is provided for outpatient use must be dispensed by a retail drug outlet.

(5) When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.

(6) When a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that includes the:

(a) Name, quantity and concentration of the drug added and the primary solution;

(b) Date and time of addition;

(c) Expiration date;

(d) Scheduled time for administration;

(e) Infusion rate, when applicable;

(f) Name or initials of person performing admixture;

(g) Identification of the pharmacy where the admixture was performed; and

(h) Name or initials of the verifying pharmacist.

(7) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.

(8) Nothing in this rule is intended to restrict or conflict with HB 2395 (2023), SB 450 (2023), SB 1043 (2023).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155,ORS 689.505, 2023 HB 2395, 2023 SB 450, 2023 SB 1043

855-041-6410
Emergency Department Distribution *View current rule on SOS website ***View 12/22/2023 Notice of Proposed Rulemaking**

(1) A practitioner or associate practitioner with prescriptive authority in Oregon who is a member of the hospital's medical staff may dispense an emergency supply of drugs to a patient examined by them or by an associate practitioner subject to the following requirements:

(a) The prescriber must offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice;

(b) During consultation with the patient or the patient's caregiver, the prescriber must clearly explain the appropriate use of the drug supplied and the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice;

(c) The patient must be given instructions on the use and precautions for taking the drug;

(d) Except as described in SB 450 (2023), the drug is in a manufacturer's unit-of-use container, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(B) Accessory cautionary information as required for patient safety;

(C) Product identification label if the drug is not in unit-of-use packaging;

(D) An expiration date after which the patient should not use the drug; and

(E) Name, address and phone number of the hospital pharmacy.

(e) Except as described in SB 450 (2023), the following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

(D) Unique identifying number as determined by policy and procedure;

(E) Name of prescribing practitioner; and

(F) Initials of the dispensing nurse or practitioner.

(f) A prescription or record of the distribution must be completed by the practitioner or nurse. This record must contain:

(A) Name of patient;

(B) Date of issuance;

(C) Drug name and strength distributed;

(D) Units issued;

(E) Name of practitioner;

(F) Initials of the dispensing nurse or practitioner; and

(G) Instructions given to the patient as labeled.

(g) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient;

(h) The record must be reviewed and documented by a pharmacist for accuracy and completeness. The pharmacist must review the record of dispensing of drugs within 24 hours. However, if the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open but not to exceed 72 hours following the dispensing; and

(i) Errors and discrepancies will be included in hospital and pharmacy QA review process and available to the board.

(2) A controlled substance may only be distributed or dispensed to an outpatient by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined. Distribution of a controlled substance must comply with all applicable state and federal laws and regulations.

(3) The CPO or PIC and appropriate hospital committee will establish a limited selection and quantity of drugs to be included in the Emergency Department formulary and the amount contained in each pre-pack that may be distributed to meet only the acute care needs of a patient; for example, an emergency supply of drugs. The amount dispensed may not exceed a 48 hour supply except for:

(a) A drug in the manufacturer's unit-of-use packaging such as an inhalant or a topical drug;

(b) A full course of therapy that may be dispensed if in the professional judgment of the pharmacist or practitioner this would be in the patient's best interest such as an antibiotic;

(4) Any additional preparation for use of the medication must be completed prior to discharge; for example, reconstituting antibiotics;

(5) For the purpose of this rule an Automated Dispensing Machine (ADM) is a machine or contrivance which will prepare a completed and labeled prescription which is ready for dispensing to the patient or patient's representative.

(6) An Automated Dispensing Machine; may only be located within the Emergency Department in a secure environment that has no direct public access, and when used, must be part of the discharge procedure;

(7) When the patient or patient's representative receives the prescription from an ADM;

(a) A registered nurse or practitioner or pharmacist must be present at the time of dispensing; and

(b) A registered nurse or practitioner or pharmacist will grant access to the ADM for the release of the drugs to be dispensed using a password protected or biometric access; and

(c) The patient or patient's representative will obtain the drug using a specific patient access code.

(8) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may access the drug supply in the ADM.

(9) The CPO or PIC will establish policies and procedures for use of the ADM including, but not limited to emergency access and down time procedures for the ADM.

(10) Upon written request, the board may waive any of the requirements of this rule if a waiver will further public health or safety. A waiver granted under this section must only be effective when it is issued in writing and will be time limited.

(11) Nothing in this rule is intended to restrict or conflict with HB 2395 (2023), SB 450 (2023), SB 1043 (2023).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.505, 2023 HB 2395, 2023 SB 450, 2023 SB 1043

Division 115: Pharmacists (Applicability)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Applicability of Pharmacy Practice Regulations and Licensing Requirements for Pharmacists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed new rule relocates and revises OAR 855-019-0100 related to applicability of pharmacy practice regulations and licensing requirements for pharmacists.

Documents Relied Upon per ORS 183.335(2)(b)(D): None

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 proposed rule is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal anticipated. When the board sends the proposed rule to a rulemaking hearing, licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): (1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).
(1) The proposed rule will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a)The proposed rule applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not convened. Why? The resources involved in convening a RAC were not necessary to amend this rule. Board members represent the interests of persons and communities likely to be affected by a proposed rule and were able to provide information necessary to amend the rule.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed new rule relocates and revises existing rule language from OAR 855-019-0100 to OAR 855-115-0001 related to applicability. Removes provision for Interns that is now included in OAR 855-120-0135 and removes board waiver of rule. Clarifies which pharmacists working for out-of-state pharmacies must be licensed by the board.

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 working for 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).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.255

Division 115: Pharmacists (CDTM)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Pharmacists; Collaborative Drug Therapy Management (CDTM)

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Relocates and existing CDTM rules from Division 019 into Division 115.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 115 Pharmacists Permanent Administrative Order

5/4/2023 CDTM - CPA Workgroup Meeting Minutes: https://www.oregon.gov/pharmacy/Documents/May_CDTM_CPA_Workgroup_Meeting_Minutes.pdf

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 proposed rule is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No anticipated fiscal and economic impact. Licensees, registrants and interested parties may provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): (1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) The proposed new rule has no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy.

Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on

small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rule for the board's consideration.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The board directed staff to convene a CDTM – CPA Workgroup consisting of Subject Matter Experts with expertise related to CDTMs/CPAs to

assist with the development of rule amendments. The CDTM/CPA workgroup held a meeting on 5/4/2023 and reviewed and provided input on amendments related to CDTM and CPAs. The board reviewed and discussed the proposed amendments to the rules at the October 2023 board meeting, sent the rules to rulemaking in November 2023, but decided not to adopt the proposed rules in December 2023. Thus, the proposed rule for the January 2024 rulemaking copies the currently enacted language in OAR 855-019-0260 into the new Division 115.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Relocates existing CDTM rules from OAR 855-019-0260 to OAR 855-115-0315. The board adopted Division 115 Pharmacists rules in August, October and December 2023, effective 3/1/2024 which replaces Division 019. Division 019 needs to be repealed effective 3/1/2024 to allow Division 115 rules to become effective.

Division 115
PHARMACISTS

855-115-0315
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;

(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 & 689.155

Division 115: Pharmacists (Prohibited Practices)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Pharmacist Prohibited Practices

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes to remove "Diagnosis" from list of prohibited practices. On December 15, 2023 the board motioned to initiate rulemaking on this rule pursuant to a petition filed under OAR 137-001-0070 on September 25, 2023.

Documents Relied Upon per ORS 183.335(2)(b)(D): December 2023 Bd Mtg Agenda, mailing #F https://www.oregon.gov/pharmacy/Documents/December_2023_Bd_Mtg_Agenda.pdf

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 proposed revisions to the rules are not anticipated to have a racial equity impact as the ability to 'diagnose' is not included within a pharmacist's statutory scope of practice as defined in Oregon Revised Statutes chapter 689. By removing the prohibition on 'diagnosis' in Oregon Administrative Rules chapter 855, the rules will no longer address this practice.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No anticipated fiscal and economic impact. Licensees, registrants and stakeholders may provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): (1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s). The proposed new rule has no additional economic impact on state agencies, units of local government, or the public.
Describe how small businesses were involved in development of the rules: Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The board did not direct staff to convene a RAC or Workgroup to advise on the proposed rules. Board members represent the interests of persons and communities likely to be affected by the proposed rules and were able to provide expertise when drafting the proposed rules.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposes to remove "Diagnosis" from list of prohibited practices. On December 15, 2023 the board motioned to initiate rulemaking on this rule pursuant to a petition filed under OAR 137-001-0070 on September 25, 2023.

Division 115
PHARMACISTS

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.~~ *PROPOSED AMENDMENT IS TO STRIKE (3) "DIAGNOSE"

(**3**4) Engage in any form of discrimination, harassment, intimidation, or assault.

(**4**~~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.

(**5**~~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

Division 120: Licensure: Renewal or Reinstatement (Preceptor)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Preceptor License Renewal or Reinstatement

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed new rule that adds Preceptor licensure renewal or reinstatement requirements to be effective at 12:00AM on 3/1/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 120 Interns and Preceptors Permanent Administrative Order

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 proposed rule is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s). The proposed rule will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 120 Interns and Preceptors in August 2023, effective 3/1/2024. The nature of the proposed rule does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed new rule adds Preceptor licensure renewal or reinstatement requirements. To be effective at 12:00AM on 3/1/2024.

Division 120
INTERNS AND PRECEPTORS

855-120-1035

Licensure: Renewal or Reinstatement - Preceptor

(1) A Preceptor who holds a Pharmacist license will be automatically renewed with each Pharmacist license renewal unless the Pharmacist requests to lapse their Preceptor license per OAR 855-120-1040.

(2) Each Healthcare Preceptor or Other Preceptor must complete a new Preceptor application for license renewal per OAR 855-120-1010.

(3) A Preceptor 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.

(4) A Preceptor 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 855-120-1010; and

(5) A person whose Preceptor 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 and may apply to reinstate per OAR 855-120-1010.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.275, ORS 689.445

Divisions: 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.

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

Flavoring:

- USP <795> Adding Flavor to Conventionally Manufactured Nonsterile Products (v. 11/2022)

- USP <795> FAQs #21 (v. 11/2023)

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): The proposed new rules and existing rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): On 8/4/2023 board staff sent out an email notification via GovDelivery to 19,647 licensee and registrant subscribers and 3,882 rulemaking interested party subscribers requesting fiscal and economic impact of the proposed rules. A Workgroup was utilized in the development of the proposed rules. Workgroup members provided estimated fiscal and economic impact of the proposed rules on 05/16/2023 and 07/18/2023. All Workgroup and board meetings where proposed rules were discussed were noticed to the public and public comment was requested. The board noticed the proposed rules for rulemaking hearing on 6/16/2023; however, the board was seeking public comment only and did not intend to adopt the rules in August 2023. The public had an opportunity to provide estimated fiscal impact information during the public comment period from 6/16/2023 – 7/26/2023.

To comply, Drug Outlet pharmacies, DPDOs, CFs and CHCs who engage in compounding will need to pay for access to the USP Compounding Compendium which is estimated to cost $250 per year per user.

-The board received estimated fiscal impact statements from six different licensee/registrant/stakeholders who provided a wide range of estimated costs that could potentially cost their organizations/patients/customers anywhere from $1.00 to $10 Million to comply with the proposed rules.

- 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.

Interested parties will have an additional opportunity to provide fiscal and economic impact statements during future rulemaking.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): (1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small

businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) The proposed new rules and existing rule amendments will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed new rules and existing amendments apply to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.

(b) The rulemaking imposes the same mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) In order to comply, Drug Outlet pharmacies, DPDOs, CFs and CHCs who identify as a small business and engage in compounding will need to pay for access to the USP Compounding Compendium which is estimated to cost $250 per year per user.

Describe how small businesses were involved in development of the rules ORS 183.335: Licensees and registrants identify as small businesses were sent an email notice of proposed rulemaking via GovDelivery and had an opportunity to provide public comment when the proposed rules were noticed for rulemaking hearing on 6/16/2023. On 08/04/2023 the board sent out an email communication via GovDelivery to licensees and registrants requesting fiscal impact information on the proposed rules and small businesses had an opportunity to provide estimated fiscal information.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not consulted. The board directed staff to convene a Drug Compounding Workgroup consisting of Subject Matter Experts who had expertise related to drug compounding to assist with the development of proposed rules/amendments. The Compounding Workgroup held meetings on 2/21/2023, 4/18/2023, 5/16/2023, 6/20/2023 and 7/18/2023 and provided expertise and information that board staff utilized to draft proposed rules related to drug compounding.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

Proposed new rules and existing rule 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. 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.

OAR 855-041-1018 - Proposed amendments add compliance requirements related to dispensing compounded preparations and radiopharmaceutical prescriptions.

OAR 855-043-0545 - Proposed amendment adds compliance requirements for a DPDO who dispenses compounded preparations.

OAR 855-043-0630 - Proposed amendments include revising "shall" to "must" and adds that a correctional facility must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

OAR 855-043-0740 - Proposed amendment adds that a CHC must ensure that compounded preparations are dispensed in compliance with OAR 855-183

OAR 855-045-0200 – Repeals rule

OAR 855-045-0210 – Repeals rule

OAR 855-045-0220 – Repeals rule

OAR 855-045-0240 – Repeals rule

OAR 855-045-0270 – Repeals rule

OAR 855-183-0001 - Proposed rule revises and relocates existing rule OAR 855-045-0200 to OAR 855-183-0001 related to applicability.

OAR 855-183-0005 - Proposed rule revises and relocates rule OAR 855-006-0005(11) to OAR 855-183-0005 and adds new language related to compounding definitions.

OAR 855-183-0010 - Proposed new rule adds general designation requirements for each Drug Outlet that practices drug compounding.

OAR 855-183-0050 - Proposed rule revises and relocates existing rule OAR 855-045-0220 to OAR 855-183-0050 related to personnel requirements.

OAR 855-183-0200 - Proposed rule revises and relocates existing rule OAR 855-045-0200(3) to OAR 855-183-0200 and adds general requirements for drug compounding.

OAR 855-183-0205 - Proposed new rule adds compounding technology requirements related to Automated Compounding Devices (ACDs).

OAR 855-183-0370 - Proposed new rule adds delivery requirements for each Drug Outlet Pharmacy who ships or delivers compounded preparations.

OAR 855-183-0400 - Proposed rule revises and relocates existing rule OAR 855-045-0240 to OAR 855-183-0400 related to labeling requirements for compounded non-sterile preparations (CNSPs).

OAR 855-183-0410 - Proposed rule revises and relocates existing rule OAR 855-045-0240 to OAR 855-183-0410 related to labeling requirements for compounded sterile preparations.

OAR 855-183-0420 - Proposed new rule adds labeling requirements for Compounded Non-Sterile Preparations (CNSPs) and Compounded Sterile Preparations (CSPs) for future use.

OAR 855-183-0450 - Proposed new rule adds drug disposal requirements for hazardous and infectious waste.

OAR 855-183-0500 - Proposed rule revises and relocates existing rule OAR 855-045-0220 to OAR 855-183-0500 related to policies and procedures for registrants who practice drug compounding.

OAR 855-183-0520 - Proposed new rule adds requirements for compounded drug recalls.

OAR 855-183-0550 - Proposed rule revises and relocates existing rule OAR 855-045-0270 to OAR 855-183-0550 related to general records requirements.

OAR 855-183-0560 - Proposed rule revises and relocates existing rule OAR 855-045-0270(2) to OAR 855-183-0560 related to master formulation records (MFR) for compounded non-sterile preparations.

OAR 855-183-0565 - Proposed rule revises and relocates existing rule OAR 855-045-0270(2) to OAR 855-183-0565 related to master formulation records (MFR) for compounded sterile preparations.

OAR 855-183-0570 - Proposed rule revises and relocates existing rule OAR 855-045-0270(3) to OAR 855-183-0570 related to requirements for compounding records for compounded non-sterile preparations.

OAR 855-183-0575 - Proposed rule revises and relocates existing rule OAR 855-045-0270(3) to OAR 855-183-0575 related to requirements for compounding records for compounded sterile preparations.

OAR 855-183-0600 - Proposed new rule adds prohibited practices related to compounded drug preparation.

OAR 855-183-0700 - Proposed new rule adds requirements for compounding services related to preparation according to FDA approved labeling.

OAR 855-183-0710 - Proposed new rule adds requirements for compounding services related to copies of an approved drug.

OAR 855-183-0730 - Proposed new rule adds requirements for compounding services related to use by a veterinarian.

NOTES:

- History of rule package review
  - June/July 2023: The rules were sent to rulemaking at the June 2023 board meeting for the July 2023 rulemaking hearing for public comment only.
  - August 2023: The board reviewed OAR 855-006-0005, OAR 855-041-1018, OAR 855-043-0545, OAR 855-043-0630, OAR 855-043-0740, OAR 855-183-0001, OAR 855-183-0005 and OAR 855-183-0010.
  - December 2023: The board reviewed OAR 855-183-0050 and began its review of OAR 855-183-0200.
  - February 2024: The board will continue its review of OAR 855-183.

- Highlights/Markup
  - Rule language highlighted in yellow denote staff proposed amendments made since the rule package was sent to rulemaking at the June 2023 board meeting for the July 2023 rulemaking hearing for public comment only.
  - **The markup** in this package is in comparison to the current rules for Div 006, 041, 043, and 045.

Division 6
DEFINITIONS

855-006-0005
Definitions

*Note: Div 006 Definitions in its entirety is being considered for adoption in 2024 February Bd Mtg mailing #E1

(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.~~

Division 41
OPERATION OF PHARMACIES

855-041-1018
NOTE: *The Board adopted amendments to this rule at the December 2023 board meeting to be effective 3/1/2024. The mark-up shown below is against the language effective 3/1/2024.*

A drug outlet pharmacy must:

(1) Ensure each:

(a) Prescription is dispensed in compliance with OAR 855-041, OAR 855-115, OAR 855-120, OAR 855-125, OAR 855-139, OAR 855-141 and OAR 855-143;

(b) Controlled substance is dispensed in compliance with OAR 855-080;

(c) Compounded preparation is dispensed in compliance with OAR 855-~~045~~**183**; and

(d) 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 each licensed and non-licensed individual only perform duties they are licensed and trained to perform.

(5) Be responsible for the actions of each licensed and non-licensed individual.

(6) Establish, maintain and enforce the drug outlet written procedures required in OAR 855-041-1040.

(7) Comply with the Pharmacist's determination in OAR 855-115-0120(1)(k);

(8) 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
Statutes/Other Implemented: ORS 689.151, 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.

(~~9~~**10**) **Unless an exemption applies,** ~~E~~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: The Board adopted amendments to this rule related to short-acting opioid antagonists in October 2023 effective upon filing.

(1) Policies and Procedures: The Pharmacist and the practitioner representing the facility 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 must be reviewed and updated annually by the Pharmacist and the practitioner, maintained in the facility; and be made available to the board for inspection. The facility must submit to the board for approval~~,~~ the name of any employee Pharmacist or a written agreement between the Pharmacist and the facility regarding drug policies and procedures. The facility must notify the board of any change of Pharmacist within 15 days of the change.

(2) Dispensing: Prescription drugs must be dispensed by a Pharmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system. **The Correctional Facility (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 must:

(A) By nature of the system;

(i) Provide for separation of medications by patient name and location; and

(ii) Provide for separating medications by day of administration.

(B) By means of an individual patient medication record:

(i) Record the drug and dosing regimen of those drugs dispensed by the pharmacy;

(ii) Record the actual doses dispensed and returned to the pharmacy;

(iii) Record the date of the original order and the date the order is discontinued;

(iv) Provide a means for the Pharmacist to verify the prescriber's original order;

(v) Provide a means for the Pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient; and

(vi) Provide a mechanism to easily identify those drugs dispensed by pharmacy that are controlled substances.

(b) Each CF utilizing a unit dose dispensing system must establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies must be available in the pharmacy for inspection by the board:

(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 (4).

(c) The Pharmacist must certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.

(d) All medication must be stored in a locked area or locked cart.

(4) Labeling: Except as described in SB 450 (2023), prescription drugs dispensed in individual containers or medication cards must be labeled with the following information:

(a) Name and identifying number of the patient/inmate;

(b) Name, strength, and quantity of the drug dispensed. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(c) Name of the prescriber;

(d) Initials of the dispenser and the date of dispensing;

(e) Directions for use;

(f) Auxiliary labels and cautionary statements as required;

(g) Manufacturer's expiration date, or an earlier date if preferable; and

(h) Name of the pharmacy.

(5) Patient counseling:

(a) Upon receipt of a prescription drug order and following review by the Pharmacist of the patient's record, the Pharmacist must initiate and provide oral counseling to the patient or to the patient's agent or care giver in all ambulatory care settings and for discharge medications in institutions:

(A) Upon request; or

(B) On matters which a reasonable and prudent Pharmacist would deem significant; or

(C) Whenever the drug prescribed has not previously been dispensed to the patient; or

(D) Whenever the patient's medication record shows the drug has not been previously dispensed to the patient in the same dosage, form, strength or with the same written directions.

(b) When counseling is provided it must include information that a reasonable and prudent Pharmacist would deem necessary to provide for the safe and effective use of the drug. Such information may include the following:

(A) The name and description of the drug;

(B) The dosage form, dose, route of administration, and duration of drug therapy;

(C) The intended use of the drug and expected actions;

(D) Special directions and precautions for preparation, administration, and use by the patient;

(E) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(F) The possible dangers of taking the drug with alcohol, or taking the drug and then operating a motor vehicle or other hazardous machinery;

(G) Techniques for self-monitoring drug therapy;

(H) Proper storage;

(I) Prescription refill information;

(J) Action to be taken in the event of a missed dose; and

(K) Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Patient counseling must be in person whenever practicable. Whenever the prescription is delivered outside the confines of the pharmacy by mail or other third-party delivery, counseling must be in writing and by free access to the Pharmacist by phone.

(d) Subsections (a) and (b) of this section must not apply to those prescription drug orders for inpatients in hospitals or institutions where the drug is to be administered by a nurse or other individual authorized to administer drugs.

(e) Notwithstanding the requirements set forth in subsection (a), a Pharmacist is not required to provide oral counseling when a patient refuses the Pharmacist 's attempt to counsel, or when the Pharmacist, on a case-by-case basis and in the exercise of professional judgment, determines that another form of counseling would be more effective.

(f) Board rules for patient counseling must be observed for **each inmate /** patient~~/inmates~~ who self-administer**s** or who ~~are~~ **is** ~~given~~ **dispensed** prescription drugs when they are released from the CF.

(6) Administration: Drugs must be administered to **each** inmate/ patient~~s~~ by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined by the Oregon State Board of Nursing in OAR 851-045-0060. Drugs selected by **a** registered nurse~~s~~ from ~~manufacturer's container or Pharmacist's~~ **a** bulk drug container~~s~~ **as defined in OAR 855-043-0610** must not be administered by **an** unlicensed person~~s~~, 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

855-043-0740
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.

(13) **Unless an exemption applies,** ~~E~~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**

Effective XX/XX/20XX:

(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

Effective XX/XX/20XX:

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**

Effective XX/XX/20XX:

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~~

Effective XX/XX/20XX:

(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~~

Effective XX/XX/20XX:

(~~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)~~;

POLICY DISCUSSION: Flavoring

(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)

Effective XX/XX/20XX:

(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

Effective XX/XX/20XX:

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)

Effective XX/XX/20XX:

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 **CNSP** ~~compounded drug dispensed or distributed~~ 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)**

Effective XX/XX/20XX:

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 **CSP** ~~compounded drug dispensed or distributed~~ 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 **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

Effective XX/XX/20XX:

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

Effective XX/XX/20XX:

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~~

Effective XX/XX/20XX:

~~(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

Effective XX/XX/20XX:

(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

Effective XX/XX/20XX:

~~(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

Effective XX/XX/20XX:

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

Effective XX/XX/20XX:

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;~~

Effective XX/XX/20XX:

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~~Formula~~;~~;

(b) ~~c~~Calculations **to determine and verify quantities and/or concentrations of components and strength or activity of each API;~~;**

(c) ~~q~~Quantities ~~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;~~

Effective XX/XX/20XX:

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

Effective XX/XX/20XX:

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

Effective XX/XX/20XX:

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

Effective XX/XX/20XX:

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

Effective XX/XX/20XX:

(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

~~855-045-0200~~
~~Application~~

~~(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for use 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.~~

(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 (08/01/2022), 1231 (12/01/2021), and 1821 (05/01/2017).

[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

855-045-0210
Registration

(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
Personnel and Responsibilities

(1) All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties.

(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.~~

~~(3) The Pharmacist-in-Charge (PIC) must annually complete a self-inspection using the board's Compounding Self-Inspection Form by July 1 and retain for board inspection.~~

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

~~855-045-0240~~
~~Labeling of Compounded Drugs~~

~~In addition to the labeling requirements specified in OAR 855-041, 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) The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation;~~

~~(3) 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

(7) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.

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

855-045-0270
Records

(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:

(a) Standard operating procedures, including documented annual review;

(b) Personnel training according to the type of compounding performed, including competency assessment, and qualification records, including corrective actions for any failures, including gloved fingertip and thumb sampling test and aseptic manipulation validation. The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations. At a minimum, the record must contain:

(A) Name and signature of the person receiving the training;

(B) Documentation of initial and continuing competency evaluation, to include dates and results of required elements outlined in the outlet's policies and procedures; and

(C) Name and signature of the pharmacist who is designated as responsible for validation of the completion of all training.

(c) Engineering and environmental control records, including equipment, calibration, certification, environmental air and surface monitoring procedures and results, as well as documentation of any corrective actions taken; and

(d) Cleaning and disinfecting of all compounding areas and equipment.

(2) Master formulation records, including as appropriate:

(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~~

Division 115: Pharmacists (PIC Qualifications & Limitations)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals PIC Qualifications & Limitations Rule

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals OAR 855-115-0200 rule for PIC Qualifications and Limitations.

Documents Relied Upon per ORS 183.335(2)(b)(D):

Division 115 related to Pharmacist Supervision, Counseling, PIC: Qualifications & Limitations *Effective 3/1/2024

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 proposed repeal of this rule is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed repeal of this rule has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): The proposed repeal of this rule will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in determining to repeal this rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): The board adopted new Division 115 Pharmacists rules in August, October and December 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposes to repeal OAR 855-115-0200, effective upon filing. The board adopted OAR 855-115-0205 in December 2023, effective 3/1/2024 which replaces OAR 855-115-0200.

- **History of rule package review**
  - The board will complete a 1st review of this rule at the February 2024 board meeting.

- **Highlights/Markup**
  - Highlights- None, 1st review
  - Markup – None, repeal

~~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~~

Division 115: Pharmacists (Protocol Compendium-Vaccines)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds Vaccine Protocols to Protocol Compendium

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes permanently adding vaccine protocols to protocol compendium and adopts each protocol as a standard adopted by reference.

Documents Relied Upon per ORS 183.335(2)(b)(D):

Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway

Standard Protocol for All Vaccines: Managing Adverse Reactions

Cholera

Coronavirus 19

Haemophilus Influenzae type b

Hepatitis A containing vaccines

Hepatitis B containing vaccines

Human Papillomavirus

Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024

Influenza Live Attenuated Influenza Vaccine 2023-2024

Japanese Encephalitis

Measles, Mumps & Rubella containing vaccines

Meningococcal containing vaccines

Pneumococcal

Polio

Rabies

Respiratory Syncytial Virus

Tetanus, Diphtheria containing vaccines

Typhoid

Varicella containing vaccines

Yellow Fever

Zoster

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 proposed rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal anticipated. Licensees, registrants and stakeholders will have an opportunity to provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): Effect on Small Businesses: Number/Type: Reporting, Recordkeeping and Administrative Activities Cost: Professional Services, Equipment/ Supplies, Labor Cost: The proposed rule amendments will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in development of the rules: Registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Subject Matter Experts (SME) are responsible for drafting proposed protocols and then the Public Health and Pharmacy Formulary Advisory Committee is responsible for recommending changes to the drafts or recommending the proposed protocols are sent to the board for consideration.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-115-0345: Proposed amendments add vaccine protocols to the compendium, effective upon filing.

- History of rule package review
  - The board will complete a 1st review of this rule at the February 2024 board meeting.

- Highlights/Markup
  - Highlights- None, 1st review
  - **Mark**~~up~~ – None, new rule

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)~~.~~**; and**

(h) Vaccines:

(A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 2/2024);

(B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 2/2024);

(C) Cholera (v. 2/2024);

(D) Coronavirus 2019 (v. 2/2024);

(E) Haemophilus Influenza type b (v. 2/2024);

(F) Hepatitis A containing vaccines (v. 2/2024);

(G) Hepatitis B containing vaccines (v. 2/2024);

(H) Human Papillomavirus (v. 2/2024);

(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 2/2024);

(J) Influenza - Live Attenuated Influenza Vaccine 2023-24 (v. 2/2024);

(K) Japanese Encephalitis (v. 2/2024);

(L) Meningococcal containing vaccines (v. 2/2024);

(M) Measles Mumps & Rubella containing vaccines (v. 2/2024);

(N) Pneumococcal (v. 2/2024);

(O) Polio (v. 2/2024);

(P) Rabies (v. 2/2024);

(Q) Respiratory Syncytial Virus (v. 2/2024);

(R) Tetanus Diphtheria containing vaccines (v. 2/2024);

(S) Typhoid (v. 2/2024);

(T) Varicella containing vaccines (v. 2/2024);

(U) Yellow fever (v. 2/2024); and

(V) Zoster (v. 2/2024).

[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

Division 115: Pharmacists (Prescribing Practices - Short-acting Opioid Antagonists)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends rule to limit labeling exemption to nasal sprays consistent with 2023 SB 450

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes to amend rule by adding requirements that limit labeling exemption to nasal sprays consistent with the directives of 2023 SB 450.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 SB 450

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 proposed amendment is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed amendment has no anticipated fiscal and economic impact.
Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): 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 amendment to the rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): Proposed amendments are consistent with the legislative mandate of 2023 SB 450.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposes amending existing rule by adding that the labeling exemption only applies to nasal sprays as stated in 2023 SB 450.

- History of rule package review
  - The board will complete a 1st review of this rule at the February 2024 board meeting.

- Highlights/Markup
  - Highlights- None, 1st review
  - **Mark~~up~~** – Compared to rule currently adopted by board, effective 3/1/2024

855-115-0350
Services: Prescribing Practices - Short-acting Opioid Antagonists

(1) A Pharmacist may prescribe any FDA approved short-acting opioid antagonist (e.g., naloxone, nalmefene) and the necessary medical supplies to administer 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 a short-acting opioid antagonist;

(c) To an entity seeking a short-acting opioid antagonist.

(2) A Pharmacist is not required to label the prescription according to OAR 855-041-1130 if dispensing a FDA-approved short-acting opioid antagonist **in the form of a nasal spray**.

(3) The Pharmacist must document the encounter, the prescription and maintain records according to OAR 855-104-0055.

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

Division 120: Interns & Preceptors (Prohibited Practices- Intern)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Permits a supervising Pharmacist fluent in patient language to supervise Intern interpretation during counseling

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): To align with OAR 855-115-0145, this proposed amendment clarifies that a supervising Pharmacist who is also fluent in the language being interpreted may communicate directly with a patient who prefers to communicate in a language other than English or who communicates in signed language without mandating the use of a health care interpreter registered by the Oregon Health Authority.

Documents Relied Upon per ORS 183.335(2)(b)(D): ORS 413.558, OAR 855-120-0150

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 proposed amendment may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal or economic impacts are anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): 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 determining to amend the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule amendment.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): The board adopted Division 120 Interns and Preceptors in August 2023 which become effective 3/1/2024. The resources involved in convening an RAC were not necessary to amend this rule.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-120-0150: Proposes amending (1)(c) by incorporating "Pharmacist or" to allow a supervising Pharmacist or a Preceptor who is also fluent in the language being interpreted to communicate with a patient who prefers to communicate in a language other than English or who communicates in signed language without mandating the use of a health care interpreter registered by the Oregon Health Authority. Interns are only permitted to practice pharmacy under the supervision of a Pharmacist or a Healthcare Preceptor with the practice of pharmacy within their scope.

- History of rule package review
  - The board will complete a 1st review of this rule at the February 2024 board meeting.

- Highlights/Markup
  - Highlights- None, 1st review
  - **Mark**~~up~~ – Compared to rule currently adopted by board, effective 3/1/2024

Division 120
INTERNS AND PRECEPTORS

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 **Pharmacist or** 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

Division 020: Pharmacist Prescriptive Authority (Protocol Compendium)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Div 020 Protocol Compendium

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes to permanently repeal OAR 855-020-0300 Protocol Compendium.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 115 Pharmacists Permanent Administrative Order https://www.oregon.gov/pharmacy/Documents/Div_115_Pharmacists_BP_16-2023TrackedChanges.pdf

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 proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): The proposed rule repeal will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 115 Pharmacists rules in August, October and December 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Permanently repeals OAR 855-020-0300 Protocol Compendium. The board adopted Division 115 Pharmacists rules in August, October and December 2023, which replaces Division 020. This rule needs to be repealed to allow the Protocol Compendium to be permanently adopted in OAR 855-115-0345 which includes current versions of protocols.

- **History of rule package review**
  - The board will complete a 1st review of this rule at the February 2024 board meeting.

- **Highlights/Markup**
  - Highlights- None, 1st review
  - Markup – None, repeal

Division 020
PHARMACIST PRESCRIPTIVE AUTHORITY

~~855-020-0300~~
~~Protocol Compendium~~

~~A Pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium:~~

~~(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 (NRT) 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);~~

~~(g) Contraception (v. 06/2023); and~~

~~(h) Vaccinations:~~

~~(A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 2/2024);~~

~~(B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 2/2024);~~

~~(C) Cholera (v. 2/2024);~~
~~(D) Coronavirus 2019 (v. 2/2024);~~

~~(E) Haemophilus Influenza type b (v. 2/2024);~~

~~(F) Hepatitis A containing vaccines (v. 2/2024);~~

~~(G) Hepatitis B containing vaccines (v. 2/2024);~~

~~(H) Human Papillomavirus (v. 2/2024);~~

~~(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 2/2024);~~

~~(J) Influenza - Live Attenuated Influenza Vaccine 2023-24 (v. 2/2024);~~

~~(K) Japanese Encephalitis (v. 2/2024);~~

~~(L) Meningococcal containing vaccines (v. 2/2024);~~

~~(M) Measles Mumps & Rubella containing vaccines (v. 2/2024);~~

~~(N) Pneumococcal (v. 2/2024);~~

~~(O) Polio (v. 2/2024);~~

~~(P) Rabies (v. 2/2024);~~

~~(Q) Respiratory Syncytial Virus (v. 2/2024);~~

~~(R) Tetanus Diphtheria containing vaccines (v. 2/2024);~~

~~(S) Typhoid (v. 2/2024);~~

~~(T) Varicella containing vaccines (v. 2/2024);~~

~~(U) Yellow fever (v. 2/2024);~~

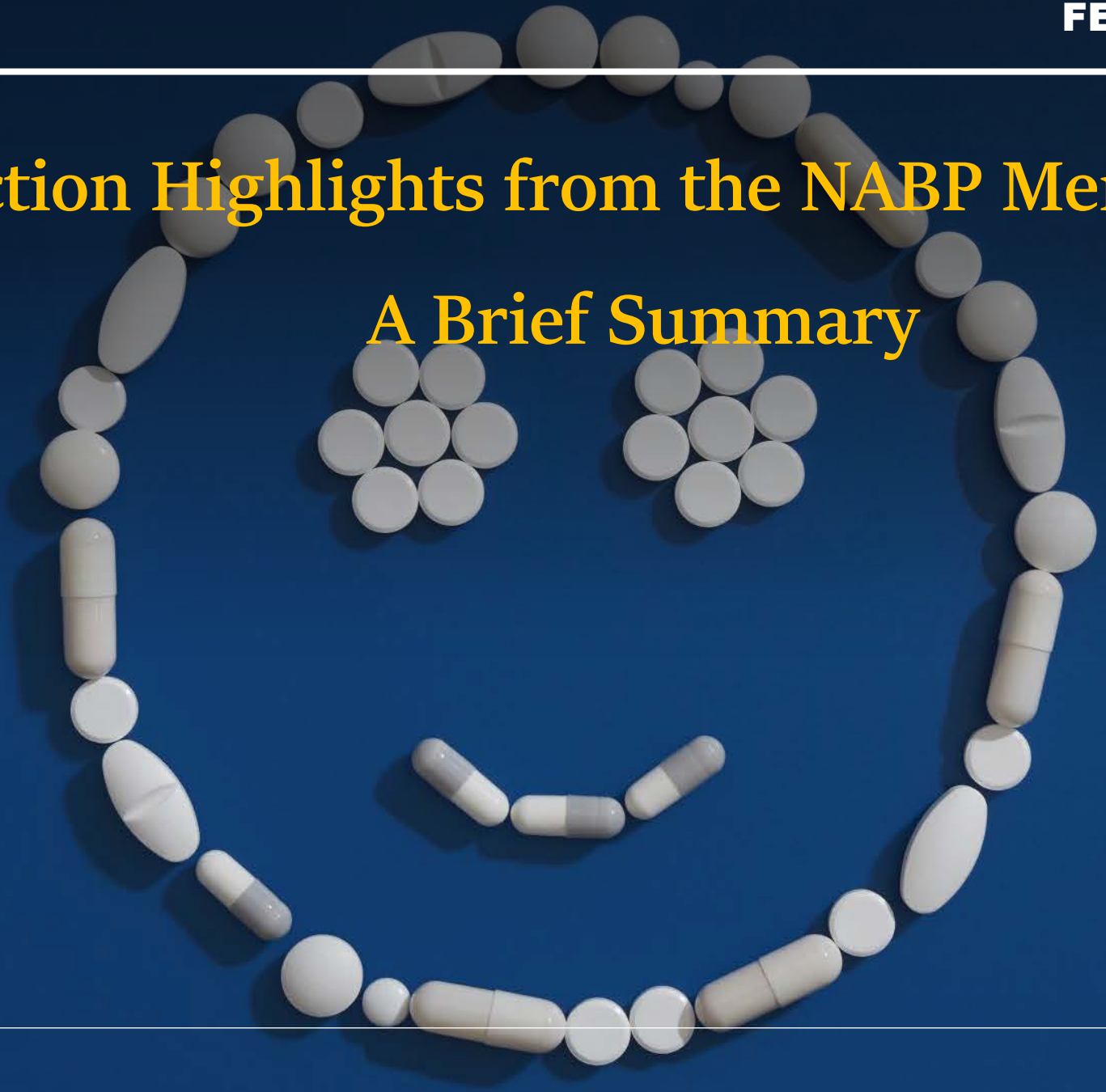
~~(V) Zoster (v. 2/2024).~~

~~[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, ORS 689.696~~

Recollection Highlights from the NABP Member Forum:

A Brief Summary



Board Member Patel

NABP

Member Forum

Networking to Drive Pharmacist Well-Being, Patient Safety

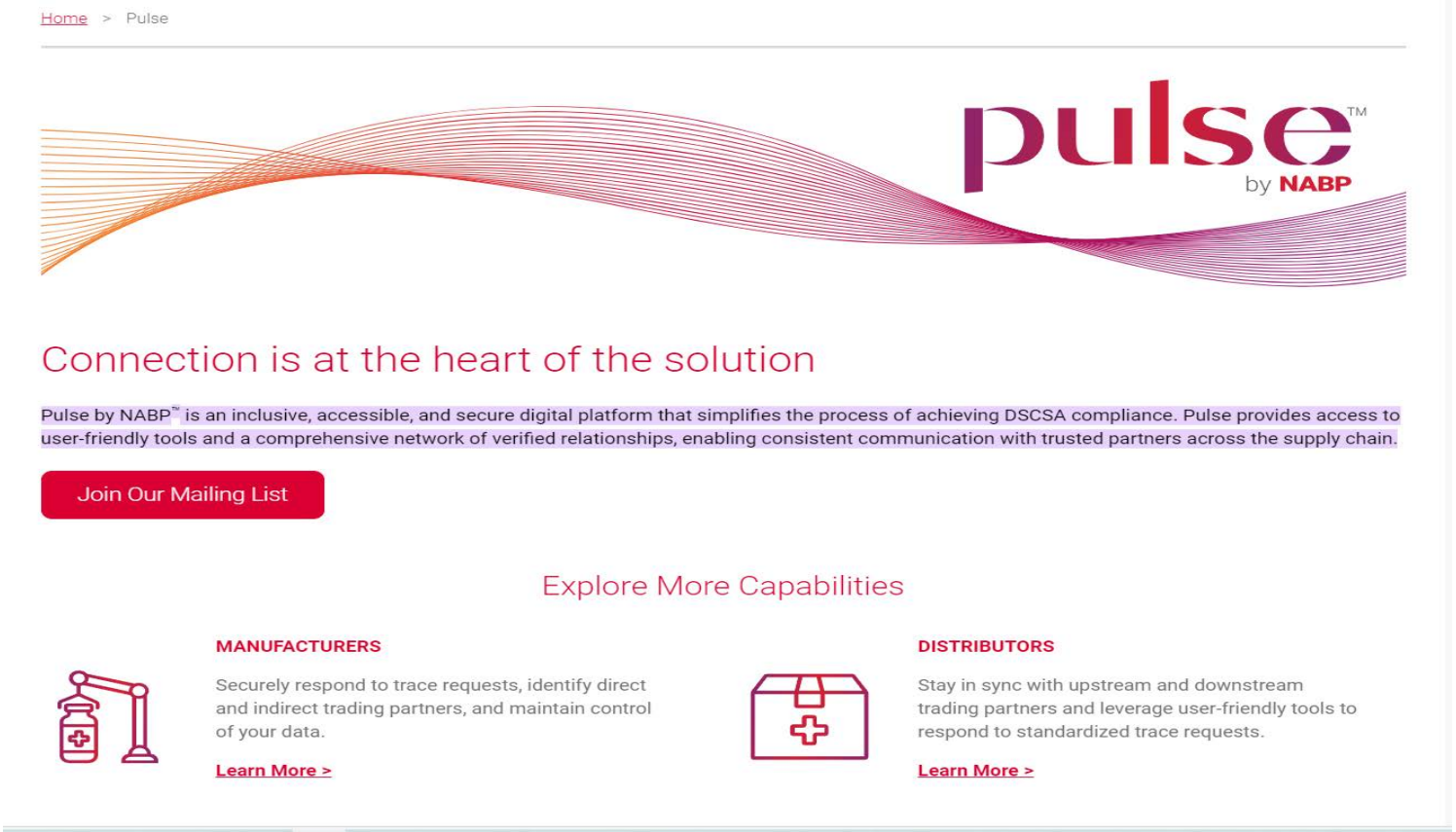
- NABP Verify and the Boards of Pharmacy
- All About Shared Services, Automated Pharmacy Systems, Remote Dispensing Sites, and Telepharmacy
- Drug Shortages, Compounding, & USP Revisions
    - USP <795> Updates
- AI Applications – How Can Pharmacy Regulators Ensure Patient Safety, Pharmacist Well-being?

NABP

Member Forum

Networking to Drive Pharmacist Well-Being, Patient Safety

- Driving Supply Chain Security Under DSCSA With Pulse by NABP



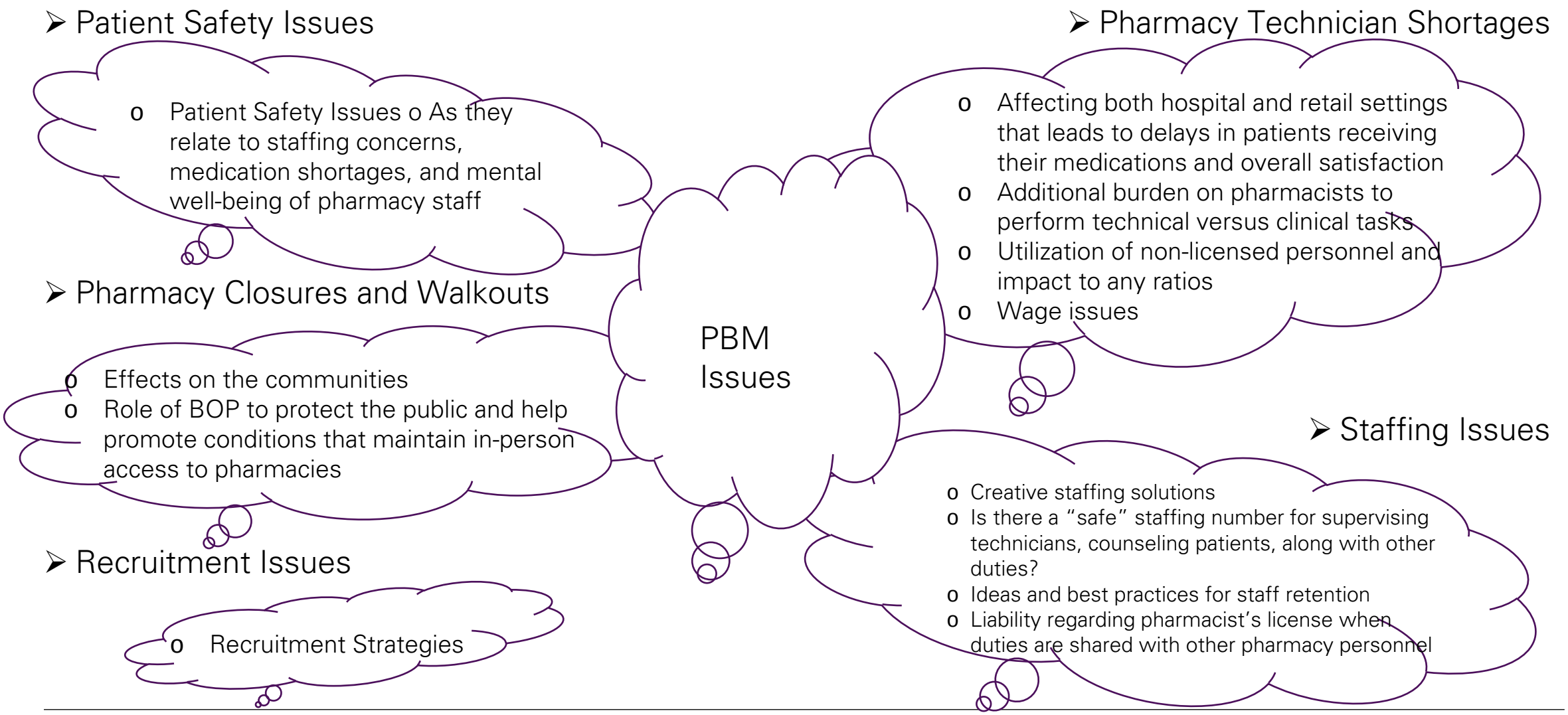
NABP

Member Forum

Networking to Drive Pharmacist Well-Being, Patient Safety

- Emerging Topics
  - MPJE Issues :
  - NAPLEX Testing Options
  - Marijuana (Medicinal and Recreational) and Psychedelic Mushroom Regulation

Pharmacy Working Conditions and Pharmacy Personnel Well-Being



- PBM Issues :

  - In the past, it was more of a business decision but has become a factor regarding access to care.
  - What can/are boards of pharmacy doing regarding PBM regulation? o Impact on retail, community, and specialty infusion pharmacies

- Reducing Regulatory Barriers and Administrative Burdens

  - Evaluating and reevaluating pharmacy regulations with the lens that existing regulations are necessary
  - Each regulation would need to be justified based on current needs, efficiency, and impact with the aim of creating a more streamlined and efficient regulatory framework

Tennessee State Board Of Pharmacy

Georgia State Board Of Pharmacy

Minnesota Updates Rules on Cannabinoids, Medication Repositories, and PBMs

Minnesota Governor Tim Walz recently signed legislation that has several provisions that will affect licensees and registrants of the Minnesota Board of Pharmacy. The changes address labeling of products that contain cannabinoids extracted from hemp, medication repositories, and PBM gag clauses.

New Arizona Legislation Impacts Several Areas of Pharmacy Practice

Several bills were recently signed into law by Arizona Governor Doug Ducey that address controlled substances, pharmacy benefit managers (PBMs), donated medicine, remote dispensing pharmacies, and more. Some specific highlights include House Bill 2787 – Occupational Regulation; Good Character; Definition, which defines moral turpitude and allows an individual to petition the Board to evaluate their documents prior to submitting an application. In addition, Senate Bill 1087 – Pharmacy Board; Regulation was signed, which allows for a remote hospital pharmacy, defines durable medical equipment (DME), allows for a DME distributor permit to be issued, clarifies third-party logistics provider, allows the Board to issue nondisciplinary civil penalty, and eliminates the requirement of a wall certificate for technician trainees.

For more details on all the legislative bills signed by Ducey, visit the Arizona State Legislature website at *https://apps.azleg.gov/BillStatus/BillOverview*. More information can also be found in the Arizona State Board of Pharmacy's July 2021 *Newsletter*.

Louisiana Regulatory Projects Address PBMs, CDS Licenses, Marijuana Products, and More

The Louisiana Board of Pharmacy has initiated several regulatory projects that are currently in various stages of the promulgation process, including:

- Project 2020-4 – Pharmacy Benefit Managers (PBMs), which requires a PBM engaged in certain activities construed to be within the scope of the practice of pharmacy to obtain and maintain a PBM permit from the Board;
- Project 2020-10 – CDS License for Hemp Facility, which establishes a hemp facility as an entity authorized to obtain a controlled dangerous substances (CDS) license;
- Project 2020-11 – Labeling and Delivery of Marijuana Products, which simplifies the labeling requirement imposed on producers of marijuana products, and authorizes marijuana pharmacies to deliver dispensed marijuana products to patients; and
- Project 2021-2 – Transfer of Marijuana Recommendations, which requires a marijuana pharmacy to transfer an

➢ Infusion Clinics :

- Do any boards have oversight responsibilities and if so , how ?
- Do other governmental agencies have oversight responsibilities ?
- Are any boards considering promulgating regulations and if so, where are you at in the process and can you share the specifics ?

NABP, FSMB, NCSBN Join Federal Agencies in Educating Regulators and Practitioners on Risks of IV Hydration Clinics

August 16, 2023
Categories: Industry News and Topics

IV hydration clinics allow consumers to select an IV infusion from a menu of various vitamins and supplements advertised for various uses and are purported to boost immunity, promote recovery, and remediate hangovers or fatigue. However, consumer caution is advised, as FDA has received reports of adverse events at medical offices, clinics, and other business models, such as IV hydration clinics, medical spas, and mobile IV infusion services.

FDA issued a compounding risk alert in October 2021 to caution health care providers about drug products being prepared under insanitary conditions at IV hydration clinics. The alert warns that businesses are compounding drugs that may not meet the conditions of the Federal Food, Drug, and Cosmetic Act or comply with state regulations.

As FSMB, NABP, and NCSBN have continued to see concerning activity in this area, the three organizations worked with FDA and FTC to develop this webinar as a means to inform regulators and practitioners on how to protect and educate patients. Following are the key points presented and discussed at the webinar:

- Regulators from the state boards of nursing, medicine, and pharmacy need to work together to ensure that businesses that offer IV hydration products are being inspected by the appropriate agency.
- Basic knowledge of FTC regulations as they relate to claims made by IV hydration product providers can be helpful for regulators and practitioners.
- Educating patients about these products, the claims being made, and the fact that such products need to be prescribed and administered by a licensed health care professional is important to the health and safety of patients.

The three organizations will continue to work with federal agencies and keep their members informed of what is happening in this space. Regulators and practitioners are encouraged to familiarize themselves with this issue so that they can do their part to protect patients. Slides and resources from the webinar can be viewed here.

- Removing Barriers to Practice at the Top of Training/Experience
  - While already able to practice at the top of their license, can boards be nimbler with rules to allow or encourage pharmacists to practice at the level of their training?
- Standard Of Care
  - Creating regulations that rely on "standards of care" versus rule-based prescriptive regulations
- OUD Stigma; Buprenorphine Stocking & Dispensing
- Substance Use Disorders
  - Use of collaborative practice to prescribe medications
  - The Idaho State Board of Pharmacy works in conjunction with the DEA to enable pharmacists to obtain a DEA license for prescribing Suboxone, Buprenorphine….

Activity Report

Report Date: February 5, 2024

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 4002 INTRO	Oregon Board of Pharmacy: No Position	Oregon Board of Pharmacy: 1	2/5/2024 - First reading. Referred to Speaker's desk.	
Digest: The Act requires the OHA to study the problems in this state caused by drug use and to send a report on its findings to the legislature.				
HB 4010 INTRO	Oregon Board of Pharmacy: No Position	Oregon Board of Pharmacy: 1	2/5/2024 - First reading. Referred to Speaker's desk.	
Digest: This Act makes changes to laws about prescription drugs, health insurance and some health care providers.				
HB 4071 INTRO	Oregon Board of Pharmacy: No Position	Oregon Board of Pharmacy: 1	2/5/2024 - First reading. Referred to Speaker's desk.	
Digest: Tells health care boards to give short-term permission to work.				
HB 4117 INTRO	Oregon Board of Pharmacy: No Position	Oregon Board of Pharmacy: 1	2/5/2024 - First reading. Referred to Speaker's desk.	1:00 PM 02/06/2024 House Committee Rules Public Hearing HR D
Digest: Allows OGEC and OGEC staff to give advice on the public meetings law.				
SB 1506 INTRO	Oregon Board of Pharmacy: No Position	Oregon Board of Pharmacy: 1	2/5/2024 - Introduction and first reading. Referred to President's desk.	1:00 PM 02/07/2024 Senate Committee Health Care Public Hearing and Possible Work Session HR E
Digest: The Act tells the Oregon Health Authority to pay a pharmacist who tests or treats a person for a virus.				
SB 1552 INTRO	Oregon Board of Pharmacy: No Position	Oregon Board of Pharmacy: 1	2/5/2024 - Introduction and first reading. Referred to President's desk.	
Digest: Makes many changes to the education laws of this state.				