Oregon Board of Pharmacy
***REVISED BOARD MEETING AGENDA**
December 14-16, 2022

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: 595 890 65#**

Multnomah County Health officials are urging everyone to wear masks in public indoor spaces until at least January 1, 2023 due to the surge in respiratory Winter viruses.

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, December 14, 2022 @ 8:30AM
Thursday, December 15, 2022 @ 8:30AM
Friday, December 16, 2022 @ 8:30AM

- All OBOP meetings except Executive or Closed Sessions are open to the public. Pursuant to ORS 192.660(1)(2)(f)(L), Executive Sessions are closed, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the board will return to Open Session
- To sign up for Public Comment, email your request to pharmacy.board@bop.oregon.gov by **12:00PM on 12/16/2022**.

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, DECEMBER 14, 2022

I. OPEN SESSION, Michelle Murray RPh, Presiding
***Please note that the board will meet in Executive Session for most of the day and anticipates resuming Open Session at 4:30PM.**

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

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

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

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

Adjourn *Action Necessary*

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THURSDAY, DECEMBER 15, 2022

I. **OPEN SESSION, Michelle Murray RPh, Presiding *Please note that the board will meet in Executive Session immediately after roll call. If you plan on attending the meeting in person, the board anticipates resuming Open Session at 1:00PM.**
   a. Roll Call

II. **EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 192.660(1)(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. **GENERAL ADMINISTRATION**
   a. Rules
      i. Review Rulemaking Hearing Report & Comments - *Melvin* **#A** *Action Necessary*
      ii. Consider Adoption of Temporary Rules – *None*
      iii. Consider Adoption of Rules – *Melvin*
         1. **Div 019** – 2022 HB 4034 Duties of a Pharmacist **#B** *Action Necessary*
         2. **Div 139** – 2022 HB 4034 Prohibited Practices **#B1** *Action Necessary*
         3. **Div 019** – 2022 HB 4096 Out-of-State Volunteer Pharmacist **#B2** *Action Necessary*
         4. **Div 062** – Drug Distribution Agent **#B3** *Action Necessary*
         5. **Div 010/019/020** – Pharmacist Prescriptive Authority **#B4** *Action Necessary*
            - COVID-19 Antiviral (Paxlovid) **#B4a**
            - Travel Medications **#B4b**
            - PEP **#B4c**
            - PrEP **#B4d**
            - Contraception **#B4e**
         6. **Div 021/135** – Continuing Pharmacy Education (CPE) **#B5** *Action Necessary*
         7. **Div 019/141** – Pharmacy Prescription Kiosk (PPK) **#B6** *Action Necessary*
         8. **Div 006/019/031** – Definitions **#B7** *Action Necessary*
         9. **Div 041** – Prescription Labeling Expiration Date **#B8** *Action Necessary*

      iv. Rulemaking Policy Discussion Items – *Davis*
         1. **Div 019/041** – Safe Pharmacy Practice Conditions **#C** *Action Necessary*
         2. **Div 019/020/031/041/115** – Pharmacists **#C1**
         3. **Div 001/102** – Procedural & Universal Rules **#C2**
         4. **Div 025/125** – Pharmacy Technicians **#C3**
         5. **Div 019/041/139** – Patient Demographics **#C4**
         6. **Div 110** – Fees **#C5** *Action Necessary*
         7. **Div 019** – Deficiency/Non-compliance notice **#C6** *Action Necessary*

Oregon Board of Pharmacy
***REVISED BOARD MEETING AGENDA**
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Adjourn *Action Necessary*

FRIDAY, DECEMBER 16, 2022

I. OPEN SESSION, Michelle Murray RPh, Presiding
   a. Roll Call

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

III. GENERAL ADMINISTRATION
   a. Staff Delegated Authority – *Efremoff* **#D** *Action Necessary*
   b. Resume Rulemaking Policy Discussion Items - *Davis*
   c. Discussion Items
      i. Public Health and Pharmacy Formulary Advisory Committee Update - *Davis*
      ii. Workgroup Update - *Davis*
      iii. Strategic Plan Update – *Schnabel*
      iv. Financial/Budget Report – *Schnabel* **#E**

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

2023 Revised Board Meeting Dates *Action Necessary*

**(Please note the board anticipates 3-day board meetings for the majority of 2023.)*

- February 8-10, 2023* Portland
- April 12-14 2023* Portland
- June 7-9, 2023* Portland
- August 9-11, 2023* Portland
- October 11-13, 2023* Portland
- November 8-9, 2023 TBA (Strategic Planning)
- December 13-15, 2023* Portland

Rulemaking Hearing Dates

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

- May 23, 2023
- November 21, 2023

Conferences/Meetings – *Schnabel*

- NABP 119th Annual Meeting – May 11 – 13, 2023, Nashville, TN

V. APPROVE CONSENT AGENDA* *Action Necessary*

**Items listed under the consent agenda are considered to be 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 - **# CONSENT-1**
   b. Board Meeting Minutes – October 2022 - **# CONSENT-2**
   c. Strategic Planning Minutes – November 2022 - **#CONSENT-3**

VI. PUBLIC COMMENT

Adjourn *Action Necessary*

Oregon
Kate Brown, 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: November 23, 2022
To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: November 22, 2022

Hearing Location: Virtual via Teams

Proposed Rules:

- Division 019 related to 2022 HB 4034 Duties of a Pharmacist
- Division 139 related to 2022 HB 4034 Prohibited Practices
- Division 019 related to 2022 HB 4096 Out-of-State Volunteer Pharmacist
- Division 062 related to Drug Distribution Agent
- Divisions 010/019/020 related to Pharmacist Prescriptive Authority - COVID Antiviral (Paxlovid), Travel Medications, PEP, PrEP & Contraception
- Divisions 021/135 related to Continuing Pharmacy Education
- Divisions 019/141 related to Pharmacy Prescription Kiosk (PPK)
- Divisions 006/019/031 related to Definitions
- Division 041 related to Prescription Labeling Expiration Date
- Divisions 001/102 related to Procedural & Universal Rules - **The board does not intend to adopt these rules in December 2022 - seeking public comment only*
- Divisions 025/125 related to Pharmacy Technicians - **The board does not intend to adopt these rules in December 2022 - seeking public comment only*
- Divisions 019/020/031/041/115 related to Pharmacists - **The board does not intend to adopt these rules in December 2022 - seeking public comment only*

On October 26, 2022, the November 22, 2022 Rulemaking Hearing public notice was sent out via GovDelivery to 2,950 rulemaking/adopted rules subscribers and 21,263 licensee/registrant subscribers (24,213 total subscribers). The following statement was added to the rule filing notice, rulemaking webpage and GovDelivery notice for Divisions 001/102 related to Procedural & Universal Rules, Divisions 025/125 related to Pharmacy Technicians and Divisions 019/020/031/041/115 related to Pharmacists: "the board does not intend to adopt these rules in December 2022 – seeking public comment only".

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

The rulemaking hearing convened at 9:32AM and adjourned at 10:32AM. #32 people joined the public call to listen, #7 people signed up in advance to provide oral testimony during the hearing, however only #5 people joined the meeting. There were #12 oral comments provided during the hearing. The hearing was recorded, and copies of the proposed rules were available for attendees via the board website. #61 written comments were received during the open comment period from 10/26/2022 though 4:30PM 11/22/2022.

The following board and staff members participated virtually:

Board President Murray
Board Vice President Doyle
Staff Member Davis
Staff Member Efremoff
Staff Member Melvin
Staff Member Schnabel

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: 2022 HB 4034 Duties of a Pharmacist
AMEND: OAR 855-019-0210

- No oral testimony was provided.

RULES PROPOSED: 2022 HB 4034 Prohibited Practices
AMEND: OAR 855-139-0600

- Todd B. MacLeod, Circle Medical Care of Oregon
    - Supports this measure
    - Has seen recent problems with pharmacies accepting telemedicine prescriptions
    - Believes this will increase patient access to medicines and has seen great improvements in patient care when they are able to receive telemedicine care
    - Pharmacies supporting these processes will improve patient care

- Michael Millard on behalf of Oregon Society of Health-System Pharmacists
    - Confused about section 1, retail drug outlet must NOT allow technician to ask questions of patient or patients agent that would limit interaction with the pharmacist
    - See's intent to allow patients access to pharmacist but believes that any question a technician asks a patient is a screener (e.g., do you have allergies)
    - Asked if this could be worded differently so that it would not prevent technicians from gathering information that pharmacists need them to gather so pharmacist can provide services
    - Supports pharmacist providing non distributive pharmacy services and would not want this rule to limit this ability,(e.g., medication reconciliation etc.), where technicians are used to gather information to assist pharmacist in clinical pharmacy services.

- Requested deletion of section or enhancement or clarification of this section, is this only for retail drug outlets or what are technicians permitted to do to gather information to assist pharmacists in clinical
- Agreed that technician should not be asking patient if they want counselling or not

RULES PROPOSED: 2022 HB 4096 Out-of-State Volunteer Pharmacist
ADOPT: OAR 855-019-0124

- No oral testimony was provided.

RULES PROPOSED: Drug Distribution Agent (DDA)
AMEND: OAR 855-062-0020

- No oral testimony was provided.

RULES PROPOSED: Pharmacist Prescriptive Authority – COVID Antiviral (Paxlovid), Travel Medications, PEP, PrEP & Contraception
ADOPT: OAR 855-010-0018

AMEND: OAR 855-020-0110, OAR 855-020-0120, and OAR 855-020-0300.

REPEAL: OAR 855-019-0400, OAR 855-019-0405, OAR 855-019-0410, OAR 855-019-0415, OAR 855-019-0425, OAR 855-019-0430, OAR 855-019-0435, and OAR 855-020-0105.

- Lauren Paul, CVS Health
  - Stated that she also emailed extensive written comments
  - Summarized:
    - Supportive of continued work by board and committee
    - Barrier is inability to reformat the protocol into electronic format. Requested the pharmacy's ability to implement an electronic document that includes the required elements.
    - Allow the pharmacy to modify how they ask the question and the order they put them in
    - Transition to EHR (electronic health record) to allow patient access to their records and interface between pharmacy and providers
  - Requests to amend rule to allow modification of the protocol but not to remove required elements

RULES PROPOSED: Continuing Pharmacy Education (CPE)
ADOPT: OAR 855-135-0001, OAR 855-135-0010, OAR 855-135-0030, OAR 855-135-0040, OAR 855-135-0050, OAR 855-135-0060, OAR 855-135-0070, OAR 855-135-0080, OAR 855-135-0085, and OAR 855-135-0090.

REPEAL: OAR 855-021-0001, OAR 855-021-0005, OAR 855-021-0007, OAR 855-021-0009, OAR 855-021-0010, OAR 855-021-0045, and OAR 855-021-0050.

- No oral testimony was provided.

RULES PROPOSED: Pharmacy Prescription Kiosk (PPK)
ADOPT: OAR 855-141-0001, OAR 855-141-0005, OAR 855-141-0010, OAR 855-141-0015, OAR 855-141-0020, OAR 855-141-0030, OAR 855-141-0050, OAR 855-141-0100, OAR 855-141-0120, OAR 855-141-0125, OAR 855-141-0130, OAR 855-141-0145, OAR 855-141-0150, OAR 855-141-0155, OAR 855-141-0200, OAR 855-141-0205, OAR 855-141-0210, OAR 855-141-0215, OAR 855-141-0225, OAR 855-141-0300, OAR 855-141-0305, OAR 855-141-0310, OAR 855-141-0315, OAR 855-141-0320, OAR 855-141-0325, OAR 855-141-0345, OAR 855-141-0350, OAR 855-141-0400, OAR 855-141-0405, OAR 855-141-0410, OAR 855-141-0450, OAR 855-141-0455, OAR 855-141-0500, OAR 855-141-0550, OAR 855-141-0555, OAR 855-141-0600, OAR 855-141-0602, and OAR 855-141-0650.

AMEND: OAR 855-019-0300

- No oral testimony was provided

RULES PROPOSED: Definitions
AMEND: OAR 855-006-0005 and OAR 855-031-0005.

REPEAL: OAR 855-019-0110

- Michael Millard on behalf of Oregon Society of Health-System Pharmacists
    - Supports comprehensive review of rules and general administrative change in rules
    - Believes this exceeds scope board intended (e.g., change in definition of CDTM) and they strongly opposed to change of definition of CDTM to CPA.
    - Oppose because the board has not taken into account any public comment
    - Believe this needs a lot of review
    - CDTM exists currently in hospitals, there are hundreds of them. To be able to switch over and change the language throughout the state is needless and unwanted change
    - Understands that CDTM and CPA may be confusing, but this is not a welcome change
    - They believe there are distinct differences between the two and putting them together is not appropriate:
        - CDTM is tied to a prescription
        - CPA are agreements between physician and groups that may not be tied to an organization
        - With 2 different statutorily authority and CDTM has different history. (inferred 1980 AG opinion.)
    - Believe this needs rules advisory committee at minimum and legal consequences are great.

- Unbalanced approach that some rules are going for adoption in December (e.g., CDTM definition), but they relate to things that are still open for comment and continuing review.

RULES PROPOSED: Prescription Labeling Expiration Date
AMEND: OAR 855-041-1130

- No oral testimony was provided.

RULES PROPOSED: Procedural & Universal Rules *The board does not intend to adopt these rules in December 2022 – seeking public comment only
ADOPT: OAR 855-102-0005, OAR 855-102-0010, OAR 855-102-0015, OAR 855-102-0020, OAR 855-102-0025, OAR 855-102-0035, OAR 855-102-0040, and OAR 855-102-0050.

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.

- Michael Millard on behalf of Oregon Society of Health-System Pharmacists
  - Does not believe there is such thing as independent pharmacy practice and does not believe there is any need to keep records
  - Definition of pharmacy practice is well defined, and section 3 should be deleted

RULES PROPOSED: Pharmacy Technicians *The board does not intend to adopt these rules in December 2022 – seeking public comment only
ADOPT: OAR 855-125-0001, OAR 855-125-0005, OAR 855-125-0010, OAR 855-125-0020, OAR 855-125-0030, OAR 855-125-0040, OAR 855-125-0046, OAR 855-125-0070, OAR 855-125-0072, OAR 855-125-0074, OAR 855-125-0076, OAR 855-125-0080, and OAR 855-125-0090.

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.

- Rob Geddes, Albertsons Companies
  - Thanked the board for allowing stakeholder input earlier on in the process
  - Will submit written comments with broader information by end of day
  - 855-125-0080- responsibility and permitted practices
    - Significant changes of what non-licensed personal have been permitted to perform
    - Common practice to run register and sell prescriptions
    - Practice includes dispensing in which definition in statute includes preparation and deliver
    - Concerns this would further stress staffing requirements related to selling prescription in pharmacies if non-licensed personnel are not permitted

        - Encourage to carve out the sale of prescriptions at the pharmacy register under the supervision of pharmacist

- Michael Millard on behalf of Oregon Society of Health-System Pharmacists
    - Supports the use of licensed technicians under the supervision of pharmacist and delegation of technicians related to the function involved
    - This overall looks good
    - But again, have questions related to technicians being prohibited to ask questions related to screening question and would request some clarification of what this means
    - Related to comments made previously in prohibited practice section
    - Perhaps language to allow technicians to gather information to provide to the pharmacist of their assessment

- Lauren Paul, CVS Health
    - Submitted written comments
    - Appreciates rules released early to solicit feedback from public and licensees
    - Difficult to understand the allotment in rule related to technicians
        - Is the intent to allow full delegation model?
    - Supports simplicity but would like board confirmation this supports the board permitted the delegation model. They read this to say as long as technician is supervised and trained, they can delegate task to perform transfers, clarify prescriptions with doctor, take verbal prescription.
    - Have issues with technician not being able to access pharmacy when a pharmacist is not present
    - Stated that other states permit access during emergency circumstances or declared state of emergency to sell prescription to patient only

RULES PROPOSED: Pharmacists *The board does not intend to adopt these rules in December 2022 – seeking public comment only

ADOPT: OAR 855-115-0001, OAR 855-115-0005, OAR 855-115-0010, OAR 855-115-0013, OAR 855-115-0016, OAR 855-115-0019, OAR 855-115-0020, OAR 855-115-0030, OAR 855-115-0040, OAR 855-115-0043, OAR 855-115-0046, OAR 855-115-0055, OAR 855-115-0060, OAR 855-115-0063, OAR 855-115-0066, OAR 855-115-0070, OAR 855-115-0072, OAR 855-115-0074, OAR 855-115-0076, OAR 855-115-0082, OAR 855-115-0084, OAR 855-115-0086, OAR 855-115-0100, OAR 855-115-0105, OAR 855-115-0110, OAR 855-115-0115, OAR 855-115-0120, OAR 855-115-0125, OAR 855-115-0130, OAR 855-115-0135, OAR 855-115-0140, OAR 855-115-0145, OAR 855-115-0180, and OAR 855-115-0185.

AMEND: OAR 855-041-3000

REPEAL: OAR 855-019-0100, OAR 855-019-0120, OAR 855-019-0122, OAR 855-019-0123, 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 855-019-0220, OAR 855-019-0230, OAR 855-019-0240, OAR 855-019-0250, OAR 855-019-0260, OAR 855-019-0265, OAR 855-019-0270, OAR 855-019-0280, OAR 855-019-0290, OAR 855-019-0310, OAR 855-019-0460, OAR 855-019-0470, OAR 855-020-0200, OAR 855-031-0045, 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.

- Peter Fjelstad, Pharmaceutical Care Management Association (PCMA)
    - Represents pharmacist benefit managers (PBMs)
    - Concern for Oregon licensed pharmacist to require counseling prior to shipment and will create barrier to necessary prescription
    - Potentially delay in medications and withdrawals or serious side effects when lapse in therapy
    - Interactive counseling would be administratively burdensome and then would require staff must be able to provide counseling

- Rob Geddes, Albertsons Companies
    - 115-0001 applicability (3) removal of counseling from having to be an Oregon licensed pharmacist
        - Believes this is onerous and pharmacist licensed in another state would have the education to counsel
    - 115-0084 requires pharmacist to provide offer to counsel before prescription is released from drug outlet, would impact home delivery
        - Difficult to get patient on phone to offer counseling, could delay care and possible access
        - Encourage board to strike this regulation
    - 115-0086 PIC qualification
        - 1a (2,000 hours) and 1b (PIC Training Course): previously was "or" and is moving to "and"
        - Concern is primarily in the hard to staff areas in rural Oregon
        - 106 locations in Oregon, 18 locations would not have met these requirements and would not be eligible to serve as PIC.
            - 15 of these are in those rural areas
    - If the board does proceed would ask for a grace period of effective time

- Michael Millard on behalf of Oregon Society of Health-System Pharmacists
    - 115-0070 linked to definition changes previously stated
        - Oppose to limiting the CDTM language. If action is taken in December, you will have something in the rules that does not have definition and would be a disconnection.
        - Requests add CPA in general rules
    - 115-0070 opposed to holding the pharmacist ONLY on duty for the staffing of the pharmacy
        - Strongly supports holding both the outlet and the pharmacist responsible for this
        - Refer to the board minutes to where the board agreed that both should hold responsibility and ask the rules reflect that
    - 115-0074 CS duty to report

        - Strongly opposed to section b. Reporting DEA requirements
        - Words of concern “any”, DEA allows the registrant to determine
        - Word of concern “suspected”, many losses could be considered suspected
        - Is the board willing to add enough staff to process all of the potential suspected losses?
        - Requests striking this
    - 115-0010
        - Opposed to addition of independent pharmacy practice
    - 115-0230 add back current language to facilitate mail order processes
        - Is offering counseling in writing not efficient

- Lauren Paul, CVS Health
    - Submitted written comments
    - Echo comments related to counseling and delivery amendments
    - 115-0084 (2)(b) and (4) might be a conflict
    - 115-0086 plan of correction for discrepancy noted on board inspection
        - Variable time frame does not permit licensees a consistent expectation
        - Request clarity to provide clarity to licensees

All written comments received by the public comment deadline date of 11/22/2022 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 10/26/2022 Notice of Proposed Rulemaking.

From:	Rob Geddes
To:	PHARMACY RULEMAKING * BOP
Subject:	Emailing: Regulation 11-22 Hearing Comments - Protocols Final 11-22-22, Regulation 11-22 Hearing Comments Final 11-18-22
Date:	Tuesday, November 22, 2022 10:59:40 AM
Attachments:	Regulation 11-22 Hearing Comments - Protocols Final 11-22-22.pdf Regulation 11-22 Hearing Comments Final 11-18-22.pdf

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Rachel,

Please accept my written comments to supplement the comments I made during today's meeting.

Rob Geddes, PharmD
Director, Pharmacy Legislative and Regulatory Affairs
Albertsons Companies, Inc.
(M) 208.513.3470
(O) 208.395.3987
(F) 623.336.6641
Rob.Geddes@albertsons.com

Your message is ready to be sent with the following file or link attachments:

Regulation 11-22 Hearing Comments - Protocols Final 11-22-22
Regulation 11-22 Hearing Comments Final 11-18-22

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

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November 22, 2022

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

Re: Divisions 010/019/020 – Related to Pharmacist Prescriptive Authority

Dear Dr. Schnabel:

Albertsons Companies Inc. ("ACI") family of pharmacies is one of the largest pharmacy providers in the state of Oregon. We currently operate 106 locations in the state, under the Albertsons and Safeway banners. Nationwide ACI operates 1726 pharmacies across 34 states and the District of Columbia. We appreciate the work of the Pharmacy Formulary Committee and the board in developing protocols for pharmacists to advance patient care in their pharmacy settings.

HIV Post-Exposure Prophylaxis (PEP)

One of the inherent challenges with a detailed protocol is when guidelines and recommendations for the use of the medications change. HIV is an area of medicine where the guidelines and recommendations change rapidly, and there needs to be flexibility to meet the standard of care when offering Post-Exposure Prophylaxis.

Based on evolving guidelines from HHS, the medication Dolutegravir (DTG) should be added to the therapeutic options in this protocol. This medication has more favorable dosing frequency at once daily compared to other options. Previously the guidelines recommended against its use in during pregnancy, however, recently (6/13/2022) those recommendations have given way to this medication being a preferred antiretroviral to be used throughout pregnancy and while trying to conceive.[1]

We would also suggest removing the age minimum of 13 years. The need for PEP is a medical emergency. We acknowledge that a patient under 13 years of age has an urgent need for additional care (and will receive a referral for that), but that is not a reason to add an additional barrier based on age. Pharmacists are capable of following the weight-based dosing recommendations clearly outlined in CDC guidelines for the preferred course of PEP for patients aged 2-12 (tenofovir DF, emtricitabine, and raltegravir).[2]

[1] United States Health and Human Services, Updated HHS Perinatal Antiretroviral Treatment Guidelines Released | NIH (hiv.gov). Accessed 11/15/2022.
[2] Dosing on pg 33, table 6: Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016 (cdc.gov)

Lastly, on the patient assessment form it requires a warm referral to a provider for required baseline and follow up testing. It isn't always possible to connect with another provider or clinic at all hours a pharmacy may provide services. We would recommend removing the word "warm" to allow flexibility in the referral process to a clinic or provider. At the end of the day the requirement to refer the patient stands and it will be the responsibility of the pharmacist to facilitate that referral.

13. Does the patient have known chronic kidney disease or reduced renal function?		
☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.	☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.	Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min

HIV Pre-Exposure Prophylaxis (PrEP)

There is an inconsistency in the timeframe considered to be acceptable for HIV test results. On page 3 of the intake form it references within the last 2 weeks as being acceptable and on page 5 of the protocol it references the test mut be within 7 days. If these different timelines are referring to different scenarios (initial fill vs. refills, for example), clarification is needed. See images below for reference:

Page 3 Intake Form:

Testing and Treatment:

1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription.
   - I may be able to have tests performed at the pharmacy.
   - I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks.
     - I brought my labs in today ☐ Yes ☐ No

   I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV.
   I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate.
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.

Page 5 Protocol:

Testing:

The pharmacist must verify appropriate labs are complete. *Italics* below indicate need for referral.

Test Name	Date of Test	Result	Needs referral
• HIV Ag/Ab (4th gen) test:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• HIV RNA test:	____/____/_____	□ *detected* □ *indeterminate* □ not detected	□ *Yes*

Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing. NOTE: HIV Ag/Ab test must be performed within the 7 days prior to prescribing and dispensing. Order lab at initial intake and every 90 days thereafter.

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
Director, Pharmacy Legislative and Regulatory Affairs

November 22, 2022

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

Re: Definitions 855-006-0005, 855-019-0300, New Division 125 for Pharmacy Technicians, and New Division 115 for Pharmacists.

Dear Dr. Schnabel:

Albertsons Companies Inc. ("ACI") family of pharmacies is one of the largest pharmacy providers in the state of Oregon. We currently operate 106 locations in the state under both the Albertsons and Safeway banners. Nationwide, ACI operates 1726 pharmacies across 34 states and the District of Columbia.

The practice of pharmacy in Oregon, as well as the environment, have become more complex over time. The recent closure of Bimart, a major regional pharmacy player, primarily affecting Oregon has caused disruptions to both patients and open pharmacies in proximity. These disruptions have been challenging for patients, pharmacists, technicians, and unlicensed personnel. The transfers between pharmacies as patients seek long term solutions have increased workload and contribute to the increasing complex environment in Oregon. We believe that over time the challenges that have arisen from the Bimart closures that were layered on top of COVID pandemic complexities will ease and the practice of pharmacy will stabilize. We encourage the Board to not take any knee jerk reactions at this time and to wait for the stabilization to occur before reassessing.

While we certainly understand and appreciate the mission of the Oregon Board of Pharmacy, there are two potential pitfalls regulatory boards should avoid. The first is an urge to regulate based on "What If?" scenarios. Trying to propose language to address every scenario that could possibly happen leads to very prescriptive and complex regulations, which become challenging for a pharmacist to recall and comply with, which leads to onerous requirements based on potential edge cases. The second pitfall is regulating to the lowest common denominator. Devaluing the education, training, and experience of a pharmacist because a peer made a mistake or refuses to practice at a high level of competency leads to limiting the ability of a pharmacist or technician to practice at the top of their license. Both of these approaches have the potential to negatively impact the profession and operation of pharmacy, which directly impacts the mission of the Board by limiting access to pharmacy services in the community. It is through this lens that I will be making comments related to the many proposed rules up for public comment.

Definitions 855-006-0005

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

We agree that counseling is meant to be a meaningful interaction between a pharmacist and a patient to ensure they understand the risks and benefits of taking the medication as directed by their prescriber. While we believe this is the standard of care in the profession, we disagree that this needs to be included in the definition of counseling. In theory, this begins to regulate how the patient must behave in addition to the way a pharmacist must perform. We would suggest amending this definition to read as follows:

"Counseling" or "Counsel" means an ~~interactive communication~~ interaction 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.

With this minor change we believe the intent of the Board will be met without regulating how a patient behaves, which is altogether out of the control of the pharmacist.

"Pharmacist" means an individual licensed by the state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.

This definition exists with identical language in statute and the Board does not have the authority to change this language directly. With that in mind, we would like to point out that this definition is inaccurate because a pharmacist does not need to be licensed in Oregon to be considered a pharmacist. To clarify, an Oregon Licensed Pharmacist would be a more accurate defined term by this definition. The label or title of pharmacist is achieved through education and training versus licensure, which is achieved by meeting the requirements set forth by a state to practice as a pharmacist in a defined geographic area. We do not recommend a change to this regulation, but rather encourage the Board to work through the appropriate channels to amend the statutory definition of a pharmacist and in turn update this definition in rule at that point.

(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.

We support the simplification of the "Drug Utilization Review" definition by removing the prescriptive list of items included in that definition. The items listed in the definition previously are necessary to perform an adequate DUR by a pharmacist, but we agree they do not need to be outlined as part of the definition.

855-019-0300 Duties of a Pharmacist in Charge

(f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within~~:~~
~~(A) 15 days of receiving a deficiency notice; or~~
~~(B) 30 days of receiving a non-compliance notice~~ the time allowed by the board.

We have concerns with the feasibility of removing these timelines from the regulation. If an inspector asks for less time than is already required in the regulation, we are concerned with the ability of a PIC to adequately review the areas of non-compliance and be able to construct a thorough plan of correction. We would suggest the Board consider maintaining the language in the regulation as previously written.

New Division 125 for Pharmacy Technicians

We appreciate the opportunity to comment on these regulations in advance of the language being finalized by the Board and sent for a public hearing. We believe this will help ensure that these regulations will eventually yield a better regulation and hopefully avoid unintended consequences. This does pose some challenge because the Board has not discussed each aspect so the intent and context behind some of the changes are unknown. We would encourage the Board to seek ways to allow active public participation during the Board discussions in meetings to allow more active collaboration. By hearing from stakeholders early in the process, there will be fewer surprises when the official public comment hearings occur. The California Board of Pharmacy is a great example of balanced public participation. They allow for public comment before each decision or motion by the Board. This allows the Board members to be informed ahead of voting on a motion put forward.

855-125-0070 Responsibilities: General-Certified Oregon Pharmacy Technician and Pharmacy Technician

This section addresses final verification performed by a certified Oregon pharmacy technician or a pharmacy technician. We agree that a technician should not perform any aspect of the process that would require the training, education, or experience of a pharmacist. Section (4) (c) states "No discretion is needed" as a qualification for when technicians may perform the final verification. This phrase is ambiguous. It would be clearer to rephrase it as "No professional judgement is required." This is a more readily understood term to draw a distinction between what a pharmacy technician and a pharmacist may perform.

855-125-0074 Responsibilities: Duty to Report

This section, for the most part, clearly outlines scenarios and events that require a technician to report information to the Board. However, subsection (1) (a) (C) creates ambiguity:

<u>(C) Have a reasonable cause to believe that any suspected violation of ORS 475, ORS 689 or OAR 855 has occurred.</u>

The use of "suspected" sets up a situation where a technician may erroneously report something as a violation, which may be a simple misunderstanding. If the technician had all the information, they may realize no violation has in fact occurred. As the Board is required to investigate every complaint filed by the public or a licensee, we believe requiring suspected violations to be reported to the Board increases the costs associated with operating the Board as well as operational costs associated with responding to an investigation by a drug outlet. We would suggest the Board consider changing the language to read as follows to remove these ambiguous and erroneous situations in the following manner:

(C) Have a reasonable cause to believe that a ~~suspected~~ violation of ORS 475, ORS 689 or OAR 855 has occurred.

855-125-0076 Responsibilities: Training

(2) Complete ongoing training to ensure continued competency in tasks that are performed.

While we do not disagree with this proposed provision, we do feel it lacks specificity. We would recommend the Board consider discussing this in more detail to understand what exactly a pharmacy should be doing. Alternatively, the Board could consider adopting and relying on a rule that only allows a pharmacist to delegate tasks to an individual who has the appropriate training, education, and experience to complete the task.

855-125-0080 Responsibilities: Permitted Practices

It has become common practice to employ non-licensed personnel in Oregon to aide in the operation of the pharmacy. These individuals provide assistance with operating the cash register, stocking the shelves, filing and maintaining records, and cleaning, among other duties. These individuals have been critical, especially when the availability of qualified licensed technicians is in short supply. It is far easier to hire a non-licensed individual and allow them to work in a pharmacy until they become interested in furthering their career as a pharmacy technician. We believe their use is critical and have concerns that the change being made in this section may prohibit them from operating a cash register. Item (1) reads as follows:

(1) Non-licensed pharmacy personnel may perform any function that does not constitute the practice of pharmacy as defined in ORS 689 or assistance in the practice of pharmacy. Non-licensed personnel must only perform functions permitted by the pharmacist providing supervision, direction, and control.

When reviewing the definition of the practice of pharmacy in ORS 689 it includes the act of dispensing as highlighted below.

(31) "Practice of pharmacy" means:
(a) The interpretation and evaluation of prescription orders;
(b) The compounding, dispensing and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices;
(c) The prescribing and administering of vaccines and immunizations and the providing of patient care services pursuant to ORS 689.645;
(d) The administering of drugs and devices to the extent permitted under ORS 689.655;
(e) The participation in drug selection and drug utilization reviews;
(f) The proper and safe storage of drugs and devices and the maintenance of proper records regarding the safe storage of drugs and devices;
(g) The responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices;
(h) The monitoring of therapeutic response or adverse effect to drug therapy;
(i) The optimizing of drug therapy through the practice of clinical pharmacy;

(j) Patient care services, including medication therapy management and comprehensive medication review;

(k) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy;

(L) The prescribing and administering of injectable hormonal contraceptives and the prescribing and dispensing of self-administered hormonal contraceptives pursuant to ORS 689.689;

(m) The prescribing and dispensing of emergency refills of insulin and associated insulin-related devices and supplies pursuant to ORS 689.696; and

(n) The 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.

The definition of dispensing in ORS 689 states:

(9) "Dispense" or "dispensing" 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.

Based on the definition of dispensing including delivery of a prescription drug pursuant to a lawful order of a practitioner, we are worried this may include delivering a prescription to a patient via the cash register interaction or even home delivery. This would lead to a full paradigm shift in the operation and support of pharmacies. Given the increased stresses on community pharmacies, we believe this would negatively impact patient safety by putting more pressure on the licensed individuals in a pharmacy, including technicians and pharmacists, to perform the duties currently being performed by non-licensed personnel. We suggest at a very minimum the Board clarify the intent of this provision and consider explicitly permitting non-licensed individuals to assist in the dispensing or delivery of prescription drugs under the supervision of a pharmacist.

855-124-0090 Prohibited Practices

Currently item (5) of this section prohibits a technician from asking questions that screen or limit interaction with the Pharmacist. An area where this principle can become onerous is when a patient is picking up a refill medication that is a continuation of their current therapy. During this interaction it is natural for technician or non-licensed personnel as a matter of providing good customer service to ask the patient if they have questions for the pharmacist. A prohibition on this goes against customer service best practices. This question is not meant to limit interaction with the pharmacist. On the contrary, there may be situations where, based on the professional judgement of a pharmacist, there is no proactive reason the pharmacist needs to speak with or counsel the patient on the medication they are picking up, but the patient may still, nonetheless, have questions. Without being prompted by the technician or non-licensed personnel, the patient may forget they needed to ask something or feel as though the pharmacist is too busy for them.. The act of asking a patient if they would like to speak to the pharmacist or if they have any questions about their course of therapy should not be considered limiting interaction with a pharmacist, but rather a mechanism that can increase and foster that interaction between a patient and their pharmacist. We would suggest amending this provision to allow for support personnel to aid the patient in initiating contact with the pharmacist when they have questions. We would suggest the following change:

(5) Ask questions of a patient or patient's agent ~~which screen or limit~~ with the intent to eliminate interaction with the Pharmacist.

We recognize that there are situations such as dispensing a new prescription where the pharmacist has a duty to offer counseling to a patient or patient's agent that are very different from what was described above. The requirement for a pharmacist or intern to counsel or accept the refusal of counseling would remain in effect for these situations. Our proposed change would simply allow for support personnel to prompt interaction between the pharmacist and patient or patient's agent without fear of violating Oregon law.

855-115-0001 Applicability

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

As this section will repeal and replace 855-019-0100, it is important to compare the proposed new language to the existing law. The deletion of one critical word - "counseling" - from the exceptions listed in (3) has serious implications to what has been accepted practice by pharmacists at non-resident pharmacies for many years. We believe that a pharmacist licensed in good standing in another state has the training, education, and experience to counsel patients on the safe and appropriate use of their medication in the state of Oregon when working from an Oregon licensed out-of-state facility. We would urge the Board to add counseling back to the list of exemptions for pharmacists located in another state as part of item (3) as noted below.

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

855-115-0070 Pharmacist: General Responsibilities

We appreciate the extent of the conversation regarding the duties an intern may perform under the supervision of a pharmacist. Thank you for starting the process to set up a rules advisory committee to engage appropriate stakeholders on this topic. We agree with the need to refresh the requirement in (4) (a) of this section, which only allows an intern to perform duties of the pharmacist after the completion of their first academic year. There are different models in academia now, which should be considered when reviewing what an intern should be allowed to do based on their current education, training, and experience. We believe an intern can begin supporting the pharmacist with their duties much earlier than the completion of their first year and look forward to the committee diving into these topics.

(l) Ensure there is sufficient staff to provide services in a safe and timely manner. The Pharmacist on duty may temporarily shut down touchpoints and services at the discretion of the Pharmacist, if determined in their reasonable professional judgment, that there is insufficient staff to provide services in a safe and timely manner.

We agree that the pharmacist is tasked with being responsible for the practice of pharmacy occurring while they are on duty. We also agree that a pharmacist that is supervising the practice of pharmacy should do so in a safe manner. Pharmacists have differing talents when managing people and workflow in a pharmacy. There are many variables that may contribute to a pharmacist determining whether it is reasonable to offer certain services or allow varying touchpoints to remain intact. What one pharmacist considers reasonable may not be considered reasonable by another. Some of the variables may include but are not limited to workload, staffing, training and experience of support personnel, state of mind of the pharmacist and personnel, time of the day, and type of service. Considering the subjective nature of each variable and how it may differ based on the personal feelings, beliefs, education, training, and experience of a pharmacist, there is no way to create a true standard of care related to this principle. Based on this, while we believe the principle and intent of the language to be good, the enforcement will be very challenging. If a pharmacist exercises their professional judgement and decides not to temporarily shut down a touchpoint or service and a poor outcome occurs, will the Board automatically assume the pharmacist did not exercise reasonable professional judgment?

855-115-0076 Responsibilities: Training

As stated above in our comments related to 855-125-0076, we believe this section lacks clarity on what the ongoing training must involve. We recognize that this cannot be detailed, nor should it be detailed, in a prescriptive manner. We believe that pharmacists are already required to maintain competency to perform their duties in a professional manner. In general, this is accomplished by completing continuing education ("CE") relevant to the areas in which they practice. We would recommend referring this section to the CE requirements that exist in OAR 855.

855-115-0084 Counseling

(4) A pharmacist must not allow a prescription to be released from the drug outlet when counseling is required, prior to the counseling or acceptance of the request not to be counseled by the pharmacist:

We have significant concerns with this requirement and its potential unintended consequences related to patient safety and patient access and health equity. It has become customary to deliver or mail a prescription to a patient upon request by the patient. Within the delivery packaging, our pharmacies include a written offer to counsel which includes the contact information for the pharmacy. There are many advantages to this widely accepted process, particularly for patients who are not ambulatory or may lack transportation.

One concern is, if pharmacists are required to counsel the patient on the drug prior to dispensing and mailing or delivering to the patient, the patient will not have the medication in hand when the counseling occurs. We believe that counseling a patient without the medication in hand may result in the patient missing critical information when they receive the medication in some cases five days later. Additionally, due to the separation of counseling and medication in hand it will likely result in patients calling the pharmacy again

after they do receive their medication to refresh their understanding or clarify questions they have after seeing the product. This will increase the workload of pharmacists and may take away from the meaningful interactions and responsibilities.

Our primary concern, however, is related to the impact this will have on patient access and health equity. It is extremely difficult to establish contact with a patient and an attempt to contact usually results in leaving a message and waiting for a patient to return the call. Considering how challenging it is to get ahold of a patient, we believe having to counsel before mailing or delivering the medication will result in a delay of shipment or home delivery. The populations which rely most heavily upon delivery services from their pharmacy will be disproportionately affected by this rule. We urge you to strike this requirement from this proposed rule altogether.

~~(4) A pharmacist must not allow a prescription to be released from the drug outlet when counseling is required, prior to the counseling or acceptance of the request not to be counseled by the pharmacist:~~

855-115-0086 Pharmacist-in-Charge: Qualifications, Limitations, and Duties

We also have significant concerns with changes being made to this section, specifically regarding the qualifications for serving as a Pharmacist-in-Charge ("PIC"). Oregon currently has strict requirements for those who can qualify to be a PIC and these proposed regulations would enact much more robust requirements. The PIC position is an already challenging position to fill in many areas of the state and we believe, if enacted, these requirements will lead to pharmacies being unable to operate because they will not have an individual willing or "qualified" to serve as a PIC.

(1) In order to be a Pharmacist-in-Charge (PIC), a pharmacist must:
(a) Complete at least 2000 hours of pharmacy practice as a Pharmacist within the last 2 years in a US state or jurisdiction;
(b) Complete a board provided PIC training course either before the appointment or within 90 days after the appointment and every 5 years thereafter effective July 1, 2025;
(c) Be employed by the outlet; and
(d) Be active engaged in pharmacy activities at the drug outlet and be physically present at the drug outlet for a sufficient amount of time as needed to effectively supervise drug outlet activities, be responsible for the daily operation of the drug outlet and ensure drug outlet compliance.

The previous requirement allowed for a pharmacist to have one year of experience, which is less stringent than a specific number of hours. We have concerns that the Board is not considering situations where a pharmacist may work part time for a year or more and would not be eligible to move to a full time PIC position even if otherwise qualified as a pharmacist. We do not believe that the number of hours worked equates to experience, but rather the experiences a pharmacist gains during their employment yield a qualified candidate. This also immediately disqualifies highly talented individuals who display quality leadership attributes from becoming a PIC until they have completed the required number of hours. Instead of coming to work in Oregon, these high talent individuals may choose to begin their career in another state where the trajectory of their career is not hampered by arbitrary requirements that are applied equally without regard to variations in previous experience and training obtained by an individual. This rule would also have a disparate impact on female pharmacists. By requiring at least 2000 hours of pharmacy practice,

pharmacists who become pregnant and take maternity leave would be set back months behind their peers in career advancement, leaving the This rule would also have a disparate impact on female pharmacists, who would essentially be disincentivized to take maternity leave because taking it would set them back months behind their peers in career advancement, leaving the Board open to potential equal protection claims.

Under current regulations there is a mechanism to allow for less tenured pharmacists to qualify as a PIC by requiring those individuals to go through a Board PIC training course within 30 days of becoming a PIC. The proposed regulation changes an "or" to an "and" which eliminates the valid pathway to compromise. We assure the Board that a pharmacist who has less than one year of experience is not generally the target individual for a PIC role, however, in some cases they may be the only option. This is in part due to the requirement to have no gap between an outgoing and incoming PIC when a change occurs. The lack of a grace period for identifying the best candidate for the PIC role often results in resorting to placing a pharmacist who is either unwilling to perform the duties of PIC or who lacks experience or qualifications. To illustrate how necessary the "or" is in the current regulations, we reviewed the PICs in place at our 106 pharmacies in the state and concluded that 18 individuals would not have been allowed to become the PIC for lack of 2000 hours at the time they assumed the position. Today they were allowed to by virtue of completing the Board provided training course in lieu of the one year of experience. Fifteen of the eighteen individuals are the PIC for a pharmacy located in a rural area in Oregon. These are the areas of most concern now because they are some of the hardest to staff areas in the state. Additionally, since 2020 we have experienced 131 PIC changes across our network of pharmacies in the state. This means on average we would need to have 44 individuals meet the 2000-hour requirement and take the board course to replace those positions each year. The most pressing question the Board should ask itself is what will a pharmacy do if they have an upcoming absence in PIC and do not have a candidate meeting the 2000-hour requirement waiting in the wings? Will there be a waiver process or will that pharmacy have to cease operation causing further disruption to patient care in an already stressed environment. Lastly, it is customary for a pharmacy to name a temporary PIC when there is an extended absence in employment with the current PIC. The absence could be related to a leave of absence to care for an illness or possibly a lengthy vacation. These proposed regulations would require a pharmacy to find a qualified tenured pharmacist who is willing to transfer for a temporary opportunity, which may not be possible. Conversely, today we have an option to name a less tenured pharmacist as PIC and have them undergo the required training to qualify. We believe this change has negative consequences that far outweigh any benefit the public would experience from their enactment. We urge the board to preserve the pathway for a pharmacist with less than 2000 hours of experience to qualify for the position of PIC.

We understand the drug outlet's requirement to name a PIC without a gap in time is not within the scope of these proposed regulations, but this is an area that must be addressed during this discussion. Many states allow for a 30-day grace period to identify a new PIC and there are several states that do not require a PIC at all. We urge the Board to consider a grace period for the benefit of public safety to ensure there is time for a qualified candidate to be identified and placed in a position as important as PIC.

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
Director, Pharmacy Legislative and Regulatory Affairs

From:	Kate Jelline
To:	PHARMACY RULEMAKING * BOP
Cc:	Molly Bell
Subject:	Written testimony-comment to Agency
Date:	Tuesday, November 22, 2022 1:27:32 PM
Attachments:	image002.png OBOP Rule Change written comment.Kate Jelline 11.22.22.docx

Hello,
Thank you for the opportunity to provide written comment opposing language in proposed rule 855-115-000.

Please see attachment for written comment.

Regards,

Kate Jelline, PharmD, CSP, MSCS
Director of Partnerships & Innovation
Ardon Health
cell 503-312-5063 | kate.jelline@ardonhealth.com

Inspiring people and improving lives

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Oregon Board of Pharmacy

800 NE Oregon St., Suite 15

Portland, OR 97232

Officer Melvin and distinguished members of the Board,

Thank you for the opportunity to provide written testimony opposing proposed rule 855-115-0001. For the record, my name is Kate Jelline, Director of Partnerships and Innovation at Ardon Health Specialty Pharmacy in Portland, Oregon. I am a graduate of Oregon State University, College of Pharmacy and I have 25 years of Pharmacy experience.

I have devoted the last 11 years to specialty pharmacy, serving patients across the nation and in my Oregon community. I am a licensed pharmacist in ten states and for 7 years I held the PIC position for a nationally licensed pharmacy. I have experience with the nuances of operating under and maintaining multi-state licensure, while caring for patients beyond the borders of my home state. Even though the proposed rule will not initially impact my organization, it will have a ripple effect on patients, pharmacists, and pharmacies across the country including in Oregon.

Today I provide testimony on proposed Rule 855-115-0001. The language suggests an out-of-state pharmacist providing counseling to a patient in Oregon would be required to hold an active Oregon license, in addition to an active license in the state they currently practice. It is my experience that the current rule 855-019-0100 is sufficient to provide safe and effective patient care to patients in Oregon. This is because Oregon is one of the few states that already requires a non-resident pharmacy to appoint a Pharmacist In Charge (PIC) licensed in Oregon. Under the current rules this pharmacist would be responsible for ensuring that all pharmacists working with patients located in Oregon act, at all times, in accordance with Oregon pharmacy laws and rules, as well as providing patient consultations in accordance with OBRA 90. A pharmacist's ability to counsel comes from extensive schooling and training and is validated through the NAPLEX. State exams ensure the understanding of the operations of pharmacy in the state, but a pharmacist's ability to counsel goes above and beyond. Counseling is the very essence of pharmacy. It allows us to use the education we received to make a difference in our patient's lives. As a pharmacist, my goal is to support my patient in their moment of need, no matter the location. If the rule is changed, I believe the interpretation will be varied and result in hesitation to care for patients pending confirmation of their location and create an unnecessary barrier to care. Many Oregon residents, especially those residing in rural areas, travel across state lines to access care. The proposed changes will impact a pharmacy's ability to serve patients in bordering states.

My second concern is regarding the Board's evaluation of cost of compliance. No known economic impacts were found by the Board to the agency, other state or local government, small businesses or members of the public. I respectfully disagree. This rule update will increase

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the administrative burden for pharmacies, pharmacists, and the Oregon Board of Pharmacy. Health care staffing and sustainability is at an all-time low, so we must be prudent in applying laws that promote access to care, not the opposite. Costs have risen, staffing crises are still apparent, and health care burn-out is rampant. I implore the board to consider both the administrative burden and the operational burden on all parties involved, especially pharmacists. Additional administrative costs associated with licensure cannot be fully absorbed by pharmacies and can be expected to be passed on to payers and patients, further challenging the affordability of prescription medications.

While I understand there is a desire to align with other health care boards, the practice of pharmacy is unique. Pharmacists work in a pharmacy, and the pharmacy as well as the PIC is required to be licensed. A prescriber can, and often does, work alone or independent of an Oregon licensed clinic.

I respectfully suggest the Board add counseling back into the list of professional tasks listed in proposed rule OAR 855-115-0001 and allow an out of state pharmacist, operating under the direction of an Oregon licensed PIC, to counsel and care for patients in Oregon without an individual Oregon pharmacist license. I do not believe the proposed changes will result in improved patient care, and will in turn, further burden and add additional strain to healthcare professionals, will increase the cost of doing business in the State of Oregon and ultimately increase the cost of delivering pharmacy services.

Please consider the barriers to patient care that will be created by proposed Rule 855-115-0001. We must all work together to continue putting patients first and providing high quality and compassionate care.

Respectfully submitted,

Kate Jelline, PharmD

Ardon Health

Director of Partnerships and Innovation

ardon

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From:	Tom Mann
To:	PHARMACY RULEMAKING * BOP
Cc:	Kyle Zebley; Alexis Apple
Subject:	ATA Letter to Oregon Board of Pharmacy
Date:	Monday, November 21, 2022 12:47:44 PM
Attachments:	image001.png ATA_Letter to Oregon Board of Pharmacy_Nov212022.pdf

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Dear Members of the Oregon Board of Pharmacy,

On behalf of ATA Action, I am writing in support of proposed amendments to OAR 855-019-0210(2)(a) to align with recent changes to Oregon's telemedicine law pursuant to HB 4034.

Please let us know if you have any questions.

Regards,

Tom Mann
Policy Associate
901 N. Glebe Road, Ste. 850 | Arlington, VA 22203
Mobile: 708.269.3834
ataaction.org

www.ataaction.org

ataACTION
Telehealth Policy to Transform Healthcare

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

RE: Support for Revision to OAR 855-019-0210

Dear Members of the Oregon Board of Pharmacy

On behalf of ATA Action, I am writing in support of proposed amendments to OAR 855-019-0210(2)(a) to align with recent changes to Oregon's telemedicine law pursuant to HB 4034.

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

As ATA Action shared in feedback to the Oregon Board of Pharmacy ("Board") in May and June of this year, regulation OAC 855-019-0210 was in conflict with newly-passed HB4034. HB4034 made clear licensed practitioners should be able to utilize the full range of available telemedicine technologies while delivering virtual care so long as the technologies being used are appropriate to meet the standard of care for the condition presented by the patient.

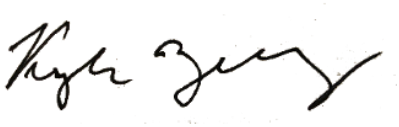
ATA Action strongly supports the Board's proposed amendments to OAC 855-019-0210 to align with HB4034 and appreciates the Board's efficient response to public comment. While we understand that older regulations included terms like "questionnaire" and "internet-based relationship" to prohibit dangerous and rogue pill mills who were primarily prescribing pain medication, we believe these undefined and outdated terms in OAC 855-019-0210 created unnecessary uncertainty for pharmacists about dispensing prescriptions resulting from appropriate and permissible telemedicine visits. Oregon's telemedicine law clearly contemplates telemedicine encounters where a physician "prescr[ibes] drugs" using the internet -- including video visits and those using "asynchronous technologies to facilitate an exchange of information between a patient and a physician or physician assistant in other than real time." (HB4034, Sec. 14(1)).

ata ACTION
Telehealth Policy to Transform Healthcare

The Board's proposed revision reinforces the existing protections under OAR 855-019-0210 that ensure patient safety, including that the prescription be issued pursuant to a valid patient-practitioner relationship and for a legitimate medical purpose. Further, it brings consistency to Oregon's telemedicine policy and ensure that patients can access their medications without unnecessary hurdles or delay.

We appreciate the Board's quick response to public feedback and support how the proposed amendment will provide clarity to providers and patients. If you have any questions or would like to engage in additional discussion regarding ATA Action's perspective, please contact me at kzebley@ataaction.org.

Kind regards,



Kyle Zebley
Executive Director
ATA Action

From:	Molly Bloom
To:	PHARMACY RULEMAKING * BOP
Subject:	Rulemaking comments
Date:	Saturday, November 19, 2022 9:46:00 PM
Attachments:	855-115-0070.docx 855-115-0120.docx 855-115-0125.docx

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Please see attached comments to proposed rules,

Thank you,
Molly Bloom, PharmD

Dear Oregon Board of Pharmacy Members,

I am opposed to the proposed changes to 855-115-0070, holding the **pharmacist on duty solely responsible** for the staffing of the pharmacy outlet but I do encourage the Board of Pharmacy to proceed with **holding the pharmacy outlet responsible and liable for discipline** by the Board for the various patient safety aspects contained in this section of the proposed rules. Holding the PIC or staff pharmacist responsible for workplace conditions over which they may have no organizational control is unfair, and does not protect Oregon patients. Appropriate investigation and discipline of outlets will be a key factor in improving patient safety but the burden should not be placed solely on the PIC.

The accountability should be shared by both the PIC and drug outlet, but the rules should not be written that imply sole responsibility of either party.

Thank you,
Molly Bloom, PharmD

11/18/2022

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern and provide feedback about the proposed changes to the Collaborative Drug Therapy Management (CDTM) rules. I am strongly opposed to removing all OARs that discuss CDTM and proposed OAR, 855-115-0120. It appears that the Board voted to send these proposed changes to rulemaking for feedback from the public however, changes were not discussed in public comment during either the August or October Board of Pharmacy meeting making thorough feedback difficult.

I urge you to use a rules advisory committee to provide feedback on the impact these additional rules will have, but especially with the proposed rules for 855-115-0120. I feel there are consequences of removing CDTMs from rules and replacing them with a redefined clinical pharmacy agreement (CPA). One implication, though certainly not the least, is the ability of pharmacists to be reimbursed for and thus provide services to Medicaid recipients enrolled in Coordinated Care Organizations (CCOs). In addition, these rules impact pharmacists in all settings, not just community pharmacy. The intent of these rules is unclear yet feels as though the intent is to limit our current scope of practice.

The Oregon Medical Board does not have corresponding rules that recognize a CPA. When/if these draft rules go into effect, there will be no ability for pharmacists to collaboratively manage drug therapy. This will greatly affect many of the pharmacists currently working in a clinical environment and could cause patient harm. It may also disrupt care for many Oregonians whose only access to a healthcare provider is their pharmacist and further erode efforts made to address health equity for rural and minority populations in Oregon. Before passing these rules I urge you to press pause and let subject matter experts weigh in on what these rule changes will mean for the current practice of pharmacy, the evolution of pharmacy practice, and patient safety.

Thank you,
Molly Bloom, Oregon RPh

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern about the proposed rule changes to Medication Therapy Management. I, Molly Bloom, urge you to reject changing the word “may” to “must” in proposed rule 855-115-0125 (2). It appears the Board voted to send these proposed changes to rulemaking for feedback from the public. However, the changes to the definition of MTM were not discussed in public comment during either the August or October Board of pharmacy meeting making the reason for the changes unclear and thorough feedback difficult.

MTM encompasses a variety of services provided by pharmacists, generally for Medicare Part D plans which have their own definition. Changing the definition of MTM in this rule to require that “all elements listed be completed” is unnecessary and puts an undue burden on Oregon Pharmacists who complete MTM visits for Medicare recipients. Some Part D MTM interventions may be as simple and brief as a telephone call to determine why a patient is late for a maintenance medication refill or if an intervention or refill is needed. The proposed change would mandate a provision of services that are not indicated and increase the documentation and administrative burden on the pharmacist providing said service. This may in turn, entice Medicare plans to contract with pharmacists outside of Oregon (as they are not held to the same rules) rather than their local pharmacist who they see and trust when filling their prescription medications. The Oregon Board of Pharmacy should be doing everything they can to develop and encourage the pharmacist-patient relationship which results in improved patient safety outcomes, not burden it with cumbersome mandates. **This proposed rule change from “may include” to “must include” is unnecessary.**

Thank you,
Molly Bloom, PharmD

From:	Stefan Shearer
To:	PHARMACY RULEMAKING * BOP
Cc:	James Slater
Subject:	11/22 Rule Hearing - Written Comments
Date:	Thursday, November 17, 2022 10:30:44 AM
Attachments:	image001.png CareOregon Pharmacy Rulemaking Comments 20221116.pdf

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Good morning,

Attached are written comments on behalf of CareOregon, Columbia Pacific CCO, and Jackson Care Connect. Please do not hesitate to reach out if you have any questions or if anything needs clarification.

Thank you!

Stefan

Stefan F. Shearer, MPA:HA
Public Policy & Regulatory Affairs Specialist
Work | 503-416-3418 | Mobile | 503-688-0580
careoregon.org

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November 16, 2022

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

RE: Divisions 006/019/031 related to definitions and Divisions 019/020/031/041/115 related to Pharmacists

Dear Dr. Schnabel,

CareOregon is a community non-profit organization serving over 500,000 Oregonians covered by the Oregon Health Plan. CareOregon wholly owns two coordinated care organizations (CCOs), Jackson Care Connect and Columbia Pacific CCO. We also are a founding member of Health Share of Oregon, managing an integrated community network and the behavioral health benefit for all Health Share of Oregon members.

CareOregon would like to express concern and caution regarding the proposed definition changes to the Collaborative Drug Therapy Management and Clinical Pharmacy Agreements rules. Removing the definition of Collaborative Drug Therapy Management is a substantial definition change which has not had time for adequate review or discussion among stakeholders. The changes involving 855-019-0260, and replacement provisions within 855-115-0120 Services: Clinical Pharmacy Agreement, have systemic implications that need to be studied. Specifically, the state must assess the impact of these changes on the Medicaid rules and statutes, and more importantly, the effect on access to clinical pharmacy services by the Medicaid population.

In addition, we strongly recommend the board reflect on the legislative intent HB 2028 that created the definitions for Clinical Pharmacy Practice and Clinical Pharmacy Agreements. Oregon law permits collaborative drug therapy management (CDTM) to enable a pharmacist to participate in drug therapy, provided by a written agreement with physicians and other practitioners. The bill added language permitting Oregon Health Authority and Coordinated Care Organization to reimburse a pharmacist or pharmacy under specified situations. Coordinated Care Organizations enter into Clinical Pharmacy Agreements pharmacists and pharmacy to reimburse pharmacists for covered health services that are within scope of practice of a pharmacist.

Removing CDTMs from rule and altering guidance on the use of collaborative pharmacy agreement may have unintended consequences. Furthermore, we do not believe the CCO's role is to define the pharmacist(s) patient care process, standards of care, and decision criteria for managing chronic disease

states. Therefore, CareOregon requests current rule language for Collaborative Drug Therapy Management and Clinical Pharmacy Agreement remains in place until further study of the operational effect to all stakeholders. We also recommend the Board of Pharmacy convene a rules advisory committee to discuss the proposed changes to these rules, with participation from CCO pharmacists, practicing clinical pharmacists, and physicians that have direct experience utilizing CDTMs and Clinical Pharmacy Agreements to the benefit of their patient populations.

More robust public, and system-wide stakeholder input is needed to ensure the integrity of clinical pharmacy services, and that they continue to be accessible to vulnerable Oregonians with these proposed changes.

Thank you,

Amit Shah, MD
Chief Medical Officer
CareOregon

James Slater. PharmD
Vice President of Pharmacy
CareOregon

From:	Emily Colborn
To:	PHARMACY RULEMAKING * BOP
Cc:	Daniel Luce; Emily Colborn
Subject:	Comments to November 22, 2022 Rulemaking Hearing
Date:	Tuesday, November 22, 2022 10:12:49 AM
Attachments:	Promulgated Division 115 Rules and Division 6 Amendments - CLM Comments Submitted - 22Nov22.docx

Please see the attached comments to the November 22, 2022 Rulemaking Hearing.

Dan Luce, RPh, MBA, FAPhA
President and Founding Partner
Catizone, Luce & Menighan LLC
CLM Pharmacy Advisors
daniel.luce@pharmacyadvisors.pharmacy
Cell (847)942-6570

Joseph Schnabel
Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232

Dear Mr Schnabel

Thank you for your consideration of comments submitted regarding promulgated Division 115 rules proposing new counseling and licensing requirements for pharmacists who engage in the practice of pharmacy in Oregon (OR) and amendments proposed to Division 6.

The rule states in part:

855-115-0001 Applicability[1]

1. Applies to any pharmacist who engages in the practice of pharmacy
2. Only persons licensed with the board may practice pharmacy
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 OR, must be licensed by the board in accordance with the following rules, except that a pharmacist located in another state who is working for an out-of-state pharmacy, who only performs the professional tasks of (…), is not required to be licensed
4. A Pharmacist must not allow a prescription to be released from the drug outlet when counseling is required prior to the counseling or acceptance of the request not to be counseled by a Pharmacist.
5. For each prescription, the Pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device.

Additionally, Amendments to Division 6 proposed at the November 22 Board meeting and define counseling to be "an interactive communication between a pharmacist and a patient or a patient's agent ...."

The promulgated rules and proposed amendments seem to conflict or confound each other and are a dramatic reversal from existing provisions. Foundational questions and concerns include whether non-resident pharmacies are allowed to provide a written offer to counsel in compliance with patient counseling definitions and requirements, the elimination of counseling from the professional task of a non-resident (NR) pharmacy, and the required presence and licensure of pharmacists in OR to provide patient counseling.

[1] NOTICE OF PROPOSED RULEMAKING, 10/25/2022.

Legal and Patient Care Precedents
If the promulgated rules and proposed amendments do eliminate the ability of non-resident pharmacies to provide written forms of counseling, the resulting restrictions will overturn years of precedent regarding the provision of patient counseling and care by non-resident pharmacies and pharmacists. The Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), modified a section of the federal Medicaid Act such that the Drug Use Review (DUR) required and performed by a pharmacist include the "offer to counsel" to each individual (or a caregiver) who presents a prescription. OBRA '90 and subsequently the majority of states codified that the "offer to counsel" could be made in writing or via telephone.

Although the Act noted the preference for in person counseling, it recognized that in person counseling should occur wherever practicable and allowed for the provision of counseling through a telephone service. Since the enactment of OBRA '90, more than 30 years ago, millions of patients have received important patient counseling and care from non-resident pharmacies and pharmacists utilizing the written "offer to counsel" and telephonic or video interactions.

Unnecessary Burdens, Pharmacy Regulation, and COVID-19
More importantly, the removal of counseling from the professional task of a non-resident pharmacy and pharmacist could result in unnecessary patient harm and additional financial burdens to the health care system. The justification for this significant change is that "other healthcare boards in OR and other states consider counseling to patients who are located in OR to require licensure." The justification fails to note that the regulation of other individuals by "other healthcare boards in OR" for the most part do not mandate, require, and regulate the physical offices of the practitioners, the records and record keeping systems, the security of the practitioners' offices and places of practice, the personnel assisting the other practitioners, and the actual information presented to a patient when counseling occurs. Those safeguards ensure the Board with compliance and the provision of appropriate patient counseling and care as has been demonstrated by non-resident pharmacies over the past thirty plus years, similarly to the compliance of resident pharmacies.

Furthermore, COVID-19 created a new dynamic for patient interactions and care. When the pandemic virtually closed all in person activities, the entire world moved to telehealth, telepharmacy, and tele-life. Vital and basic needs and services were transferred from in person interactions to remote and "tele" interactions. Telemedicine and telepharmacy services maintained the needed lifeline to millions of patients who would have been denied care and probably suffered serious consequences. The promulgated rules and proposed amendments seem to ignore the important concepts and improvements in care taught by the pandemic and solutions that resulted in pharmacy.

From a practical identity protection concern unknown cell phone numbers are in the least considered suspect or ignored and deleted. Most calls are blocked with a caller ID noting "spam risk" for any number unknown to the cell plan and / or cell phone. Delaying the mailing of a prescription due to the inability to reach a patient within the current cell phone privacy parameters is a definite risk for adverse patient care. It is also worth noting that the proposed

counseling standards for delivery are stricter than in person. With the new requirements, a pharmacy delivering its prescriptions will be mandated to reach someone by phone to even collect a refusal. In the pharmacy where the patient presents a prescription, the refusal may not be collected but the medication can still be dispensed in a timely manner.

Regulatory Consistency

The Board has long aligned with licensing standards and requirements for non-resident pharmacies of other states and the National Association of Boards of Pharmacy (NABP). According to the "2022 NABP Survey of Pharmacy Law on Patient Counseling Requirements," 27 states, including OR, allow a written offer to counsel or alternative manner to initiate the counseling process. Similarly, approximately 30 states allow for counseling to occur via telephone or video when in person counseling is not practicable and/or for prescriptions not physically presented to the pharmacy, including but not limited to non-resident and mail order pharmacies. In fact, the focus of most states regarding counseling is an "offer to counsel" versus the actual provision of counseling.

Recommendations:

It is respectively requested that the Board consider the following recommendations in moving forward with the Division 115 promulgated rules and amendments to Division 6:

- Allow the existing rules to remain in place so that patients who are served by pharmacists practicing at resident and non-resident pharmacies are afforded the appropriate oversight and regulation that has served the citizens and patients of OR well for almost three decades.
- Incorporate in any changes to the rules and requirements existing provisions that continue to recognize that remote, non-resident services address the urgent pharmacy care needs of a significant proportion of OR citizens who prefer or are unable to present prescriptions in person. Doing so would continue the practices and patient care services that exist across the majority of states and federal programs such as Medicaid.
- Avoid repercussions and patient harm that will result from requiring a patient to reach an OR licensed pharmacist prior to counseling and cause delays in receiving the needed medication.
- Avoid unnecessary burdening the provision of patient care services to patients utilizing pharmacies that deliver medications to patients by requiring licensure in OR of every pharmacist providing counseling. The current safeguards in place that require licensure of the non-resident pharmacy and pharmacist-in-charge provide the accountability and enforcement means to ensure that patients are protected and when necessary, appropriate disciplinary action can be taken against the pharmacy and any responsible pharmacist.
- Utilize the experience and data from the relaxing of requirements during the pandemic to implement changes to OR rules and requirements that recognize the changes that benefited patient care and increased patient access.

From:	Breann Westmore
To:	PHARMACY RULEMAKING * BOP
Subject:	Stakeholder Feedback
Date:	Tuesday, November 22, 2022 12:47:02 PM
Attachments:	image001.png CenterWell_Pharmacy_Inc_Comments - Creation of New Division 115 for Pharmacists FINAL.pdf

Dear Ms. Melvin –

Attached you will find CenterWell Pharmacy's comments in response to the solicitation for stakeholder feedback on proposed rulemaking that the Office of the Secretary of State issued on October 25, 2022. If there is anything further please don't hesitate to reach out.
Thank you.

Breann Westmore
Director |Government Affairs

Humana

C 480-828-3869
bwestmore@humana.com

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Kreyòl Ayisyen (Haitian Creole): ATANSION: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-877-320-1235 (TTY: 711).

Polski (Polish): UWAGA: Jezeli mówisz po polsku, mozesz skorzystac z bezplatnej pomocy jezykowej. Zadzwon pod numer 1-877-320-1235 (TTY: 711).

CenterWell Pharmacy

November 22, 2022

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

Submitted via email to pharmacy.rulemaking@bop.oregon.gov

RE: Proposed Rulemaking – Proactive procedural rule review; Creates new Division 115 for Pharmacists

Dear Executive Director Schnabel:

This letter is in response to the solicitation for stakeholder feedback on proposed rulemaking that the Office of the Secretary of State issued on October 25, 2022.

CenterWell Pharmacy, Inc. (CenterWell Pharmacy) is a full-service home delivery pharmacy serving patients across all 50 states. CenterWell Pharmacy provides holistic care that is personalized and coordinated with easy-to-use options so our customers and members can receive the care and prescriptions they need exactly when they need them. This includes home delivery services, as well as retail and specialty pharmacies. These pharmacies employ many pharmacists and pharmacy technicians who are critical to ensuring that patients across the country have access to the medication that they need. Of these pharmacists, many provide access to medication counseling 24 hours a day, 7 days a week to patients across the country, including those in Oregon.

CenterWell Pharmacy appreciates the opportunity to provide comments on this proposed rule.

Overall, CenterWell Pharmacy recognizes the Board's efforts to update the rules pertaining to the responsibilities of a pharmacist and ensure broad access to counseling services. However, ***the Board's proposal will increase costs, limit patient access to counseling services, and create delays in the delivery of care for Oregonians.***

- ***Changes to the licensure requirements will increase costs and potentially limit patient access to counseling services.***

  At CenterWell Pharmacy, we believe counseling services are essential for patients to better understand their medications while also improving adherence and health outcomes. Home delivery pharmacies provide a unique service related to counseling. We have registered pharmacists available 24 hours a day, 7 days a week to assist our patients with questions they may have about their medication or to provide counseling services. These services can be accessed by our members in all 50 states, including Oregon. This service offering is considerably more robust than those offered by retail and community pharmacies, which may only be open at limited times. Therefore, patients who are using CenterWell Pharmacy often have greater access to a pharmacist than those who use other pharmacies.

  Today, non-resident pharmacies and the pharmacist-in-charge are already licensed by the Board. Proposed rule 855-115-0001 would require non-resident pharmacies to staff Oregon-licensed pharmacists to provide counseling services to patients located in Oregon. Requiring

pharmacists to have an Oregon license is duplicative. Should the Board choose to move forward with this requirement, home delivery pharmacies like CenterWell Pharmacy will be required to modify their operations significantly to provide patient counseling for Oregonians. This would include software and information technology enhancements to ensure only Oregon-licensed pharmacists perform patient counseling functions. These investments, coupled with the cost to obtain licenses, could lead to additional administrative costs creating increased costs to the overall healthcare system and the patients of Oregon and other states.

Additionally, the health outcomes and well-being of patients are not adversely impacted when a pharmacist not licensed in Oregon but working for an Oregon-licensed pharmacy provides counseling. The pharmacy profession is guided by an evidence-based methodology, and licensed pharmacists in states other than Oregon will provide equivalent counseling services as pharmacists licensed in Oregon. Pharmacist education, training, and clinical licensing standards are very similar, if not the same, for most states. As such, patients will continue to receive compliant and clinically appropriate counseling services by out-of-state pharmacists. For this reason, requiring Oregon licensure will not provide any additional clinical value to the patients in Oregon.

Lastly, one of the Board's objectives is to ensure that patients in Oregon have broad access to medication counseling services. However, this change could limit the availability of counseling services for patients by limiting the number of pharmacists who are able to provide the service. For example, restricting patient counseling to only Oregon-licensed pharmacists could create access to care issues if a pharmacy's Oregon-licensed staff are unable to work due to emergency circumstances like a pandemic or natural disaster.

- ***Requiring counseling prior to dispensing could create delays for patients to receive their medication.***

  In addition to the changes related to pharmacist licensure for counseling, proposed rule 855-115-0001 would require a pharmacist to provide counseling prior to releasing a medication to the patient. This model may be appropriate in retail and community settings given the face-to-face interactions. However, there are critical differences in a home delivery model. Today, the home delivery pharmacies provide a written offer to counsel at the time the patient enrolls and with every prescription that is dispensed. Patients are notified multiple times about opportunities for counseling and how to contact a pharmacist. As previously mentioned, our comprehensive counseling services are available around the clock. Our goal is to answer all calls within 30 seconds. Additionally, we do not place time limits on these interactions with our patients. Our pharmacists will work with a patient one-on-one for as long as necessary to answer questions and provide counseling services.

  The proposal would require us to attempt to contact a patient to offer counseling prior to dispensing. If contacting the patient is required, we run the risk of the patient being unavailable to respond, which could create delays for the medication to be dispensed and may lead to therapy interruptions. Any potential delays in home delivery may pose a risk to patients. Patients choose home delivery due to a variety of reasons including home-bound status, convenience, and affordability. This is particularly true for seniors as one in six Medicare beneficiaries

CenterWell Pharmacy

currently depend on home delivery for at least one of their prescription drugs.[1] Timely delivery of medications is critical for patients, and this proposal fails to take nuances of the various pharmacy delivery models into account.

Recommendation

As previously stated, the proposed rule will increase costs, limit patient access to counseling services, and create delays in the delivery of care for Oregonians. Given these factors, ***CenterWell Pharmacy strongly recommends that the Board reconsider the draft rule's changes and continue allowing licensed pharmacists who are not licensed in Oregon but working for an Oregon-licensed pharmacy to provide counseling services at the request of a patient.***

Further, we suggest altering the definition in proposed rule 855-115-0001 so that counseling is included in the list of professional tasks performed by a pharmacist that would not require licensure in Oregon:

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

We also suggest altering the definition in proposed rule 855-115-0084 so that patients have the choice to decide if they need counseling services instead of it being a requirement that could potentially cause delays in care. To do so, we recommend the following change:

> *(4) For a prescription delivered outside of the pharmacy, the Pharmacist must offer in writing, to provide direct counseling and information about the drug, including information on how to contact the Pharmacist.*

Thank you for the opportunity to provide feedback to the Board on these proposed rules. Please feel free to contact me if you have any questions related to the comments.

Sincerely,

Scott Clark
Market Vice President
Pharmacy Professional Practice
Email: sclark8@humana.com

[1] https://www.kff.org/coronavirus-covid-19/issue-brief/mail-delays-could-affect-mail-order-prescriptions-for-millions-of-medicare-part-d-and-large-employer-plan-enrollees/

From:	Arsalan Shah
To:	PHARMACY RULEMAKING * BOP
Cc:	Andrew Mendenhall; Kimberly Leathley
Subject:	Comments on Proposed Draft Rules
Date:	Tuesday, November 22, 2022 9:11:19 AM
Attachments:	OBOP 11-22 RuleMaking Comments - CCC.docx

Hi there,

Please see attached for our comments on proposed rules. Please let me know if there are any questions.

Sincerely,

Arsalan "RC" Shah, PharmD, MBA
Sr. Director of Pharmacy
Central City Concern
727 W Burnside St
Portland, OR 97209
Direct Line: 971-271-6175
arsalan.shah@ccconcern.org

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November 22nd, 2022

Oregon Board of Pharmacy

RE: Proposed Draft Rule(s) 855-006-005(10), 855-115-0070 (3) (a)-(p), 855-115-0070(3)(m), 855-115-0115, 855-115-0120, 855-115-0125

President Murray, Vice President Doyle and members of the Oregon Board of Pharmacy:

Central City Concern (CCC) is a non-profit direct service organization that provides integrated primary and behavioral health care, supportive and affordable housing, and employment services to people impacted by homelessness in the Tri-County area. Central City Concern serves 13,000 people annually through 2,200 units of affordable supportive housing, direct patient care through our 13 Federally Qualified Health Centers, makes 1,200 job placements annually through our Employment Access Center.

Health centers are highly regarded and trusted within their communities because they tailor their health care services and supporting programs including pharmacy operations to meet the unique needs of their patients. Rooted in the civil rights movement, health centers prioritize providing high quality, affordable, and accessible health care to anyone who walks through their doors.

CCC wants to applaud the Oregon Board of Pharmacy's efforts to streamline how clinical pharmacists can practice in primary care. Over the last seven years clinical pharmacists have helped our health center stay connected to our patients, build new patient relationships, and expand the reach of the health center program all while improving outcomes and driving down the cost of care.

Health centers are located in medically underserved areas, where a majority of our patients live in poverty and experience significant disparities in social determinants of health relative to general population. Health centers have proven highly effective at utilizing clinical pharmacist services in primary care to the most vulnerable and underserved communities. As clinical pharmacists gain more popularity, it's critical that health centers can continue to utilize this important provider type to meet the complex needs of the patients they serve.

The need for our organization to have both a collaborative drug therapy management (CDTM) and clinical pharmacy agreement (CPA) has been confusing but is presently an established practice. It is in this context where the unintended consequences of the proposed rule changes are causing fundamental and grave concerns for the sustainability of integrated clinical pharmacy services at Oregon's community health centers. CCC appreciates the opportunity to provide comments on the proposed rules and has detailed them below:

A. 855-006-005(10) Definitions for OAR Chapter 855

CCC strongly urges the Oregon Board of Pharmacy to keep the definition of Collaborative Drug Therapy Management (CDTM)

Health Centers are required to serve "medically underserved, or special medically underserved populations", which face barriers in accessing health care services. HRSA requires health centers to address these barriers and disparities among patients' health status and through the health center's operations – including pharmacy programs. Health centers rely on the ability to bill for pharmacy services to not only meet this requirement for their insured patients but also for those who do not have health insurance.

Transitioning the authorities of CDTMs into the CPA rules alone will not permit physicians to engage in collaborative drug therapy management unless the Oregon Medical Board changes their administrative rules. OAR 847-015-0040 presently prohibits physicians from engaging in management of drug therapy pursuant to a written protocol with pharmacists without a collaborative drug therapy management protocol. Oregon Medical Board rules presently mirror the existing Pharmacy Board CDTM rules and definitions. We suggest that the Board wait to make this change until the Oregon Medical Board updates their rules from CDTM to CPA.

B. 855-115-0070 (3) (a)-(p) Pharmacist General Responsibilities

CCC urges the Oregon Board of Pharmacy to maintain a pharmacist's ability to practice to the fullest extent of their scope.

The new OAR which replaces 855-019-0200 (3) in general removes language which may limit the dynamic utilization of pharmacists in Oregon's community health centers. **Given ongoing health care workforce challenges, it's imperative the finalized OAR recognizes how pharmacists can be a solution to increasing capacity at health centers to meet the rising needs of underserved patients.** Our pharmacists work closely with our providers to provide much needed access to patients that are often most vulnerable and marginalized.

Maintaining the existing scope of practice for Oregon pharmacists under 855-019-0200 (3) enables more patients to receive comprehensive and affordable care. Besides the workforce challenges that can adversely affect health center patients, they often experience challenges accessing health care services due to disparity in social determinants of health. **Health centers tailor their pharmacy services to meet the unique needs of their surrounding communities and address barriers to culturally competent and comprehensive primary health care services.**

CCC encourages the Board of Pharmacy to retain aspects of the existing OAR by adding back the following language to 855-115-0070 (3) “but are not limited to”

C. 855-115-0070(3)(m) Pharmacist: General Responsibilities and 855-115-0115 Services: Laboratory

CCC is concerned that this change will remove the broad ability for pharmacists to order, interpret and monitor lab tests.

The proposed OARs essentially remove the long-established ability of a pharmacist to independently order and interpret laboratory tests and limits their scope of testing to pharmacy services expressly defined and permitted in ORS 689. This is a crucial component of how community health centers utilize clinical pharmacists as a member of the primary care team. In a time when providers and care teams are stretched to capacity and the pipeline for new providers to enter practice areas is long, we are concerned that this deviation away from nationally accepted scope of practice for pharmacists will mean patients experience extended wait times, fewer touch points with their care team, and ultimately poorer outcomes. This change will only serve to further exacerbate the existing health care workforce crisis by essentially adding additional workload onto exhausted providers.

D. 855-115-0120 Clinical Pharmacy Agreement

CCC is concerned that draft OAR 855-115-0120 does not align with the legislative intent of HB 2028 (2015). The result of this deviation in the proposed draft rule would complicate rather than simplify administrative rule obligations for pharmacists.

Clinical pharmacy agreements are synonymous with a health care providers professional services agreement and are in common use in Oregon today with this purpose. It is a contract between a physician, naturopathic physician, or health care organization permitting a pharmacist or pharmacies to engage in the practice of pharmacy and provide patient care services. HB 2028 (2015) permits health insurers and the Oregon Health Authority to provide payment or reimbursement for services pursuant to a clinical pharmacy agreement or statewide drug therapy protocol.

Moreover, the additional requirements set forth in proposed **OAR 855-115-0120 (B)(C)** would make the administrative burden and actual ability to implement new CPA services or transition existing CDTM agreements into CPAs overwhelming and unworkable for many community-based pharmacy programs.

The bill included statutory language specific to Coordinated Care Organizations contained within ORS 414.764 (2)(a)(b). “A coordinated care organization may reimburse a pharmacist or pharmacy for any health service: a) Provided to a medical assistance recipient who is enrolled in the coordinated care organization or prepaid managed care health service organization that enters into a clinical pharmacy agreement with the pharmacist or pharmacy; and b) That is within the lawful scope of practice of a pharmacist.”

Removing the OARs for Collaborative Drug Therapy Management and adding the language to Clinical Pharmacy Agreement implies that the CCO must create an agreement that contains all requirement in OAR 855-115-0120 including the types of decisions the pharmacist is allowed to make. These proposed rule changes in 855-115-0120 would require CCOs to create protocols that define the pharmacist(s) patient care process, referral process, standards of care, and decision criteria for conditions like diabetes for the purposes of reimbursement. It was never intended for CCOs to take on the role of defining pharmacist, pharmacies, or a clinic’s scope of work for the pharmacists under their employ or have health plan physician and pharmacist staff fill the role of principle physician or pharmacist. It is not feasible or appropriate to require CCO providers to take on this level of liability without a patient-provider relationship or physician-pharmacist relationship within their health care provider contracts. This may create a situation where clinical pharmacists may have two or more different clinical pharmacy agreements dictating how they manage chronic conditions such as diabetes.

E. 855-115-0125 Medication Therapy Management (MTM)

CCC seeks clarity around changes to Medication Therapy Management practices. New language directs pharmacists to fulfill certain requirements when performing MTM. The change from “may” to “must” in the draft OAR potentially creates a requirement that certain actions be taken during every encounter. **This shift implies MTM must include all the listed elements at every encounter for a pharmacist to be in compliance.** However, in practice all of these elements are not performed in a single visit for various reasons. We worry about additional administrative burden on providers who are already at the breaking point.

CCC encourages the Board to amend the proposed OAR back to the original language or to offer additional clarity to guide pharmacists in successful implementation as we do not believe it was the Board’s intention to layer on additional administrative burden in cases such as this.

CCC thanks the Oregon Board of Pharmacy for the opportunity to comment on draft rule changes and urges the Board to consider the broader practice and policy implications of moving forward without additional public engagement. Health Center pharmacy programs have proven successful in expanding access to care and improving health outcomes for the most vulnerable patients. We look forward to answering any questions you might have.

Sincerely,

Andrew B. Mendenhall, MD, DABFM, DABPM, FASAM
President & CEO
Central City Concern

Arsalan Shah, PharmD, MBA
Sr. Director of Pharmacy
Central City Concern
arsalan.shah@ccconcern.org

From: Petrus Oliphant
To: PHARMACY RULEMAKING * BOP
Subject: Thoughts and Concerns RE: Nov 22nd Rulemaking
Date: Friday, November 18, 2022 1:13:51 PM
Attachments: Outlook-k1qdwili.png
OBOP CDTM Letter.pdf
OBOP MTM Letter.pdf

To Whom it may concern,

Please review the attached documents, which include my concerns related to the rulemaking hearing scheduled November 22, 2022.

Providing psychiatric pharmacy services for an underserved patient population in downtown Portland for the last eight years, I fear the proposed CDTM and MTM rule changes may have a negative impact on access to care for my patients. Access to psychiatric services in Oregon is severely limited. We cannot afford to enact rule changes that will further limit the essential care we deliver to those most in need.

I appreciate your time and consideration.

CENTRAL CITY CONCERN
40 YEARS OF HOPE + HEALING

Petrus Oliphant, PharmD, BCPP
Clinical Pharmacist
Old Town Clinic Pharmacy
t. 971.271.6296 | f. 971.271.6124
petrus.oliphant@ccconcern.org

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November 18, 2022

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern and provide feedback about the proposed changes to the Collaborative Drug Therapy Management (CDTM) rules. I am strongly opposed to removing all OARs that discuss CDTM and proposed OAR, 855-115-0120. It appears that the Board voted to send these proposed changes to rulemaking for feedback from the public however, changes were not discussed in public comment during the August or October Board of pharmacy meeting making thorough feedback difficult.

I urge you to use a rules advisory committee to provide feedback on the impact additional rules will have, but especially with the proposed rules for 855-115-0120. I feel there are consequences of removing CDTMs from rules and replacing them with a redefined clinical pharmacy agreement. One implication, though certainly not the least, is the ability of pharmacists to be reimbursed for and thus provide services to Medicaid recipients enrolled in Coordinated Care Organizations (CCOs). In addition, these rules impact pharmacists in all settings, not just community pharmacy. The intent of these rules is unclear, as they have not been discussed and it feels as though the intent is to limit our current scope of practice. Licensees have no idea what the intent of these rules are, because they have not been discussed, and therefore we are unclear if your intent is to limit pharmacist's scope of practice or to replace CDTM with something new.

The Oregon Medical Board does not have corresponding rules that recognize a CPA. When these draft rules go into effect, there will be no ability for pharmacists to have a way to collaboratively manage drug therapy. This will greatly affect many of the pharmacists currently working in a clinical environment and could cause patient harm. It may also disrupt care for many Oregonians without access to healthcare providers other than their pharmacist and further erode efforts made to address health inequities for rural and minority populations in Oregon. Before passing these rules, I urge you to press pause and let subject matter experts weigh in on what these rule changes will mean for the current practice of pharmacy, the evolution of pharmacy practice, and patient safety.

Thank you,

Petrus Oliphant, Oregon RPh

November 18, 2022

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern about the proposed rule changes to Medication Therapy Management. I urge you to reject changing the word “may” to “must” in proposed rule 855-115-0125 (2). It appears the Board voted to send these proposed changes to rulemaking for feedback from the public. However, the changes to the definition of MTM were not discussed in public comment during either the August or October Board of pharmacy meeting making the reasoning for the changes unclear and thorough feedback difficult.

MTM encompasses a variety of services provided by pharmacists, generally for Medicare Part D plans which have their own definition. Changing the definition of MTM in this rule to require that “all elements listed be completed” is unnecessary and puts an undue burden on Oregon Pharmacists who complete MTM visits for Medicare recipients. Some Part D MTM interventions may be as simple and brief as a telephone call to determine why a patient is late for a maintenance medication refill or if an intervention or refill is needed. The proposed change would mandate the provision of services that are not indicated and increases the documentation and administrative burden of the pharmacist providing said service. This may in turn, entice Medicare plans to contract with pharmacists outside of Oregon (as they are not held to the same rules) to complete their yearly MTM visit instead of their local pharmacist whom they see on a routine basis when filling their prescription medications. I urge the Oregon Board of Pharmacy to do everything they can to develop and encourage the pharmacist-patient relationship which results in improved patient safety outcomes.

Thank you,
Petrus Oliphant, Oregon RPh

From: Todd MacLeod
To: PHARMACY RULEMAKING * BOP
Subject: Comments Supporting Div 019 & 139 Proposed Ammendments
Date: Tuesday, November 22, 2022 11:52:21 AM

Although I gave video comment supporting proposed measure 139, "*Removing language that states a Retail Drug Outlet RDSP may not deliver a prescription*," I would also like to provide comment supporting the proposed measure 019 relating to the "*duties of a pharmacist*." Specifically, removing language that places restrictions on accepting prescriptions from telemedicine practices.

For some brief background on myself, I have worked in medicine for over 10 years, predominantly in emergency medicine as well as orthopedic surgery. Although I had some experience in telemedicine previously, once the COVID-19 pandemic started, I found this to be an excellent opportunity to reach out to patients who both were unable to see a primary care provider in person as well as patients who were limited geographically or financially from seeing a provider even prior to the COVID-19 pandemic.

Telemedicine has been proven to be quite revolutionary and I feel that over the past two years it has proven to be an invaluable resource at permitting and expanding access to medical services to those patients that might otherwise have none. Telemedicine, of course, does not intend to supplant any in-person visits, particularly for more complicated patients; however it can work very well in a hybrid model for these types of patients. For generally healthy, young patients, who are always on the go and will simply not go see a provider if they are unable to do so within their schedules, Telemedicine offers them access to medicine that fits their lifestyles.

The telemedicine practice that I currently work with, Circle Medical, is a primary care practice that has physical clinic locations in San Francisco, California and is affiliated with the University of California, San Francisco. Although we do provide many primary care services via telemedicine and are active in approximately 30 states so far, the majority of what we treat is in the behavioral health spectrum. This includes diagnoses such as depression, anxiety, ADHD, PTSD, etc.

Unfortunately, we have noticed more and more pharmacies becoming less and less friendly toward telemedicine practices. Some of these feelings may be well deserved, as in the cases of "Done" and "Get Cerebral" in which these practices had poor documentation standards and minimal protocols. Unfortunately these few "bad apples" have tarnished the reputation for all telemedicine practices, leading many pharmacies to deny prescriptions from telemedicine providers entirely, without regard to the verifiable legitimacy of the practice. These unilateral and unjustifiable actions create a breakdown in the telemedicine system. A system which has been praised by many health authorities and regulatory bodies, cannot exist if a key partner in that system refuses to participate.

I strongly support removing any language that specifically prohibits or denies a pharmacist from being able to accept a prescription from a legitimate, state licensed & DEA licensed provider simply because they are on a Telemedicine platform.

Thank you for your consideration,

--
Todd B. MacLeod, EdD, MS, PA-C
Todd.MacLeod@circlemedical.com
TBMacLeod@gmail.com

From:	Jess Wright
To:	PHARMACY RULEMAKING * BOP
Subject:	In support of Division 019, 139
Date:	Tuesday, November 22, 2022 12:31:59 PM

Hello,

I am sending this email today in strong support of following measures:

- Division 019 - related to 2022 HB 4034 Duties of a Pharmacist, which removes language that a pharmacist cannot dispense for a telemedicine practitioner:
  - Amendments include removing “not result solely from a questionnaire or an internet-based relationship” and adding “issued pursuant to a valid patient-practitioner relationship” in OAR 855-019-0210(2)(a).

- Division 139 - related to 2022 HB 4034 Prohibited Practices
  - RULE SUMMARY: Proposed amendment removes language that states a Retail Drug Outlet RDSP may not “Deliver a prescription.” Per 2022 HB 4034, the board may not establish standards for telepharmacy that are more restrictive than standards for the delivery of in-person pharmacy services, including standards regarding prescription and dispensation of drugs

I graduated from the University of Nebraska Medical Center in 2017 and have been a full-time practicing PA since that time.

I currently work part time for a telemedicine platform. Through this platform I have a patient panel ranaging from the age of 18 to 80, and consult on nearly every primary care concern. I receive constant positive feedback about our platform's ability to reach Oregon rural populations, patients that work jobs that do not allow them to be seen in primary care 8-5 clinics, and patients that have anxieties around the traditional medication system.

Specifically in the topic of stimulant medication, as we are aware, there is lengthy wait times to see psychiatry in the state of Oregon right now. Our mental health evaluations appointments are 60 minutes face-to-face, in addition to extensive record review, to ensure that we are providing our patients with the best possible care management. And prior to this telemedicine position I worked in-person for a large, multi-speciality group in Eugene. It was rather standard for our ADHD patients to go 6-12 months at a time, without any type of proper follow-up with their PCP, and the PCP would just automatically fill for another 30-day supply without any patient input. With my current telemedicine position I am, on a monthly basis, checking patients' vital signs, reassessing their response to the medication and side-effects, discussing lower doses/drug holidays, and screening for inappropriate or red-flag behaviors.

As a provider who has worked extensively in both practice settings I can reassure that in-person does not equate to superior ADHD and primary care management, and for pharmacies to prioritize patients that have the means to be seen in-person is discriminatory.

Please let me know if you have any further questions.

Thank you,

Jessica Wright PA-C

From:	RAMIREZ Stacy
To:	PHARMACY RULEMAKING * BOP
Cc:	Marty Carty; RAMIREZ Stacy (SMTP); MOSBAUGH Christine; MOLLEL Lacey; JONES Carla
Subject:	Written Comment
Date:	Tuesday, November 22, 2022 3:15:45 PM
Attachments:	11-22-22 OBOP Letter.docx

Hello-

Please see the following written comment related to your rule making meeting. Feel free to reach out if I may be of assistance.

Sincerely,

Stacy Ramirez, Pharm.D.
Director of Pharmacy/Clinical Pharmacist
Community Health Centers of Benton and Linn Counties

November 22, 2022

Oregon Board of Pharmacy

RE: Proposed Draft Rule(s) 855-006-005(10), 855-115-0070 (3) (a)-(p), 855-115-0070(3)(m), 855-115-0115, 855-115-0120, 855-115-0125

President Murray, Vice President Doyle and members of the Oregon Board of Pharmacy:

The Community Health Centers of Benton and Linn Counties operate six access points in two counties. We have traditional health centers as well as school-based health centers and offer a wide variety of services to our communities. Pharmacists have been an integral part of our healthcare teams for 15 years and provide invaluable services for our patients.

Health centers are highly regarded and trusted within their communities because they tailor their health care services and supporting programs including pharmacy operations to meet the unique needs of their patients. Rooted in the civil rights movement, health centers prioritize providing high quality, affordable, and accessible health care to anyone who walks through their doors.

CHC of Benton and Linn Counties wants to applaud the Oregon Board of Pharmacy's efforts to streamline how clinical pharmacists can practice in primary care. Over the last 15 years, clinical pharmacists have helped our health center stay connected to our patients, build new patient relationships, and expand the reach of the health center program all while improving outcomes and driving down the cost of care.

Health centers are in medically underserved areas, where many of our patients live in poverty and face significant social determinants of health that create barriers to affordable health care services. Health centers have proven highly effective at utilizing clinical pharmacist services in primary care to the most vulnerable and underserved communities. In our communities, clinical pharmacists are an integral part of the healthcare team and participate in the care of patients with 12 different disease states. As clinical pharmacists gain more popularity, it's critical that health centers can continue to utilize this important provider type to meet the complex needs of the patients they serve.

The need for our organization to have both a collaborative drug therapy management (CDTM) and clinical pharmacy agreement (CPA) has been confusing but is presently an established practice. It is in this context where the unintended consequences of the proposed rule changes are causing fundamental and grave concerns for the sustainability of integrated clinical pharmacy services at Oregon's community health centers. CHC of Benton and Linn Counties appreciates the opportunity to provide comments on the proposed rules and has detailed them below:

A. 855-006-005(10) Definitions for OAR Chapter 855

CHC of Benton and Linn Counties strongly urges the Oregon Board of Pharmacy to keep the definition of Collaborative Drug Therapy Management (CDTM)

Health Centers are required to serve "medically underserved, or special medically underserved populations", which face barriers in accessing health care services. HRSA requires health centers to address these barriers and disparities among patients' health status and through the health center's operations – including pharmacy programs. Health centers rely on the ability to bill for pharmacy services to not only meet this requirement for their insured patients but also for those who do not have health insurance.

Transitioning the authorities of CDTMs into the CPA rules alone will not permit physicians to engage in collaborative drug therapy management unless the Oregon Medical Board changes their administrative rules. OAR 847-015-0040 presently prohibits physicians from engaging in management of drug therapy pursuant to a written protocol with pharmacists without a collaborative drug therapy management protocol. Oregon Medical Board rules presently mirror the existing Pharmacy Board CDTM rules and definitions. We suggest that the Board wait to make this change until the Oregon Medical Board updates their rules from CDTM to CPA.

B. 855-115-0070 (3) (a)-(p) Pharmacist General Responsibilities

CHC of Benton and Linn Counties urges the Oregon Board of Pharmacy to maintain a pharmacist's ability to practice to the fullest extent of their scope.

The new OAR which replaces 855-019-0200 (3) in general removes language which may limit the dynamic utilization of pharmacists in Oregon's community health centers. **Given ongoing health care workforce challenges, it's imperative the finalized OAR recognizes how pharmacists can be a solution to increasing capacity at health centers to meet the rising needs of underserved patients.** Clinical pharmacists in our health centers participate in the care of patients diagnosed with everything from diabetes to transgender care to conditions requiring anticoagulation. Combined, our clinical pharmacists see approximately 40 patients per week, alleviating some of the burden from our primary care providers.

Maintaining the existing scope of practice for Oregon pharmacists under 855-019-0200 (3) enables more patients to receive comprehensive and affordable care. Besides the workforce challenges that can adversely affect health center patients, they often experience challenges accessing health care services due to social determinants of health. **Health centers tailor their pharmacy services to meet the unique needs of their surrounding communities and address barriers to culturally competent and comprehensive primary health care services.**

CHC of Benton and Linn Counties encourages the Board of Pharmacy to retain aspects of the existing OAR by adding back the following language to 855-115-0070 (3) “but are not limited to”

C. 855-115-0070(3)(m) Pharmacist: General Responsibilities and 855-115-0115 Services: Laboratory

CHC of Benton and Linn Counties is concerned that this change will remove the broad ability for pharmacists to order, interpret and monitor lab tests.

The proposed OARs essentially remove the long-established ability of a pharmacist to independently order and interpret laboratory tests and limits their scope of testing to pharmacy services expressly defined and permitted in ORS 689. This is a crucial component of how community health centers utilize clinical pharmacists as a member of the primary care team. In a time when providers and care teams are stretched to capacity and the pipeline for new providers to enter practice areas is long, we are concerned that this deviation away from nationally accepted scope of practice for pharmacists will mean patients experience extended wait times, fewer touch points with their care team, and ultimately poorer outcomes. This change will only serve to further exacerbate the existing health care workforce crisis by essentially adding additional workload onto exhausted providers.

D. 855-115-0120 Clinical Pharmacy Agreement

CHC of Benton and Linn Counties is concerned that draft OAR 855-115-0120 does not align with the legislative intent of HB 2028 (2015). The result of this deviation in the proposed draft rule would complicate rather than simplify administrative rule obligations for pharmacists.

Clinical pharmacy agreements are synonymous with a health care providers professional services agreement and are in common use in Oregon today with this purpose. It is a contract between a physician, naturopathic physician, or health care organization permitting a pharmacist or pharmacies to engage in the practice of pharmacy and provide patient care services. HB 2028 (2015) permits health insurers and the Oregon Health Authority to provide payment or reimbursement for services pursuant to a clinical pharmacy agreement or statewide drug therapy protocol.

Moreover, the additional requirements set forth in proposed **OAR 855-115-0120 (B)(C)** would make the administrative burden and actual ability to implement new CPA services or

transition existing CDTM agreements into CPAs overwhelming and unworkable for many community-based pharmacy programs.

The bill included statutory language specific to Coordinated Care Organizations contained within ORS 414.764 (2)(a)(b). “A coordinated care organization may reimburse a pharmacist or pharmacy for any health service: a) Provided to a medical assistance recipient who is enrolled in the coordinated care organization or prepaid managed care health service organization that enters into a clinical pharmacy agreement with the pharmacist or pharmacy; and b) That is within the lawful scope of practice of a pharmacist.”

Removing the OARs for Collaborative Drug Therapy Management and adding the language to Clinical Pharmacy Agreement implies that the CCO must create an agreement that contains all requirement in OAR 855-115-0120 including the types of decisions the pharmacist is allowed to make. These proposed rule changes in 855-115-0120 would require CCOs to create protocols that define the pharmacist(s) patient care process, referral process, standards of care, and decision criteria for conditions like diabetes for the purposes of reimbursement. It was never intended for CCOs to take on the role of defining pharmacist, pharmacies, or a clinic’s scope of work for the pharmacists under their employ or have health plan physician and pharmacist staff fill the role of principle physician or pharmacist. It is not feasible or appropriate to require CCO providers to take on this level of liability without a patient-provider relationship or physician-pharmacist relationship within their health care provider contracts. This may create a situation where clinical pharmacists may have two or more different clinical pharmacy agreements dictating how they manage chronic conditions such as diabetes.

E. 855-115-0125 Medication Therapy Management (MTM)

CHC of Benton and Linn Counties seeks clarity around changes to Medication Therapy Management practices. New language directs pharmacists to fulfill certain requirements when performing MTM. The change from “may” to “must” in the draft OAR potentially creates a requirement that certain actions be taken during every encounter. **This shift implies MTM must include all the listed elements at every encounter for a pharmacist to be in compliance.** However, in practice all of these elements are not performed in a single visit for various reasons. We worry about additional administrative burden on providers who are already at the breaking point.

CHC of Benton and Linn Counties encourages the Board to amend the proposed OAR back to the original language or to offer additional clarity to guide pharmacists in successful implementation as we do not believe it was the Board’s intention to layer on additional administrative burden in cases such as this.

CHC of Benton and Linn Counties thanks the Oregon Board of Pharmacy for the opportunity to comment on draft rule changes and urge the Board to consider the broader practice and policy implications of moving forward without additional public engagement. Health Center pharmacy programs have proven successful in expanding access to care and improving health outcomes for the most vulnerable patients. We look forward to answering any questions you might have.

Sincerely,
Stacy Ramirez, Pharm.D.
Director of Pharmacy/Clinical Pharmacist
Community Health Centers of Benton and Linn Counties
Stacy.ramirez@co.benton.or.us

From:	Zack D Korstian
To:	PHARMACY RULEMAKING * BOP
Subject:	Public Comment for Proposed Rules
Date:	Wednesday, November 16, 2022 9:12:35 AM
Attachments:	CDTM Proposed Rule Changes 11.16.22.docx MTM Proposed Changes Comment 11.15.22.docx

Good Morning,

Please accept the following for public comment of proposed rules.

Thank you

Zack Korstian, PharmD
Director of Pharmacy
Consonus Pharmacy, Oregon

—
p. 971-206-2067
f. 503-652-0383
e. zdkorstian@consonushealth.com

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Zachary Korstian

Consonus Pharmacy Services

11/16/2022

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern and provide feedback about the proposed changes to the Collaborative Drug Therapy Management (CDTM) rules. I am strongly opposed to removing all OARs that discuss CDTM and proposed OAR, 855-115-0120. It appears that the Board voted to send these proposed changes to rulemaking for feedback from the public however, changes were not discussed in public comment during either the August or October Board of pharmacy meeting making thorough feedback difficult.

I urge you to use a rules advisory committee to provide feedback on the impact additional rules will have, but especially with the proposed rules for 855-115-0120. I feel there are consequences of removing CDTMs from rules and replacing them with a redefined clinical pharmacy agreement (CPA). One implication, though certainly not the least, is the ability of pharmacists to be reimbursed for and thus provide services to Medicaid recipients enrolled in Coordinated Care Organizations (CCOs). In addition, these rules impact pharmacists in all settings, not just community pharmacy. The intent of these rules is unclear, as they have not been discussed and it feels as though the intent is to limit our current scope of practice. Licensees have no idea what the intent of these rules are because they have not been discussed, and therefore we are unclear if your intent is to limit our current scope of practice or to replace CDTM with something new.

The Oregon Medical Board does not have corresponding rules that recognize a CPA. When these draft rules go into effect, there will be no ability for pharmacists to have a way to collaboratively manage drug therapy. This will greatly affect many of the pharmacists currently working in a clinical environment and could cause patient harm. It may also disrupt care for many Oregonians without access to healthcare providers other than their pharmacist and further erode efforts made to address health equity for rural and minority populations in Oregon. Before passing these rules I urge you to press pause and let subject matter experts weigh in on what these rule changes will mean for the current practice of pharmacy, the evolution of pharmacy practice, and patient safety.

Thank you for consideration,

Zachary Korstian, Oregon Pharmacist License# RPH-0014986

Zachary Korstian

11/15/22

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern about the proposed rule changes to Medication Therapy Management. I urge you to reject changing the word “may” to “must” in proposed rule 855-115-0125 (2). It appears the Board voted to send these proposed changes to rulemaking for feedback from the public. However, the changes to the definition of MTM were not discussed in public comment during either the August or October Board of pharmacy meeting making the reasoning for the changes and thorough feedback difficult.

MTM encompasses a variety of services provided by pharmacists, generally for Medicare Part D plans which have their own definition. Changing the definition of MTM in this rule to require that “all elements listed be completed” is unnecessary and puts an undue burden on Oregon Pharmacists who complete MTM visits for Medicare recipients. Some Part D MTM interventions may be as simple and brief as a telephone call to determine why a patient is late for a maintenance medication refill or if an intervention or refill is needed. The proposed change would mandate the provision of services that are not indicated and increases the documentation and administrative burden of the pharmacist providing said service. This may in turn, entice Medicare plans to contract with pharmacists outside of Oregon (as they are not held to the same rules) to complete their yearly MTM visit instead of their local pharmacist who they see when filling their prescription medications. The Oregon Board of Pharmacy should be doing everything they can to develop and encourage the pharmacist-patient relationship which results in improved patient safety outcomes, not burden it with cumbersome mandates. **This proposed rule change from “may include” to “must include” is unnecessary and I would urge the Board to reconsider.**

Thank you,

Zachary Korstian, Oregon RPh, License #RPH-0014986

From: farmycist
To: PHARMACY RULEMAKING * BOP
Subject: Upcoming Rulemaking Hearing on Nov 22, 2022
Date: Tuesday, November 15, 2022 2:18:54 PM

Dear Oregon Board of Pharmacy Members:

I am writing to express my concern and some feedback about proposed changes to the CDTM rules. I am co owner and Pharmacist in Charge of Coordinated MEDucation Team LLC, a consulting/Drugless Pharmacy here in Oregon which strongly opposes removal of all OARs that discuss CDTM and proposed OAR 855-115-0120. It appears that Board voted to send these proposed changes to rulemaking for feedback from the public however- changes were not discussed in public comment during either the Aug or Oct Board of pharmacy meetings making thorough feedback difficult.

I am urging you to use a rules advisory committee to provide the necessary feedback on the impact these additional rules will have, especially the proposed rules for 855-115-0120. My organization can foresee consequences of the removal of CDTMs from rules and replacing them with a redefined clinical pharmacy agreement. One of the largest complications this change will have on my operation will be the reimbursement we may not be able to collect from those recipients in CCOs. It also seems as though these changes will limit our current scope of practice which we have worked so hard to be inclusive for all Oregon residents. Licensees have no idea what the intent of these rules are, because they have not been discussed and therefore I am unclear as to your intent to possibly limit my current scope of practice or to replace CDTM with something new.
The Oregon Medical Board does not have any corresponding rules that recognize a CPA. When and with if these draft rules go into effect ,there will be no ability for pharmacists to have a way to collaboratively manage drug therapy. This will greatly affect many of the pharmacists currently working in a clinical environment and actually cause some patient harm. It o may also disrupt care for the many Oregonians without access to healthcare and minority populations in Oregon. Before passing these rules, I, Carol Van Horn RPH for over 50 years, and my Coordinated MEDucation Team, a licensed Drugless/Consulting Pharmacy, urge to pause and let the experts in this field weigh in on what these rules changes will mean for the current and future practice of pharmacy , as well the more important patient safety to the State of Oregon residents.

Secondly, I am also concerned about the proposed changes to MTM. My organization and myself urge you to change wording of “may” to “must “ in proposed rule 855-115-0125. MTM encompasses a wide variety of services provided by pharmacists, generally for Medicare Part D plans which have their own definitions. Changing the definition of MTM in this rule to require that “all elements listed by completed” is unnecessary and could put a larger burden on already overworked staff, or it might even entice some Medicare plans to contract with providers outside of Oregon where rules might not be as burdensome. My history with the Oregon Board of Pharmacy over the last 30 years has been one of encouragement of the pharmacist-patient relationship which results in improved patient safety outcomes and a truly patient centered relationship with Oregonians. Thus, this proposed rule change from MAY include to MUST include is totally unnecessary.

Thank you for your consideration;

Sincerely
Carol Van Horn RPh MBA
Co-owner Coordinated MEDucation Team LLC
Sent from Mail for Windows

From: ic.rx@comcast.net
Sent: Monday, November 21, 2022 at 1:50 PM
To: pharmacy.rulemaking@bop.oregon.gov
Subject: Upcoming Rulemaking Hearing on November 22, 2022

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern and provide feedback about the proposed changes to the Collaborative Drug Therapy Management (CDTM) rules. I am co-owner of and consultant pharmacist with Coordinated MEDucation Team, LLC, a consulting / drugless pharmacy licensed in Oregon. As a practicing pharmacist with Coordinated MEDucation Team, I, Irene Croswell, am strongly opposed to removing all OARs that discuss CDTM and proposed OAR, 855-115-0120. It appears that the Board voted to send these proposed changes to rulemaking for feedback from the public. However, changes were not discussed in public comment during either the August or October Board of pharmacy meeting making thorough feedback difficult.

I urge you to use a rules advisory committee to provide the necessary feedback on the impact these proposed additional rules will have, especially with the proposed rules for 855-115-0120. My organization recognizes there are potential, impactful consequences of removing CDTMs from rules and replacing them with a redefined clinical pharmacy agreement. One of the largest impacts would affect the ability of pharmacists to be reimbursed for services to Medicaid recipients enrolled in Coordinated Care Organizations (CCOs) thereby potentially limiting patient access to the clinical pharmacy services and improved outcomes for certain populations. In addition, these rules impact pharmacists in all settings, not just community pharmacy. It feels as though the intent of these proposed rule changes is to replace CDTM with something new and / or limit our current scope of practice for which we have worked so hard to expand. Because they have not been discussed, licensees have no idea what the intent of these rules are.

The Oregon Medical Board does not have corresponding rules that recognize a CPA. When and if these draft rules go into effect, there will be no ability for pharmacists to have a way to collaboratively manage drug therapy. This will greatly affect many of the pharmacists currently working in a clinical environment and could cause patient harm. It may also disrupt care for many Oregonians without access to healthcare providers other than their pharmacist and further erode efforts made to address health equity for rural and minority populations in Oregon. Before passing these rules I, Irene Croswell, PharmD, RPh for over 40 years and my organization, Coordinated MEDucation Team, urge you to press pause and let subject matter experts weigh in on what these rule changes will mean for the current practice of pharmacy, the evolution of pharmacy practice, and more importantly health outcomes and patient safety for Oregonians.

Additionally, I am writing to express my concern about the proposed rule changes to Medication Therapy Management. Both I and my organization, Coordinated MEDucation Team urge you to reject changing the word “may” to “must” in proposed rule 855-115-0125 (2). MTM encompasses a variety of services provided by pharmacists, generally for Medicare Part D plans which have their own definition. Changing the definition of MTM in this rule to require that “all elements listed be completed” is unnecessary and puts a larger, undue burden on Oregon pharmacists who complete MTM visits for Medicare or other recipients. Some Part D MTM interventions may be as simple and brief as a telephone call to determine why a patient is late for a maintenance medication refill or if an intervention or refill is needed. The proposed change would mandate the provision of services that are not indicated and increases the documentation and administrative burden of the pharmacist providing said service. This may in turn, entice Medicare plans to contract with pharmacists outside of Oregon (as they are not held to the same rules) to complete the yearly MTM review and possibly result in patient confusion and frustration leading to missed opportunities for health interventions and improvements. In my professional experience, I recognize and appreciate that the Oregon Board of Pharmacy has always prioritized patient health and safety as well as the importance of developing and encouraging the pharmacist-patient relationship without the use of cumbersome mandates. This proposed rule change from “may include” to “must include” is unnecessary.

Thank you for your consideration,
Irene Croswell, PharmD, Oregon RPh

From:	Paul, Lauren N.
To:	PHARMACY RULEMAKING * BOP
Cc:	Paul, Lauren N.
Subject:	CVS Comments on Proposed Amendments to Various Divisions
Date:	Tuesday, November 22, 2022 6:30:46 AM
Attachments:	CVS Health Comments on Proposed Amendments to Division 102 Procedural and Universal Rules.pdf CVS Health Comments on Proposed Amendments to Division 115 Pharmacists.pdf CVS Health Comments on Proposed Amendments to Division 006-019-031 Division 041 Division 010-019-020 Division 19-141.pdf CVS Health Comments on Proposed Amendments to Division 125 Pharmacy Technicians.pdf

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Good Morning,

Attached you will find comments from CVS Health on proposed amendments to various divisions. Should the Board have any additional questions on these comments, please do not hesitate to reach out directly to me.

Thanks,
Lauren

Lauren Paul, PharmD, MS | Executive Director, Pharmacy Regulatory Affairs
p 540-604-3661 | **f** 401-733-0479
1 CVS Drive, Mail Code 2325, Woonsocket, RI 02895

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

November 22, 2022

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

Re: Proposed Amendments to Division 006/019/031, Division 041, Division 010/019/020, Division 019/141

Dear Executive Director Schnabel:

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

Division 006/019/031 related to Definitions

CVS Health appreciates the Board's efforts to amend the definition sections in various Divisions of Board rules. However, we have concern that the Board is amending definitions related to Divisions that are still in draft format or not being considered at this time for Board adoption. The understanding of a definition weighs heavily on the context in which it is used. The Office of the Federal Register has addressed the use of definitions in their Regulatory Drafting Guide, which is pertinent here. That guide makes clear that it is difficult to determine how many times a particular word or concept will be used in a set of regulations before you start drafting. If you draft definitions before you draft your regulations, you may define a word that is not used. Often a concept that is used in a set of regulations is complex and you must develop a phrase to use as shorthand for that concept. If you develop the phrase before you draft the regulations, the phrase may not be as appropriate as one developed during the process of drafting. Additionally, O.R.S. § 183.335 states that prior to the adoption, amendment or repeal of any rule, the agency shall give notice of its intended action via a purpose of the intended action and a statement of the need. It is unclear how a definition without usage or context is either purposeful or needed. Therefore, we request the Board not move forward with adoption of definitions for rules that are not being considered for adoption at the December 2022 Board of Pharmacy meeting, holding outstanding definitions for amendment when the rule with context is proposed with intention for adoption.

Division 041 – related to Prescription Labeling Expiration Date

We appreciate the proposed amendments to expiration date labeling which provides flexibility for labeling of prescriptions dispensed in a manufacture's container to have an expiration date match the manufacture's expiration date and not limited to one year from the date of dispensing. CVS health supports the permanent adoption of this rule to improve patient access to medications dispensed in a manufacture container.

Division 010/0019/020 related to Pharmacist Prescriptive Authority

CVS Health *supports* the continued work of both the Public Health and Pharmacist Formulary Advisory Committee (PHPFAC) in the arduous process of taking a new concept from the beginning to a complete formalized recommendation of the Board to adopt by rule and the Board for continually expanding the protocol compendium from which pharmacists may prescribe. We also are appreciative of the proposed language which allows a pharmacist to schedule an appointment with a patient for prescribing or administering an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive.

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

One CVS Health implementation reality for pharmacist prescribing that has proven to be a barrier is the inability to reformat or manipulate the self-screening assessment questionnaires and standard procedures algorithm. We recognize the PHPFAC and Board have spent significant time reviewing and considering clinical guideline evidence, public health data, and disease state experts' recommendations to develop all drug therapy management protocols in OAR Division 20. We also recognize the statutory requirement for the PHPFAC to develop a protocol, which depending on the disease state and drugs can include detailed prescriptive information. CVS Health simply requests the Board permit pharmacists and pharmacies to create and implement an electronic documentation process that includes the required elements of the *patient intake forms* and *assessment and treatment care pathway* but is not standardized in the current paper-based style of formatting.

Our request is not to remove any of the existing requirements/elements of the protocol inclusion, exclusion, or referral criteria that were recommended by the PHPFAC to be adopted by rule for each drug/disease state category, but rather allow for the ability for pharmacists to modify the basic order, question style, and structure of how forms are documented. Technology and healthcare documentation is moving towards a more complete electronic health record (EHR) that has the potential for integration and sharing between all providers. Another basic component of this EHR transition is the ability for patients to take ownership of their health by having access to their own patient records and visit summaries, as well as complete online intake forms prior to coming to the pharmacy for a visit or pharmacist assessment.

While this request for autonomous flexibility in electronic documentation may seem minor and inconsequential, it has proven to be a critical factor in preventing our pharmacists from engaging in Oregon prescribing services. We are appreciative of the Board's work in developing standardized intake forms, algorithms, and protocols for Oregon patients, but if those efforts are halted or even fragmented by outdated methods for patient care documentation, we've completely missed the mark on the legislative point on expanding pharmacist prescriptive authority, which is to provide safe patient access to pharmacist provided care that improves clinical outcomes. The Board and board staff have often stated they envision a future where the model of pharmacy is as safe or safer than the current standards of practice. CVS Health does not believe placing pharmacists in a position to perform paper documentation or scannable copy documentation of standardized patient intake forms, algorithm, assessments, treatment care pathway, or visit summaries is the model of the future, much less the current standard of care for other healthcare professionals performing similar patient care services.

Division 019/141 related to Pharmacy Prescription Kiosks (PPK)

CVS Health feels the newly proposed Division 141 related to Pharmacy Prescription Kiosks (PPK) does not allow for increased patient access due to the onerous and unnecessary requirements for operation of a kiosk within Oregon, which will prevent utilization of a PPK. The intent of a PPK is to allow for access as an extension of the pharmacy without a pharmacist on site. Requiring a pharmacist to supervise a PPK in real time limits the timeframe in which a PPK could be used remotely by a patient, which is most often after hours when pharmacies are closed. A mileage limitation on where the PPK can be placed is also a barrier to implementation, amongst other recordkeeping requirements in the proposed rules. CVS Health also has concerns with a plan of correction for a discrepancy noted on a board inspection to be submitted within a "time allowed by the board" in lieu of the current requirement of a submission within 15 days of a deficiency notice or 30 days of receiving a noncompliance notice. This variable timeframe does not provide licensees a consistent and expected timeframe for response, which can cause confusion and further disciplinary action. If this rule is adopted, we request the Board not strike the timeframe for submission of the plan of correction. Overall, we call on the Board to not adopt the rule and continue discussion with stakeholders to simplify the rule, while reviewing other state's laws, rules and/or regulations which address the use of a PPK. CVS Health has provided language from Arizona Revised Statute 32-1901(6) and Board of Pharmacy

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Administrative Code R4-23-677 as an example of operable requirements by a drug outlet to provide additional patient access through a kiosk system.

Suggested Language of Arizona for Review and Consideration
ARS 32-1901. Definitions
In this chapter, unless the context otherwise requires:
6. "Automated prescription-dispensing kiosk" means a mechanical system that is operated as an extension of a pharmacy, that maintains all transaction information within the pharmacy operating system, that is separately permitted from the pharmacy and that performs operations that either:
(a) Accept a prescription or refill order, store prepackaged or repackaged medications, label and dispense patient-specific prescriptions and provide counseling on new or refilled prescriptions.
(b) Dispense or deliver a prescription or refill that has been prepared by or on behalf of the pharmacy that oversees the automated prescription-dispensing kiosk.
R4-23-677. Automated Prescription-dispensing Kiosk Permit
A. General provisions.
1. Only a person issued a Board permit under A.R.S. § 32-1929 to operate a pharmacy in Arizona may apply to the Board under A.R.S. § 32-1930 for a permit to operate an automated prescription-dispensing kiosk.
2. A pharmacy permittee described under subsection (A)(1) shall apply for a separate permit for each automated prescription-dispensing kiosk to be operated.
3. To obtain an automated prescription-dispensing kiosk permit, a pharmacy permittee shall submit a completed application, using a form available on the Board's website, and the fee specified in R4-23-205.
4. A pharmacy permittee to which the Board issues an automated prescription-dispensing kiosk permit shall designate a pharmacist in charge of the automated prescription-dispensing kiosk.
5. A pharmacy permittee to which the Board issues an automated prescription-dispensing kiosk permit shall not place the automated prescription-dispensing kiosk in a gas station or convenience store.
B. Policies and procedures. A pharmacy permittee to which the Board issues an automated prescription-dispensing kiosk permit shall:
1. Ensure policies and procedures are established for the appropriate performance and use of the automated prescription-dispensing kiosk. The policies and procedures shall address:
a. Maintaining a record of each transaction in a manner that attaches the record to the permit number of the automated prescription-dispensing kiosk;
b. Controlling access to the automated prescription-dispensing kiosk;
c. Operating the automated prescription-dispensing kiosk;
d. Training personnel who use the automated prescription-dispensing kiosk;
e. Maintaining patient services when the automated prescription-dispensing kiosk is not operating or the prescribed drug or device is not available;
f. Securing the automated prescription-dispensing kiosk against unauthorized removal of the kiosk or access to or removal of drugs or devices from the kiosk;
g. Assuring a patient receives the pharmacy services necessary for appropriate pharmaceutical care including consultation with a pharmacist;
h. Maintaining integrity of information in the system and patient confidentiality;
i. Stocking and restocking the automated prescription-dispensing kiosk;
j. Ensuring compliance with packaging and labeling requirements; and
k. Removing drugs and devices from the automated prescription-dispensing kiosk without dispensing them and handling wasted or discarded drugs and devices;
2. Ensure the policies and procedures are implemented and complied with by all personnel using the automated prescription-dispensing kiosk;
3. Maintain the policies and procedures by:

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a. Reviewing the policies and procedures biennially and making needed revisions, if any;
b. Documenting the review required under subsection (B)(3)(a);
c. Assembling the policies and procedures as a written or electronic manual; and
d. Making the policies and procedures available within the pharmacy permittee to which the Board issued an automated prescription-dispensing kiosk permit for reference by pharmacy personnel and inspection by the Board; and
4. Implement a quality assurance program to monitor compliance with the policies and procedures and all state and federal law.
C. Change of ownership. An automated prescription-dispensing kiosk permittee shall comply with R4-23-601(F).
D. An automated prescription-dispensing kiosk permittee shall renew the permit as specified under R4-23-602(D).
E. The Board shall adhere to the time frames specified under R4-23-602(C) when processing an initial or renewal application for an automated prescription-dispensing kiosk permit.

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

Sincerely,

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

CVSHealth

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

November 22, 2022

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

Re: Proposed Rules of Division 001 Related to Procedural Rules

Dear Executive Director Schnabel:

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

CVS Health feels the Board has other avenues to obtain public comment outside of posting rules for scheduled rule hearings. As is the case with many other Boards of pharmacy, stakeholder input or public comment is solicited during the discussion and development of rules, most often after the Board has discussed a section and prior to moving to the next. We feel this is a more beneficial way to illicit feedback in real time and allows the Board to hear from various perspectives and understand current trends in rules not only in neighboring states but across the United States.

OAR 855-102-0040 Inspections

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

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

We also request the language in OAR 855-102-0040 be amended to require photographs and recordings be kept to the minimum necessary for investigations and that personal identifying information (PII) and protected health information (PHI) only be recorded if required for a specific investigation. An additional concern is the lack of exclusion for Patient Safety Work Product (PSWP), which includes patient safety event reports. CVS Health, and many other pharmacies, report through an Agency for Healthcare Research and Quality listed Patient Safety Organization (PSO) to enhance the patient safety and quality improvement activities. Confidentiality and privilege protections are provided for patient safety and quality improvement information through the Patient Safety Quality

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

Improvement Act of 2005 (Patient Safety Act). We additionally request exceptions for this information to not be photographed, recorded or required to be produced upon inspection. Furthermore, we request language be added to not allow personal devices of the Compliance Officer be used for video and audio recording. Finally, we ask the Board to add language, in accordance with the NABP Model Act, Section 16, that requires Compliance Officers to secure photographs and recordings taken during the inspection as confidential and privileged. Without this proposed revision, proprietary information that may be copied or recorded during an inspection may be subject to a public records request.

Suggested Language 855-102-0040 Inspections

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

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

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

(b) Inspecting all drugs and devices;

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

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

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

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

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

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

(d) Reviewing, verifying and making copies of records and documents required by ORS 475, ORS 689 and OAR 855

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

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

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

Sincerely,

Lauren Paul, PharmD

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

CVSHealth

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

November 22, 2022

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

Re: Proposed Amendments to Division 115 Pharmacists

Dear Executive Director Schnabel:

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

CVS Health is appreciative of the Board releasing the newly proposed Division 115 for Pharmacists for the purpose of soliciting feedback from stakeholders and the public. CVS Health feels the Board has other avenues to obtain public comment outside of posting rules for scheduled rule hearings. As is the case with many other Boards of pharmacy, stakeholder input or public comment is solicited during the discussion and development of rules, most often after the Board has discussed a section and prior to moving to the next. We feel this is a more beneficial way to illicit feedback in real time and allows the Board to hear from various perspectives and understand current trends in rules not only in neighboring states but across the United States. Therefore, it would not only save the Board and board staff time but would also align Oregon with national trends and expansion of pharmacy practice.

OAR 855-115-0001 Applicability and OAR 855-115-0084 Counseling

While we fully support appropriate patient counseling based on each pharmacy practice setting, CVS Health has significant concerns with the removal of counseling from the practice of pharmacy activities that a pharmacist who is in another state working for an out of state pharmacy is exempt from performing without holding an Oregon pharmacist license. A nonresident pharmacy, by the nature of being located outside of Oregon, would have a limited number of Oregon licensed pharmacists, as current requirements only require a pharmacist in charge to be licensed in Oregon. When requiring an Oregon licensed pharmacist to complete counseling for an Oregon patient, coupled with proposed changes in the counseling section which require a pharmacist to hold a prescription for delivery when counseling is required to either counsel the patient or obtain acceptance of declination, the Board is not only restricting patient access but also potentially causing significant delays in patient's receiving therapy. With these proposed amendments the Board is not fulfilling their responsibility to promote and protect public health.[1] While this proposed counseling language is impactful to those pharmacies located out of the state, the COVID-19 pandemic has also changed the way patients in Oregon and across the country expect to receive care. In a recent survey that CVS Health conducted, it was confirmed that the current way pharmacy care is delivered does not match the patient's expectations of how they engage and want to receive care, creating a challenging work environment for our pharmacists, interns/externs and technicians as well as a broken patient experience.[2] Pharmacies within the state of Oregon have developed and implemented various delivery programs for patients, which would now be impacted and cause delay in patients receiving medication therapy as a pharmacist attempts to contact a patient to provide counseling or receive declination of counseling. Additionally, there seems to be a conflict in OAR 855-115-0084(2)(b) and (4) with one section using "may" and the other using "must" in reference to releasing the prescription when counseling is required.

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There is an absence of (negative) safety data or clinical evidence showing a patient safety issue currently exists for patients in Oregon based on compliance with existing patient consultation requirements. Discussion at Board meetings in August and October 2022, provided no patient safety data, study, or other evidence that would suggest the current offer in writing for a prescription being delivered, either by a resident or nonresident pharmacy and subsequent counseling that occurs post-delivery, is insufficient or causes safety issues for the patients of Oregon. The same is true for requiring an Oregon licensed pharmacist to provide counseling to an Oregon patient. Therefore, based on lack of evidence of a patient safety issue, we request the Board to review and amend language for these sections as provided below.

Suggested Language OAR 855-115-0001 Applicability

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

Suggested Language OAR 855-115-0084 Counseling

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

~~(a)~~ ~~O~~only the Pharmacist or intern can accept a patient's or patient's agent's request not to be counseled, when counseling is required~~;~~.

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

(3) The Pharmacist or intern that provides counseling or accepts the request not to be counseled must document their identity and the provision or declination of counseling at the time of the interaction~~;~~.

~~(4) A Pharmacist must not allow a prescription to be released from the drug outlet when counseling is required, prior to the counseling or acceptance of the request not to be counseled by a Pharmacist;~~

(~~5~~4) For each prescription, the Pharmacist or intern must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(5) For a prescription delivered to a patient, except at a pharmacy, the Pharmacist must offer in writing to provide direct counseling and information about the drug, including the information on how to contact the Pharmacist.

OAR 855-115-0070 Pharmacist: General Responsibilities

Paramount and centric to all Board rules, including pharmacy technician roles and responsibilities, is patient safety. Increasing the scope of pharmacy technician practice to include administrative and supportive tasks for pharmacist-provided patient care services will allow pharmacists to more effectively and efficiently provide for patients' medication-related needs.[3] Most importantly, some states have a patient safety track record of success with expanded pharmacy technicians roles that spans over four decades.[4] Pharmacist delegation is individualistic and takes into account the individual technician's capabilities, the pharmacist's comfort level, facility policies, and the risk mitigation strategies present at the facility, among other factors.[5] The ability for a pharmacist to utilize their discretion in task delegation provides a pharmacist better control over which functions to delegate in the interest of patient care, and to whom. In our review of proposed Division 125 addressing pharmacy technicians, we believe the amended rules achieve that objective rather than supplanting the professional judgment of pharmacists with one-size-fits-all rules.[6] However, in review of the Pharmacist general responsibilities and the list of activities only a pharmacist may perform, we request the Board amend (3)(d) to include consultation with a healthcare professional or authorized agent for clinical interactions or interventions. This would allow a pharmacy technician to contact a healthcare professional or authorized agent for nonclinical clarifications or to obtain information that is missing from

a prescription. We also request the Board consider striking (3)(n) requiring only a pharmacist to receive a new or transferred prescription orally. Currently, 18 states permit a pharmacy technician to obtain nonclinical clarifications, receive new verbal prescription orders and provide a prescription transfer in some fashion, with Arizona being the most recent state to adopt rules which allow these pharmacy technician practices.

CVS Health also requests the Board strike (6)(o)(C) which would permit a pharmacy technician to access a pharmacy when a pharmacist is not present to retrieve a patient's already-filled prescription that is ready for delivery to the patient, as we suggested in our letter addressing proposed Division 125 Pharmacy Technicians.

OAR 855-115-0076 Responsibilities: Training

Without context of intent and discussion, CVS Health has concerns with section (1)(b) of this section which requires ongoing training to ensure continued competence. Since January 2015, Accreditation Council for Pharmacy Education (ACPE) addresses continued professional development for both "pharmacists and pharmacy technicians to meet and maintain defined competences in areas relevant to their respective professional responsibilities" as continuing professional development (CPD), which includes continuing pharmacy education (CPE).[7] As competency can be subjective, we ask the Board to consider this language to align with ACPE guidance on continuing professional development, as shown below.

Suggested Language OAR 855-115-0076 Responsibilities: Training

(1) Pharmacists must complete:

(b) Ongoing training to ensure ~~continued competency in tasks that are performed~~ continuing professional development.

OAR 855-115-0086 Pharmacist-in-Charge: Qualifications, Limitations, and Duties

In our review of the notice for proposed new Division 115, we do not see where OAR 855-019-0300 is proposed to be struck. Current rule in Division 19 outlines the duties of a pharmacist, which is overlapping with new section OAR 855-115-0086. We request the Board ensure that all sections are properly notated in future proposed rule filings for clarity of intent for what is being amended. CVS Health is opposed to the amended language in (1)(a) and (b) which requires a pharmacist to complete at least 2000 hours of pharmacy practice as a pharmacist within the last 2 years prior to becoming a PIC in addition to taking a board approved training program every 5 years, effective July 1, 2025. These requirements will shrink the pool of eligible pharmacists who are qualified to serve as PIC at a time when designating a PIC is already strained due to lack of pharmacists joining the profession. These requirements also limit a pharmacist who has experience in leadership roles or possibly has been with an employer for many years as a pharmacy technician, intern and now pharmacist, from becoming PIC. This individual may be better suited for a role as PIC than someone who meets the proposed criteria set forth by the Board due to their experience with the employer. Additionally, these requirements may force pharmacies to close if they are unable to secure a PIC, further preventing patient access not only to prescription medication, but all other pharmacy services that are permitted and offered in Oregon. Most recently, the New Hampshire Board of Pharmacy repealed rule Ph704.11 addressing practice requirements prior to becoming a PIC which included a practice requirement of 2 years as a pharmacist, obtaining an 80% passing score on an exam designed by the Board as well as hours requirements to be present and practicing within the pharmacy effective on June 15, 2022.[8] CVS Health requests the Board not move forward with the requirements outlined in the proposed new rule and replace the language with requirements for practice or board approved training program as currently required in OAR 855-019-0300.

CVS Health also has concerns with a plan of correction for a discrepancy noted on a board inspection to be submitted within a "time allowed by the board" in lieu of the current requirement of a submission within 15 days of a deficiency notice or 30 days of receiving a noncompliance notice. This variable timeframe does not provide licensees a consistent and expected timeframe for response, which can cause confusion and further disciplinary action. We

request the Board amend this language to the previous version with outlined timeframes to meet the Board's strategic goal of providing clarity to licensees.

Suggested Language OAR 855-115-0086 Pharmacist-in-Charge: Qualifications, Limitations and Duties
(1) In order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:
(a) Completed ~~at least 2000 hours of pharmacy practice as a Pharmacist within the last 2 years in a US state or jurisdiction~~ at least one year of pharmacy practice; or
(b) Completed a board provided PIC training course either before the appointment or within 90 days after the appointment ~~and every 5 years thereafter effective July 1, 2025~~;
(c) Be employed by the outlet; and
(d) Be actively engaged in pharmacy activities at the drug outlet and be physically present at the drug outlet for a sufficient amount of time as needed to effectively supervise drug outlet activities, be responsible for the daily operation of the drug outlet and ensure drug outlet compliance.

(3) The PIC must perform all of the following:
(o) Submit a plan of correction for observations noted on an inspection within: ~~the time allowed by the board;~~
(A) 15 days of receiving a deficiency notice; or
(B) 30 days of receiving a noncompliance notice:

OAR 855-115-0130 Services: Prescribing Practices – Formulary or Protocol Compendia
CVS Health is generally supportive of expansion in pharmacist prescribing allowance which allows a pharmacist to practice at the top of their education and training and provides patients with an option for access to care apart from their primary care provider, urgent care or emergency department. We ask the Board to reconsider the requirement that physical assessments be performed face to face and in person versus allowing the assessment to occur through electronic means which is currently required and reflected in (4)(c). As technological advances continue through practice of telemedicine, we request a pharmacist be afforded the same allowances to perform an assessment using technology or in a manner they see fit for the patient and their ability to properly assess the patient.

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

Sincerely,

Lauren Paul, PharmD

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

References

1. Oregon Board of Pharmacy, Board Members website. Available from https://www.oregon.gov/pharmacy/Pages/Board-Members.aspx (Accessed November 7, 2022)
2. The Rx Report: A new day in retail pharmacy. Available from: https://www.cvshealth.com/sites/default/files/media-gallery/cvs-health-rx-report-2022-fall.pdf (Accessed November 7, 2022)

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3. Zellmer WA, et al. Toward uniform standards for pharmacy technicians: Summary of the 2017 Pharmacy Technician Stakeholder Consensus Conference. Am J Health Syst Pharm. 2017;74(17):1321-1332.
4. Frost TP, Adams AJ. Expanded pharmacy technician roles: Accepting verbal prescriptions and communicating prescription transfers. Res Social Adm Pharm. 2017;13(6):1191-1195.
5. Adams AJ. Toward permissionless innovation in health care. J Am Pharm Assoc. 2015; 55:359e362.
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8. New Hampshire Board of Pharmacy, ph 700 Adopted Text 6/15/2022. Available from: https://www.oplc.nh.gov/sites/g/files/ehbemt441/files/inline-documents/sonh/ph-700-adopted-text-20220615.pdf (Accessed November 8, 2022).

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November 22, 2022

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

Re: Proposed Amendments to Division 125 Pharmacy Technicians

Dear Executive Director Schnabel:

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

CVS Health is appreciative of the Board releasing the newly proposed Division 125 for Pharmacy Technicians for the purpose of soliciting feedback from stakeholders and the public. We understand from reading the proposal that these rules change the structure and create a separate division for pharmacy technicians by replacing lists of what technicians can and cannot do, as technician functions are advancing with not only changes in technology but adoption of delegation models to allow pharmacist discretion of what duties and tasks a technician can perform. However, without Board related discussion on these rules prior to releasing them for public comment, it is extremely difficult to understand the full intent and allowances of tasks that a pharmacy technician or certified Oregon pharmacy technician can perform or if the intent is to allow for a pharmacist delegation model. CVS Health also feels the Board has other avenues to obtain public comment outside of posting rules for scheduled rule hearings. As is the case with many other Boards of pharmacy, stakeholder input or public comment is solicited during the discussion and development of rules, most often after the Board has discussed a section and prior to moving to the next. We feel this is a more beneficial way to illicit feedback in real time and allows the Board to hear from various perspectives and understand current trends in rules not only in neighboring states but across the United States. Therefore, it would not only save the Board and board staff time but would also align Oregon with national trends and expansion of pharmacy practice.

OAR 855-125-0070 Responsibilities – General- Certified Oregon Pharmacy Technician and Pharmacy Technician

As we review the proposed changes with new Division 125, it is apparent that OAR 855-025-0040 detailing pharmacy technician tasks and guidelines was struck with a smaller portion of the section contained in OAR 855-125-0700. While CVS Health supports the simplicity of the rule without a list of tasks, we would prefer Board confirmation that new section OAR 855-125-0700 outlines the responsibilities of a certified Oregon pharmacy technician and pharmacy technician in a delegation model. Specifically, we interpret OAR 855-125-0070(3)(e-g) to permit this. In delegation models, as long as a technician is properly supervised, trained and has the skill set to perform a task, a pharmacist can delegate such tasks as receiving a verbal prescription order, performing a transfer or have nonclinical discussions with a healthcare provider or authorized agent for clarification of a prescription or to obtain missing information on a prescription.

CVS Health has concerns with the restrictions outlined in OAR 855-125-0070(3)(h) which only allow access to the pharmacy area when a pharmacist is physically present, or the outlet is operating under a RDSP registration in compliance with Division 139. Division 139 was promulgated with onerous and unnecessary requirements not found

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in any other states laws or rules for operating a remote site. Three states, Alabama, Colorado and Virginia, have promulgated rules which allow a technician to access the pharmacy area when a pharmacist is not present to obtain already filled prescriptions to provide to patients. Another state, Louisiana, continues to discuss promulgation of such a rule. The access is granted in an emergency when a pharmacist may be running late or is unable to work while other coverage is found or in the case of Alabama, when a state of emergency is declared. This allows pharmacies to still provide medications to patients in these types of situations without requiring additional licensure/registration with onerous requirements to operate. We request the Board to consider the below suggested language, incorporating language from Virginia, to allow access without a pharmacist present.

Suggested Language

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

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

OAR 855-125-0076 Responsibilities: Training

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

Suggested Language

(2) Complete ongoing training to ensure ~~continued competency in tasks that are performed~~ continuing professional development.

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

Sincerely,

Lauren Paul, PharmD

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

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References

1. Accreditation Counsel for Pharmacy Education Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy. Available from: https://www.acpe-accredit.org/pdf/CPDGuidance%20ProfessionPharmacyJan2015.pdf (Accessed November 7, 2022).

From:	PHARMACY BOARD * BOP
To:	PHARMACY RULEMAKING * BOP
Subject:	FW: New Regulation Requiring Live Pharmacist before mail delivery prescriptions
Date:	Monday, November 7, 2022 8:21:10 AM

From: Ted de Looze <teddelooze@gmail.com>
Sent: Monday, November 7, 2022 6:21 AM
To: PHARMACY BOARD * BOP <PHARMACY.BOARD@oregon.gov>
Subject: New Regulation Requiring Live Pharmacist before mail delivery prescriptions

To Whom It May Concern:

While realizing that the objective of the Board of Pharmacy is to provide safe prescription services to patients, the new rule requiring a discussion with a pharmacist prior to every home delivery is an extreme and expensive waste of time.

For many years, our family members have avoided having to wait in line at a pharmacy for chronic medications. I have ordered them from Walgreens Alliance mail order for many years. Now, each time I renew a medication, for example, a specialty medication I require every 28 days, I need to wade through the update questionnaire 3 times. The first is online, the second is with the technician who confirms all details including medical details, and finally, after a long wait, I review the third time with a pharmacist.

Pharmacy technicians are licensed to ask all the same questions when a patient goes into a pharmacy for a vaccination. It makes no sense to waste the time of the patient, the pharmacy technicians, and a pharmacist. This adds expense and frustration to our medical care system, already the most expensive in the world and 22nd in quality of care.

It would be in the interest of patient care and efficiency to rescind this expensive and duplicative rule.

Thank you,

Ted de Looze, MD

From:	Elkins, Michael S.
To:	PHARMACY RULEMAKING * BOP
Cc:	Rickert, Edward D.
Subject:	Written comments on proposed rulemaking (855-115-0001; 855-115-0084; 855-006-0005) [QBLLP-ACTIVE.FID37463807]
Date:	Tuesday, November 22, 2022 3:45:51 PM
Attachments:	Express Scripts and Accredo"s Comments on Proposed Rulemaking (11-22-2022).pdf

Good afternoon,

We hope this email finds you well. Attached please find our clients' written comments on the Oregon Board of Pharmacy's Notice of Proposed Rulemaking dated October 25, 2022 – specifically, proposed rules 855-115-0001 and 855-115-0084; and Notice of Proposed Rulemaking dated October 21, 2022 – specifically, rule 855-006-0005.

These comments are submitted on behalf of Express Scripts Pharmacy, Inc., ESI Mail Pharmacy Service Inc., and Accredo Health Group, Inc.

Thank you and please let us know if you need any additional information.

-Ed Rickert and Mike Elkins

125+ YEARS OF SERVICE | Quarles & Brady LLP

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November 22, 2022

VIA ELECTRONIC MAIL:

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

Re: Comments in Opposition to Notice of Proposed Rulemaking Dated October 21st and 25th, 2022, Concerning Proposed New Rule 855-115-0001; Proposed New Rule 855-115-0084; and Proposed Amended Rule 855-006-0005

Dear Ms. Melvin:

We are writing on behalf of Express Scripts Pharmacy, Inc., and ESI Mail Pharmacy Service Inc. (collectively "Express Scripts"), and Accredo Health Group, Inc. ("Accredo)" (referred to collectively in this letter as "Express Scripts/Accredo") to provide comments to the Oregon Board of Pharmacy's ("Board") Notice of Proposed Rulemaking dated October 25, 2022 ("Notice"). The Notice announces the Board's intention to accept and consider public comments on proposed rule changes.

Among other changes, the Board proposes to recodify rule 855-019-0100 – under new Division 115 as 855-115-0001 – with amendments affecting non-resident pharmacies and pharmacists' ability to counsel patients located in Oregon. Specifically, presently, a pharmacist working at a non-resident pharmacy licensed as a Retail Drug Outlet in Oregon is permitted to perform certain activities, including patient counseling, under the license of the pharmacy, and is not required to be individually licensed as a pharmacist in Oregon. The Board seeks to delete the word "counseling" from the list of professional tasks that a non-resident pharmacist can perform when associated with a registered non-resident Retail Drug Outlet. This will require pharmacists who have been counseling Oregon residents on their medication therapy for many, many years, without incident, to now take an Oregon law exam, pay a fee, and obtain an Oregon pharmacist's license.

In addition, the Board proposes to (A) repeal the current definition of "counseling" in rule 855-019-0110, (B) add the new definition of "counseling" in rule 855-006-0005, and (C) repeal the rule on counseling (855-019-0230) and recodify it – with amendments under the new Division 115 as 855-115-0084. Among other changes in proposed 115-0084, the Board seeks to (1) eliminate the ability of a non-resident mail-order pharmacy to offer in writing to provide direct counseling and (2) require pharmacists and pharmacies to provide mandatory counseling in specified instances. Significantly, the proposed revision would also require the pharmacy to withhold delivery of the patient's medication until mandatory counseling is provided.

In effect, the proposed changes to current rules 855-019-0100 and 019-0230 (proposed 855-115-0001 and 115-0084) will create an unjustified and significant operational burden for Express Scripts/Accredo without a commensurate positive effect on patient safety. In fact, as proposed, the new rule could result in delays in dispensing that could cause significant patient harm. Likewise, the proposed rules, as written, are violative of the Commerce Clause of the United States Constitution.

All Express Scripts/Accredo pharmacies are opposed to the proposed rule change, and these comments are submitted on behalf of all Express Scripts/Accredo pharmacies. We respectfully submit these comments for the Board's consideration and request that they be considered following the public hearing on November 22, 2022, and at future Board meetings on these proposed rules.

I. Background:

Express Scripts operates both traditional mail order and specialty pharmacies, that are located outside the state of Oregon, and dispense prescription drugs to patients located in Oregon. Combined, the Express Scripts/Accredo pharmacies employ 2,160 pharmacists who are responsible for ensuring that prescription medications are dispensed appropriately and safely to patients, including patients residing in Oregon.

Although all of their pharmacists are qualified and trained to ensure that the pharmaceutical care delivered to their patients is of the highest quality, many of the pharmacists employed by the pharmacies are clinical pharmacists who focus exclusively on specific disease states and medication therapies, and have the expertise to ensure that Oregon patients are educated on the medications prescribed to them by their medical practitioners. Most (though not all) of those pharmacists are not presently licensed in Oregon. If this rule takes effect, those pharmacists will be forced to take the Oregon pharmacy law exam, or alternatively, Oregon patients will be transferred to pharmacists who hold an Oregon license, but may not have the specific clinical expertise held by the pharmacist who had been counseling Oregon patients for many years before the rule took effect.

A. Proposed Rule 855-115-0001 (currently 855-019-0100): Applicability

As seen below, the Board's proposed changes include modification of the tasks for which a non-resident pharmacist is exempt from obtaining a license in Oregon.[1] Specifically, "counseling" will no longer be one of the professional tasks a non-resident pharmacist may perform without a license in Oregon.

> (1) This Division applies to any ~~p~~**P**harmacist **who engages in the practice of pharmacy** ~~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~~**2**) ~~Any pharmacist who engages in the~~ **Only persons licensed with the board as a Pharmacist may** practice ~~of~~ pharmacy ~~in Oregon~~ **and** must ~~be licensed by the Board in accordance with the following~~ **act in compliance with statutes and** rules.
>
> (4**3**) A **P**~~p~~harmacist 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 ~~B~~**b**oard in accordance with the following rules, except that a **P**~~p~~harmacist **located in another state who is** working ~~in~~ **for** an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, ~~counseling~~ and verification associated with the~~ir~~ **out-of-state pharmacy** dispensing of a drug **in**to ~~a patient in~~ Oregon, is not required to be licensed by the ~~B~~**b**oard ~~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.~~

B. Board's purpose for the rule change

Based on a review of the Board's prior meeting minutes and agenda, it appears the idea for the change originated during the Safe Pharmacy Practice Conditions Workgroup meeting on May 10, 2022:

> The workgroup provided feedback related to Pharmacist Scope (counseling, DUR, volume) and suggested that outlets measure time needed to perform these tasks and

[1] Note, the Board's October 25, 2022 Notice of Proposed Rulemaking does not include an accurate track-changed version of the proposed changes to rule 855-019-0100, which can be found in the Board's October 2022 Board Meeting Agenda. https://www.oregon.gov/pharmacy/Documents/October_2022_Bd_Mtg_Agenda.pdf (last visited 11/15/2022).

> consider requiring that time to be accounted for in the staffing algorithm, consider possibly revising rules to focus on what is permitted vs. what is not permitted, clarity on utilizing telework, clarity on transferring prescriptions, **consider counseling rules that are the same for mail order and in-person pharmacies,** consider adopting rules allowing the Pharmacist to determine what needs counseling and allowing the Pharmacist to override counseling generated by pharmacy software, suggested measuring and accounting for time needed for DUR and adding it to staffing algorithm, consider focusing on patient-centered metrics vs. profit-based metrics and making them objective and measurable.[2]

Per minutes from the Board's August 2022 general meeting, at which time a second prospective rule review took place, "[t]he board discussed when counseling is required [and] … **provided guidance to make the counseling requirement for mail order pharmacies the same as for in person pharmacies**."[3]

Per *draft* minutes from the Board's October 12-14, 2022 general meeting, "[t]he board discussed when counselling is necessary and the difference in standards between in person pharmacies and mail order pharmacies with the goal for counseling to be consistent for patients in any setting."[4]

While the focus appeared to be on pharmacies, proposed rule 855-115-0001's Rule Summary indicates otherwise[5]:

> Other health care boards in Oregon and other states consider counseling to patients who are located in Oregon to require licensure. This would bring us in alignment with other boards and ensure that the Board is following statutory mandates regarding licensure requirements for those practicing pharmacy in Oregon.

The Board's reliance on approaches taken by other health care boards is misplaced, in that Oregon, by statute, already requires drug outlets to be licensed, and Oregon regulations require pharmacists who practice independently to hold an individual license. No other licensing board in Oregon has a similar licensing scheme, and we submit that the current approach taken by the Board of Pharmacy is consistent with Oregon law, and adequately protects the public.

[2] https://www.oregon.gov/pharmacy/Documents/March_2022_SPPC_WKGP_Mtg_Minutes.pdf.
[3] https://www.oregon.gov/pharmacy/Documents/August_2022_Bd_Mtg_Minutes.pdf.
[4] https://www.oregon.gov/pharmacy/Documents/October_2022_Draft_Bd_Mtg_Minutes.pdf.
[5] *See* the Board's October 24, 2022 Notice of Proposed Rulemaking.

II. Proposed Rule 855-115-0001 Is Not Supported by Clearly Demonstrated and Documented Safety Concerns

Express Scripts/Accredo understand and appreciate that the role of the Oregon Board of Pharmacy is to protect the health and welfare of Oregon residents. However, we respectfully disagree that eliminating "counseling" from proposed rule 855-115-0001 would improve patient safety for Oregon patients. The proposed rule appears to be intended to level the playing field between resident and non-resident pharmacies, without any patient safety justification. In other words, the proposed rule addresses competition, not safety, a purpose that is not aligned with the statutory purpose of the Oregon Pharmacy Practice Act, or the role of the Board of Pharmacy. *See,* ORS 689.025 (the purpose of the Oregon Board of Pharmacy is to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy).

If implemented as proposed, instead of promoting and protecting public health, safety, and welfare, the amended regulation could cause patient harm by reducing available prescription services for Oregon residents. For instance, in order to comply with the pharmacist licensure requirement, pharmacies like Express Scripts/Accredo that employ a large number of pharmacists, some of whom may be unwilling to obtain Oregon licensure, will likely no longer have counseling available to Oregon patients on a 24/7 basis.

Oregon patients may also lose the benefit of receiving counseling from a pharmacist with clinical expertise specific to the patient's medical condition and/or medication. There is nothing in the Oregon pharmacist licensure requirements that would require a non-resident pharmacist to demonstrate clinical expertise in order to obtain licensure. All that is required is passing a law exam, and paying a license fee. Likewise, the proposed change interrupts continuity in pharmacy workflow, as it will require bringing in an Oregon-registered pharmacist solely to provide counseling, despite the fact that this pharmacist may not have otherwise been involved in any other aspect of filling the subject prescription.

Further, it is not clear from the Board's October 25th Notice, or prior meeting materials/agenda items, that there is any data to show the current regulation, exempting non-resident pharmacists from licensure, created any increased risk of harm to patients. In fact, Express Scripts'/Accredo's data shows that there have been no errors attributable to patient counseling. Of equal significance, the Board has not presented any data to show that pharmacists who do not hold an Oregon license, but have provided counseling to Oregon patients under the pharmacy's non-resident license, have a higher incidence of errors or negative patient outcomes when compared to Oregon licensed pharmacists.

Moreover, the administrative burden of requiring these non-resident pharmacists to obtain Oregon licensure does not change anything with respect the education or knowledge requirements a pharmacist needs in order to provide patients with advice regarding safe and effective use of a medication or device. (Under the Board's proposed new definition of "counseling" in 855-006-0005, "counseling" means "an interactive communication between a Pharmacist and a patient or a

patient's agent in which the Pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.")

If the Board's concern is to ensure that Oregon-registered non-resident pharmacies follow Board rules on requirements for counseling, the Board may exercise recourse through the pharmacy's permit. According to the Board's February 2022 Non-Resident Pharmacy Self-Inspection Form, the Board already expects non-resident pharmacies to ensure compliance with requirements for counseling under current rule 855-019-0230. ("Is the pharmacy compliant with the Oregon requirements for counseling and documentation of counseling?")[6] As such, the Board should provide an explanation as to why it believes the counseling requirement for patients of resident pharmacies cannot be the same/similar for registered non-resident/mail-order pharmacies without requiring the non-resident pharmacists to obtain a license.

Additionally, the Board's elimination of "counseling" from proposed rule 855-115-0001 seems to suggest that counseling requires a different level of professional licensure/certification than other parts of the medication dispensing process. While this is likely not the Board's intent, if the Board is concerned with ensuring that non-resident pharmacists are licensed in good standing in their respective states before they provide counseling to Oregon patients, then Express Scripts/Accredo suggest the Board consider NABP Verify as an alternative.

Further, it is not clear from the Board's Notice or prior meeting materials/agenda items that there is any data to show that the current regulation, exempting non-resident pharmacists from licensure, created any increased risk of harm to patients. In fact, Express Scripts'/Accredo's data shows that there have been no errors attributable to patient counseling. Of equal significance, the Board has presented no data to show that pharmacists who do not hold an Oregon license, but have provided counseling to Oregon patients under the pharmacy's non-resident license, have a higher incidence of errors or negative patient outcomes when compared to Oregon licensed pharmacists.

Accordingly, we are requesting that the Board revise the proposed regulation to remove the requirement for a non-resident pharmacist to obtain an Oregon license in order to perform counseling.

III. Standards Imposed on Community Pharmacies Located in Oregon are Based on Practices that May Fall Short of the Practices Employed by Express Scripts/Accredo and Other Mail Order Pharmacies

Whatever the justification, before the Board can impose the requirement for all non-resident pharmacists performing counseling through registered mail-order pharmacies to be licensed by the Board, the Board must examine the practices employed in the mail-order industry and compare those practices to the practices of community pharmacies located in the state.

[6] https://www.oregon.gov/pharmacy/Documents/Non-ResidentPharmacySelf-InspectionForm.pdf

By their very nature, mail-order pharmacies operate differently than community pharmacies, which enables mail-order to provide innovative and convenient care to patients. For instance, the Accredo model leverages Therapeutic Resource Centers of Excellence with clinical pharmacists located across the country, who have expertise on certain disease states and specialty medication therapy, and counseling calls are routed to the appropriate clinical pharmacist. With pharmacy services available on a 24/7/365 basis, Oregon patients currently have a higher level of access to counseling then they can obtain from an in-person community pharmacy. Not to mention, community pharmacies are currently faced with staff shortages, increasing demands, and the like. The Board's proposed elimination of the license exemption for counseling threatens the ability of Oregon patients to receive these unique clinical services.

As the Board is well aware, patient counseling is a clinical activity, and imposing a licensure requirement in order to provide counseling will not improve patient care. The status quo – with the non-resident pharmacy obtaining registration in Oregon and not individual pharmacists – provides adequate protections for Oregon patients.

IV. Proposed Rule 855-115-0084 (currently 855-019-0230): Counseling; and Proposed New Definition of Counseling

A. Rule on Counseling

Among other changes, the proposed amendments seek to impose mandatory counseling requirements for pharmacists, noted below. If counseling is required, the pharmacist "must not allow a prescription to be released from the drug outlet" prior to the counseling or acceptance of the patient's request not to be counseled. This proposed new requirement will have a critical impact on mail-order pharmacies, in that it would require patient outreach before arranging for delivery, and conditions the delivery of the patient's medication on the availability of the patient to answer the phone to receive counseling. If a patient is unavailable to receive counseling, this threatens patient continuity of care and multiplies the risk of interruption of therapy for patients who cannot immediately be reached. Likewise, the proposed changes create ambiguity on whether written counseling alone is permissible under the proposed changes.

The proposed changes to the rule on counseling are as follows:

(1) The ~~p~~**P**harmacist ~~or intern~~ must ~~orally~~ counsel the patient or patient's agent on the use of a drug or device ~~as appropriate~~:

(**a**) **Upon request;** ~~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) When the drug or device has not been previously dispensed to the patient by the pharmacy;

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

…

(d) When the prescription has been transferred to the drug outlet by oral, written or electronic means; or

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

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

(~~b~~**a**) Only the Pharmacist ~~or Intern~~ may accept a patient's or patient's agent's request not to be counseled**, when counseling is required**;

(b) ~~If, in their reasonable professional judgment, the pharmacist or intern believes that the patient's safety may be affected, t~~**T**he Pharmacist ~~or Intern~~ may choose not to release the prescription until counseling has been completed;

(~~c~~3) The Pharmacist ~~or Intern~~ that provides counseling or accepts the request not to be counseled must document **their identity and** the **provision or declination of counseling at the time of the** interaction;

(~~d~~4) A Pharmacist must not allow ~~non-Pharmacist personnel~~ **a prescription** to **be** release**d from the drug outlet when** ~~a prescription that requires~~ counseling **is required**, **prior to the counseling** or accept**ance of** the request not to be counseled **by a Pharmacist**;

~~(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**5**) For each **prescription** ~~patient~~, the Pharmacist ~~or Intern~~ must determine the **manner and** amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

***

~~(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.~~

(9) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.

***

Express Scripts and Accredo understand the importance of patient counseling. Indeed, from 11/2/21 through 10/31/2022, the Express Scripts pharmacies counseled 1,499,619 patients nationwide, and 37,609 patients in the state of Oregon. Accredo has specially trained pharmacists available 24/7/365 to match patients with the most clinically appropriate pharmacist to answer counseling questions for specialty medications. In addition, Accredo pharmacists receive and make outbound counseling outreaches to patients based on an advanced therapy management system of clinical rules to provide initial counseling, therapy management assessment, and adherence management for select specialty medications. As a high touch pharmacy, pharmacists routinely interact with patients regarding their medication therapy, but would rarely, if ever, delay delivery of a medication if a patient could not be reached. There is concern that the language in the proposed rule – requiring the pharmacy to withhold delivery of a medication until counseling is provided – is certain to result in delays in therapy and disruption of care in situations where a patient cannot be reached; or a patient fails to return a call to the pharmacist regarding the need to provide counseling prior to shipment of the drug.

The current processes followed by Express Scripts and Accredo, which comply with current pharmacy regulations in every state, including Oregon, are adequate to protect the public. These processes combine written information, a toll-free telephone number to allow patients to contact a pharmacist 24/7/365, as well as patient outreach, but do not include withholding needed medication until personal contact with the patient can be made.

We therefore request that the Board either clarify the regulation, to confirm that withholding medication delivery does not apply when medications are delivered through the mail or common carrier, or alternatively, to simply remove that language altogether.

B. Definition of Counseling

The current definition of "counseling" is found in rule 855-019-0110, as follows and is proposed to be repealed in its entirety:

> "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.

The proposed new definition of "counseling" in rule 855-006-0005 is as follows:

> "Counseling" or "counsel" means an interactive communication between a Pharmacist and a patient or a patient's agent in which the Pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

These proposed changes – namely repeal of "oral or other appropriate communication" to make way for "*interactive* communication" – in conjunction with the changes to the rule on counseling, appear to show the Board's intent to level the playing field between community and mail-order pharmacies, without a sufficient justification. In other words, if "counseling" cannot be accomplished until there has been "interactive communication" between a patient and an Oregon licensed pharmacist, the potential benefit of requiring interactive communication is not outweighed by the substantial risk to patient continuity of care and interruption of therapy. Accordingly, we respectfully request that the Board revise the proposed definition of "counseling" to enable mail-order pharmacies to accomplish the act in writing.

We note further that the requirement of interactive counseling, though laudable, is ineffective when counseling is provided to a patient's agent, as would be allowed under the proposed rule. It is likely that the patient's agent would be unable to effectively communicate the counseling provided by the pharmacist to the patient, and would be unable to anticipate follow-up questions the patient may have. The patient would then be required to rely on potentially inaccurate or incomplete information received second hand, or would be required to call the pharmacy to speak to the pharmacist to receive counseling directly. That is why the current regulation, which allows for written information as well as an ability for the patient to call the pharmacist to receive interactive counseling (at a time when the patient is available and ready to receive counseling), is in our view preferrable. Again, the proposed revision would do little to ensure that the patient is appropriately counseled, and further potentially creates an access to care issue resulting from potential delays in a patient receiving their medications in a timely manner.

V. The Oregon Board of Pharmacy Has Not Performed a Financial or Regulatory Impact Analysis for the Proposed Regulations.

When promulgating an administrative regulation, Oregon law requires the Board to submit a statement of fiscal impact. *See* Or. Rev. Stat. Ann. § 183.335(b)(E). However, the Board's October 25, 2022 Notice does not include such a statement. Rather, in the section for "Fiscal and Economic Impact", the Notice states, "[n]one anticipated." This could not be further from the truth.

Clearly, the Board has yet to conduct the required fiscal impact analysis and we urge them to consider the impact to non-resident pharmacies and pharmacists. As of July 30, 2021, there were at least 714 out-of-state or non-resident pharmacies registered in Oregon.[7] Currently, the cost of an Oregon pharmacist application is $100 (by reciprocity), $50 (if by score transfer), plus a $46.25 fee for the National fingerprint-based background check, in addition to the biennial license fee of $250 and $70 Rx Monitoring Fund fee, on each odd numbered year. As such, if each non-resident pharmacy is required to license between one and 10 pharmacists, the two-year cost alone could be in the range of $332,902.50 to $3,329,025, on top of the cost of licensing Pharmacists-in-Charge. Those costs are in addition to costs incurred by the individual pharmacist, who would be required to pay for, prepare for, and pass an Oregon licensure exam, and pay ongoing costs associated with Oregon pharmacist continuing education requirements in order to maintain licensure.

[7] *See* NABP 2022 Survey of Pharmacy Law.

We would respectfully request the Board perform and publicly provide a complete fiscal impact analysis depicting the potential costs to entities and adequately reflecting the regulatory impact of this proposed regulation to currently licensed entities.

VI. The U.S. Constitutional's Dormant Commerce Clause and Extraterritorial Application of Regulations

If passed, in addition to challenging the arbitrary, capricious, and anti-competitive nature of the proposed rules, the rules are also susceptible to a constitutional challenge. The Board's attempt to reach across its borders and impose its requirements on entities that are already regulated by their home states is the type of regulation that has repeatedly been found to be in violation of the Commerce Clause to the United States Constitution.

A. Commerce Clause Background

Under the U.S. Constitution's Commerce Clause, Congress has explicit power to "regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. A state's pharmacy regulatory scheme "must comply with--and are not exempt from--the limitations of the Commerce Clause." *National Pharms., Inc. v. De Melecio,* 51 F. Supp. 2d 45, 56 (D.P.R. 1999), affirmed, *National Pharms v. Feliciano*, 221 F.3d 235, 238-239 (1st Cir. P.R. 2000). The Commerce Clause covers three broad categories of activity: (1) the use of the channels of interstate commerce; (2) the instrumentalities of interstate commerce or persons or things in interstate commerce; and (3) activities having a substantial effect on interstate commerce. *U.S. v.* Lopez, 514 U.S. 549, 558-59 (1995). Thus, a pharmacy that uses the U.S. Mail or other carrier will trigger the Commerce Clause. *See, e.g., Colon Health Centers of Am., LLC v. Hazel,* 733 F.3d 535, 542 (4th Cir. 2013) ("The dormant Commerce Clause is implicated by burdens placed on the flow . . . of goods, materials, and other articles of commerce across state lines.").

Like here, state laws which purport to regulate commerce occurring outside of the State's border, are particularly suspect. The prohibition on state and local laws regulating extraterritorial commerce has been developed in a line of Supreme Court cases stretching back to the 1930s. *See Healy v. The Beer Inst*., 491 U.S. 324, 336 (1989*); CTS Corp. v. Dynamics Corp. of Am*., 481 U.S. 69 (1987); *Brown Forman*, 476 U.S. at 573; *Edgar v. MITE Corp*., 457 U.S. 624 (1982) (plurality opinion); *Baldwin v. G.A.F. Seelig, Inc*., 294 U.S. 511 (1935).

In *Healy*, the Court crystallized the principles embodied by these decisions, noting "the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State." 491 U.S. at 336. The Commerce Clause prevents "the application of a state statute to commerce that takes place wholly of the State's borders" and therefore bars a state from forcing an out-of-state merchant from seeking regulatory approval in one state before undertaking a transaction in another. *Id.* As the Supreme Court explained in *Mite Corp.*, "any attempt 'directly' to assert extraterritorial jurisdiction over persons or property would offend sister States and exceed the inherent limits of the State's power." 457 U.S. at 642-643.

B. Extraterritorial Statutes

The proposed rules are problematic because they would regulate commerce occurring wholly outside of Oregon and unjustifiably burden interstate commerce.

First, the proposed amendments attempt to regulate commerce that occurs solely outside the state by imposing pharmacist licensure requirements that conflict with those of the pharmacy's home state. As previously mentioned, the Commerce Clause bars a state statute or regulation from regulating commerce occurring wholly outside of Oregon. *Healy*, 491 U.S. at 336. The amendment would require all non-resident pharmacies and non-resident pharmacists to comply with Oregon's regulation and ensure that a non-resident pharmacist licensed in Oregon engage in the practice of pharmacy for an Oregon patient, despite being qualified to practice pharmacy in their home state. It is not possible for a pharmacy to establish a licensure requirement depending on where the patient is located, and if required to comply a non-resident pharmacist licensure approach, the Express Scripts/Accredo pharmacies would be required to adjust pharmacist staffing for all prescriptions filled for Oregon residents in order to meet the newly created and unnecessary licensure/registration requirements.

Further, the Board's proposed amendments would "offend sister States" by asserting jurisdiction and superseding their legislative decisions. All states have established criteria, including but not limited to examination, schooling, residency, or experiential requirements, for licensure of individuals engaged in the practice of pharmacy. By requiring non-resident pharmacists to comply with Oregon's licensure requirement, Oregon would offend sister states by overruling their deliberate decisions regarding the appropriate pharmacist licensure requirements and would substitute the sister states' judgment with Oregon's. Essentially, the proposed amendments would prevent other states from granting rights to their citizens that promote public health and safety.

In addition to its extraterritorial reach, the Board's proposed rule unjustifiably burdens interstate commerce. A law is invalid if its burden on interstate commerce clearly exceeds its local benefits. *Fla. Transp. Servs. V. Miami- Dade Cty.*, 703 F.3d 1230, 1244 (11th. 2012). Under this analysis, the first step is identifying the burden on interstate commerce, which considers the practical affects if all states adopted a similar provision. *Id.* at 1245. The next step is identifying the local benefit and then comparing the benefits and burdens. *Id.*

The proposed rules requiring non-resident pharmacist licensure would burden interstate commerce. If all states regulated non-resident pharmacists in a similar manner, the state with the strictest standards would essentially set the national standard. The state with the strictest pharmacist licensure requirements would set the national standard that all non-resident pharmacists would have to follow, and would interfere with the authority of resident states to regulate in the manner they deem to be appropriate, based on the overall regulatory scheme in place in that state. To resolve any discrepancies, non-resident pharmacies could hire more pharmacists to meet the stricter standards. However, increasing the number of pharmacists would increase the cost of patient care, without any additional safety benefit.

We note that the burden associated with creating a pharmacist licensure requirement far exceeds any burden associated with the licensure or registration of a non-resident pharmacy. Unlike a pharmacy, in order to obtain a pharmacist license, individually employed pharmacists would be required to pay for, sit for, and pass an Oregon law exam. The pharmacist would further be required to pay fees associated with licensure, and comply with continuing education requirements that may be different from, and in addition to, CE required by the pharmacist's home state. The costs of compliance far exceed a more minimal burden associated with registration or licensure. That is why the NABP Verify credential, instead of full licensure, should be considered as a less burdensome alternative to licensure.

Lastly, regarding burdens on interstate commerce, the requirement that a pharmacy withhold delivery of a medication until a patient is contacted and counseled is, effectively, a ban against the sale and delivery of a product. It is well settled that a state cannot, in most circumstances, prohibit the importation of goods or other materials from other states. *See, City of Philadelphia v. New Jersey*, 437 U.S. 617 (1978), (New Jersey law preventing Philadelphia from shipping its waste to New Jersey landfills struck down as an impermissible ban on interstate commerce). The burden here is far worse than that in the Philadelphia, or any other Commerce Clause case of which we are aware. The proposed rule would prevent a pharmacy from delivering potentially life-saving medications to Oregon patients until that patient is available to be counseled, or available to decline counseling, even though the patient has requested that the non-resident pharmacy fill the prescription. Further, the proposed rule creates no exception to this blanket prohibition, even if the pharmacy cannot reach the patient to counsel, or to obtain an affirmative declination of counseling from the patient, for reasons that are wholly beyond the control of either the patient or the pharmacy.

The Commerce Clause concerns are further heightened by the lack of any demonstrable local benefit associated with the proposed rule. The Oregon Pharmacy Practice Act is meant to promote public health and safety. However, the proposed rules are specifically meant **"to make the counseling requirement for mail order pharmacies the same as for in person pharmacies**."[8] We are aware of nothing in the proposed rule or in any the Board discussions leading up to the proposed rule, that ties improved public health and safety to the requirement of a non-resident pharmacist to hold an Oregon license in order to perform counseling. Further, for the reasons stated above, the licensure requirement adds no patient care benefit, because the licensure requirement does nothing to ensure that the pharmacist providing the counseling has the clinical skills needed to convey drug information to the patient. Finally, requiring a pharmacy to withhold delivery of a medication until the patient can be reached will almost certainly cause delays and interruptions in drug therapy.

[8] https://www.oregon.gov/pharmacy/Documents/August_2022_Bd_Mtg_Minutes.pdf.

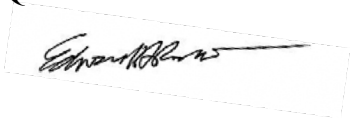
VII. Conclusion

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

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

Very truly yours,

QUARLES & BRADY LLP



Edward D. Rickert

From:	Temple, Jeffery P
To:	PHARMACY RULEMAKING * BOP
Cc:	Bass, Steven W; Gary Oxley; Samantha Siegner
Subject:	Fred Meyer comments to OR BoP proposed rules
Date:	Tuesday, November 22, 2022 12:53:31 PM
Attachments:	Fred Meyer Comments to OR BoP on Proposed Rules - Nov 2022.docx

Dear Rachel Melvin,

Please find the attached comments from Fred Meyer regarding the Oregon Board of Pharmacy proposed rulemaking. We appreciate your consideration, and we welcome any opportunity to discuss.

Sincerely,

Jeffery Temple
Director of Corporate Affairs
Fred Meyer Stores, Inc
jeffery.temple@fredmeyer.com
503.797.3830 (o)
503.708.8890 (c)

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November 22, 2022

Submitted Electronically to: pharmacy.rulemaking@bop.oregon.gov

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

Re: Proposed Rules Reorganizing Divisions 019/020/031/041/115 - related to Pharmacists and Divisions 006/019/031 - related to Definitions.

Dear Ms. Melvin:

Fred Meyer appreciates the opportunity to submit comments in reference to the Oregon Board of Pharmacy proposed rule changes to **Divisions 019/020/031/041/115 - related to Pharmacists** and **Divisions 006/019/031 - related to Definitions**. We appreciate the efforts of the Board to update and reorganize pharmacy rules in such a way that clearly articulates the roles and responsibilities of pharmacists. Upon review of this proposed rule, however, we have identified a number of changes that could drastically hinder the ability of pharmacists to meet the needs of Oregon patients.

855-115-0082 – Drug Utilization Review (DUR)

> *(2) Upon recognizing a concern with any of the items in (1)(a)-(h), the Pharmacist must take steps to mitigate or resolve the problem and document the steps taken and outcome.*

The proposed requirements for documenting the steps taken to resolve a problem and outcome under Section 855-115-0082 (2) – Drug Utilization Review (DUR) are overly burdensome to pharmacist workload and should be limited only to certain drugs or categories of drugs, not all drugs.

855-115-0086 – Pharmacist-in-Charge: Qualifications, Limitations, and Duties

(1)(b) Complete a board provided PIC training course either before the appointment or within 90 days after the appointment and every 5 years thereafter effective July 1, 2025.

Could the Board please provide clarity on what a PIC training course would entail? Given the short time frame that a pharmacy has in naming a new PIC if a PIC leaves, we want to make sure that the training is appropriate in length and detail. If the Board requires this training, it would be nice for this training to be completed on-demand and the completion records to be publicly available to pharmacies in Oregon.

855-115-0086 – Pharmacist-in-Charge: Qualifications, Limitations, and Duties

> *(3) The PIC must perform all of the following:*
> *(q) Complete and document a controlled substance inventory with discrepancy reconciliation as follows:*
> *(C) Monthly (within 31 days) for Schedule II controlled drugs.*

We would suggest that Board clarifies that this requirement only applies to discrepancy reconciliations.

855-115-0135 – Prescribing: Prohibited Practices

(1) A Pharmacist must not prescribe a vaccine, drug or device:
(a) 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;

We have found no evidence to suggest this restriction has been placed on other qualified medical professionals and, if this is the case, pharmacists should not be made subject to this limitation. Further, according to the Health Resources and Services Administration, more than 46% of Oregonians live in designated Health Professional Shortage Areas.[1] Often a relative pharmacist represents both the most accessible and most trusted healthcare provider. In the most remote of areas, including designated frontiers, a relative pharmacist may be the only option within a reasonable distance to deliver care. As such, pharmacists should be able to use their professional expertise to provide care to relatives for minor ailments, vaccines, and in the event of a medical emergency.

Pharmacist Counseling

Under current counseling regulations, 885-019-0230 states:

(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;

However, under section 855-115-0084 of the proposed rule, the language included in 885-019-0230 (e) is eliminated and replaced with:

855-006-0005 Definitions

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

Counseling is redefined as an “interactive communication,” implying that including written instructions, as may currently occur, would be prohibited. Concurrently, section 855-115-0084 of the proposed rule adds:

855-115-0084 Counseling

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

These rule changes leave to question the manner in which it is acceptable to provide counseling to a patient following a prescription delivered via mail order. The need for an “interactive communication” for prescriptions delivered by mail seems to eliminate the ability for a “pharmacist (to) determine the manner…of counseling that is reasonable and necessary…” If the intent here is that an oral communication with the patient or patient’s agent would be required for each mail order prescription, patient adherence would suffer significantly.

[1] https://www.ruralhealth.us/getmedia/b7940651-4292-40d3-82d0-36bd21db5892/BCD_HPSA_SCR50_Qtr_Smry-(4).aspx

If pharmacists are required to wait until a patient answers their phone or checks their voicemail and returns the call before sending out a prescription, considerable delays will result for that patient in receiving their medication. Studies of Americans' phone habits have shown that less than half of people answer the calls they receive,[2] while 67% of people ignore voicemails from businesses – even if that business' number is saved in their phone – and a whopping 82% of people ignore voicemails from numbers they do not recognize.[3] Further still, just 4.5% of people ever respond to a voicemail.[4]

The implications of this portion of the proposed rule can be foretold by what our pharmacists experience when attempting to get Medicare customers to return calls to approve new prescriptions or medications with a high co-pay: significant delays in getting those medications to the patient.

Again, thank you for the opportunity to share these concerns and we look forward to working with the Board to ensure pharmacist remain well-equipped to meet the healthcare needs of Oregonians. If there is any other information we can provide, please reach out to Evan Sarris, Deputy Director, Government Relations at evan.sarris@kroger.com.

Sincerely,

Steve Bass Pharm.D., R.Ph.
Coordinator, Health & Wellness
Fred Meyer Stores, Inc.

Jeffery Temple
Director, Corporate Affairs
Fred Meyer Stores, Inc.

[2] https://assets.hiya.com/public/pdf/HiyaStateOfTheCall2019H1.pdf
[3] https://www.cbsnews.com/news/are-you-still-checking-voice-mail/
[4] https://www.salesleadsinc.com/blog/2019/nov/6-voicemail-statistics-your-security-company-need-to-know/

From: Gibson, Ian
To: PHARMACY RULEMAKING * BOP
Subject: CDTM Comment
Date: Wednesday, November 16, 2022 10:11:39 AM

Ian Gibson
16 November 2022

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern and provide feedback about the proposed changes to the Collaborative Drug Therapy Management (CDTM) rules. I am strongly opposed to removing all OARs that discuss CDTM and proposed OAR, 855-115-0120. It appears that the Board voted to send these proposed changes to rulemaking for feedback from the public; however, changes were not discussed in public comment during either the August or October Board of Pharmacy meeting, making thorough feedback difficult.
I urge you to use a rules advisory committee to provide feedback on the impact additional rules will have, but especially with the proposed rules for 855-115-0120. I feel there are consequences of removing CDTMs from rules and replacing them with a redefined clinical pharmacy agreement. One implication, though certainly not the least, is the ability of pharmacists to be reimbursed for and thus provide services to Medicaid recipients enrolled in Coordinated Care Organizations (CCOs). In addition, these rules impact pharmacists in all settings, not just community pharmacy. The intent of these rules is unclear, as they have not been discussed and it feels as though the intent is to limit our current scope of practice. Licensees have no idea what the intent of these rules are, because they have not been discussed, and therefore we are unclear if your intent is to limit our current scope of practice or to replace CDTM with something new.
The Oregon Medical Board does not have corresponding rules that recognize a CPA. When these draft rules go into effect, there will be no ability for pharmacists to have a way to collaboratively manage drug therapy. This will greatly affect many of the pharmacists currently working in a clinical environment and could **cause patient harm**. It may also disrupt care for many Oregonians without access to healthcare providers other than their pharmacist and further erode efforts made to address health equity for rural and minority populations in Oregon. Before passing these rules I urge you to press pause and let subject matter experts weigh in on what these rule changes will mean for the current practice of pharmacy, the evolution of pharmacy practice, and patient safety.

Thank you for your consideration,
Ian Gibson, Oregon student pharmacist

--

Ian Gibson **(he/him)**
Pharm.D. Candidate | 2026
Oregon State University | Oregon Health and Sciences University
bentsoni@oregonstate.edu

From: Amber Grant
To: PHARMACY RULEMAKING * BOP
Subject: CDTM rules
Date: Thursday, November 17, 2022 10:10:15 PM

Amber Grant
11/17/22
Dear Oregon Board of Pharmacy Members,
I am writing to express my concern and provide feedback about the proposed changes to the
Collaborative Drug Therapy Management (CDTM) rules. I am strongly opposed to removing all OARs that discuss CDTM and proposed OAR, 855-115-0120. It appears that the
Board voted to send these proposed changes to rulemaking for feedback from the public however,
changes were not discussed in public comment during either the August or October Board of pharmacy
meeting making thorough feedback difficult.
I urge you to use a rules advisory committee to provide feedback on the impact additional rules will
have, but especially with the proposed rules for 855-115-0120. I feel/my organization feels there are
consequences of removing CDTMs from rules and replacing them with a redefined clinical pharmacy
agreement. One implication, though certainly not the least, is the ability of pharmacists to be
reimbursed for and thus provide services to Medicaid recipients enrolled in Coordinated Care
Organizations (CCOs). In addition, these rules impact pharmacists in all settings, not just community
pharmacy. The intent of these rules is unclear, as they have not been discussed and it feels as though
the intent is to limit our current scope of practice. Licensees have no idea what the intent of these rules
are, because they have not been discussed, and therefore we are unclear if your intent is to limit our
current scope of practice or to replace CDTM with something new.
The Oregon Medical Board does not have corresponding rules that recognize a CPA. When these draft
rules go into effect, there will be no ability for pharmacists to have a way to collaboratively manage drug

therapy. This will greatly affect many of the pharmacists currently working in a clinical environment and
could cause patient harm. It may also disrupt care for many Oregonians without access to healthcare
providers other than their pharmacist and further erode efforts made to address health equity for rural
and minority populations in Oregon. Before passing these rules I urge you to press pause and let subject matter experts weigh in on what these rule changes will mean for the
current practice of pharmacy, the evolution of pharmacy practice, and patient safety.
Thank you,
Amber Grant, Oregon RPh

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From: Amber Grant
To: PHARMACY RULEMAKING * BOP
Subject: RULES CHANGES TO MTM
Date: Thursday, November 17, 2022 10:13:42 PM

AMBER GRANT
11/17/22

Dear Oregon Board of Pharmacy Members,
I am writing to express my concern about the proposed rule changes to Medication Therapy
Management. I] urge you to reject changing the word "may" to "must" in proposed
rule 855-115-0125 (2). It appears the Board voted to send these proposed changes to rulemaking for
feedback from the public. However, the changes to the definition of MTM were not discussed in public
comment during either the August or October Board of pharmacy meeting making the reasoning for the
changes and thorough feedback difficult.
MTM encompasses a variety of services provided by pharmacists, generally for Medicare Part D plans
which have their own definition. Changing the definition of MTM in this rule to require that "all
elements listed be completed" is unnecessary and puts an undue burden on Oregon Pharmacists who
complete MTM visits for Medicare recipients. Some Part D MTM interventions may be as simple and
brief as a telephone call to determine why a patient is late for a maintenance medication refill or if an
intervention or refill is needed. The proposed change would mandate the provision of services that are
not indicated and increases the documentation and administrative burden of the pharmacist providing
said service. This may in turn, entice Medicare plans to contract with pharmacists outside of Oregon (as
they are not held to the same rules) to complete their yearly MTM visit instead of their local pharmacist
who they see when filling their prescription medications. The Oregon Board of Pharmacy should be
doing everything they can to develop and encourage the pharmacist-patient relationship which results

in improved patient safety outcomes, not burden it with cumbersome mandates. This proposed rule
change from "may include" to "must include" is unnecessary.
Thank you,
AMBER GRANT, Oregon RPh

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From:	Katie Jaeger
To:	PHARMACY RULEMAKING * BOP
Subject:	OBOP rulemaking comments
Date:	Tuesday, November 22, 2022 1:19:18 PM
Attachments:	Kaiser Permanente_OBOP Rulemaking 11.22.22 Divisions 006_019_031 related to Definitions.pdf Kaiser Permenente_OBOP Rulemaking 11.22.22_Rules for Public Comment.pdf

Thank you for the opportunity to comment.

Thanks,

Katie Jaeger, Pharmacy Regulatory

Kaiser Permanente Northwest Region

Cell: 503-758-6887

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November 22, 2022

Kaiser Foundation Health Plan of the Northwest
Pharmacy Administration
5725 NE 138th Ave.
Portland, OR 97230

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

RE: Rulemaking **Divisions 006/019/031 – related to Definitions**

Officer Melvin,

Thank you for the opportunity to provide comment on the proposed rulemaking. Our submission is related to the proposed changes and additions to Definitions in Division 006.

Collaborative Drug Therapy Management

We understand the amended definition of Clinical Pharmacy Agreement brings the definition in line with statutory language. It appears, with the removal of the definition of Collaborative Drug Therapy Management (CDTM) and the subsequent proposed rules in OAR 855-115-0120, the Board is moving away from the term (CDTM) to the broader term of Clinical Pharmacy Agreement.

The proposed language in OAR 855-115-0120 Services: Clinical Pharmacy Agreement does closely mirror what is currently in OAR 855-019-0260 Collaborative Drug Therapy Management.

Kaiser Permanente is concerned there may be unintended consequence to protocols that have been in place within our health care organization for many years. Within the Oregon Medical Board rules, OAR 847-015-0040, the term Collaborative Drug Therapy Management is utilized to describe this relationship between physicians and pharmacists.

We would ask at this time that the Board not remove the definition of Collaborative Drug Therapy Management until it is better understood if there would be impact to the significant number of long-standing CDTM agreements already in place with physicians.

Independent Practice of Pharmacy

Kaiser Permanente is opposed to adding a definition to Division 006 for Independent Pharmacy Practice for permanent adoption, as well as the subsequent addition of the proposed rules OAR 855-115-0100 Services: Independent Pharmacy Practice out for comment. Current Oregon statute and rules clearly define the practice of pharmacy and clinical pharmacy. These are widely accepted and understood terms used within the pharmacy industry.

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We would ask at this time that the Board remove the definition of Independent Practice of Pharmacy from rulemaking for permanent adoption. It is an unnecessary addition. We would recommend adding additional clarification to the definition of Practice of Clinical Pharmacy to include "(d) may or may not be related to the dispensing, distribution and delivery of drugs or devices".

Pharmacy Area

Kaiser Permanente is opposed to adding a definition to Division 006 for Pharmacy Area for permanent adoption. Current Oregon statute defines pharmacy and drug outlet. The definition proposed for Pharmacy Area is overly broad, will lead to confusion, and is unnecessary. We would ask at this time that the Board remove the definition of Pharmacy Area from rulemaking for permanent adoption.

Thank you for the opportunity to comment.

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

Kaiser Foundation Health Plan of the Northwest
Pharmacy Administration
5725 NE 138th Ave.
Portland, OR 97230

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November 22, 2022

Kaiser Foundation Health Plan of the Northwest
Pharmacy Administration
5725 NE 138th Ave.
Portland, OR 97230

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

RE: Proposed Rules for Public Comment

Divisions 001/102 – related to Procedural & Universal Rules
Divisions 025/125 – related to Pharmacy Technicians
Divisions 019/020/031/041/115 – related to Pharmacists

Officer Melvin,

Thank you for providing stakeholders the opportunity to comment on proposed rules early in rulemaking. We appreciate the Board is seeking public feedback during the drafting process.

Divisions 001/102 – related to Procedural & Universal Rules

855-102-0050 Records and Document Retention
(1)(a)(B) Training records for patient care services, when required, must be retained for 3 years after ceasing participation in the activity requiring training

Kaiser Permanente (KP) would ask the Board to consider modifying the proposed language around retention of training records for patient care services to a more reasonable/relevant time. Many statewide pharmacy protocols include CE requirements. Pharmacists may practice and participate in patient care services for many years. Requiring a pharmacist to maintain a record of CE throughout their career (and potentially 3 years beyond) seems excessive and in many cases may be irrelevant.

(2) Records must be stored at the Drug Outlet for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days.
(3) Records generated under Independent Pharmacy Practice, must be stored at a health care organization, practitioner, pharmacy, or pharmacist office or in a secure location by the Pharmacist according to OAR 855-115- 0100 for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days.
(4) Records must be written, electronic or a combination of the two.

KP would ask the Board to remove (2), (3) and (4). The requirement for the retention of records is already clearly outlined in (1) and everything included in (2), (3) and (4) is duplicative and unnecessary.

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Divisions 025/125 – related to Pharmacy Technicians

855-125-0070 Responsibilities: General

(3)(h) Only access the pharmacy area when a Pharmacist is physically present or when the outlet is operating under a Remote Dispensing Site Pharmacy (RDSP) registration and following the requirements in OAR 855-139;

KP would request the Board remove the broad, ambiguous term 'pharmacy area' and replace it with a more clearly understood and defined term like 'drug outlet'.

855-125-0090 Prohibited Practices

(5) Ask questions of a patient of patient's agent which screen or limit interaction with the Pharmacist.

The purpose of this statement is unclear. KP would ask that the broad, subjective language be deleted or modified to clarify the Board's intent. A suggested modification, "Ask questions that are intended to prospectively screen patients out of interacting with the Pharmacist; however, a pharmacy technician can ask questions to assist the pharmacist with data-gathering and questions necessary for the mechanics of filling and dispensing a prescription."

Divisions 019/020/031/041/115 – related to Pharmacists

855-115-0001 Applicability

(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).

KP would ask the Board to reconsider removing the task of counseling from the allowed tasks an out-of-state pharmacist can perform when associated with dispensing a drug to a patient in Oregon. An example of potential significant impact to Oregonians the Board should consider are the many specialty and limited distribution medications used to treat complex and chronic conditions that are only made available to a selected network of pharmacies nationwide. The specialty or limited distribution pharmacies are almost always mail order pharmacies and many located outside of Oregon. Requiring all pharmacists that interact with an Oregon patient during the dispensing of a medication to be licensed in Oregon, when the facility is already registered as a non-resident pharmacy and has an Oregon licensed pharmacist-in-charge, will potentially impact access to life-saving medications for Oregon residents.

How will this proposed change, restricting a patient's ability to speak with a pharmacist who is dispensing their medications from another state unless they are licensed in Oregon, improve public safety more than the protections that are already in place? Pharmacists practicing in a mail-order pharmacy located in another state have had the ability to counsel patients related to prescriptions filled in that non-resident pharmacy since the addition of OAR 855-019-0100(4) to the Board of Pharmacy administrative rules effective in 2009. At that time, establishing the requirement that only the PIC must be licensed in Oregon.

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> *855-019-0100 (4) Effective April 1, 2009, any 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 mail-order pharmacy located in another state is only required to have the pharmacist-in-charge, or similar position, licensed by the Oregon Board of Pharmacy*. BP 2-2008, f. & cert. ef. 2-20-08

In 2010, the Board made further clarifications to this rule, expanding from 'mail-order pharmacy' to more generally an 'out-of-state' pharmacy, as well as listing the specific tasks a pharmacist located out-of-state could provide when associated with dispensing a prescription, which included counseling. This part of the rule has not been altered since.

> *855-019-0100 (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). BP 6-2010, f. & cert. ef. 6-29-10*

The ability for the pharmacist to interact with the patient during the prescription fulfillment process is critical. Requiring any pharmacist from a non-resident registered pharmacy interacting or consulting with a patient to be licensed in Oregon, will impact non-resident pharmacies' ability to provide medications to Oregonians. There will be pharmacies faced with not being able to, or simply choosing not to, ship medications to Oregon patients, further reducing access. More volume and pressure will be placed on local pharmacies who are already struggling with workload and staffing, creating a potentially greater patient safety issue. There have not been significant changes to the practice of dispensing prescriptions or counseling that would necessitate this proposed rule change. We urge you not to.

855-155-0070 Pharmacist: General Responsibilities
(3)(a) Practice pharmacy as defined in ORS 689.005

Section (3) appears to be intended to capture those items only a pharmacist can do, starting with 'practice pharmacy as defined in ORS 689.005'. Nearly all the following items listed under (3) are included in ORS 689.005. It seems duplicative and unnecessary to reference a statute and then list nearly all the same elements within the rule. It would make more sense to either include in (3) what is not found in ORS 689.005 or list everything from ORS 689.005 and leave out the reference.

(4) A Pharmacist may permit an Intern under their supervision to perform any task listed in (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;

KP would ask the Board to modify this section to allow the supervising pharmacist to determine at what point each intern they are responsible for is capable and ready to perform allowed duties of a

pharmacist. Each intern comes with different backgrounds and levels of experience. A pharmacist should be allowed to evaluate when an intern is ready to perform additional tasks.

(6) A Pharmacist must:
(l) Ensure there is sufficient staff to provide services in a safe and timely manner. The Pharmacist on duty may temporarily shut down touchpoints and services at the discretion of the Pharmacist, if determined in their reasonable professional judgment, that there is insufficient staff to provide services in a safe and timely manner.

While KP understands and appreciates the Board's attempt to address workload and staffing issues pharmacists are facing, the proposed language is troublesome. "Touchpoints and services" provide access to a pharmacy, pharmacist and/or service needed for the health, safety, and welfare of Oregonians. What is considered a touchpoint or service that is more important or less important than another?

Is drive through access to pick up a prescription less important than a walk up window inside a pharmacy? If a pharmacist chooses to shut down the drive through touchpoint, this may restrict expected access to needed medications a handicapped or disabled person had. Is telephone access to the pharmacy a touchpoint that can be shut down? A patient may not be able to reach the pharmacist to receive the counseling they need, to know how to safely take their medication or get questions answered - or have their new prescription released so it can be delivered to their home, because they are too sick or contagious to physically come into the pharmacy.

As proposed, this could be a significant disrupter to patient access to care, creating potentially daily changes in services available or how a patient can access their medications from a pharmacy. We would ask the Board to remove the proposed language and continue to engage stakeholders and/or licensees to collaboratively find solutions.

855-115-0074 Responsibilities: Duty to Report
(1)(a)(B) Any loss related to suspected drug theft of a controlled substance

KP would ask the Board to consider re-alignment with the DEA's requirement for reporting theft and significant losses. The DEA does not require suspected drug theft to be reported. A determination of suspected theft is very subjective. In areas where staff outside of the pharmacy are also accessing drugs (e.g., hospitals, ASCs, etc.), additional time is often required to interview staff and review records and data before a determination can be made of theft or loss. Requiring suspected theft to be reported within 1 business day would create additional administrative burden when, most often, controlled substance discrepancies are able to be reconciled, but in longer than 1 business day. The proposed language is more restrictive than existing DEA controls and places additional administrative burden on PICs.

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855-115-0084 Counseling
(4) A Pharmacist must not allow a prescription to be released from the drug outlet when counseling is required, prior to the counseling or acceptance of the request not to be counseled by a Pharmacist.

Patients that choose mail order or delivery of their medications can be difficult to reach during normal pharmacy operating hours. Requiring a pharmacist consultation before a medication is released from the pharmacy may potentially delay a patient's receipt of the prescription. Delaying shipping or delivery until a pharmacist reaches the patient for consultation may cause the patient to go without medication.

Current practice for prescriptions mailed or delivered directly to a patient is providing comprehensive written medication information, as well as a contact phone number for a patient to call to reach a pharmacist. This practice is consistent with many state boards of pharmacy counseling requirements for mailed or delivered prescriptions. KP is not aware of any patient safety issues that have resulted from providing written medication information and phone access to a pharmacist.

Convenience, especially for those with mobility issues or access to reliable transportation, is a big reason patients choose to receive their prescriptions by mail-order or delivery: Mail-order pharmacies remove the necessity of going to the pharmacy to pick up medications. When medications are delivered to the patient's door, there is a lower chance of having gaps in their treatment. Using mail-order or delivery can also help patients save additional costs, such as transportation.

A systematic review of studies showed that patients who use mail-order pharmacies are more adherent to their medications (*https://www.goodrx.com/hcp/providers/mail-order-pharmacies-patient-adherence*). Greater adherence can lead to better health outcomes, reduction in hospitalizations and reduction in other costs for patients and healthcare overall.

KP would also ask the Board to reconsider removing the language currently found below in:

855-019-0230 Counseling
(1)(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.

855-115-0086 Pharmacist-in-Charge: Qualifications, Limitations, and Duties
(1) In order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:
(a) Complete at least 2000 hours of pharmacy practice as a Pharmacist within the last 2 years in a US state or jurisdiction;

KP would ask the Board to remove the requirement that a pharmacist must complete 2000 hours of pharmacy practice prior to becoming a PIC. A pharmacist's experience both before becoming a pharmacist and throughout their training and post licensure varies greatly. To make a broad requirement for all pharmacists is arbitrary and unnecessary. It should be determined by the employer, essentially the outlet, if a pharmacist has the skills and ability to perform the functions of a pharmacist and PIC.

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(3) The PIC must perform all of the following:
(q) Complete and document a controlled substance inventory with discrepancy reconciliation as follows:
(C) Monthly (within 31 days) for Schedule II controlled drugs.

KP would request the Board maintain the current requirement for Quarterly Schedule II controlled drug reconciliation. There has not been any public discussion at Board meetings related to issues around this current process, so it is unclear what the motivation would be to make this change.

Moving from quarterly reconciliation to monthly reconciliation will add another administrative task to already overly burdened PICs. Should a pharmacy determine this would add additional value to complete a reconciliation more frequently, that should be a business decision and not mandated by the Board without some explanation how this will improve the health, safety and welfare of Oregonians.

855-115-0100 Services: Independent Practice of Pharmacy

KP strongly opposes the need for the additional regulatory language titled 'Independent Practice of Pharmacy'. The practice of pharmacy is already clearly defined. Pharmacist responsibilities are also outlined in great detail. The requirements around drug storage and possession, intern and pharmacy technician supervision, and remote supervision are covered elsewhere in regulation or can be integrated into Pharmacist: General Responsibilities. The additional distinction of the Independent Practice of Pharmacy is duplicative, unnecessary and should be removed in its entirety.

Thank you for the opportunity to comment.

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

Kaiser Foundation Health Plan of the Northwest
Pharmacy Administration
5725 NE 138th Ave.
Portland, OR 97230

From:	Cox, Marcus
To:	PHARMACY RULEMAKING * BOP
Subject:	Submission of written comment for November 22, 2022 Rulemaking Hearing
Date:	Tuesday, November 22, 2022 3:55:17 PM
Attachments:	2022 11-22 ORBOP Written Letter comment.pdf

Please accept the attached letter of written comment from our organization.

Thank you

Marcus Cox, RPh
Chief Pharmacy Officer
Klamath Health Partnership, Inc
2074 S 6th St, Klamath Falls, OR 97601
Phone: 541-887-8188
Email: mcox@kodfp.org

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From: Oregon Board of Pharmacy <OregonBOP@public.govdelivery.com>
Sent: Wednesday, October 26, 2022 9:15 AM
To: Cox, Marcus <mcox@kodfp.org>
Subject: OBOP Rulemaking Hearing Notification - November 22, 2022

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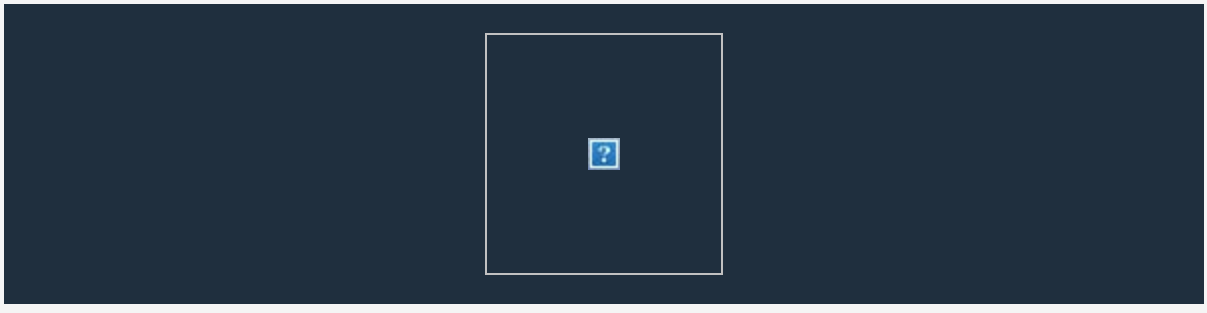


Oregon

Oregon Board of Pharmacy

Proposed Oregon Administrative Rules

Rulemaking Hearing November 22, 2022

Public Notice

The Oregon Board of Pharmacy is proposing to adopt the following rules:

- Division 019 - related to 2022 HB 4034 Duties of a Pharmacist
- Division 139 - related to 2022 HB 4034 Prohibited Practices
- Division 019 - related to 2022 HB 4096 Out-of-state Volunteer Pharmacist
- Division 062 - related to Drug Distribution Agent
- Divisions 010/019/020 - related to Pharmacist Prescriptive Authority
  - COVID-19 Antiviral (Paxlovid)
  - Travel Medications
  - PEP
  - PrEP
  - Contraception
- Divisions 021/135 - related to Continuing Pharmacy Education
- Divisions 019/141 - related to Pharmacy Prescription Kiosk (PPK)

- Divisions 006/019/031 - related to Definitions
- Division 041 - related to Prescription Labeling Expiration Date
- Divisions 001/102 - related to Procedural & Universal Rules - *The board does not intend to adopt these rules in December 2022 - seeking public comment only
- Divisions 025/125 - related to Pharmacy Technicians - *The board does not intend to adopt these rules in December 2022 - seeking public comment only
- Divisions 019/020/031/041/115 - related to Pharmacists - *The board does not intend to adopt these rules in December 2022 - seeking public comment only

November 22, 2022 Rulemaking Hearing Information

Please review and provide comment on proposed draft rule language including the Fiscal Impact statement and Racial Equity statement. You can find the filing notices and rule text on our website.

The rulemaking hearing will be held virtually via Microsoft Teams on 11/22/2022 at 9:30AM. If you wish to present oral testimony during this hearing, sign up on our website or email your first and last name, email address and which rules you would like to comment on to pharmacy.rulemaking@bop.oregon.gov to receive the link to join the virtual meeting.

You may file written comments before 4:30PM on November 22, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 146 611 440# for audio only.

NOVEMBER 22, 2022 RULEMAKING HEARING

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.

oregon.gov/pharmacy

The Oregon Board of Pharmacy is an equal opportunity, affirmative action employer committed to a diverse work force.
We respect, reflect and respond to the diverse people we serve.

Klamath Health Partnership, Inc.

Our mission is to provide accessible, culturally sensitive,affordable and quality-driven patient-centered health services to the community with an emphasis on the underserved.
Nuestra misión es brindar a nuestra comunidad servicios de salud de alta calidad, accesibles, centrados en el paciente, con énfasis en aquellos que mas nos necesitan

November 22, 2022

FROM: Klamath Health Partnership, Inc
2074 S 6th Street, Klamath Falls OR 97601

TO: Oregon Board of Pharmacy

RE: Proposed Draft Rule(s) 855-006-005(10), 855-115-0070 (3) (a)-(p), 855-115-0070(3)(m), 855-115-0115, 855-115-0120, 855-115-0125

President Murray, Vice President Doyle and members of the Oregon Board of Pharmacy:

Please accept this letter to provide commentary to the Proposed Draft Rules referred to within that affect Pharmacist Scope of Practice, Laboratory order and monitoring, Drug Therapy Management and MTM.

About Klamath Health Partnership

Klamath Health Partnership is a community health clinic operating as a Federally Qualified Health Center (FQHC) in Klamath Falls Oregon. We serve over 10,000 patients annually and many of our patients live in poverty and face significant social determinants of health that create barriers to affordable health care services.

Our health centers mission is to provide accessible, culturally sensitive, affordable, quality-driven, responsive, patient-centered health services to the community, with an emphasis on the underserved.

Klamath Health Partnership operates 6 clinics throughout Klamath County providing a primary medical home of health care services including medical, behavioral health, dental, pharmacy, transportation and other supportive services to our patients. Our pharmacy services include an inhouse pharmacy where patient care receive affordable prescriptions, quality and professional service and pharmacist medication management services that help our patients improve adherence and use of their medications.

We sincerely appreciate the Oregon Board of Pharmacy's efforts to streamline how clinical pharmacists can practice in primary care.

We recognize that Medication management services is very important to our patients. This is a valuable service that helps our patients to provide understanding, best use of medication, adherence and monitoring. This improves efficiencies in the health care system, supportive to the patient primary care providers, and works to improve transition and coordination of care.

We are concerned with the proposed rule changes could have unintended consequences.

We recommend further discussion and analysis to the consequences of the proposed draft rules prior to final approval.

Klamath Health Partnership, Inc.

Our mission is to provide accessible, culturally sensitive,affordable and quality-driven patient-centered health services to the community with an emphasis on the underserved.

Nuestra misión es brindar a nuestra comunidad servicios de salud de alta calidad, accesibles, centrados en el paciente, con énfasis en aquellos que mas nos necesitan

Klamath Health Partnership appreciates the opportunity to provide comments on the proposed rules and has detailed them below:

1. 855-006-005(10) Definitions for OAR Chapter 855

   Klamath Health Partnership recommends the Board retain the definition of Collaborative Drug Therapy Management (CDTM)

   Health Centers are required to serve "medically underserved, or special medically underserved populations", which face barriers in accessing health care services. HRSA requires health centers to address these barriers and disparities among patients' health status and through the health center's operations – including pharmacy programs. Health centers rely on the ability to bill for pharmacy services to not only meet this requirement for their insured patients but also for those who do not have health insurance.

   Transitioning the authorities of CDTMs into the CPA rules alone will not permit physicians to engage in collaborative drug therapy management unless the Oregon Medical Board changes their administrative rules. OAR 847-015-0040 presently prohibits physicians from engaging in management of drug therapy pursuant to a written protocol with pharmacists without a collaborative drug therapy management protocol. Oregon Medical Board rules presently mirror the existing Pharmacy Board CDTM rules and definitions. We suggest that the Board wait to make this change until the Oregon Medical Board updates their rules from CDTM to CPA.

2. 855-115-0070 (3) (a)-(p) Pharmacist General Responsibilities

   Klamath Health Partnership requests that the proposed changes to OAR 855-115-0070 do not limit a pharmacist's ability to practice to the fullest extent of their scope, and the dynamic utilization of pharmacists in Oregon's community health centers.

   The new OAR which replaces 855-019-0200 (3) in general removes language which may limit the dynamic utilization of pharmacists in Oregon's community health centers. Given ongoing health care workforce challenges, it's imperative the finalized OAR recognizes how pharmacists can be a solution to increasing capacity at health centers to meet the rising needs of underserved patients.

   Maintaining the existing scope of practice for Oregon pharmacists under 855-019-0200 (3) enables more patients to receive comprehensive and affordable care. Besides the workforce challenges that can adversely affect health center patients, they often experience challenges accessing health care services due to social determinants of health. Health centers tailor their pharmacy services to meet the unique needs of their surrounding communities and address barriers to culturally competent and comprehensive primary health care services.

3. 855-115-0070(3)(m) Pharmacist: General Responsibilities and 855-115-0115 Services: Laboratory

Klamath Health Partnership seeks clarity to how the proposed changes will affect pharmacists to order, interpret and monitor lab tests.

The proposed OARs essentially remove the long-established ability of a pharmacist to independently order and interpret laboratory tests and limits their scope of testing to pharmacy services expressly defined and permitted in ORS 689. This is a crucial component of how community health centers utilize clinical pharmacists as a member of the primary care team. In a time when providers and care teams are stretched to capacity and the pipeline for new providers to enter practice areas is long, we are concerned that this deviation away from nationally accepted scope of practice for pharmacists will mean patients experience extended wait times, fewer touch points with their care team, and ultimately poorer outcomes. This change will only serve to further exacerbate the existing health care workforce crisis by essentially adding additional workload onto exhausted providers.

4. 855-115-0120 Clinical Pharmacy Agreement

Klamath Health Partnership seeks clarity to proposed draft rule OAR 855-115-0120 that appears to complicate rather than simplify administrative rule obligations for pharmacists. The concern is that the proposed rule does not align with the legislative intent of HB 2028 (2015).

Klamath Health Partnership is concerned that draft OAR 855-115-0120 does not align with the legislative intent of HB 2028 (2015). The result of this deviation in the proposed draft rule would complicate rather than simplify administrative rule obligations for pharmacists.

HB 2028 (2015) permits health insurers and the Oregon Health Authority to provide payment or reimbursement for services pursuant to a clinical pharmacy agreement or statewide drug therapy protocol. The additional requirements set forth in proposed **OAR 855-115-0120 (B)(C)** would make the administrative burden and actual ability to implement new CPA services or transition existing CDTM agreements into CPAs overwhelming and unworkable for many community-based pharmacy programs.

The bill included statutory language specific to Coordinated Care Organizations contained within ORS 414.764 (2)(a)(b). "A coordinated care organization may reimburse a pharmacist or pharmacy for any health service: a) Provided to a medical assistance recipient who is enrolled in the coordinated care organization or prepaid managed care health service organization that enters into a clinical pharmacy agreement with the pharmacist or pharmacy; and b) That is within the lawful scope of practice of a pharmacist."

Removing the OARs for Collaborative Drug Therapy Management and adding the language to Clinical Pharmacy Agreement implies that the CCO must create an agreement that contains all requirement in OAR 855-115-0120 including the types of decisions the pharmacist is allowed to make. These proposed rule

changes in 855-115-0120 would require CCOs to create protocols that define the pharmacist(s) patient care process, referral process, standards of care, and decision criteria for conditions like diabetes for the purposes of reimbursement. It was never intended for CCOs to take on the role of defining pharmacist, pharmacies, or a clinic's scope of work for the pharmacists under their employ or have health plan physician and pharmacist staff fill the role of principle physician or pharmacist. It is not feasible or appropriate to require CCO providers to take on this level of liability without a patient-provider relationship or physician-pharmacist relationship within their health care provider contracts. This may create a situation where clinical pharmacists may have two or more different clinical pharmacy agreements dictating how they manage chronic conditions such as diabetes.

5. 855-115-0125 Medication Therapy Management (MTM)

Klamath Health Partnership seeks clarity around changes to Medication Therapy Management practices, and how the use of "may" instead of "must" in the draft OAR potentially creates a requirement include all the listed elements at every encounter for a pharmacist to be in compliance.

The change from "may" to "must" in the draft OAR potentially creates a requirement that certain actions be taken during every encounter. **This shift implies MTM must include all the listed elements at every encounter for a pharmacist to be in compliance.** However, in practice all of these elements are not performed in a single visit for various reasons.

Klamath Health Partnership thanks the Oregon Board of Pharmacy for the opportunity to comment on draft rule changes. We urge the Board on going to seek input from Health Center programs to help expand access to care and improving health outcomes for the most vulnerable patients.

Sincerely,

Klamath Health Partnership, Inc

Signe Porter

Signe Porter
Chief Executive Officer

Amanda Blodgett, MBA
Chief Operations Officer

Patrick "Paki" Story, LMFT, MAC
Director of Behavioral Health

Marcus Cox, RPh
Chief Pharmacy Officer

From:	Cole-Plasker, Gina E :LSO VP Government Affairs
To:	PHARMACY RULEMAKING * BOP
Subject:	Proposed Rule Change OAR 855-115-0070 and OAR 855-115-0120
Date:	Tuesday, November 22, 2022 11:55:44 AM
Attachments:	Legacy Health Comments Oregon Board of Pharmacy Nov 22 2022.pdf

Please see attached Legacy Health comment letter on proposed rule change OAR 855-115-0070 and OAR 855-115-0120.

Thanks.
Gina

Gina Cole (she/her/hers)
Vice President | Government Affairs
1919 NW Lovejoy Street | Portland, Oregon 97209
503-803-3491 cell | 503-415-5576 office | gecole@lhs.org

LEGACY
HEALTH

Legacy Health
1919 N.W. Lovejoy St.
Portland, OR 97209
503.415.5600 *phone*
50.415.5777 *fax*

November 21, 2022

Submitted Electronically: pharmacy.rulemaking@bop.oregon.gov

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

Re: Proposed Rule Change OAR 855-115-0070 and OAR 855-115-0120

Legacy Health appreciates the opportunity to provide comments on the proposed changes to OAR 855-115-0070 and OAR 855-115-0120.

Legacy is a nonprofit health care provider serving the Portland-Vancouver area and mid-Willamette Valley. We are an integrated care network that includes six community-based and nationally recognized hospitals, over 100 primary care, urgent care, and specialty care clinics, and nearly 14,000 employees.

While we appreciate the intent to systematically organize the divisions, we strongly oppose the removal of Collaborative Drug Therapy Management (CDTM) from OAR 855-115-0070 and the transfer of this language to the definition for Clinical Pharmacy Agreement (CPA) as written in proposed rule OAR 855-115-0120. This proposed change is a detriment to the intent of the CPA statute, which broadened and modernized the ability for pharmacists to practice clinical pharmacy by allowing agreements to exist between individuals as well as organizations, and by removing those agreements from the constraints of a prescription-based relationship. Furthermore, the omission of CDTM in OAR 855-115-0070 and the proposed language for CPA in OAR 855-115-0120 impedes the ability for our highly trained pharmacists to collaborate and make a positive impact on patient care.

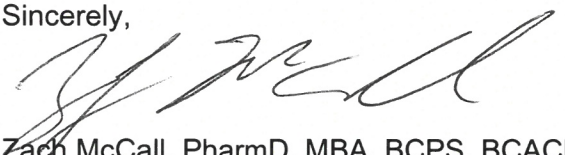
We request that CPA language be once again defined as agreements allowing the practice of clinical pharmacy based on the agreement, not on a prescription. Namely, the language in proposed OAR 855-115-0120 (1)(B) requires drug information must include the dosage, frequency, duration, and route of administration of the drug. This is unnecessarily onerous and for all intent and purpose would establish the expectation to restate drug compendium in our CPAs. In addition, OAR 855-115-0120 (2) is unnecessarily onerous as it requires the pharmacist to document and keep a record of each patient encounter where the clinical pharmacy agreement is utilized. While it is important to ensure that our pharmacists are working within the scope of a particular CPA, satisfying the provision in OAR 855-115-0120 (1)(A), "Methods by which a physician or naturopathic physician or a provider on behalf of a healthcare organization enters a patient into the agreement", should be sufficient to document why any patient encounter is applicable to the CPA.

Regarding proposed rule OAR 855-102-0050, we recommend the Oregon Board of Pharmacy modernize the language on documentation to include electronic health records. Additionally, it is

unclear from current rules which pharmacists would be considered Independent Pharmacy Practice. We request the board clarify whether pharmacists practicing under a CPA would be held to the records and document retention rules for Independent Pharmacy Practice.

Legacy Health is driven by our mission to improve the health of our communities, and we are committed to providing safe, quality care. We welcome the opportunity to partner with the Oregon Board of Pharmacy to ensure all Oregonians have access to safe, quality care.

Sincerely,



Zach McCall, PharmD, MBA, BCPS, BCACP, FOSHP
Ambulatory Pharmacy Services Director

From:	Kiyomi Lehman, PharmD, BCPS, BCACP
To:	PHARMACY RULEMAKING * BOP
Subject:	Board of Pharmacy Rulemaking 11/22/22 - Public Comment
Date:	Monday, November 21, 2022 11:05:28 PM
Attachments:	mm_signature_logo_a69b1467-25cc-4046-a5c9-1301eef5b56e.png 036_sm_fb_a1347472-45be-4a0b-af83-b901fa688c57.png 036_sm_in_468e365e-e301-4c97-a0b4-805cb9a8926e.png 036_sm_instagram_9927e091-e056-4b30-a2b6-e681664c9634.png

Kiyomi Lehman
November 21, 2022

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern and provide feedback about the proposed changes to the Collaborative Drug Therapy Management (CDTM) rules. I, Kiyomi Lehman, am strongly opposed to removing all OARs that discuss CDTM and proposed OAR, 855-115-0120. It appears that the Board voted to send these proposed changes to rulemaking for feedback from the public however, changes were not discussed in public comment during either the August or October Board of pharmacy meeting making thorough feedback difficult. I urge you to use a rules advisory committee to provide feedback on the impact additional rules will have, but especially with the proposed rules for 855-115-0120. As a practicing ambulatory pharmacist I feel there are consequences of removing CDTMs from rules and replacing them with a redefined clinical pharmacy agreement. One implication, though certainly not the least, is the ability of pharmacists to be reimbursed for and thus provide services to Medicaid recipients enrolled in Coordinated Care Organizations (CCOs). In addition, these rules impact pharmacists in all settings, not just ambulatory care pharmacy. The intent of these rules is unclear, as they have not been discussed and I am concerned about it limiting our current scope of practice. Licensees have no idea what the intent of these rules are, because they have not been discussed, and therefore we are unclear if your intent is to limit our current scope of practice or to replace CDTM with something new. The Oregon Medical Board does not have corresponding rules that recognize a CPA. When these draft rules go into effect, there will be no ability for pharmacists to have a way to collaboratively manage drug therapy. This will greatly affect many of the pharmacists, including myself, currently working in a clinical environment and could cause patient harm. It may also disrupt care for many Oregonians without access to healthcare providers other than their pharmacist and further erode efforts made to address health equity for rural and minority populations in Oregon. Before passing these rules I urge you to press pause and let subject matter experts weigh in on what these rule changes will mean for the current practice of pharmacy, the evolution of pharmacy practice, and patient safety.

Sincerely,
Kiyomi Lehman, PharmD, BCPS, BCACP

Kiyomi Lehman, PharmD, BCPS, BCACP
Clinical Pharmacist

Phone: 541-383-3005
Fax: 541-383-1883
Website - www.mosaicmedical.org
Bend - Redmond - Madras - Prineville

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From: Michele Koder
To: PHARMACY RULEMAKING * BOP
Subject: MCHD Nov 22, 2022 Rulemaking Comments
Date: Tuesday, November 22, 2022 8:36:19 AM
Attachments: Multnomah County Health Center Nov 22 2022 Rulemaking Comments (1).pdf

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Dear Oregon Board of Pharmacy,

On behalf of Multnomah County Health Department's Community Health Center, I am respectfully submitting the attached comments pursuant to rulemaking specific to Divisions 019/020/031/041/115 related to Pharmacists.

Sincerely,

Michele Koder, PharmD (she/her/hers)
Pharmacy Director
Multnomah County Health Department
503-988-7278 (office)
503-502-1396 (cell)
michele.koder@multco.us

Multnomah County
Community Health Center

November 17, 2022

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
(971) 673-0001

On behalf of the Multnomah County Health Department's Community Health Center, we thank you for the opportunity to comment on the Board's proposed rules.

The Health Center welcomes all persons, regardless of insurance status, ability to pay, or documentation status. Our Health Center prioritizes culturally and linguistically appropriate care, supporting patients in a way that works for them. Over 60% of our patients identify as people of color, and more than 40% are best served in a language other than English, including more than 100 different languages. Nearly 15% of our patients are uninsured and 95% live below 200% of the Federal Poverty Guideline. Our programs, including pharmacy, are committed to improving health outcomes, reducing health disparities, and ensuring safe, affordable and access to high quality healthcare.

Our retail outlet and clinical pharmacists are an integral component of the delivery of high quality and culturally responsive care. Our seven in-house pharmacies serve a geographic region from North Portland to Gresham and dispense approximately 350,000 prescriptions per year to health center patients regardless of ability to pay.

Over the last 9 years, clinical pharmacists working on multidisciplinary teams have helped our health center expand the reach of the health center program all while improving outcomes and driving down the cost of care. This year we plan to nearly double our clinical pharmacist workforce to help provide continued access to services in the face of other healthcare workforce shortages. We currently have 10 credentialed clinical pharmacists working on multidisciplinary teams who provide comprehensive clinical pharmacy services including medication therapy management, individualized adherence support, post-diagnostic collaborative drug therapy management and Medicare Wellness Visits. In 2021, clinical pharmacists completed over 6,000 patient encounters including over 3,000 patient visits, providing access to patient care services in a strained primary care healthcare system.

As we observed during the past two years' response and recovery efforts, pharmacists are critical healthcare providers in supplementing primary care teams and providing easy, trusted, and accurate information about COVID19. The Oregon Health Authority's Test to Treat initiative is a testament to the

success of how pharmacy staff are valuable resources to low income and vulnerable patient populations.

We write to you today to express our opposition to the following rules as written and offer recommendations for consideration by the Board. We find these proposals to be regressive, and ultimately undermine the strategic initiatives of the Oregon Health Authority and community health centers: ensuring access to care for all Oregonians, regardless of their ability to pay.

1. **855-006-055(10): Definitions**

    a. The proposed rule removes the definition of "Collaborative Drug Therapy Management" and replaces it with "Clinical Pharmacy Agreement".

    b. Collaborative Drug Therapy Management is explicitly referenced in the Oregon Medical Board's rule, OAR 847-015-0040. Until such time as the Oregon Medical Board updates their rule to be consistent with the Board of Pharmacy proposed rule, this practice of clinical pharmacy will end. The impact on underserved patients who partner with clinical pharmacists, upon referral by primary care providers, to manage their diabetes and other chronic health conditions would be devastating. Ending CDTM not only removes the ability for clinical pharmacists to support healthcare teams, but will disproportionately impact patient populations who rely on pharmacies as primary access points for healthcare.

    c. Recommendation: Multnomah County encourages the Board to retain the definition of Collaborative Drug Therapy Management as it exists today in 855-0006-05.

2. **855-115-0070(3)(a)-(p): Pharmacist General Responsibilities**

    a. The language in the new rule suggests (a)-(p) is all a pharmacist is permitted to do within the scope of their license and does not account for the dynamic nature of the practice of pharmacy which has evolved significantly over the past 10+ years.

    b. Given the ongoing Oregon healthcare workforce challenges, it is imperative the finalized OAR recognizes how pharmacists can be a solution to increasing capacity at health centers to meet the rising need of underserved patients. Multnomah County urges the Oregon Board of Pharmacy to maintain a pharmacist's ability to practice to the fullest extent of the scope based on their licensure.

    c. Recommendation: Multnomah County encourages the Board retain aspects of the existing OAR by adding back the following language "but are not limited to".

3. **855-115-0120: Clinical Pharmacy Agreement**

   a. Multnomah County is concerned that the proposed rule does not align with the legislative intent of HB 2028 (2015) which permits pharmacists to engage in the practice of clinical pharmacy and permits health insurers and Oregon Health Authority to provide payment for clinical pharmacy services. In addition, the proposed draft rule would complicate rather than simplify administrative rule obligations for pharmacists.

   b. A clinical pharmacy agreement is synonymous with a health care provider's professional services agreement or contract between a provider or healthcare organization. HB2028 (2015) included statutory language specific to Coordinated Care Organizations (ORS 414.764 (2)(a)(b)) which states “A coordinated care organization may reimburse a pharmacist or pharmacy for any health service: a) Provided to a medical assistance recipient who is enrolled in the coordinated care organization or prepaid managed care health service organization that enters into a clinical pharmacy agreement with the pharmacist or pharmacy; and b) That is within the lawful scope of practice of a pharmacist.”

   c. Removing OAR 855-019-0200 and replacing it with OAR 855-115-0120 implies a Coordinated Care Organization (CCO) must create a clinical pharmacy agreement with a pharmacist that meets all of the elements in the proposed rule. These proposed rule changes would require CCOs to create protocols that define the pharmacist(s) patient care process, referral process, standards of care, and decision criteria for conditions like diabetes for the purposes of reimbursement. It was never intended for CCOs to take on the role of defining a pharmacist’s or a clinic’s scope of work for the pharmacists under their employ or have health plan physician and pharmacist staff fill the role of principal physician or pharmacist. It is not feasible or appropriate to require CCO providers to take on this level of liability without a patient-provider relationship or provider-pharmacist relationship within their health care provider contracts. This may create a situation where clinical pharmacists may have two or more different clinical pharmacy agreements dictating how they manage chronic conditions such as diabetes and will likely result in non-payment of critical services.

   d. Moreover, the additional requirements set forth in proposed OAR 855-115-0120 (B)(C) would make the administrative burden and actual ability to implement new services or transition existing CDTM agreements into CPAs overwhelming and unworkable for many community-based pharmacy programs.

   e. The overall effect on many FQHCs, including Multnomah County, which rely on clinical pharmacists to provide access to high quality care under the supervision of licensed

independent providers, will be the dissolution of clinical pharmacy programs, as well as a decrease in access and positive patient outcomes for our state's most vulnerable populations.

f. Recommendation: Multnomah County encourages the Board to retain the original language in OAR 855-019-0200.

4. **855-115-0070(3)(m): Laboratory Tests**

   a. The proposed OAR removes the long-established ability of a pharmacist to independently order and interpret laboratory tests and limits their scope of testing to pharmacy services expressly defined and permitted in ORS 689. This is a crucial component of how community health centers utilize clinical pharmacists as a member of the primary care team. In a time when providers and care teams are stretched to capacity and the pipeline for new providers to enter practice areas is long, we are concerned that this deviation away from nationally accepted scope of practice for pharmacists will mean patients experience extended wait times, fewer touch points with their care team, and ultimately poorer outcomes. This change will only serve to further exacerbate the existing health care workforce crisis by essentially adding additional workload onto exhausted providers.

   b. Recommendation: Multnomah County recommends the Board delete "as authorized under ORS.689".

5. **855-115-0125: Medication Therapy Management**

   a. The proposed OAR changes language from *may include* to *must include* which implies all MTM visits must include all of the elements listed to be in compliance. MTM is a very patient-centered service pursuant to a pharmacist's professional judgment and a patient's individual needs. In practice, all of these elements are not performed in a single visit for various reasons.

   b. Health care payers and CCOs are unlikely to cover this service if they are unable to audit every single encounter in order to determine if all of the newly required elements are present, placing vulnerable patients in need of customized MTM services, including comprehensive medication reconciliation during transitions of care, at risk.

   c. Recommendation: Multnomah County recommends the Board retain *may include* in MTM OARs.

6. **855-115-0071(6)(l): Pharmacist General Responsibilities**

a. The proposed language gives pharmacists unilateral authority to cease operations based on a subjective assessment of adequate staffing. While we understand and sympathize with the intent of this language, we oppose this rule as written. Closing a pharmacy, as many of our patients who utilize external retail outlets are experiencing, creates an undue hardship and safety risk for clients who for many reasons are unable to effectively plan trips to the pharmacy. This rule *can* and current practice *is* harming the most vulnerable individuals in our community who are going without critical access to medications. As a safety net provider, we prioritize maintaining access to our patients without compromising safety. This language will have the opposite effect of what is intended.

b. Recommendation: Multnomah County encourages the Board to change language to (l) Ensure there is sufficient staff to provide services in a safe and timely manner. The Pharmacist on duty may, in consultation with the drug outlet, temporarily alter the services provided (e.g. drive through and vaccinations) at the discretion of the Pharmacist, if determined in their reasonable professional judgment, that there is insufficient staff to provide services in a safe and timely manner.

Multnomah County's Community Health Center thanks the Board of Pharmacy for the opportunity to comment on draft rule changes and the likely unintended harm they may cause the most vulnerable populations in our community. We would be glad to supplement our comment with discussion and further conversation with the Board.

Adrienne Daniels, MPH
Interim Executive Director
adrienne.daniels@multco.us

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Bernadette Thomas, APRN,DNP, MPH
Chief Clinical Officer
bernadette.thomas@multco.us

From:	Cover, William
To:	PHARMACY RULEMAKING * BOP
Cc:	SCHNABEL Joseph * BOP
Subject:	Written Comments and Request to appear on December 15 related to Proposed Rule 855-115-0001
Date:	Tuesday, November 22, 2022 1:02:39 PM
Attachments:	image001.png image003.png image004.png image005.png image006.png image007.png NABP OR Board of Pharmacy Comments to Rule 855-115-0001.pdf

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Ms. Melvin: Please note the attached written comments for proposed rule 855-115-0001 as part of the hearing notice filed on 10/25/2022.
In addition, please note the request to present further information on the NABP Verify program on December 15, 2022. Thank you.

Best regards, Bill

Bill Cover BSPharm, RPh
Associate Executive Director, State Pharmacy Affairs
Phone: 224-565-5694

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | **wcover@nabp.pharmacy**

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

November 21, 2022

Oregon Board of Pharmacy
Attention: Joseph Schnabel, Executive Director
C/O Rachel Melvin, Rules Coordinator
800 NE Oregon Street, Suite 150
Portland, OR 97232
Email: pharmacy.rulemaking@bop.oregon.gov

Dear Dr. Schnabel and Oregon Board of Pharmacy Members,

I am writing today in regard to proposed changes to Oregon rules 855-115-0001 related to out of state pharmacist practice into Oregon.

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP is the only professional association that represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and 10 Canadian provinces.

NABP understands and respects the great responsibility of safeguarding the practice of pharmacy for your citizens and that nonresident practice models rely upon the oversight and disciplinary processes of other member boards of pharmacy.

It is with these matters in mind that NABP created the Verify program. This program continuously monitors a pharmacist license(s) to ensure they are in good standing. A pharmacist that continues to meet this high standard is issued and can maintain a state specific Verify credential, for the participating jurisdiction(s) they choose, which allows them to practice according to statutory, regulatory or policy reference.

This program began in April of this year and was first implemented in the State of North Carolina as part of a state issued registration that enables a nonresident pharmacist to provide remote medication order processing services. The State of Delaware is in initial stages of rule promulgation referencing the program based on a vote of their board. In addition, the Kentucky Board of Pharmacy recently voted unanimously to incorporate the NABP Verify credential to be the primary requirement for the issuance of a nonresident pharmacist license.

The issuance of a state specific Verify credential for out of state pharmacists providing services to Oregon residents could provide this nonresident practice authority by reference in Section 855-115-0001 as proposed below:

Oregon Board of Pharmacy
Proposed changes to OR 855-115-0001
November 21, 2022

855-115-0001

Applicability

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

(2) ~~Only P~~persons, physically located in Oregon and licensed with the board as a Pharmacist, may practice pharmacy and must act in compliance with statutes and rules.

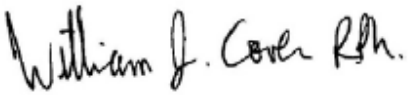
(3) A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be either licensed by the board or maintain an active Oregon Verify Credential issued by the National Association of Boards of Pharmacy. ~~in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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.255

I respectfully submit, on behalf of NABP, a slide deck that further details the program and how it can provide your board and staff a high level of insight and oversight on nonresident pharmacists practicing into your state without all of the requirements of full licensure in Oregon. To further emphasize, the Verify program is not designed, nor intended to replace licensure for pharmacists physically practicing within the State of Oregon.

Thank you for the opportunity to provide these comments and I also extend my interest in participating in your December public meeting. My attendance would allow me to provide additional information and afford the board of pharmacy members and staff the opportunity to ask questions on the Verify program as part of supporting your board in its vital public safety mission.

Sincerely,



William J. Cover, RPh

NABP Associate Executive Director, State Pharmacy Affairs

NABP
National Association of
Boards of Pharmacy

NABP Mission Statement

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial Association that assists its member boards in protecting the public health.

Vision Statement

Innovating and collaborating today for a safer public health tomorrow.

NABP Purpose

Founded in 1904, the purpose of the Association is to provide for interstate and interjurisdictional transfer in pharmacist licensure, based upon a uniform minimum standard of pharmacist education and uniform legislation, and to improve the standards of pharmacist education, licensure, and practice by cooperating with state, national, and international governmental agencies and associations having similar objectives.

NABP
National Association of Boards of Pharmacy

Emergency Passport Program

- NABP service created in March 2020 in response to the coronavirus disease 2019 pandemic
- No cost to the states and no fees for the applicants
- Launched to support our member boards in meeting the state executive order requirements for practice without full in-state licensure
- As seen in most states the emergency orders required:
  - ✓ *A license in good standing in another state*
  - ✓ *The individual has no record of disciplinary action on their professional license*
- NABP staff completed a review of all licenses and the NABP Clearinghouse for disciplinary action
  - Individuals were denied upon application or removed from the program if they did not meet the criteria detailed above
- A state-specific passport was issued to the individual for all participating states where the individual wanted to practice, according to executive order or PREP Act authority
- This program will continue to be offered as a free service to the states and to participating pharmacists, technicians, and interns based on state requests related to emergency events

NABP
National Association of Boards of Pharmacy

Emergency Passport Program

8% of applicants were denied due to license sanction or past discipline

NABP National Association of Boards of Pharmacy

COVID Application Statistics For Application Submitted Date Range 3/1/2020 6/25/2021

Profession Type	Number Of Applicants	Number Of Applications	Number Of Requests	Number Of Approvals	Number Of Rejections	Requests In Process	% Approved	% Rejected	% In Process
	1	1	1	0	1	0	0.00	100.00	0.00
Business	17	20	82	56	26	0	68.29	31.71	0.00
Other	2	2	3	1	2	0	33.33	66.67	0.00
Pharmacist	5,264	6,980	39,039	36,300	2,739	0	92.98	7.02	0.00
Pharmacist Intern	90	103	320	266	54	0	83.13	16.88	0.00
Pharmacist Student	46	48	108	105	3	0	97.22	2.78	0.00
Technician	2,099	2,529	22,134	20,034	2,100	0	90.51	9.49	0.00
Technician In Training	5	6	47	9	38	0	19.15	80.85	0.00
GRAND TOTALS	**7,524**	**9,689**	**61,734**	**56,771**	**4,963**	**0**	**91.96**	**8.04**	**0.00**

NABP
National Association of Boards of Pharmacy

NABP Verify – Overview

- Monitoring service supporting member boards' new and existing license verification needs
- NABP Verify is a monitoring program that enables the issuance of a state credential based upon continued evidence of ongoing licensure in good standing, as determined via the NABP Verify monitoring service
- The State credential practice authority is defined in each state according to statutory, regulatory, or policy reference.
  - ✓ *Practice outside of these references would exceed the credential authority and require full licensure in that state.*
- NABP Verify can serve as a new tool to provide appropriate board oversight to enable nonresident practice models
  - ✓ *Verify program does not serve as an alternative to state licensure, either by examination or via endorsement, for in person practice within a state.*

NABP
National Association of Boards of Pharmacy

NABP Verify – Eligibility

- Pharmacists who are licensed by a US board of pharmacy are eligible to apply
  - ✓ *A state-specific credential will be issued to applicants who hold at least one active, unconditional license in good standing*
- Once initially verified, licensees are subject to ongoing monitoring of their license status and disciplinary actions through the NABP Clearinghouse
  - ✓ *Program participants pay an annual subscription fee for the ongoing verification and monitoring services*
  - ✓ *$50 annual fee covers all participating states*
- Applicants with the following are not eligible to receive an NABP Verify credential:
  - ✓ *Any active license that has been suspended or sanctioned (ie, probation, suspension, or revocation); or*
  - ✓ *An expired, inactive, or non-renewed license that is associated with an unresolved disciplinary sanction*

NABP
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NABP Verify – Member Board Benefits

- Significant reduction in administrative burden for board staff to verify out-of-state pharmacists
- Provides a new tool for interstate practice models to ensure that pharmacists are in good standing without the need to require full licensure
- State defines practice authority via reference in statutes, regulations or policies
- Enables insight and individual accountability for out of state pharmacists practicing within or outside of a nonresident licensed facility

NABP Verify – Member Board Benefits

Reduces administrative burden on board staff to verify license status

Provides a system for continuous monitoring of license status across all states

State specific credential issued which has authority defined within statutes, regulations, or policies

Provides member boards with insight and oversight on interstate practitioners

NABP
National Association of Boards of Pharmacy

NABP Verify – Pharmacist Practice Benefits

- Trusted source of license verification and monitory across all states
- Enables interstate practice opportunities for pharmacists
- Digital badge provides easy evidence of licensure in good standing across all licenses
- Low-cost and easy-to-manage credential program for practice across multiple states

Pharmacist Practice Benefits

Ongoing monitoring across all states provides evidence of "licensed in good standing"

Access new practice opportunities with state-specific credentials

Digital badge issued to provide real-time credential status

Easily manage credentials from multiple states with one subscription

NABP
National Association of Boards of Pharmacy

NABP Verify Process

APPLY
The individual applies for Verify via their NABP e-Profile

VERIFY
NABP confirms that applicant meets program Requirements; Approves or Denies application

FEE
Applicant pays NABP for Verify monitoring subscription

CONFIRMATION
Applicant receives state credential and digital badge or denial; participating boards notified via portal

MONITORING
Ongoing licensing and disciplinary monitoring; participating boards notified via portal if status changes

RENEWAL
The individual applies for an annual renewal of Verify subscription via their NABP e-Profile

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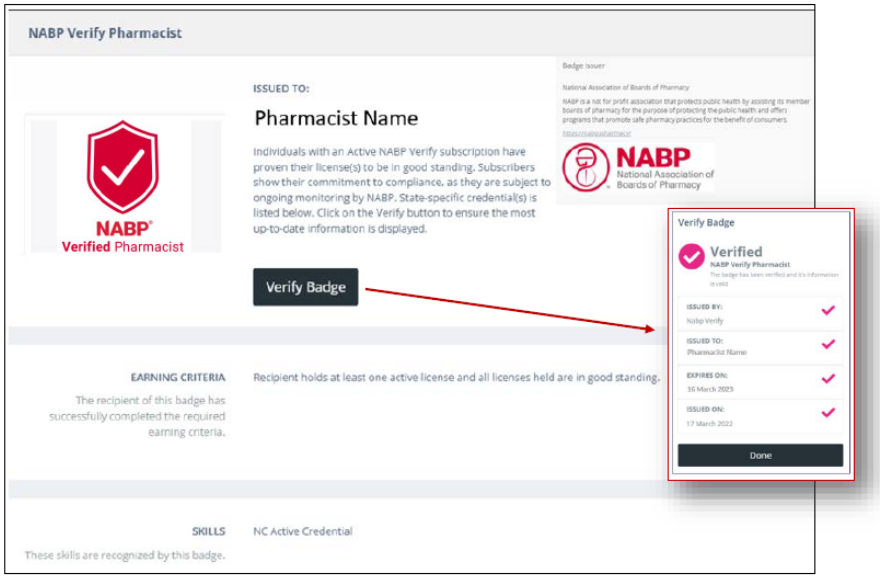
National Association of Boards of Pharmacy

NABP Verify – Digital Badge

- Pharmacists who meet program requirements are issued a digital badge
- Real-time display of pharmacist who meets “in good standing” standard
- Displays the status of any state-specific credentials issued to the pharmacist
- Pharmacist can provide to organization for compliance auditing
  - *No sensitive data displayed*



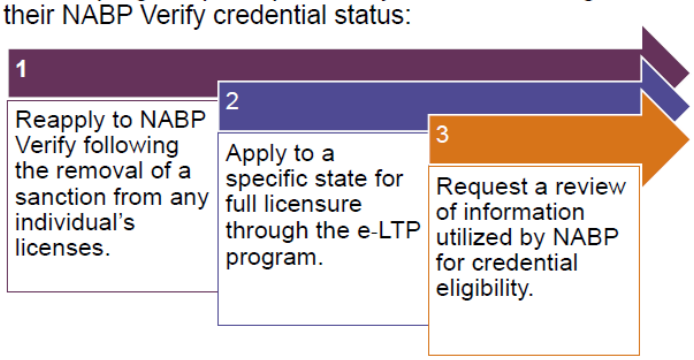
NABP
National Association of Boards of Pharmacy

Removal of an NABP Verify Credential Holder

A state may direct NABP to remove an NABP Verify credential holder from active status in the state if the credential holder failed to comply with state or federal laws or rules applicable to the practice of pharmacy in the state*

Enables individual pharmacist accountability in the event of a substantiated error by a pharmacist unrelated to permit holder and/or pharmacist in charge responsibilities for the nonresident facility.

Applicants and program participants may use the following three methods to appeal their NABP Verify credential status:



**NABP is not responsible for the state's decision to remove a credential holder from active status in its state.*

NABP
National Association of Boards of Pharmacy

How Does A Board Participate?

Boards of pharmacy that wish to recognize NABP Verify in their state will sign a memorandum of understanding that specifies the responsibilities of NABP and the boards

- To "opt-in," email governmentaffairs@nabp.pharmacy
- NABP has suggested language that you may choose to use on your websites and in communications
- NABP will set up (individual or group) training for all participating states

NABP
National Association of Boards of Pharmacy

For additional information go to:

nabp.pharmacy/programs/licensure/verify/

Thank you

From:	Couture, Taryn
To:	PHARMACY RULEMAKING * BOP
Subject:	NASP Comments on Proposed Rule 855
Date:	Tuesday, November 22, 2022 3:00:54 PM
Attachments:	NASP letter to Oregon Board of Pharmacy on Licensure_Final (D1032438).pdf

To Whom it May Concern,

Please find attached comments from the National Association of Specialty Pharmacy (NASP) in response to the proposed rule 855-115-0001.

Please let me know if you have any questions.

Taryn Couture, Director of Government Relations
POWERS
Powers Pyles Sutter & Verville PC
1501 M Street NW, Seventh Floor
Washington, DC 20005-1700
tel 202.466.6550 | fax 202.785.1756
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November 22, 2022

The Honorable Michelle Murray, R.Ph.
Oregon Board of Pharmacy
President
800 NE Oregon St., Suite 150
Portland, OR 97232

RE: Response to Oregon Notice of Proposed Rulemaking: Chapter 855

Dear President Murray:

I write today on behalf of the National Association of Specialty Pharmacy (NASP) and our specialty pharmacy members that operate in the state of Oregon in response to the state's proposed revision to existing pharmacy operating rule 855-115-0001. We believe that it is important for you to understand the impact that this rule will have on non-resident specialty pharmacy practice settings and patients who require access to specialty medications in Oregon.

NASP represents the entire spectrum of the specialty pharmacy industry including the Nation's leading specialty pharmacies and practicing pharmacists; nurses and pharmacy technicians; pharmacy benefit managers (PBMs); pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; and technology, logistics and data management companies. NASP defines a specialty pharmacy as a state licensed and registered pharmacy that is accredited by an independent, third-party accreditor and solely or largely provides medications and patient medication management services to patients with complex and chronic diseases requiring expensive and challenging treatment with complex medication therapies. Specialty pharmacies that work in Oregon have unique expertise in supporting patients with conditions like cancer, multiple sclerosis, cystic fibrosis, and HIV/AIDS.

Licensure Regulation of Non-Resident Pharmacies:

Rule 855-115-0001 updates the existing rule, 855-019-0100 which regulates pharmacy licensure in the state. Specifically, the proposed rule makes one very concerning change, removing counseling as a task that a pharmacist who is located in another state and who engages in the practice of pharmacy in Oregon can do without being required to obtain a license in the state.

This regulatory change constitutes a significant shift in Oregon's policy and would have a negative and consequential impact on specialty pharmacy patients and specialty pharmacy operations. NASP believes that Oregon's existing licensure requirements meet the needs of specialty patients, given that the state requires non-resident pharmacies to appoint a Pharmacist-in-Charge (PIC) to be responsible for pharmacy oversight for dispensing and services provided and also requires that the PIC be licensed in Oregon. Under current regulations, the PIC is responsible for actively supervising the pharmacy's operations, ensuring compliance with the state laws, and ensuring adequate staffing to provide safe and timely patient care, including counseling. Existing state requirements for counseling and licensure have allowed for specialty pharmacies located out of state but serving patients on a regional or national basis to operate in a way that ensures patients have timely access to the clinically complex medications that they need and receive the counseling services necessary to ensure safe use and management of those medications.

Proposed Rule's Impact on Specialty Patients and Pharmacies:

Specialty pharmacies work with patients who have serious and often life-threatening conditions. These pharmacies dispense medically complex drugs, including drugs that are not routinely available in a retail pharmacy setting. Specialty medications require specialized staff that are knowledgeable about the disease states being managed and have specific knowledge about medically complex patient needs to monitor and manage drug adherence. Because of the complexity of specialty drugs and the specialized staff required to provide counseling to specialty pharmacy patients, many specialty pharmacies operate from a centralized location and provide counseling and medication management services to patients across a number of states. For these reasons, many patients in Oregon who are living with medically complex specialty conditions receive their specialty medications and counseling from a pharmacist located outside of the state.

Counseling is an essential component within the specialty pharmacy model to ensure patients understand how to administer their medications including injectable medications FDA approved for self-administration, are aware of side effects and often the necessity of adhering to their drug regimen as they work through side effects, and to allow for regular monitoring of specialty drug interactions with other drugs the patient may take. Allowing specialty pharmacies to hire the pharmacist experts that can provide counseling to patients across a number of states helps to ensure that specialty patients get the support that they need.

For specialty pharmacies that are providing extensive services to support patients with complex health care management needs and are often the only pharmacy resource for patients, the new proposed rule by the Board is untenable as the costs and the capacity burdens would be restrictive for their ability to operate in the state. Ultimately, for patients with specialty

conditions like a rare or orphan disease, multiple sclerosis, cancer, cystic fibrosis, organ transplant, and HIV/AIDS, any potential delay, halt, or disruption in treatment that results from specialty pharmacies being unable to operate in the state due to this regulatory interpretation and its impact threatens the health and livelihood of patients. Without access to their specialty pharmacy, patients could face setbacks in their treatment, leading to increased emergency room visits, hospital admissions and healthcare costs.

Request of Oregon Board of Pharmacy:

The Board's proposed rule 855-115-0001 would have a significant negative and consequential impact of non-resident specialty pharmacies and the patients they serve. We urge the Board of Pharmacy to consider the full impact of this decision, and to reinstate the language outlined in 855-019-0100 that allows pharmacists located outside of the state to safely provide counseling to patients in Oregon with the oversight of the Oregon licensed PIC without needing to be separately licensed by the state. We want to ensure specialty pharmacies that are safely serving Oregon's residents can continue to do so.

Thank you for your consideration. If we can provide additional information, please contact me at 703-842-0122 or sarquette@naspnet.org.

Sincerely,

Sheila Arquette, R.Ph.
President and CEO

From:	Zach Rosko
To:	PHARMACY RULEMAKING * BOP
Subject:	Rulemaking Hearing
Date:	Tuesday, November 22, 2022 3:54:57 PM
Attachments:	image001.png NHC Comments on Board of Pharmacy Proposed Rules 11.22.22.docx

Please see the attached statement for the November 22nd Rulemaking Hearing.

Best,
Zach

Zach Rosko, PharmD, BCPS
DIRECTOR OF PHARMACY AND CARE TEAMS
NEIGHBORHOOD HEALTH CENTER
ROSKOZ@NHCOREGON.ORG | 503-941-3131

November 22, 2022

Oregon Board of Pharmacy

RE: Proposed Draft Rule(s) 855-006-005(10), 855-115-0070 (3) (a)-(p), 855-115-0070(3)(m), 855-115-0115, 855-115-0120, 855-115-0125

President Murray, Vice President Doyle and members of the Oregon Board of Pharmacy:

Neighborhood Health Center (NHC) is a Federally Qualified Health Center providing a wide range of medical, dental, behavioral health and pharmacy services to the safety net populations of Oregon's Washington and Clackamas Counties. NHC provided care to 17,235 unique patients in 2021 and operates 5 primary care clinics, 3 dental clinics, 2 school based health centers, 1 reproductive health clinic and 1 dispensing pharmacy.

Health centers are highly regarded and trusted within their communities because they tailor their health care services and supporting programs including pharmacy operations to meet the unique needs of their patients. Rooted in the civil rights movement, health centers prioritize providing high quality, affordable, and accessible health care to anyone who walks through their doors.

Neighborhood Health Center wants to applaud the Oregon Board of Pharmacy's efforts to streamline how clinical pharmacists can practice in primary care. Over the last six years, clinical pharmacists have helped our health center stay connected to our patients, build new patient relationships, and expand the reach of the health center program all while improving outcomes and driving down the cost of care.

Health centers are located in medically underserved areas, where the majority of our patients live in poverty and face significant social determinants of health that create barriers to affordable health care services. In Washington and Clackamas Counties, 36.5% of the low-income population, 37.1% of the uninsured population and 28.5% of the Medicaid population are served by health centers, including Neighborhood Health Center. Health centers have proven highly effective at utilizing clinical pharmacist services in primary care to the most vulnerable and underserved communities. As clinical pharmacists gain more popularity, it's critical that health centers can continue to utilize this important provider type to meet the complex needs of the patients they serve.

The need for our organization to have both a collaborative drug therapy management (CDTM) agreement and clinical pharmacy agreement (CPA) has been confusing but is presently an established practice. It is in this context where the unintended consequences of the proposed rule changes are causing fundamental and grave concerns for the sustainability of integrated clinical pharmacy services at Oregon's community health centers. Neighborhood Health Center

appreciates the opportunity to provide comments on the proposed rules and has detailed them below:

A. 855-006-005(10) Definitions for OAR Chapter 855

Neighborhood Health Center strongly urges the Oregon Board of Pharmacy to keep the definition of Collaborative Drug Therapy Management (CDTM)

Health Centers are required to serve "medically underserved, or special medically underserved populations", which face barriers in accessing health care services. HRSA requires health centers to address these barriers and disparities among patients' health status and through the health center's operations – including pharmacy programs. Health centers rely on the ability to bill for pharmacy services to not only meet this requirement for their insured patients but also for those who do not have health insurance.

Transitioning the authorities of CDTMs into the CPA rules alone will not permit physicians to engage in collaborative drug therapy management unless the Oregon Medical Board changes their administrative rules. OAR 847-015-0040 presently prohibits physicians from engaging in management of drug therapy pursuant to a written protocol with pharmacists without a collaborative drug therapy management protocol. Oregon Medical Board rules presently mirror the existing Pharmacy Board CDTM rules and definitions. We suggest that the Board wait to make this change until the Oregon Medical Board updates their rules from CDTM to CPA.

B. 855-115-0070 (3) (a)-(p) Pharmacist General Responsibilities

Neighborhood Health Center urges the Oregon Board of Pharmacy to maintain a pharmacist's ability to practice to the fullest extent of their scope.

The new OAR which replaces 855-019-0200 (3) in general removes language which may limit the dynamic utilization of pharmacists in Oregon's community health centers. **Given ongoing health care workforce challenges, it's imperative the finalized OAR recognizes how pharmacists can be a solution to increasing capacity at health centers to meet the rising needs of underserved patients.**

Maintaining the existing scope of practice for Oregon pharmacists under 855-019-0200 (3) enables more patients to receive comprehensive and affordable care. Besides the workforce challenges that can adversely affect health center patients, they often experience challenges accessing health care services due to social determinants of health. **Health centers tailor their pharmacy services to meet the unique needs of their surrounding communities and address barriers to culturally competent and comprehensive primary health care services.**

Neighborhood Health Center encourages the Board of Pharmacy to retain aspects of the existing OAR by adding back the following language to 855-115-0070 (3) “but are not limited to”

C. 855-115-0070(3)(m) Pharmacist: General Responsibilities and 855-115-0115 Services: Laboratory

Neighborhood Health Center is concerned that this change will remove the broad ability for pharmacists to order, interpret and monitor lab tests.

The proposed OARs essentially remove the long-established ability of a pharmacist to independently order and interpret laboratory tests and limits their scope of testing to pharmacy services expressly defined and permitted in ORS 689. This is a crucial component of how community health centers utilize clinical pharmacists as a member of the primary care team. In a time when providers and care teams are stretched to capacity and the pipeline for new providers to enter practice areas is long, we are concerned that this deviation away from nationally accepted scope of practice for pharmacists will mean patients experience extended wait times, fewer touch points with their care team, and ultimately poorer outcomes. This change will only serve to further exacerbate the existing health care workforce crisis by essentially adding additional workload onto exhausted providers.

D. 855-115-0120 Clinical Pharmacy Agreement

Neighborhood Health Center is concerned that draft OAR 855-115-0120 does not align with the legislative intent of HB 2028 (2015). The result of this deviation in the proposed draft rule would complicate rather than simplify administrative rule obligations for pharmacists.

Clinical pharmacy agreements are synonymous with a health care providers professional services agreement and are in common use in Oregon today with this purpose. It is a contract between a physician, naturopathic physician, or health care organization permitting a pharmacist or pharmacies to engage in the practice of pharmacy and provide patient care services. HB 2028 (2015) permits health insurers and the Oregon Health Authority to provide payment or reimbursement for services pursuant to a clinical pharmacy agreement or statewide drug therapy protocol.

Moreover, the additional requirements set forth in proposed **OAR 855-115-0120 (B)(C)** would make the administrative burden and actual ability to implement new CPA services or

transition existing CDTM agreements into CPAs overwhelming and unworkable for many community-based pharmacy programs.

The bill included statutory language specific to Coordinated Care Organizations contained within ORS 414.764 (2)(a)(b). “A coordinated care organization may reimburse a pharmacist or pharmacy for any health service: a) Provided to a medical assistance recipient who is enrolled in the coordinated care organization or prepaid managed care health service organization that enters into a clinical pharmacy agreement with the pharmacist or pharmacy; and b) That is within the lawful scope of practice of a pharmacist.”

Removing the OARs for Collaborative Drug Therapy Management and adding the language to Clinical Pharmacy Agreement implies that the CCO must create an agreement that contains all requirement in OAR 855-115-0120 including the types of decisions the pharmacist is allowed to make. These proposed rule changes in 855-115-0120 would require CCOs to create protocols that define the pharmacist(s) patient care process, referral process, standards of care, and decision criteria for conditions like diabetes for the purposes of reimbursement. It was never intended for CCOs to take on the role of defining pharmacist, pharmacies, or a clinic’s scope of work for the pharmacists under their employ or have health plan physician and pharmacist staff fill the role of principle physician or pharmacist. It is not feasible or appropriate to require CCO providers to take on this level of liability without a patient-provider relationship or physician-pharmacist relationship within their health care provider contracts. This may create a situation where clinical pharmacists may have two or more different clinical pharmacy agreements dictating how they manage chronic conditions such as diabetes, or worse, where the medically underserved patients enrolled in CCOs lose access to pharmacist provided services entirely.

E. 855-115-0125 Medication Therapy Management (MTM)

Neighborhood Health Center seeks clarity around changes to Medication Therapy Management practices. New language directs pharmacists to fulfill certain requirements when performing MTM. The change from “may” to “must” in the draft OAR potentially creates a requirement that certain actions be taken during every encounter. **This shift implies MTM must include all the listed elements at every encounter for a pharmacist to be in compliance.** However, in practice all of these elements are not performed in a single visit for various reasons. We worry about additional administrative burden on providers who are already at the breaking point.

Neighborhood Health Center encourages the Board to amend the proposed OAR back to the original language or to offer additional clarity to guide pharmacists in successful

implementation as we do not believe it was the Board's intention to layer on additional administrative burden in cases such as this.

Neighborhood Health Center thanks the Oregon Board of Pharmacy for the opportunity to comment on draft rule changes and urge the Board to consider the broader practice and policy implications of moving forward without additional public engagement. Health Center pharmacy programs have proven successful in expanding access to care and improving health outcomes for the most vulnerable patients. We look forward to answering any questions you might have.

Sincerely,

Zach Rosko, PharmD, BCPS
Director of Pharmacy and Care Teams
Neighborhood Health Center
roskoz@NHCoregon.org

From:	NUTT Rob C * DOC
To:	PHARMACY RULEMAKING * BOP
Cc:	Lysne Matthew J; Van Valkenburgh Jefry; BUGHER Joe A * DOC
Subject:	Argument to Division 041 - related to Prescription Labeling Expiration Date
Date:	Tuesday, November 22, 2022 10:24:29 AM

This communique is in response to clarification and change to the labeling requirements to Division 041 – related to Prescription Labeling Expiration Date.

The justification for this change is *"The current rule as written may limit patient access due to prescription medication expiration dates being limited to one year. Prompt action is necessary to allow licensees and registrants the ability to label prescriptions dispensed in the manufacturer's container with the manufacturer's expiration date and not being limited to one year from dispensing. This will increase patient access, especially for life saving medications such as naloxone and inhalers for asthma."*

This justification is a noble endeavor in the retail setting, but it is not applicable to correctional institutions in that all AICs have ready access to medical care and medications, and are not limited by such barriers. Even if they deplete their medications, emergency and stock supplies are available at the institutions or is available the next day by our servicing pharmacies. Oregon Adults-in-Custody (AICs) are not allowed to possess any prescribed medications outside of the dates instructed by the provider. Any medications in their possession, regardless of its expiration date as assigned by the manufacturer, are considered Contraband III under OAR 291-105-0015(1)(f) and are confiscated with potential discipline being issued to the offender. This means that there is only one date of any significance that should be shared with the patient, that of DC Date of the order written. Any additional information could lead to confusion and/or unnecessary disciplinary actions on the part of the AIC or the Correctional Officer. Furthermore, we would have to change operations as they currently exist to implement this rule change. This would incur unnecessary expense to taxpayers of Oregon for a rule that doesn't apply to the patients served by the Oregon Department of Corrections.

The DC Date on our label represents a date in which the medication should no longer be used by the patient, nor should it be in their possession. This is reflective of the expiration date of the drug itself and the order of the physician prescribing the medication. The Oregon Department of Corrections agrees with the rule change of 855-041-1130, but we also believe that it does not pertain to correctional labeling which is already defined in OAR 855-043-0630(4): Correctional Facility – Drug Delivery and Control – Labeling, of which the Oregon Department of Corrections complies. There it reads:

(4) Labeling: Prescription drugs dispensed in individual containers or medication cards shall 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.

It is our belief that when reviewing our correctional pharmacies, they be viewed through the lens of "correctional" and not simply "long term facilities" or "retail". There are significant differences between the operations of these classes of trade. As long as the Board agrees with this stance, and that the Oregon Department of Corrections' label should be held to the criteria of 855-043-0630 and not that of 855-041-1130 for medications dispensed within our institutions, then the Oregon Department of Corrections has no objection to the rule change to 855-041-1130. However, if the Board intends to hold the Oregon Department of Corrections label to 855-041-1130, then we stand opposed to the rule change as stated and would advise taking into consideration corrections class of trade and OAR 291-105-0015.

Thank you for this opportunity to voice our concern in this matter, and helping us to help our adults-in-custody with their health care.

-Rob

Rob Nutt, RPh
Chief Pharmacy Officer
Oregon Department of Corrections – Health Services Div.
Office: 503-986-6967
Cell: 541-709-1958
Fax: 503-986-6966

Four Rivers Bldg.
88 SW 3rd Ave.
Ontario, OR 97914

Four Rivers Correctional Pharmacy Line: 503-986-6969
Salem Correctional Pharmacy Line: 503-378-5569

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From:	Michael Millard
To:	PHARMACY RULEMAKING * BOP
Subject:	OSHP written testimony for Nov rule making hearing
Date:	Wednesday, November 16, 2022 1:05:10 PM
Attachments:	Comment to OBOP rule making Agenda Nov 22.docx Comment to OBOP rule making 006 Definitions.docx Comment to OBOP rule making 139 prohibited practices.docx Comment to OBOP rule making procedural rules 102.docx Comment to OBOP rule making technician rule 2.docx Comment to OBOP rule making Divisions related to Pharmacists.docx

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Hello,
Please find attached the written testimony from OSHP regarding some of the rules being considered on Nov 22. I will be providing oral testimony via remote video at the hearing itself. Thank you.

Oregon Society of Health-System Pharmacist's Comments on Oregon Board of Pharmacy Proposed Rulemaking for November 2022

2022 Proposed & Adopted Rules

November 22, 2022 Rulemaking Hearing

- Division 019 - related to 2022 HB 4034 Duties of a Pharmacist
- Division 139 - related to 2022 HB 4034 Prohibited Practices
- Division 019 - related to 2022 HB 4096 Out-of-state Volunteer Pharmacist
- Division 062 - related to Drug Distribution Agent
- Divisions 010/019/020 - related to Pharmacist Prescriptive Authority
  - COVID-19 Antiviral (Paxlovid)
  - Travel Medications
  - PEP
  - PrEP
  - Contraception
- Divisions 021/135 - related to Continuing Pharmacy Education
- Divisions 019/141 - related to Pharmacy Prescription Kiosk (PPK)
- Divisions 006/019/031 - related to Definitions
- Division 041 - related to Prescription Labeling Expiration Date
- Divisions 001/102 - related to Procedural & Universal Rules - *The board does not intend to adopt these rules in December 2022 - seeking public comment only
- Divisions 025/125 - related to Pharmacy Technicians - *The board does not intend to adopt these rules in December 2022 - seeking public comment only
- Divisions 019/020/031/041/115 - related to Pharmacists - *The board does not intend to adopt these rules in December 2022 - seeking public comment only

Oregon Society of Health-System Pharmacist's Comments on Oregon Board of Pharmacy Proposed Rulemaking for November 2022

Divisions 019/020/031/041/115 - related to Pharmacists - Comment Only

~~*855-019-0200*~~
~~*Pharmacist: General Responsibilities ¶*~~
~~*(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;*~~

~~*855-019-0260*~~
~~*Collaborative Drug Therapy Management*~~
~~*(deletion of entire section)*~~

855-115-0070
Pharmacist: General Responsibilities
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 a careful and prudent Pharmacist in the same or similar circumstances.
(1) Each Pharmacist is responsible for their own actions; however, this does not absolve the drug outlet from responsibility for the Pharmacist's actions.
(2) Each Pharmacist and each drug outlet are responsible for the actions of each Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician and non-licensed pharmacy personnel.
(3) With the exception of healthcare providers working within the scope of their licensure, only a Pharmacist is permitted to:
(a) Practice pharmacy as defined in ORS 689.005;
(b) Evaluate and interpret a prescription;
(c) Conduct a Drug Utilization Review or Drug Regimen Review;
(d) Consult with any prescriber, other healthcare professional or authorized agent;
(e) 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.
(f) Advise on therapeutic values, content, hazards and use of drugs and devices;
(g) Interpret the clinical data in a patient record system or patient chart.
(h) Conduct Medication Therapy Management;
(i) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;
(j) Practice pursuant to a Clinical Pharmacy Agreement;
(k) Practice pursuant to a Statewide Drug Therapy Management Protocol;

OSHP is strongly opposed to eliminating the Collaborative Drug Therapy Management Responsibility in the regulations. This language has been the basis of hundreds of agreements in many organizations and is in the policy and procedures of these health systems. There is no need for this change. This would create needless and undue administrative and financial burden on health-systems without any benefit in health or safety for Oregonians. We suggest adding Clinical Pharmacy Agreement to the definitions and responsibilities if needed.

855-115-0070
Pharmacist: General Responsibilities

(k) Ensure that the supervision of non-Pharmacist personnel does not exceed their capacity to safely supervise based on the workload and services being provided.
(l) Ensure there is sufficient staff to provide services in a safe and timely manner. The Pharmacist on duty may temporarily shut down touchpoints and services at the discretion of the Pharmacist, if determined in their reasonable professional judgment, that there is insufficient staff to provide services in a safe and timely manner

OSHP is opposed to holding the pharmacist on duty solely responsible for the staffing of the pharmacy outlet. In the discussions in the Board of Pharmacy meetings some proposals to regulate the pharmacy outlets for safe staffing levels were discussed, and OSHP does not find these proposals in these rules.

OSHP strongly encourages the Board of Pharmacy to proceed with the holding the pharmacy outlet responsible and liable for discipline by the Board for the various patient safety aspects contained in this section of the proposed rules. OSHP has long held that holding a PIC pharmacist or staff pharmacist responsible for workplace conditions over which they may have no organizational control is unfair, and does not protect Oregon patients. OSHP believes that the steps the Board of Pharmacy has taken to also hold the outlet license accountable for these safety measures in 855-041-1010 and 1170 are critical to improving patient safety. Appropriate investigation and discipline of outlets will be a key factor in improving patient safety. Only when both the professional pharmacist and the outlet are jointly accountable will the appropriate patient safety measures, including staffing, be implemented in the licensed pharmacy.

OSHP is concerned that the judgement of the on-duty pharmacist may be questioned by the Board when the consequences of the "touchpoints and services" shut down result in complaints to the Board that do not take into account safety concerns of the pharmacist at the time. This would place the pharmacist in double jeopardy of discipline if services shut down and unsafe conditions if they are not.

OSHP also notes that the PIC is not mentioned in the regulation, meaning that the pharmacist responsible to the Board for the safe operation of the pharmacy outlet is not involved in the safety decision. However, as previously stated, staffing levels and operational decisions are often made by large organizational managers that are outside the control of the professionals involved. OSHP believes that the PIC should be included in decisions to shut down touchpoints and non-dispensing services in the event of insufficient staffing as stated in 855-115-0070 (k) (l) above. Suggested language would be
"Ensure there is sufficient staff to provide services in a safe and timely manner. The Pharmacist on duty, after notification of the PIC, may shut down touchpoints and non-dispensing services if the Pharmacist determine, in their professional judgement, that there is insufficient staff to provide services in a safe and timely manner"

OSHP feels that these regulations requiring pharmacists to exercise judgement over the safety of the pharmacy operation is a reasonable expectation for public safety. OSHP understands that the pharmacist must have the final judgement on whether they are able to practice safely at each moment in time, and make appropriate changes in the practice to protect patient safety. However, this regulation seems to put that burden solely on a single practitioner in a complex health care environment.

Previously suggested language for joint responsibility for the drug outlet is found below.

855-041-1010
Outlet (RP & IP): Personnel ~~(Both Retail and Institutional Drug Outlets)~~

Each pharmacy must:

(1) ~~Each pharmacy must h~~Have one ~~P~~pharmacist-in-charge employed on a regular basis at that location who shall be responsible for the daily operation of the pharmacy. The ~~P~~pharmacist-in-charge shall be indicated on the application for a new or relocated pharmacy and for pharmacy renewal registration.

(2) ~~A resident pharmacy that~~ **Report** terminat**inges** or allowing~~s~~ a b**B**oard licensee to resign in lieu of termination ~~must report the termination or resignation~~ to the b**B**oard within 10 working days.

(~~3~~4) ~~A pharmacy must e~~**E**nsure that it is in compliance with all state and federal laws and rules governing the practice of pharmacy.

(5) Provide a working environment that protects the health, safety and welfare of a patient which includes but not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

(c) Adequate time for a Pharmacist to complete professional duties and responsibilities including, but not limited to:

(A) Drug Utilization Review;

(B) Immunization;

(C) Counseling;

(D) Verification of the accuracy of a prescription; and

(E) All other duties and responsibilities of a Pharmacist as specified in OAR 855-019.

(d) Adequate staffing to provide safe and timely patient care based on workload volume and services provided. If conditions exist that could cause a clinical delay in patient care or patient care to be conducted in an unsafe manner, the outlet must take timely corrective action, document, and retain records of the corrective action. Determination of adequate staffing must be based on the following:

POLICY DISCUSSION: Clinical delay, Corrective action

(A) Volume of prescriptions handled by staff to include:

(i) Prescriptions filled, dispensed, and sold;

(ii) Prescriptions placed on hold;

(iii) Prescriptions returned to stock; and

(iv) Any other prescription related metrics utilized by the outlet.

(B) Volume of non-dispensing services provided by staff to include:

(i) Vaccinations offered and provided

(ii) Prescribing services offered and provided (e.g., hormonal contraceptive, statewide drug therapy management protocols or formulary drugs and devices)

(iii) CDTM services offered and provided

(iv) MTM offered and provided; and

(v) Laboratory testing offered and provided;

(C) Security needs of the pharmacy and pharmacy staff; and

(D) Staff experience and competency related to the practice of pharmacy;

PROPOSED

855-115-0074
Responsibilities: Duty to Report

(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each Pharmacist must report to the board without undue delay, but within:
(a) 1 business day:
(A) Confirmed significant drug loss; or
(B) Any loss related to suspected drug theft of a controlled substance.

OSHP does not support reporting suspected drug theft of controlled substances in hospitals in one business day. Due to the systems and processes used to detect discrepancies and possible drug theft in hospitals from mediation cabinets and operating rooms, investigations of potential losses frequently are resolved as bookkeeping or documentation errors. Personnel off shift must be questioned, and medical records reviewed. It may be several days before a discrepancy can be confirmed as true drug loss or theft. Informing the Board of all these suspected potential errors would be a needless and burdensome process for hospitals and the Board. OSHP suggests striking (B) and retaining (A) "confirmed significant drug loss"

855-115-0100

Services: Independent Practice of Pharmacy

OSHP is opposed to the addition of Independent Pharmacy Practice in this section of the proposed rules in its entirety. The practice of pharmacy is defined in statute and this section has no regulatory value. Much of the practice of pharmacy is not related to the delivery of drugs or devices. OSHP does not understand what the "independent practice of pharmacy" is supposed to be. This entire section of regulation is unnecessary. Any practitioner providing clinical pharmacy services or counseling to a patient is regulated under current regulation of a pharmacist.

855-019-0230

Counseling

~~*(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*~~

855-115-0084
Counseling
(5) For each prescription, the Pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

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

Oregon Society of Health-System Pharmacist's Comments on Oregon Board of Pharmacy Proposed Rulemaking for November 2022

Divisions 025/125 - related to Pharmacy Technicians. - Comment Only

855-125-0090
Prohibited Practices
Certified Oregon Pharmacy Technicians and Pharmacy Technicians must not:
(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0070(5);
(2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician;
(3) Perform any task while assisting in the practice or pharmacy that requires independent judgment unless it is verified by a Pharmacist;
(4) Perform any task listed in OAR 855-115-0070(3); or
(5) Ask questions of a patient or patient's agent which screen or limit interaction with the Pharmacist

OSHP supports the broad use of licensed pharmacy technicians under the supervision of the pharmacist to allow the safe and efficient provision of medications. The delegation of tasks should be specific to the care environment and the personnel involved. It appears that the proposed rules allow for this practice.

OSHP is uncertain about the effect of 855-125-0090(5) and what was the intent of the rule? Any question asked by a technician would screen for the pharmacist. Are you allergic to any drugs? This would limit interaction with the pharmacist regarding allergies. Is this meant to refer to the refusal of consultation question? OSHP would like this section deleted or focused on the intended outcome.

OSHP supports other sections of the 855-125 division

Oregon Society of Health-System Pharmacist's Comments on Oregon Board of Pharmacy Proposed Rulemaking for November 2022

OSHP is a professional organization affiliated with the American Society of Health-system Pharmacy (ASHP), which represents over 700 licensed practitioners by the Oregon Board of Pharmacy. OSHP is dedicated to the advancement of pharmacy practice in Oregon through education, collaboration and advocacy. We appreciate the Oregon Board of Pharmacy's focus on patient safety and responsiveness to the advancing practice roles and challenges of pharmacists and pharmacy technicians.

We would like to provide our input into the current rule making process with respect to the large number of rules found in the November Rules Hearings. While the comprehensive number of rule divisions proposed for revision are presented under the general background of "administrative updating and minor revisions", OSHP finds several areas of significant change in regulation of the practice of pharmacy. We will highlight these as we comment on the broad scope of the many changes found below.

Divisions 006/019/031 - related to Definitions

855-006-0005
Definitions
(910) "Clinical Pharmacy Agreement" means an agreement between a Pharmacist or pharmacy and a health care organization or a physician ~~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~~¶
~~(10) "Collaborative Drug Therapy Management" meansas~~ defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010 the ~~participation by aat~~ permits the 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 to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization, or physician or naturopathic physician.

OSHP is strongly opposed to eliminating the Collaborative Drug Therapy Management Definition in the regulations. This language has been the basis of hundreds of agreements in many organizations and is in the policy and procedures of these health systems. There is no need for this change. This would create needless and undue administrative and financial burden on health-systems without any benefit in health or safety for Oregonians. We suggest adding Clinical Pharmacy Agreement to the definitions if needed. Having the language for both CDTM and CPA in statute and/or rules is undoubtedly confusing. While we appreciate the attempt by the Board to clarify the language of CDTM and CPA, this move to remove the term CDTM and simply transfer the language to the definition of CPAs, destroys the intent of the CPA statute. The CPA statute broadened the ability to practice clinical pharmacy by allowing agreements to exist between individuals as well as organizations, and by removing those agreements from the constraints of a prescription-based relationship. CPAs are defined as agreements allowing the practice of clinical pharmacy based on the agreement, not on a prescription. We also see that the content can be more general and set guidelines for what information should be considered in the decision process.

(25) "Independent Practice of Pharmacy" means the provision of clinical pharmacy services not related to the dispensing, distribution and delivery of drugs or devices.

OSHP is opposed to the addition of Independent Pharmacy Practice in section (25) of the proposed rules. The practice of pharmacy is defined in statute and this statement has no regulatory value. Much of the practice of pharmacy is not related to the delivery of drugs or devices.

Oregon Society of Health-System Pharmacist's Comments on Oregon Board of Pharmacy Proposed Rulemaking for November 2022

Division 139 - related to 2022 HB 4034 Prohibited Practices

855-139-0600
Prohibited Practices: General
A Retail Drug Outlet RDSP must not:
(1) Allow a Certified Oregon Pharmacy Technician or Pharmacy Technician to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;
(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the board pursuant to ORS 689.305.
(3) Deliver a prescription;
(4) Compound sterile preparations; or
(5) Repackage drugs.

OSHP is uncertain about the effect of 855-139-0600(1) and what was the intent of the rule? Is the intent to not allow technicians to ask the patient any questions? Any question asked by a technician would screen for the pharmacist. For example: Are you allergic to any drugs? Would limit interaction with the pharmacist regarding allergies. Is this the refusal of consultation question? OSHP would like this section deleted or focused on the intended outcome.
OSHP believes that certified and trained technicians are helpful and significant in the provision of clinical pharmacy services, including interviewing patients for medication histories and gathering pertinent information for use by the pharmacist delivering care.

Oregon Society of Health-System Pharmacist's Comments on Oregon Board of Pharmacy Proposed Rulemaking for November 2022

Divisions 001/102 - related to Procedural & Universal Rules - Comment Only

855-102-0050
Record and Document Retention
(1) All records and documents required by ORS 475, ORS 689, and OAR 855:
(a) Must be retained for 3 years except that:
(A) Clinical pharmacy records must be retained for 7 years;
(B) Training records for patient care services, when required, must be retained for 3 years after ceasing participation in the activity requiring training;
(b) Must be stored on-site for 12 months and must be provided to the board immediately upon request at the time of inspection;
(c) 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;
(d) May be in written or electronic format; and
(e) Made available to the board upon request.
(2) Records must be stored at the Drug Outlet for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days.
(3) Records generated under Independent Pharmacy Practice, must be stored at a health care organization, practitioner, pharmacy, or pharmacist office or in a secure location by the Pharmacist according to OAR 855-115-0100 for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days.
(4) Records must be written, electronic or a combination of the two.

OSHP opposes the false distinction of "Independent" pharmacy practice. Records generated in the practice of pharmacy should be stored under the regulations in 855-102-0050. Section (3) should be deleted as it is meaningless.

From:	Brian Mayo
To:	PHARMACY RULEMAKING * BOP
Subject:	Written comment for rulemaking
Date:	Tuesday, November 22, 2022 12:00:55 PM
Attachments:	2022 Rulemaking Letter_OSPA w surveyFINAL.pdf

Hello,

Attached are written comments on behalf of OSPA for today's rulemaking deadline. Will you please confirm receipt of this email?

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

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November 18, 2022
Oregon Board of Pharmacy
c/o Joe Schnabel
800 NE Oregon St., Suite 150
Portland, OR 97232

Dear Joe,

On behalf of the Oregon State Pharmacy Association (OSPA) members, I am submitting comments on rules proposed by the Board of Pharmacy. Throughout this letter, I have included suggestions for improvement that the association feels will benefit our patients, pharmacy personnel, and the Oregon Board of Pharmacy. By working collaboratively, we will see improved health outcomes for patients. In addition, I am also providing the Board of Pharmacy members a copy of the comments received on the 2022 OSPA member survey. As you may recall, we met with you previously to review the results and discuss these concerns. I believe it is important for the Board of Pharmacy members to read the feedback themselves as it sheds light on how pharmacists and pharmacy personnel feel about pharmacy practice in Oregon and how it directly impacts the safety of patients in our state.

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

Examples include:
1. **Proposed Rule Amendment 855-006-0005(10)**: Removing CDTMs from rule and replacing it with a redefined Clinical Pharmacy Agreement (CPA). This jeopardizes the ability of pharmacists to be reimbursed for, and thus provide services to, Medicaid recipients enrolled in Coordinated Care Organizations (CCOs). These rules impact pharmacists in all settings, not just community pharmacy. The Oregon Medical Board does not have corresponding rules that recognize a CPA. Consequently, if these rules go into effect, there will be no way for pharmacists to collaboratively manage drug therapy. This will negatively affect the many pharmacists in an ambulatory clinic environment which may then result in patient harm. It will also disrupt care for many Oregonians without access to other healthcare providers and erode pharmacist's efforts to address health equity for rural and minority populations in Oregon.

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2. **Proposed Rule 855-115-0125(2)**: MTM encompasses a variety of services provided by pharmacists, generally for Medicare Part D plans which have their own definition. Changing the definition of MTM in this rule to require that "all elements listed be completed" is unnecessary and puts undue burden on Oregon pharmacists who complete MTM visits. Some Part D MTM interventions may be as simple and brief as a telephone call to determine why a patient is late for a maintenance medication refill or if an intervention or refill is needed. The proposed change would mandate a provision of services that may not be indicated for every patient and increases the documentation and administrative burden of the pharmacist providing said service. This may, in turn, entice Medicare plans to contract with pharmacists outside of Oregon (as they are not held to the same rules). The Oregon Board of Pharmacy should be doing everything they can to develop and encourage the pharmacist-patient relationship which has a record of improving patient safety outcomes, not burden it with cumbersome mandates. This proposed rule change from "may include" to "must include" is unnecessary, and again, has unintended consequences that may endanger our patients and limit provider access.

3. Finally, during the Oregon Pharmacy Coalition meeting in October, I shared with you the number one concern our members continue to bring up; not receiving support from the Board of Pharmacy when they reach out for help. I asked you about how we can work together to provide better support to our pharmacists. Pharmacists across Oregon want to work with the Board to ensure they are following rules correctly, in the interest of their patient. Unfortunately, many feel the Board has become unapproachable. If the Board cannot interpret the rules they write, how can you expect the pharmacists to do the same? OSPA desperately wants to work with the Board of Pharmacy and have a collaborative relationship that provides the best service to our patients and pharmacy staff. We would like to set up a monthly meeting with you and any other Board staff to ensure our concerns are heard by the Board and vice versa, allowing us the opportunity to collaborate on ways to improve the health of all Oregonians. If rulemaking is the recommended avenue through which the board prefers to interact with pharmacy professionals and the public, the size/scope of the rulemaking proposals session are too cumbersome to allow for sufficient discussion to occur.

Sincerely,

Brian Mayo
Executive Director

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Results from 2022 OSPA survey titled "Oregon Board of Pharmacy Satisfaction Survey"

9. Anything else you'd like to share?

46Responses

ID	Name	Responses
1	anonymous	da ag d
2	anonymous	The board in this state does not seem supportive of pharmacists. Instead it feels like they are out to get us. It's a weird dynamic compared to the state I moved here from.
3	anonymous	In the past I have always had very positive interactions with the board the the office staff, but this has changed dramatically during covid despite communications being by phone and email which should not be reasonably impacted by covid.
4	anonymous	At the October 2021 OSPA meeting, I spoke with a representative from the Board of Pharmacy about this very issue. She said they were instructed by the Attorney General to use this canned response and to not provide "legal advise". She also said that the BOP's approach is to make the rules so clear that they did not need to be clarified. She stated that they would know there would be some work at clarity when they received multiple questions about the same subject. I explained to her that pharmacists will get so frustrated with this unhelpful canned response that we would just stop calling to ask questions. This would result in them not getting any feedback and not knowing what rules needed to be worked on. It is very frustrating as a licensed practitioner that my licensing board will not help answer questions nor provide clarity or guidance about rules that they have written and implemented in the interest of public health and safety and then judge me during an inspection. They won't provide "legal counsel" but they will administer fines if we are not following the rules that we have asked them where is the line drawn. Basically telling us "don't cross the line" without telling us where that line is.
5	anonymous	They should be more communicative with pharmacies. They should help by putting restrictions on the amount of work pharmacists and techs do. I used to consult and couldn't do more than 100 charts in a day, maybe set limits for scripts.
6	anonymous	I would share more. However I fear retaliation from bop and my employer.
7	anonymous	It is unfortunate but the Board now has the reputation of being very punitive. People are afraid to reach out for fear of spurring an investigation. The investigations are aggressive and take many months, sometimes 1-2 yrs or more to resolve. Leaving those involved hanging and afraid of what is to come.

8	anonymous	At what point does the board step in and say enough is enough. The free market is NOT working in rural areas. Staffing shortages are rampant. The skill levels of technicians varies widely across the retail scene.
9	anonymous	I appreciate the updates via email.
10	anonymous	Excessive new regulations concerning hazardous drugs during period of short staffing and pandemic
11	anonymous	I think it is sad and pathetic that the board of pharmacy isn't proactive to help pharmacists prevent issues and will only act to punish us.
12	anonymous	The Board staff has done a real 180 degree turn recently. They shouldn't be invited to professional events if they do not want to be a partner with licensees.
13	anonymous	I think the board of pharmacy has lost sight of the really crucial items going on in the profession today. Instead we get messages that we need to post hours store hours, we need to worry about tech check tech, dont waste vaccine, make vaccine appointments, then allow walk ins. These are daily operational issues while important pale in comparison to adequate reimbursement for medicaid prescriptions soon no pharmacy will accept medicaid patients with advanced health and medimpact since reimbursement is below our cost and we lose money on the prescriptions. There are bigger health care issues such as store closures leaving folks without insulin having to go to the hospital ER and often times no pharmacists to staff especially in rural areas on a routine basis.
14	anonymous	Pharmacy needs to get provider status. This is insane the amount of work we get put on our backs and no help. No help from anyone, not even the board of pharmacy. Regretted I chose this profession many times, almost walked out mid shift, switched companies. Patient safety is at risk on a daily basis. Phone off the hook, drive thru non stop, lines in store non stop, 1 pharmacist. Never hated what I do until now. Over 5 years in profession.
15	anonymous	You need to do something about the staffing in retail pharmacies. Every day gets more and more dangerous for pharmacists and the patients we serve due to lack of staff and unsafe conditions. You need to do something before there are no more pharmacists at all. Nobody cares about us not our companies not our customers and most of all the people who are supposed to protect and advocate for us, you. It’s incredibly disappointing and frankly disrespectful as a pharmacist during this time to fully know that the OBOP could care less about us. I used to like being a pharmacist and now I wake up in a state of panic and dread about getting through my workday. I can’t confidently know I am doing the best I can when working conditions are so poor. I don’t care about these ridiculous surveys

		that are a waste of time. I want someone to do something and that someone should be you. I'm ashamed to be a pharmacist in this state.
16	anonymous	The recent rules regarding remote processing are overly bureaucratic. The BME doesn't have like rules regarding physician working remotely. Why was the Board compelled to write rules like that?
17	anonymous	Is there anything the Board can do to help with burnout?
18	anonymous	I really hope this survey acts as a beacon of change. I feel like the board has changed dramatically over the past 20 years and not in a good way. They make it more difficult to practice our profession instead of supporting us to do what we're trained to do.
19	anonymous	The board of pharmacy really appears to have their head in the sand over this pandemic. Some of the rules they've implemented are all about money and do not take into consideration the actual state of retail pharmacy.
20	anonymous	Spineless . They need to read the board of pharmacy newsletters from other states Nevada, California . Too busy advancing and expanding the practice of pharmacy without considering the realities of day to day and ability to be compliant and putting in rules to help us . How about pushing for pharmacist to hourly employees like California ? We are basically shift workers .
21	anonymous	The board has gone from a entity to help you to an adversary looking to punish you.
22	anonymous	Seek to understand, firsthand, what community pharmacies are going through, through the lens of pharmacy personnel, not solely patients. There is an overwhelming perception that the Board staff office (not the official Board members, but the investigators) are out of touch with everything our teams are going through and the Board, made up of our fellow pharmacists, does not have our best interests at heart. Through their actions, they have created a very clear perception they do not and will not advocate for pharmacies and pharmacy personnel, and are viewed as someone who is working against us, not with us. While I fully recognize their mission is to serve and protect the public, I feel they could use some training to balance their obligations while also advocating and supporting pharmacy personnel on the front lines.

23	anonymous	board need to advocate for ambulatory pharmacist with BPS or NCBDE to prescribe in their fields. As a BCGP and CDE I was amazed how little knowledge PA's,NP's and MD's knew about treating diabetes and 90+% have never heard of the AACE treatment algorithms. On the positive side after educating the providers that allow to have me prescribe under their name and the VP of clinical operations gave all 3 ambulatory pharmacist the ability to prescribe under his name, Board is too entrenched in old retail practices that are going the way of the dinosaur (closing of Bi-mart retail pharmacies, etc. God forbid that the board gets in the way of current ambulatory pharmacist prescribing under MD's,(providers) names. For protecting public health get clinical pharmacist that have access for medical records, labs, and all data that provider have in medical clinics prescribing for the safety of the patient. been beating this horse for last 20 years with the board with no action so I suspect all this will fall on deaf ears until all retail outlets fail and are replaced with automated dispensing machines (robots). Its coming and to think this will remain the the same is just stupidity. Add the same training that PAs and NPs get to college pharmacy graduates the ability to prescribe and treat patients after they graduate.
24	anonymous	Thank you for this survey. I have had to respond to two of our stores in the last month regarding the lack of help from the Board of Pharmacy in answering their questions.
25	anonymous	Thanks for all that you do.
26	anonymous	Retail pharmacies are not doing enough to ensure patient safety and pharmacists are so stressed right now that we need to listen to pharmacists as much as we do patients who also raise safety concerns.
27	anonymous	Calling the board was great, my question was answered thoroughly and quickly.
28	anonymous	I think the board is prioritizing the wrong things! No regard to real patient safety, understaffing, and pharmacy staff mental health. The fact they are more worried about the fridge temperatures then preventing burnout and helping hold corporations responsible for understaffing and poor habits just so they can make more money at the risk of patient safety. Honestly it is just ridiculous, the Board should be fighting fights that actually matter.
29	anonymous	The board needs to hold the corporations accountable for their lack of proper staffing. Especially during this pandemic. Pharmacists are humans and exhausted humans tend to make mistakes.
30	anonymous	Thanks for this opportunity, show the Board and staff care, Maybe now I will call if I have a concern

31	anonymous	We need a truly responsive board not a group who thinks we need diversity training as a CE requirement. Do what they were designed to do, protect the public and support the difficulties associated with the modern practice of Pharmacy. Thank you
32	anonymous	I am concerned about recent comments and actions coming from the Board dealing with the issue of pharmacy closures, staffing, and being overwhelmed with vaccinations and other activities. Making more rules does not necessarily always help the situation and statements coming from the Board that patients should go to a mail-order pharmacy, even if they aren't likely to get to talk to a pharmacist, is not setting a good standard for what pharmacy practice in the State should be. If the Board expects pharmacists at community pharmacies in the State of Oregon to conduct DUR's, counsel patients, give vaccinations, do formulary prescribing, and be there when needed to help with Public Health emergencies yet at the same time sends the message that patients can go to a mail order (likely out of State) or transfer prescriptions if they can't get their medicine quickly is not really dealing with the problem. It is also an acknowledgment that mail-order pharmacies (and specialty pharmacies!) do not have to follow the same high standards that the rest of the community pharmacists in Oregon have to follow to be in compliance with regulations. If the definition of the practice of pharmacy is that all patients should receive counseling on their prescription by a pharmacist then any entity dispensing medication to patients in Oregon should have to follow that same standard. We should all be encouraging our patients to get to know their pharmacist, get all of their prescriptions from one pharmacy so the pharmacist can review their medication profile with each dispensing. There is not usually a complaint to the Board when someone does not get their medicine from the mail-order because for years pharmacists and technicians at community pharmacies have been taking care of people when they didn't receive their medicine on time (or got the wrong medicine) from their mail-order! We should carefully manage and regulate activities that fragment pharmacy and that force patients to use multiple providers for their pharmacy care needs, such as mandatory use of mail-order pharmacy and specialty pharmacy, or online pharmacy. Some of these other types of pharmacy businesses may be appropriate in some cases but they should follow the same rules as all other pharmacies have to follow and their practice and limits should be clearly defined. Thanks OSPA for the opportunity to provide feedback on this issue!!

33	anonymous	Why does the BOP investigate every little thing that comes their way? I feel they should apply some parameters around some complaints and triage them. Other health boards really push back on patient complaints and insist that the patient resolve it directly with the healthcare provider. The BOP also is very accusatory in verbiage when sending a complaint, almost as if GUILTY until proven innocent. The wording is not friendly nor is it conducive to productive conversation. Some compliance members are worse at this than others for sure.
34	anonymous	The Board should not waste time on unnecessary time on patient complaint resolution. The extent that the Board follows up on customer complaints/investigations seems cumbersome and it wastes valuable resources within the healthcare system. There should be a more refined process for selecting what complaints need investigating, and what complaints can be discarded. Additionally, the process for resolving complaints needs to be more streamlined. It takes far to long to find out if an investigation has been resolved.
35	anonymous	The board continues to add rule after rule making it increasingly difficult to follow the rules even if a licensee wants to! To call all responses to rules individualized legal advice is shirking their duties.
36	anonymous	Keep up the good work!
37	anonymous	I feel the Board of Pharmacy is getting out of touch of how difficult it is in pharmacies. The solution is not in more regulation. It would be nice if they were more interested in feedback from pharmacies across the state.
38	anonymous	Thank you for all your hard work!
39	anonymous	I appreciate it when they send out law and rule updates by email
40	anonymous	I have not been pleased that despite the fact that I have not quit and have continued to work throughout the pandemic early on there were letters asking to explain unprofessional conduct of not answering the phone. My pharmacy staff was dealing and is still dealing with the fact that other retail pharmacies near us have closed or are not able to keep their doors open constantly. We have been unsuccessful at getting any quality employment applicants. Leaving our team, or what is left of them to deal with a massive influx of customers and informational calls. Our county has an information hot line but not once have I seen it advertised, which leads customers to call any pharmacy that will answer the phone. It is not possible to fill prescriptions, do vaccinations and be the information service that we once were.
41	anonymous	I have practiced in 6 different states in my pharmacy career. I have never experienced a board of pharmacy so out of touch current practice standards, unwilling to help pharmacist succeed in being

		compliant, and unfamiliar with their own authority to promulgate and remove administrative rules that improve patient safety without creating "legislative fixes".
42	anonymous	Over the last 6 years the reimbursement margins are become incredibly narrow while post adjudication claw backs, and fees have gone up 4000% at our practice. The cost to operate and staff a pharmacy has increased 4-5 fold. This has created a dangerous work environment for pharmacist and staff who are overworked, burned out, and forced pharmacist to verify 200+ scripts a day just to break even per pharmacist. If we could afford to hire additional staff we would hire them on the spot. When does work safety condition start jeopardizing the public.
43	anonymous	Why is it that the Board can interpret the rules when they are onsite, and provide comments or deficiencies but when a pharmacist is reaching out ahead of time trying to get clarification that what they are doing is right and what is needed, that the Board cannot interpret or "provide individualized legal advice on how the law applies to the field"? I have talked with other pharmacists and they have also received this unhelpful, canned response. I am encouraging them to fill out this survey as well. I provided detail above about the question I sent to the Board so you would have an idea of the situation and their response but please leave out the specifics about the Telework question as it was a very recent question to the Board so it may be less anonymous if that information was included. THANK YOU for providing this survey and tackling this very important issue!!!
44	anonymous	n/a
45	anonymous	In my career the Oregon Board of pharmacy has been excellent. Timely responses and accessible information. I cannot say the same for our friends, the comission north of us. Thank you.
46	anonymous	It seems there are 2 storms colliding in Oregon and across the country. On one side, you have large retail pharmacy business models being ill-responsive to the declining reimbursements. Decreasing staff to maintain profit margins to shareholders. On the other side, you have a regulation heavy SBOP with ever increasing demands on RPh that are extremely difficult to uphold given staffing allotment. I have a few questions: 1. What are the number/ratio of independent pharmacies in Oregon v. other states? 2. What is the size (number of employees/number of regs) of SBOP of Oregon compared to other states? 3. What are the disciplinary actions of SBOP of Oregon compared to other states? As an independent pharmacy owner, I do not want to be included with large retail chains. I hire enough staff to feel confident we are performing pharmaceutical care at our best. I am less profitable

because of it. The SBOP is there to protect its citizens from negligent or harmful professionals not decrease pharmaceutical care thru invasive and insensitive language/regs. If you want fat cows, feed them. Don't weight them.

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6. If you feel like your request was not resolved, why not?

47Responses ID	Name	Responses
1	anonymous	ad
2	anonymous	I was asking a basic question about Oregon pharmacy law and was told by the board I should consult a lawyer and that it wasn't their role to help clarify the laws.
3	anonymous	Rather than answering questions, it seems that the board staff prefer to instruct pharmacists to consult their own legal council to interpret board rules
4	anonymous	I was told that they were not allowed to provide legal advise and that I should consult an attorney. I was trying to clarify a communication from the Board of Pharmacy or asking for a rule clarification.
5	anonymous	Was provided auto response that my question would not be answered.
6	anonymous	They don't clarify rule questions. They just say read the laws / the OAR. Well, I did and that's why I am asking a question.
7	anonymous	Could not get a hold of anyone.
8	anonymous	Either no response or very vague
9	anonymous	No helpful response given. They said they couldn't provide an answer to my question because it required an interpretation of law. It didn't used to be like this
10	anonymous	Inexplicable delay
11	anonymous	The compliance officers or responders simply say they are not providing legal advice and attach a copy of the rule we are asking for clarification. I can read the rule, but I cannot tell if an inspector or the board would interpret it in the same way I do.
12	anonymous	They are too concerned about answering legal questions and just say to cont a legal representative. They should help in answering questions.
13	anonymous	Reply from bop too open ended. I was only copied and pasted rules to help "guide" the answer.
14	anonymous	Pending nursing board response, which has not been resolved

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15	anonymous	No definitive answer was provided. There are many areas of pharmacy practice that are new, not found in a lot of traditional settings and rules are silent or ambiguous at best. It feels things have transitioned to a very black and white prescriptive culture and if your practice doesn't fit into the traditional box, don't bother trying to talk that through with board staff to understand what rules or licensing would apply.
16	anonymous	I can submit a question via email or phone message and no one gets back to me when I'm asking for clarification. 3 times this has happened.
17	anonymous	One of the concerns never received a return call
18	anonymous	Usually just told that the board staff cannot answer the question. Also have been told that they will not cite reasons for a denied request or guidance on what would be acceptable.
19	anonymous	was told they can't help us interpret the laws they create and it was suggested to consult a lawyer
20	anonymous	I was told to consult an attorney
21	anonymous	some were resolved but some still in limbo.
22	anonymous	No changes in pharmacies
23	anonymous	I never received a response from the Board
24	anonymous	The investigator wasn't listening to my side of the story in which I was being falsely accused. I was being told that I couldn't really defend myself but could appeal the Board's decision after they made their ruling. They made me feel terrified of having my license suspended or revoked. I felt hopeless. There was no care or concern for the actual events. I was just told that the Board protects the public forgetting the fact that I'm the public too! Where is my protection? I am a hard working, highly intelligent pharmacist that works tirelessly to keep my patients safe and provide them with the most effective treatment. I catch mistakes daily that could harm people. The Board takes none of that into consideration and makes their decision based on twisted accusations instead of facts.
25	anonymous	The Obop answer was not clear
26	anonymous	I called with some questions about being a consultant pharmacists - clarifying rules, licensing etc. they scheduled a time to call back and then never called.
27	anonymous	Fairly nebulous response.

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28	anonymous	They say do not give legal advice . Very non clarifying .
29	anonymous	My perception is that board members are afraid to make a decision or clarify a rule.
30	anonymous	I feel like the questions are so changing that I the answers are kinda vague but did get it resolved with asking lots of questions. Email is so hard to ask questions that you may not be clear still on.
31	anonymous	More recently, the Board has been unwilling to provide guidance on OARs and what their expectations are pertaining to those OARs, and instead encourage you to seek legal counsel for rule interpretations. This is a departure from how they have previously handle matters where guidance is being requested. Their change in approach, where they do not want to provide help/guidance and would rather hide behind a canned responses, is not only unhelpful, but it creates a perception of us vs them; where if you do not interpret the rule correctly or do it other than how they interpret it, you may face disciplinary action. Pharmacy is a very stressful and challenging environment right now, and it feels like people who should be on our "team" are less than helpful and it feels like they are not apart of the overall pharmacy profession team.
32	anonymous	The Board's position seems to be to not give direct answers to the questions asked. They often tell us to talk to our own attorney to gain clarification (most attorneys do not have the expertise to answer for the BOP) or are vague in their reply. Very frustrating to say the least and does not make sense for them to not be helpful in providing assistance to pharmacies who are trying to be compliant with the rules and laws that are in place.
33	anonymous	I was told I should seek legal recourse to the question I asked and there was no other suggestions provided. I was concerned about a safety issue I had noticed.
34	anonymous	poor talent at the Board Level. The Board is a classic example of those who can't to the real tasks, become board executive director, the board members and on down.
35	anonymous	Staff seemed unwilling to give specific answers as to what would constitute a violation.
36	anonymous	The BOP used to be helpful and provide guidance on OAR interpretations. Pharmacists want to AVOID getting in trouble or having issues so they look to the BOP for assistance. But lately they respond with a generic "seek your own lawyer" comment.

37	anonymous	Answers still felt vague. Was seeking clarification on a rule and it just felt like the rule was repeated back to me.
38	anonymous	The board responded with a blanket statement that they do not provide individualized legal advice and a link to laws and rules. Many of the rules are poorly written, not clear and contradictory.
39	anonymous	The staff member did not take responsibility for addressing the issue. The information provided did not match what is in the record, and the staff member seemed to want to turn the issue back on the licensee.
40	anonymous	Board refuses to answer rule interpretation questions under the guise of “legal advice” and tell pharmacists to consult an attorney. Board interprets and enforces rules, so should be able to provide interpretive guidance upon questioning.
41	anonymous	When attempting to clarify rule, the canned response of late is "The Board does not provide individualized legal advice on how the law applies to practice in the field". They write the rules and should be able to provide clarification. This is a complete lack of support.
42	anonymous	We have reached out to the OBOP compliance department regarding clarification of several OARs and they were unwilling to provide insight and told us to to seek legal counsel. Every engagement we have had with board of pharmacy regarding the interpretation of their own administrative rules were not answered. We are unclear why legal interpretation of their OBOP administrative rules and policies is needed or warranted. It is sad that instead of being proactive to help profession of pharmacy be compliant and practice within scope and intent of their rules. The OBOP seems to be more focused on finding ways to fine pharmacists, promulgating rules that prevent good patient care activities, while continuing to enforce outdated practice standards that do not reflect the current pharmacists, and pharmacy technician training requirements and practice standards.
43	anonymous	I asked the OBOP of pharmacy to confirm our interpretation of one of their rules was correct. During the phone call the OBOP compliance staff started investigating other area's of compliance not related to our original question and OAR that we inquiring about. The we did get the answer to our original question. However, three to four weeks later we were inspected by the board of pharmacy. It is now our organizations policy that any inquiries to OBOP must go through an intermediary and our organizations legal counsel.

44	anonymous	This is the response I received with a question I sent this last week: Hello, The Board does not provide individualized legal advice on how the law applies to practice in the field. Please review Board regulations at https://www.oregon.gov/pharmacy/Pages/Laws-Rules.aspx. You may also want to contact a qualified attorney. The following regulations may apply (note: additional regulations may apply): OAR 855-041-3200 through OAR 855-041-3250 Thank you, Joseph Ball, R.Ph. Chief Compliance Officer It is frustrating that when you try to do your due diligence to clarify rules to make sure you are compliant, that the Board offers no guidance whatsoever. I reviewed those OARs before I even contacted the Board and still I had questions, and that is why I emailed the Board. In reference to contacting a qualified attorney, I have to doubt that an attorney knows much about the very specific setting in which I work and if/how the Telework OAR does or doesn't apply. Not only was his response no help, it leaves me never wanting to reach out to the BOP again. Just as we are taught in pharmacy school, and professionally in our job, that you should speak up when you have a question in order to clarify it, it is not the same with the Oregon BOP. Rather they leave you afraid to contact them, as they primarily seem to serve as only a regulatory entity and not to provide any guidance to pharmacists or pharmacy staff. In my opinion they should take note from the aviation industry which the pilots used to have the same perspective of the FAA as pharmacists have of the BOP. They were afraid to contact them with questions due to the punitive nature and the 'out to get you' feeling rather than being collaborative and helpful. The aviation industry and FAA has learned this is not the safest way to do things, and now encourages any questions and actively tries to provide answers and guidance to the pilots when they reach out. There is a non-punitive approach if there are questions or even if an error was committed but the pilot was acting in good faith, they can self-report. The FAA uses this information to revise policies and procedures if necessary. The FAA interacts in a positive and helpful manner with the pilot. While the BOP may not need to take self-reports of errors, or any error-reporting, they could learn from the FAA in being more approachable and helpful as this results in an all around safer industry for the public and pilots alike. The BOP being unwilling to offer any interpretation ends up negatively impacting the public as the pharmacist does their best to interpret and follow the rules without any support. And if the pharmacist happened to interpret the rule wrong, they are potentially subject to

		disciplinary action. If the BOP cannot help the pharmacist in these specifics, who can?
45	anonymous	Couple reasons : 1) ORBOP never respond in timely manner or they never respond at all. 2) After sometime ORBOP will find a time to reach out to just to penalize you or your pharmacy. 3) ORBOP fail to listen our concern during pharmacy crisis and pandemic. 4) ORBOP making more mandatory work for pharmacist without proper compensation for pharmacy services. for example naloxone bill. 5) ORBOP is expert in limiting pharmacist scope of practice in Oregon. 6) There are some Immunization protocols are expired but there is no guidance on should we administer the vaccine or should we not since protocol is expire? 7) Overall very disappointed with ORBOP
46	anonymous	I was giving a very generic response stating that the board does not get involved and that I should contact a lawyer.
47	anonymous	some questions were answered directly, a few were indirect or just referred to regulation

From: PHARMACY FORMULARY * BOP
To: PHARMACY RULEMAKING * BOP
Subject: FW: PHPFAC protocol feedback
Date: Monday, November 21, 2022 2:20:16 PM
Attachments: formsubmission.csv

From: oregon-gov-web-services@egov.com <oregon-gov-web-services@egov.com>
Sent: Thursday, November 10, 2022 4:27 PM
To: PHARMACY FORMULARY * BOP <PHARMACY.FORMULARY@bop.oregon.gov>
Subject: PHPFAC protocol feedback

First & Last Name	Sharon Rask
Email Address	sharon.rask@oregonstate.edu
Provide Feedback	PrEP Protocol Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form Per CDC Guidelines, HIV test results must be within the past 7 days. Testing and Treatment I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks.

Submission ID: de2b4a64-f8a9-4147-b645-b24607abe906

Record ID:

From:	Peter Fjelstad
To:	PHARMACY RULEMAKING * BOP
Cc:	Peter Fjelstad
Subject:	PCMA comments - OR BoP proposed rules
Date:	Tuesday, November 22, 2022 12:23:39 PM
Attachments:	11.22.22 - Final - PCMA letter to OR BoP - proposed rules.pdf Div_019_115_Pharmacists_NoticeFilingTrackedChanges (1).pdf

OR Board of Pharmacy and/or Ms. Melvin,

Please see attached comment letter from the Pharmaceutical Care Management Association ("PCMA") in response to the OR Board of Pharmacy's proposed rules to create a new Division 115 for Pharmacists.

Also attached are the proposed rules on which we are commenting, for your reference.

We appreciate the opportunity to provide the Board with our comments on the proposed rules. If you have any questions about PCMA's comments, please feel free to contact me directly.

Thanks,

Peter Fjelstad

Director, State Regulatory & Legal Affairs
PCMA

Peter Fjelstad | PCMA | *Director, State Regulatory and Legal Affairs* **|** 202-756-5749
325 7th Street NW, 9th Floor, Washington, DC 20004
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November 22, 2022

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

SUBMITTED VIA EMAIL

Re: Notice of Proposed Rulemaking – Proactive Procedural Rule Review – Creates new Division 115 for Pharmacists

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

PCMA is the national trade association representing pharmacy benefit managers ("PBMs"). PCMA's PBM member companies administer drug benefits for more than 266 million Americans, including 3.6 million Oregonians, who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries.

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

Specifically, our concerns include:

- Lapses in medication therapy from Oregon-licensed pharmacies managed by an Oregon-licensed Pharmacist-in-Charge that provide medicines via mail or common carrier delivery if patient counseling is required BEFORE shipment is permitted;

- Untimely delivery of routine maintenance medicines, such as blood pressure medicine or depression medicines, which could result in negative outcomes or withdrawal symptoms if the medication is stopped suddenly;

- Untimely delivery of specialty medicines shipped into Oregon to treat and manage complex medical conditions such as infertility and cancer, of which lapses in therapy can have devastating outcomes;

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- Serious side effects when there is a lapse in therapy which risk is increased if the patient has been on medicine for a long time or the dose is high; and

- In-person/interactive counseling for each patient and prescription would be administratively burdensome, not only to the patient, but also to the pharmacy where qualified staff must engage in multiple outreach attempts often when patients are at work or not otherwise at home to receive counseling outreach attempts from pharmacies prior to shipment of medicines .."

In particular, in Section 855-019-0230, the Board's draft of the proposed rules removes the ability to provide counseling in writing when a prescription is delivered to a patient; further exasperating the potential lapses in therapy and untimely delivery concerns outlined above.

Currently, the proposed rules generally conflict with Oregon Revised Statutes ("ORS") Section 689.025, which provides that the purpose of the Board is to: promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy in Oregon. It is imperative that health care professionals be able to rely on patients' access to necessary medicines in order to protect their health, safety and welfare.

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

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

Sincerely,

Peter Fjelstad

Peter Fjelstad
Director, State Regulatory & Legal Affairs

Pharmaceutical Care Management Association
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www.pcmanet.org

From:	Kevin Russell
To:	PHARMACY RULEMAKING * BOP
Cc:	Kevin Russell
Subject:	Comments for Nov 22nd rulemaking hearing
Date:	Saturday, November 19, 2022 2:10:59 PM
Attachments:	image001.png Comments on proposed rules eliminating CDTM.docx Comments on proposed rules for pharmacist prescribing.docx Comments on proposed rules for MTM.docx Comments on proposed rules for labs.docx

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To: Oregon Board of Pharmacy

Attached are comment submissions from Prescryptive Health for the November 22nd rulemaking hearing. Thank you.

Kevin Russell RPh, MBA, BCACP
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Prescryptive Health
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November 18, 2022

To: Oregon Board of Pharmacy

Re: Changes to rule 855-019-0260 eliminating existing language on Collaborative Drug Therapy Management (CDTM)

Prescryptive Health opposes the proposed removal of existing CDTM language. It is unclear if the new Clinical Pharmacy Agreement (CPA) language replacing CDTM would allow for the same or improved levels of clinical practice as experienced today. Certainly, it could disrupt existing CDTM practices and create an administrative burden to re-establish services under the new CPA rules. CDTM is understood and supported by providers, health systems, and payors. We request that any needed changes to CDTM rules be addressed through a workgroup of stakeholders and subject matter experts prior to rulemaking.

About us: Prescryptive Health is a healthcare technology company that builds solutions for pharmacies. We are working to deliver better healthcare through patient engagement. Core strategies include improving patient access to needed medications and connecting patients to pharmacists who can provide value added clinical services. We have a community pharmacy in Redmond, Oregon which is piloting and demonstrating our technology.

Sincerely,

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REWRITING THE SCRIPT

November 18, 2022

To: Oregon Board of Pharmacy

Re: Proposed rule 855-115-0115 on laboratory services

Prescryptive Health opposes the proposed rule which excludes pharmacists from ordering or receiving laboratory tests except in the defined circumstances of the rule. Ordering and interpreting labs for the purposes of drug monitoring and disease state management has been a core practice of pharmacy for over 30 years. Every college of pharmacy teaches this practice standard. Timely access to appropriate lab data improves patient safety and patient outcomes. This should be unrestricted for pharmacists.

We don't know what future practice innovations will be, therefore practice rules should be inclusive, not exclusive. Consider the desired future where secure patient records are shared between all providers of care and all providers collaborate and engage the patient to improve their health. Pharmacists should be able to order and view labs for all patients as part of normal care, not just because a clinical pharmacy agreement or protocol exists. At Prescryptive Health we are working to connect all providers with real time patient data to improve health outcomes. Restricting lab data for pharmacists is a barrier to integrated care models and will reduce patient safety.

Consider also that pharmacists and pharmacies can be a lower cost and more accessible site of care that can result in broader screening services. This can ultimately reduce the total cost of care and the burden on public and private payers.

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Sincerely,

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prescryptive
REWRITING THE SCRIPT

November 18, 2022

To: Oregon Board of Pharmacy

Re: Proposed rule 855-115-0125 defining Medication Therapy Management (MTM)

Prescryptive Health is supportive of the MTM definition with one exception: in section (2) we request that the word "must" be replaced with "may".

"A Pharmacist that provides MTM services must ensure that they are provided according to the individual needs of the patient and ~~must~~ may include but are not limited to the following:"

MTM can be simple or complex and as stated in the rule, "are provided according to the individual needs of the patient." It is rare that all of the listed components of MTM would be necessary for an individual patient's circumstances. Consider that companies like Prescryptive Health are building EMRs for pharmacists to document clinical services like MTM. If every state had rules for line items that must be included in every encounter, and they varied by clinical appointment type, then an efficient documentation tool that meets the individual needs of patients would be impossible to build in such a way to be affordable for pharmacists and literate to diverse patients. Increasing complexity can materially reduce the availability and affordability of important clinical services to patients who need them the most. To engage patients in valuable encounters with pharmacists, the encounters must be delightful, efficient, and easy for both patients and pharmacists. Rules which dictate what must be discussed or documented are a barrier to care and innovation.

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prescryptive
REWRITING THE SCRIPT

November 18, 2022

To: Oregon Board of Pharmacy

Re: Proposed rules 855-115-0130, 855-020-0110, and drug therapy management protocols

Prescryptive Health would like to see clarifying language added to drug therapy management protocols and related rules which allows pharmacists to utilize forms with materially similar content, either paper or electronic. It is unclear to us and our member pharmacies if this is allowed now. Prescryptive Health is developing an EHR with electronic patient intake surveys which documents data for pharmacists to use in their treatment care pathway. Grouping questions differently allows for a more streamlined user experience. Similarly, forms for provider notification or after visit summaries can also be electronically customized, based on the visit, which creates a more concise document individualized to the patient. Perhaps a section can be added to 855-115-0130 which states:

"Forms recommended or required in drug therapy management protocols may be altered or reproduced electronically with materially similar content which meets the requirements of the protocol."

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Sincerely,

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REWRITING THE SCRIPT

From: Marc Rizzo
To: PHARMACY RULEMAKING * BOP
Subject: CDTM possible changes
Date: Tuesday, November 15, 2022 8:28:24 AM

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern and provide feedback about the proposed changes to the Collaborative Drug Therapy Management (CDTM) rules. I am [name or organization name is] strongly opposed to removing all OARs that discuss CDTM and proposed OAR, 855-115-0120. It appears that the Board voted to send these proposed changes to rulemaking for feedback from the public; however, changes were not discussed in public comment during either the August or October Board of pharmacy meeting making thorough feedback difficult.

I urge you to use a rules advisory committee to provide feedback on the impact additional rules will have, but especially with the proposed rules for 855-115-0120. I feel there are consequences of removing CDTMs from rules and replacing them with a redefined clinical pharmacy agreement. One implication, though certainly not the least, is the ability of pharmacists to be reimbursed for and thus provide services to Medicaid recipients enrolled in Coordinated Care Organizations (CCOs). In addition, these rules impact pharmacists in all settings, not just community pharmacy. The intent of these rules is unclear, as they have not been discussed and it feels as though the intent is to limit our current scope of practice. Licensees have no idea what the intent of these rules are, because they have not been discussed, and therefore we are unclear if your intent is to limit our current scope of practice or to replace CDTM with something new.

The Oregon Medical Board does not have corresponding rules that recognize a CPA. When these draft rules go into effect, there will be no ability for pharmacists to have a way to collaboratively manage drug therapy. This will greatly affect many of the pharmacists currently working in a clinical environment and could cause patient harm. It may also disrupt care for many Oregonians without access to healthcare providers other than their pharmacist and further erode efforts made to address health equity for rural and minority populations in Oregon. Before passing these rules I [or “my organization”] urge you to press pause and let subject matter experts weigh in on what these rule changes will mean for the current practice of pharmacy, the evolution of pharmacy practice, and patient safety.

--
Marc David Rizzo, PharmD RPh
503-706-6333
He/Him

From: Alison Sigler
To: PHARMACY RULEMAKING * BOP
Subject: 11-22-22 rule making hearing written comments
Date: Monday, November 21, 2022 9:10:57 PM

November 22, 2022

Re: Written comment for Nov. Rulemaking Hearing “Divisions 019/020/031/041/115 related to Pharmacists” and “Divisions 001/102 related to Procedural & Universal Rules”

Dear Oregon Board of Pharmacy,

I am a clinical pharmacist in an ambulatory setting. I spent the past 5 years working at Rogue Community Health, a small FQHC in southern Oregon where I started clinical pharmacy services which include a CPA and CDTMs for a variety of chronic disease states. I am currently transitioning to another position at Lane County and am assisting with expansion of services, the views shared here are my own. In both of these FQHC settings there are many complex patients who benefit from clinical pharmacy services as they are currently delivered.

Currently the law allows flexibility for a clinical pharmacist with appropriate competencies including polices and procedures in place to work at the top of their scope. I am concerned about the rule changes presented today regarding eliminating CDTM definitions and I strongly oppose this change. Utilization of a CPA in conjunction with CDTMs as written are the crux of my clinical practice and the model this was adopted from works well. I urge you to keep the current rule as is for now and seek further assistance from those practicing in the setting for the best path forward if simplifying the law and/or an alternative solution is required.

Finally, I also oppose the proposed section “independent practice of pharmacy” as it is an unnecessary addition. Pharmacy practice is defined in the statute.

Thank you for your time.
Regards,
Alison Sigler, PharmD, BCPS, BCACP

From:	Katrina Ratzlaff
To:	PHARMACY RULEMAKING * BOP
Subject:	Comments for November 22 Board of Pharmacy Meeting
Date:	Monday, November 21, 2022 11:12:29 AM
Attachments:	11_22_22_OBOP_Wallace_Final.pdf

Good morning—

On behalf of Wallace, I'm pleased to attach comments in advance of the November 22 meeting of the Oregon Board of Pharmacy.

Questions may be directed to Stuart Currie, MD/Chief Medical Officer at stuartc@mywallace.org.

Thank you,

Katrina Ratzlaff
Director of Community Engagement
18633 SE Stark St. Suite 401 Portland, OR 97233
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www.mywallace.org
Pronouns: she/her/hers

November 21, 2022

Oregon Board of Pharmacy

RE: Proposed Draft Rule(s) 855-006-005(10), 855-115-0070 (3) (a)-(p), 855-115-0070(3)(m), 855-115-0115, 855-115-0120, 855-115-0125

President Murray, Vice President Doyle and members of the Oregon Board of Pharmacy:

Wallace (formally, Wallace Medical Concern) is a non-profit Federally Qualified Health Center based in East Multnomah County. We provide a comprehensive and welcoming health home to Portland area residents facing economic and social barriers to care. We care for over 5,000 people of all ages each year.

We offer a full-service health "home base" for low-income individuals and families with multi-cultural staff who partner fully with them to improve their well-being. Our whole person approach unites medical, dental, and behavioral health services with a focus on addressing economic and social needs that create health disparities. The State of Oregon has designated Wallace as a Tier 5 Patient-Centered Primary Care home, the highest level.

Health centers are highly regarded and trusted within their communities because they tailor their health care services and supporting programs including pharmacy operations to meet the unique needs of their patients. Rooted in the civil rights movement, health centers prioritize providing high quality, affordable, and accessible health care to anyone who walks through their doors.

Wallace applauds the Oregon Board of Pharmacy's efforts to streamline how clinical pharmacists can practice in primary care. Over the last 18 months clinical pharmacists have helped our health center stay connected to our patients, build new patient relationships, and expand the reach of the health center program all while improving outcomes and driving down the cost of care.

Health centers are located in medically underserved areas. Over 90% of Wallace patients live in poverty and face significant social determinants of health that create barriers to affordable health care services. Access to affordable healthy foods and extreme shortages of affordable, safe and adequate housing are just two of the most pressing issues. Health centers have proven highly effective at utilizing clinical pharmacist services in primary care to the most vulnerable and underserved communities. As clinical pharmacists gain more popularity, it's critical that health centers can continue to utilize this important provider type to meet the complex needs of the patients they serve.

The need for our organization to have both a collaborative drug therapy management (CDTM) and clinical pharmacy agreement (CPA) has been confusing but is presently an established practice. It is in this context where the unintended consequences of the proposed rule changes are causing fundamental and grave concerns for the sustainability of integrated clinical pharmacy services at Oregon's community health centers. Wallace appreciates the opportunity to provide comments on the proposed rules and has detailed them below:

A. 855-006-005(10) Definitions for OAR Chapter 855

Wallace strongly urges the Oregon Board of Pharmacy to keep the definition of Collaborative Drug Therapy Management (CDTM)

Health Centers are required to serve "medically underserved, or special medically underserved populations", which face barriers in accessing health care services. HRSA requires health centers to address these barriers and disparities among patients' health status and through the health center's operations – including pharmacy programs. Health centers rely on the ability to bill for pharmacy services to not only meet this requirement for their insured patients but also for those who do not have health insurance.

Transitioning the authorities of CDTMs into the CPA rules alone will not permit physicians to engage in collaborative drug therapy management unless the Oregon Medical Board changes their administrative rules. OAR 847-015-0040 presently prohibits physicians from engaging in management of drug therapy pursuant to a written protocol with pharmacists without a collaborative drug therapy management protocol. Oregon Medical Board rules presently mirror the existing Pharmacy Board CDTM rules and definitions. We suggest that the Board wait to make this change until the Oregon Medical Board updates their rules from CDTM to CPA.

B. 855-115-0070 (3) (a)-(p) Pharmacist General Responsibilities

Wallace urges the Oregon Board of Pharmacy to maintain a pharmacist's ability to practice to the fullest extent of their scope.

The new OAR which replaces 855-019-0200 (3) in general removes language which may limit the dynamic utilization of pharmacists in Oregon's community health centers. **Given ongoing health care workforce challenges, it's imperative the finalized OAR recognizes how pharmacists can be a solution to increasing capacity at health centers to meet the rising needs of underserved patients.**

Maintaining the existing scope of practice for Oregon pharmacists under 855-019-0200 (3) enables more patients to receive comprehensive and affordable care. Besides the workforce challenges that can adversely affect health center patients, they often experience challenges accessing health care services due to social determinants of health. **Health centers tailor**

their pharmacy services to meet the unique needs of their surrounding communities and address barriers to culturally competent and comprehensive primary health care services.

Wallace encourages the Board of Pharmacy to retain aspects of the existing OAR by adding back the following language to 855-115-0070 (3) “but are not limited to”

C. 855-115-0070(3)(m) Pharmacist: General Responsibilities and 855-115-0115 Services: Laboratory

Wallace is concerned that this change will remove the broad ability for pharmacists to order, interpret and monitor lab tests.

The proposed OARs essentially remove the long-established ability of a pharmacist to independently order and interpret laboratory tests and limits their scope of testing to pharmacy services expressly defined and permitted in ORS 689. This is a crucial component of how community health centers utilize clinical pharmacists as a member of the primary care team. In a time when providers and care teams are stretched to capacity and the pipeline for new providers to enter practice areas is long, we are concerned that this deviation away from nationally accepted scope of practice for pharmacists will mean patients experience extended wait times, fewer touch points with their care team, and ultimately poorer outcomes. This change will only serve to further exacerbate the existing health care workforce crisis by essentially adding additional workload onto exhausted providers.

D. 855-115-0120 Clinical Pharmacy Agreement

Wallace is concerned that draft OAR 855-115-0120 does not align with the legislative intent of HB 2028 (2015). The result of this deviation in the proposed draft rule would complicate rather than simplify administrative rule obligations for pharmacists.

Clinical pharmacy agreements are synonymous with a health care providers professional services agreement and are in common use in Oregon today with this purpose. It is a contract between a physician, naturopathic physician, or health care organization permitting a pharmacist or pharmacies to engage in the practice of pharmacy and provide patient care services. HB 2028 (2015) permits health insurers and the Oregon Health Authority to provide payment or reimbursement for services pursuant to a clinical pharmacy agreement or statewide drug therapy protocol.

Moreover, the additional requirements set forth in proposed **OAR 855-115-0120 (B)(C)** would make the administrative burden and actual ability to implement new CPA services or

transition existing CDTM agreements into CPAs overwhelming and unworkable for many community-based pharmacy programs.

The bill included statutory language specific to Coordinated Care Organizations contained within ORS 414.764 (2)(a)(b). “A coordinated care organization may reimburse a pharmacist or pharmacy for any health service: a) Provided to a medical assistance recipient who is enrolled in the coordinated care organization or prepaid managed care health service organization that enters into a clinical pharmacy agreement with the pharmacist or pharmacy; and b) That is within the lawful scope of practice of a pharmacist.”

Removing the OARs for Collaborative Drug Therapy Management and adding the language to Clinical Pharmacy Agreement implies that the CCO must create an agreement that contains all requirement in OAR 855-115-0120 including the types of decisions the pharmacist is allowed to make. These proposed rule changes in 855-115-0120 would require CCOs to create protocols that define the pharmacist(s) patient care process, referral process, standards of care, and decision criteria for conditions like diabetes for the purposes of reimbursement. It was never intended for CCOs to take on the role of defining pharmacist, pharmacies, or a clinic’s scope of work for the pharmacists under their employ or have health plan physician and pharmacist staff fill the role of principle physician or pharmacist. It is not feasible or appropriate to require CCO providers to take on this level of liability without a patient-provider relationship or physician-pharmacist relationship within their health care provider contracts. This may create a situation where clinical pharmacists may have two or more different clinical pharmacy agreements dictating how they manage chronic conditions such as diabetes.

E. 855-115-0125 Medication Therapy Management (MTM)

Wallace seeks clarity around changes to Medication Therapy Management practices. New language directs pharmacists to fulfill certain requirements when performing MTM. The change from “may” to “must” in the draft OAR potentially creates a requirement that certain actions be taken during every encounter. **This shift implies MTM must include all the listed elements at every encounter for a pharmacist to be in compliance.** However, in practice all of these elements are not performed in a single visit for various reasons. We worry about additional administrative burden on providers who are already at the breaking point..

Wallace encourages the Board to amend the proposed OAR back to the original language or to offer additional clarity to guide pharmacists in successful implementation as we do not believe it was the Board’s intention to layer on additional administrative burden in cases such as this.

Wallace thanks the Oregon Board of Pharmacy for the opportunity to comment on draft rule changes and urge the Board to consider the broader practice and policy implications of moving forward without additional public engagement. Health Center pharmacy programs have proven successful in expanding access to care and improving health outcomes for the most vulnerable patients.

We look forward to answering any questions you might have; please don't hesitate to contact Stuart Currie, M.D., Chief Medical Officer at stuartc@mywallace.org.

From:	Walmsley, Lorri
To:	PHARMACY RULEMAKING * BOP
Cc:	SCHNABEL Joseph * BOP
Subject:	Walgreens Comments
Date:	Tuesday, November 22, 2022 9:38:41 AM
Attachments:	OR Comment Letter_Proposed Public Comment Rules not for adoption.pdf OR Comment Letter_Proposed Rules November 2022.pdf

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Hello Joe,

Please accept the attached documents on behalf of Walgreens for your proposed rules.

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs

Walgreen Co.
Telephone 602-214-6618

Member of Walgreens Boots Alliance ¦ MyWalgreens.com

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November 15, 2022

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

Via Email: joseph.schnabel@oregon.gov

RE: Divisions 001/102, 025/125, and 019/020/031/041/115

Dear Dr. Schnabel and Board Members,

On behalf of all pharmacies owned and operated by Walgreen Co., we thank the Board for the opportunity to comment on the proposed rules regarding Procedural & Universal Rules relating to pharmacy technicians and related to pharmacists. We also commend the Board for this thoughtful approach to receiving public feedback and comments before proposing regulations and publishing them for comment before adoption. The interactive process of engaging with the public is critical in the rulemaking process to ensure there are no unintended consequences for the public.

Walgreens respectfully requests the amendment as indicated below to 855-102-0040. While Walgreens and its team members will make every effort to comply with a Compliance Officer's request, we believe that our team members and our patients also have rights to be considered. Licensees should be able to consult with legal counsel before providing written or verbal statements at the time of inspection. Additionally, the recording of audio may unintentionally contain HIPAA-protected information that does not pertain to the investigation/inspection and may compromise patient confidentiality.

855-102-0040
Inspections
(1) A Compliance Officer is a board authorized representative and must be permitted entry to any drug outlet to conduct inspections at all reasonable hours.
(2) The Compliance Officer is authorized and must be permitted to perform the following to determine compliance with ORS 475, ORS 689, and OAR 855 and board orders including but not limited to:
(a) Inspecting conditions, structures, equipment, materials, and methods for compliance;
(b) Inspecting all drugs and devices;
(c) Taking photographs, ~~recording video and audio~~; and
(d) Reviewing, verifying and making copies of records and documents.
(3) All licensees and employees must fully comply and cooperate with all questions and requests made by the Compliance Officer ~~at the time of inspection.~~

Regarding the proposed changes related to pharmacy technicians, we respectfully request the two minor amendments as indicated below to 855-125-0001(2) and to 855-12-0070(3)(k.) As addressed in our comment letter regarding definitions it is important to consider that technicians that are licensed in other jurisdictions and that work in Oregon non-resident licensed outlets should not be required to hold an Oregon Pharmacy Technician or Certified Oregon Pharmacy Technician License. The requirement for these individuals working out of state on behalf of a non-resident outlet is not practical.

It may reduce access to care for Oregonians and increase the workload for in-state Oregon Outlets. Additionally, adding the word deliver under 855-125-0070(3)(k) could have significant operational impacts on outlets and patient access. We interpret as proposed that to sell a completed prescription to a patient or deliver a prescription; it would require this person to be a licensed Pharmacy Technician or Certified Oregon Pharmacy Technician, effectively eliminating the ability to use unlicensed cashiers or delivery drivers. According to the AACP Pharmacy Demand Report, there has been a 45.6% increase in the postings for Pharmacy Technicians in 2021 compared to 2022.[1] Any restrictions in the ability to utilize non-licensed personnel for simple tasks may further exacerbate staffing challenges in the state. This change would also not be consistent with recent activities of the Board to ease the process of bringing additional support staffing into the pharmacy, as evidenced by the Board's recent adoption of Divisions 021/025/110 in April 2022.

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

855-125-0070
(1) A Certified Oregon Pharmacy Technician and Pharmacy Technician must:
(j) Review and adhere to drug outlet written policies and procedures. The review must:
(A) Occur upon employment and with each update; and
~~(B) Be documented and records retained by the outlet;~~
(k) Dispense ~~and deliver~~ prescriptions accurately and to the correct party; and

Regarding the proposed rules regarding pharmacists, we have many items that we would like the Board to consider. We believe non-resident outlets must retain non-Oregon licensed pharmacists' ability to provide a patient's consultation. Allowing a non-Oregon licensed pharmacist to provide this service serves three purposes; first, to decrease workload for in-state pharmacies, second to allow for pharmacists with special disease-state specific training and expertise that may not be Oregon-licensed to provide specialized consultation for patients; and third, to allow for Pharmacists located in non-resident outlets that provide prescriptions via home delivery to have the flexibility to enable consultation for patients by any pharmacist that may be available to provide the service. We respectfully request the amendment to 855-115-0001(3) as indicated below.

855-115-0001
Applicability
(3) A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a pharmacist located in another state who is working for an out-of-state pharmacy, who only performs the professional tasks of interpretation, consultation, evaluation, DUR, and verification associated with the out-of-state pharmacy dispensing of a drug into Oregon, is not required to be licensed by the Board.

While the outlet has some responsibility for actions that occur within a pharmacy, specific activities may occur by a pharmacist, for example, a prescription filling error or the failure to counsel by a pharmacist that the outlet may have no control over. Additionally, from a regulatory construction standpoint, this section addresses the responsibilities of a pharmacist not an outlet. The board should not add additional requirements for outlets in this manner. We respectfully request the amendments outlined below to 855-115-0070(1),(2).

855-115-0070
Pharmacist: General Responsibilities
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 a careful and prudent Pharmacist in the same or similar circumstances.
(1) Each Pharmacist is responsible for their own actions; ~~however, this does not absolve the drug outlet from responsibility for the Pharmacist's actions~~.
(2) Each Pharmacist ~~and each drug outlet are~~ is responsible for the actions of each Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician and non-licensed pharmacy personnel.
(4)
(n) Review, adhere to, and enforce the drug outlet written policies and procedures. The review must:
(A) Occur upon employment and with each update; and
~~(B) Be documented and records retained by the outlet; and~~

The proposed changes as outlined in 855-115-0074(1)(b)(C) and 855-115-0074(1)(c)(A) may result in frivolous complaints to state agencies with no proof of acutal violations resulting in additional administrative costs for the state and for license and permit holders.

855-115-0074
Responsibilities: Duty to Report
(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each Pharmacist must report to the board without undue delay, but within:
(a) 1 business day:
(A) Confirmed significant drug loss; or
(B) Any loss related to suspected drug theft of a controlled substance.
(b) 10 days if they:¶ (A) Are convicted of a misdemeanor or a felony;
(B) Are arrested for a felony; or
~~(C) Have reasonable cause to believe that any suspected violation of ORS 475, ORS 689 or OAR 855 has occurred.~~
(c) 10 working days if they:
~~(A) Have reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct to that licensee's board; or~~

Pharmacists are highly educated professionals with doctoral-level education; it would be impossible for an outlet to provide training on every aspect of pharmacists' daily tasks. This proposed requirement in 855-115-0076 is overly burdensome for outlets and unnecessary.

~~855-115-0076~~
~~Responsibilities: Training~~
~~(1) Pharmacists must complete:~~
~~(a) Initial training that includes on-the-job and related education that is commensurate with the tasks that the Pharmacist will perform prior to the performance of those tasks; and~~
~~(b) Ongoing training to ensure continued competency in tasks that are performed.~~
~~(2) The outlet must retain records of training in (1).~~

As Oregon contemplates workload demands for pharmacists, it is not imperative for patient safety to require a pharmacist to complete a manual DUR on a refilled prescription. Machine-automated DUR is a standard of care for all pharmacies to identify drug utilization concerns, which prompts pharmacists when there is a specific concern that may require their attention. We respectfully ask the Board to consider amending the DUR requirement in 855-115-0082 to require a manual DUR upon dispensing a new prescription only.

Walgreens

855-115-0082
Drug Utilization Review (DUR)
(1) A Pharmacist must complete a drug utilization review (DUR) by reviewing the patient record prior to dispensing each new prescription drug or device for the purpose of identifying the following:

The proposed requirement in 855-115-0084(4) to prohibit a pharmacist from releasing a new prescription to a patient is not practical for outlets that provide home delivery. Many patients do not answer their phones, and this requirement could lead to delays in patient care if the pharmacy cannot reach the patient. We respectfully ask that this provision be removed.

855-115-0084
Counseling
(1) The Pharmacist must counsel the patient or patient's agent on the use of a drug or device:
(a) Upon request;
(b) When the drug or device has not been previously dispensed to the patient by the pharmacy;
(c) When there has been a change in the dose, formulation, or directions; or
(d) For any refill that the Pharmacist deems counseling is necessary.
(2) A Pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused:
(a) Only the Pharmacist can accept a patient's or patient's agent's request not to be counseled, when counseling is required;
(b) The Pharmacist may choose not to release the prescription until counseling has been completed;
(3) The Pharmacist that provides counseling or accepts the request not to be counseled must document their identity and the provision or declination of counseling at the time of the interaction;
~~(4) A Pharmacist must not allow a prescription to be released from the drug outlet when counseling is required, prior to the counseling or acceptance of the request not to be counseled by a Pharmacist;~~
(5) For each prescription, the Pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.
(6) When communicating (e.g. counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the Pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the Pharmacist is proficient in the patient's preferred language.
(7) Counseling on a new prescription may include, but is not limited to, the following elements:
(a) Name and description of the drug;
(b) Dosage form, dose, route of administration, and duration of drug therapy;
(c) Intended use of the drug and expected action;
(d) Special directions and precautions for preparation, administration, and use by the patient;
(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(f) Techniques for adherence and self-monitoring drug therapy;
(g) Proper storage and appropriate disposal method(s) of unwanted or unused medication;
(h) Refill information;
(i) Action to be taken in the event of a missed dose; and
(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.
(8) Counseling on a refill prescription may include, but is not limited to, the following elements:
(a) Name and purpose of the medication;
(b) Directions for use, including technique;
(c) Perceived side effects; and

(d) Adherence.
(9) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.
(10) A Pharmacist must initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

Oregon has experienced significant challenges throughout the pandemic with pharmacist staffing, evidenced by the AACP Pharmacy Workforce Demand Report showing that there has been an increase in the postings per Pharmacist of 119.7% for 2021 compared to 2020[1]. While the preference to hire a PIC with experience is preferred by all employers, that may not be the reality of the employment market. As proposed today, the minimum requirement of 2000 hours of experience as a pharmacist will create significant barriers for many outlets to remain open and may create additional pharmacy deserts in the state. The additional requirements as proposed in 855-115-0086(2)(k)(l)(m)(q) create further requirements above what is required today and will increase the administrative workload for PICs and may further deter individuals from wanting to take on the responsibility to be a PIC. Any additional requirements that may further limit the desire for pharmacists to become a PIC should be carefully considered, as it may restrict patient access if outlets cannot find a suitable PIC.

855-115-0086
Pharmacist-in-Charge: Qualifications, Limitations, and Duties
(1) In order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:
(a) Complete at least 2000 hours of pharmacy practice as a Pharmacist within the last 2 years in a US state or jurisdiction or;
(b) Complete a board provided PIC training course either before the appointment or within 90 days after the appointment ~~and every 5 years thereafter effective July 1, 2025~~;
(c) Be employed by the outlet; and
(d) Be actively engaged in pharmacy activities at the drug outlet and be physically present at the drug outlet for a sufficient amount of time as needed to effectively supervise drug outlet activities, be responsible for the ~~daily~~ operation of the drug outlet and ensure drug outlet compliance.
(2) A Pharmacist must not be designated PIC of more than three pharmacies. The following drug outlet types do not count towards this limit:
(a) Pharmacy Prescription Kiosk in OAR 855-141;
(b) Pharmacy Prescription Locker in OAR 855-143.
(3) The PIC must perform all of the following:
(a) Notify the Board of becoming the PIC within 15 days of the occurrence, on a form provided by the Board;
(b) Be responsible for the ~~daily~~ conduct, operation, management and control of the drug outlet;
(c) Establish, maintain, and enforce written policies and procedures governing the practice ~~of~~ pharmacy in coordination with the outlet;
(d) Ensure maintenance of accurate records governing the practice of pharmacy in coordination with the outlet;
(e) Ensure compliance with all federal and state laws and rules governing the practice of pharmacy;
(f) Assess and approve personnel who may access the areas where drugs and records are stored;
(g) Ensure personnel with access to the areas where drugs and records are stored are trained and records retained;
(h) Ensure personnel that require licensure have been granted and maintain licensure with the Board;
(i) Ensure licensed personnel work within the duties permitted by their licensure;
(j) Ensure non-licensed personnel only perform work that does not require licensure;
~~(k) Ensure the pharmacy is operated in a professional manner at all times;~~
~~(l) Ensure adequate staffing to provide safe and timely patient care based on workload volume and services provided in coordination with the drug outlet;~~

(m) ~~Ensure the drug outlet contains the reference material and equipment needed;~~
(n) Enforce a continuous quality improvement program for dispensing services;
(o) Submit a plan of correction for observations noted on an inspection within the time allowed by the Board;
(p) Complete an inspection on the PIC Annual Self-Inspection Form by July 1 each year and within 15 days of becoming PIC. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;
(q) Complete and document a controlled substance inventory with discrepancy reconciliation as follows:
(A) Within 15 days of a change in PIC, an inventory of all controlled drugs as required by OAR 855-080;
(B) Annually (within 367 days) for all controlled drugs as required by OAR 855-080;
~~(C) Monthly (within 31 days) for Schedule II controlled drugs.~~
(r) Ensure the drug outlet reports data as required by the Oregon Health Authority for PDMP, ALERT, Death with Dignity and communicable diseases.
(s) Ensure the drug outlet delivers prescriptions accurately;
(t) Notify the Board of ceasing to be the PIC within 15 days of the occurrence, on a form provided by the Board.

The new proposed section on the Independent Practice of Pharmacy is very confusing, especially when coupled with the new definition as proposed. This new definition and section seem intended to regulate the pharmacy practice outside a licensed outlet. To provide clarity, we respectfully suggest the amendments below.

855-115-0100
Services: Independent Practice of Pharmacy
(1) A Pharmacist engaged in the independent practice of pharmacy must:
(a) Be responsible for the daily conduct, operation, management and control of their practice;
(b) Ensure compliance with all federal and state laws and rules governing the practice of pharmacy;
(c) Document services provided and maintain a record of such services including the date, time and identification of the licensee and the specific activity or function.
(d) Ensure the Pharmacist and personnel have access to reference material and equipment needed based on the services provided;
(e) Ensure services are provided with required interpretation and translation per ORS 689.564;
(f) Ensure services occur in a sanitary, secure and confidential environment;
~~(g) Ensure all computer equipment used for the independent practice of pharmacy:~~
(A) Establishes and maintains a secure connection to patient information including but not limited to patient demographics, medical records, pharmacy records and clinical visit documentation;
(B) Prevents unauthorized access to patient information; and
(C) Is configured so information from any patient records are not duplicated, downloaded, or removed from the electronic database when an electronic database is accessed remotely;
(h) Ensure patient records are stored at a health care organization, practitioner, pharmacy, or pharmacist office and must be maintained in a secure manner that ensures only those authorized have access to such records; and
~~(i) Register as a drug outlet if involved in the dispensing, distribution or delivery of drugs.~~
~~(2) A Pharmacist who personally possesses or stores drugs or devices when acting in the usual course of business and within their scope of practice, must comply with (1) and the following:~~
~~(a) Be responsible for drugs and devices in their possession;~~
~~(b) Only receive drugs from an Oregon Registered Drug Outlet (e.g. Wholesaler, Manufacturer or Pharmacy);~~
~~(c) Restrict access to such drugs and devices;~~
~~(d) Ensure security including provisions for adequate safeguards against loss, theft or diversion of such drugs and devices;~~
~~(e) Comply with the drug storage rules for pharmacies in OAR 855-041-1036.~~
~~(f) Ensure drugs and devices that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or identified as suspect or illegitimate, or otherwise unfit for dispensing must~~

be documented, quarantined and physically separated from other drugs and devices until they are destroyed or returned to the supplier.
(g) Maintain records pertaining to the acquisition, storage, administration, and disposal of such drugs and devices.
(3) A Pharmacist who utilizes an Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician, must comply with (1) and the following:
(a) Only utilize Interns when under the Pharmacist's supervision;
(b) Only utilize Certified Oregon Pharmacy Technicians and Pharmacy Technicians when under the Pharmacist's supervision, direction and control; and
(c) Ensure licensed personnel work within the duties permitted by their licensure;
(4) A Pharmacist who utilizes licensees remotely, must comply with (1), (3) and the following:
(a) Utilize a fully operational audiovisual communication system and have appropriate technology or interface to allow access to information required to complete assigned duties;
(b) Ensure telephone audio is recorded and stored for all patient interactions completed by Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians;
(c) Supervise each Intern and supervise, direct and control each Certified Oregon Pharmacy Technician, and Pharmacy Technician via an audiovisual communication system;
(d) Use reasonable professional judgment to determine the frequency of "check-ins" for each non-Pharmacist personnel being supervised via the audiovisual communication system with a minimum of at least once per work shift to ensure patient safety, compliance with federal and state laws, and documents the interaction;
(e) Be readily available to answer questions and fully responsible for the conduct and accuracy of the licensees;

and
(f) Ensure each Intern knows the identity of the Pharmacist who is providing supervision at all times.
(g) Ensure each Certified Oregon Pharmacy Technician and Pharmacy Technician knows the identity of the Pharmacist who is providing supervision, direction, and control at all times.
(h) Use reasonable professional judgment to determine the percentage of patient interactions for each licensee that must be observed or reviewed to ensure public health and safety with a minimum of 5% of patient interactions observed or reviewed;
(i) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a Pharmacist upon request;
(j) Document the following within 24 hours of the observation or review in (i):
(A) Number of each licensee's patient interactions;
(B) Number of each licensee's patient interactions Pharmacist has observed or reviewed;
(C) Date and time of licensee patient interaction Pharmacist has observed or reviewed;
(D) Date and time of Pharmacist observation or review of licensee's patient interaction; and
(E) Pharmacist notes of each interaction observed or reviewed; and
(k) Reports any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of discovery and to the Board within 10 days.
(5) All documentation and records required by this rule must be retained and made available to the Board per 855- 102-0050.

As Oregon contemplates the workload and burnout of pharmacists, the ability for pharmacies to schedule services is an important way to manage workflow and limit the amount of work to be performed by team members. If a pharmacist or an outlet wishes only to offer certain services by an appointment model and take walk-ins by exception, that should be a business practice that is allowed. In addition, pharmacies may decide not to offer this service if they are mandated to accept walk-in appointment are unable to accommodate the walk-in model. We respectfully request that the Board consider striking 855-115-0135(3).

855-115-0135
Prescribing: Prohibited Practices
(1) A Pharmacist must not prescribe a vaccine, drug, or device:
(a) 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; and
(b) When the Formulary or Protocol Compendia requires referral to non-Pharmacist provider.
(2) An Intern must not prescribe a vaccine, 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.~~

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,

Lori Walmsley

Lorri Walmsley, RPh, FAzPA

References:

1. AACP Pharmacy Work Force Demand Report, 2021 Full Report (Q1, Q2, Q3, Q4.) Accessed November 15, 2022

Lorri Walmsley, RPh., FAzPA
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November 15, 2022

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

Via Email: joseph.schnabel@oregon.gov

RE: Divisions 019/141, Divisions 006/019/031

Dear Dr. Schnabel and Board Members,

On behalf of all pharmacies owned and operated by Walgreen Co., we thank the Board for the opportunity to comment on the proposed rules regarding Pharmacy Prescription Kiosks and rules related to Definitions.

As proposed in the regulations related to Pharmacy Prescription Kiosks there is a subtle change that is not identified as a redline in 855-019-0300(1) regarding the duties of a pharmacist-in-charge. There may be times when a PIC is employed but not "present" in a pharmacy, for example, on vacations or leaves of absence. This would allow no flexibility for pharmacies in this instance to continue to operate. We respectfully ask that the Board retain the current requirement as indicated below.

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 employed ~~present in the pharmacy~~ on a regular basis.

As proposed in the regulations related to Pharmacy Prescription Kiosks, the proposed amendment under the PIC duties and responsibilities may not allow sufficient time for the PIC to respond. Having defined timeframes in the regulation creates standards by which the Board operates to create consistency for licensees among various inspectors and other board staff. We respectfully request that the Board retain the current requirement in 855-019-0300(4)(f)(A),(B), allowing a PIC 15 days to respond after receiving a deficiency notice or within 30 days of receiving a non-compliance notice.

(4) The PIC must perform the following the duties and responsibilities:
f. If a discrepancy is noted on a board inspection the PIC must submit a plan of correction within:
(A) ~~15 days of receiving a deficiency notice;~~ or
(B) ~~30 days of receiving a non-compliance notice~~ the time allowed by the Board.

Walgreens

Within the noticed changes for definitions, Walgreens has several concerns that we believe may have unintentional consequences of limiting patient access and increasing workload within Oregon-licensed pharmacies. Adding the word interactive to 855-006-0005(10) ~~it~~ creates a potential burden for patients who choose to receive medications via home delivery methods. All pharmacies that offer home delivery offer some type of verbal communication and counseling for patients., requiring counseling to be completed interactively may delay care since it is not uncommon for patients not to answer their phones. Many patients in pharmacy deserts or with transportation challenges rely on home delivery as the primary way to receive pharmaceuticals. Another significant concern that will impact several aspects of pharmacy is the addition of the definition of "pharmacist." As currently defined in your proposed rule 855-006-0005(39), we believe that the intent would be to require that any pharmacist performing work in Oregon and from a non-resident pharmacy into Oregon for an Oregon patient would need to be Oregon-licensed. The result of this new interpretation would create a tremendous administrative burden on Board staff to register thousands of pharmacists and any delay in processing of these applications could negatively impact a non-resident outlets' ability to provide timely care for patients. This change would have significant impacts on all types of non-resident pharmacies and would also impact in-state Oregon-licensed pharmacies that receive services from a non-resident pharmacy whereby potentially increasing the workload for in-State Pharmacies. For example, many large organizations use shared services to decrease workloads for in-state pharmacies by having pharmacists at a non-resident pharmacy complete the data review portion of the prescription or alleviate some phone calls from the pharmacy. It is impractical for pharmacies licensed in all 50 states to require the pharmacists in those locations to hold licenses in all 50 states. The pharmacists in these Oregon-licensed non-resident facilities have the same educational requirements as those of Oregon-licensed pharmacists and maintain a license in the state where they are physically located. Adding the definition is unnecessary to improve patient safety and will create additional burdens for non-resident pharmacies, which may limit Oregon patients' access. Oregon has experienced significant challenges throughout the pandemic with pharmacist staffing, evidenced by the AACP Pharmacy Workforce Demand Report showing that there has been an increase in the postings per Pharmacist of 119.7% for 2021 compared to 2020[1]. Any potential changes to regulations that may reduce the number of pharmacists that may be able to assist patients in Oregon should be carefully considered. We respectfully request the amendments indicated below to address these concerns.

~~(10)~~ "Counseling" or "Counsel" means ~~an interactive~~ communication between a Pharmacist and a patient or a patient's agent in which the Pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

(39) "Pharmacist" means an individual licensed by this state ~~or individual licensed by the state in which they practice engaging to engage~~ in the practice of pharmacy or to engage in the practice of clinical pharmacy.

Walgreens also requests the changes to the definitions below to contemporize your current definitions. Currently, some activities may occur within a drug outlet that might be considered "independent practice of pharmacy," for example, MTM services. Many pharmacy practices may not dispense drugs; they may perform other pharmaceutical care services (i.e., MTM or up-front verification); these outlets would not need the same level of security, nor would they require the same equipment to perform the work. The suggested amendment below would define a pharmacy as an area where drugs or devices are dispensed, leaving more flexibility for other novel pharmacy practice environments. The definition of Independent Practice of Pharmacy is not in-line with the Board's attempt to regulate practice outside of a licensed outlet.

(~~2~~15) "Independent Practice of Pharmacy" means the provision ~~of clinical~~ pharmacy services ~~not related to the dispensing, distribution and delivery of drugs or devices~~ outside of a pharmacy outlet.

(~~3~~40) “Pharmac~~eutical Ca~~y Area” means ~~the responsible provis~~each ~~each~~ each area where prescription drugs ~~of~~ drug ~~therapy for the purpose of achieving definite outcomes that improve a patient's qualify of life. These outcomes include:~~
~~(a) Cure of a disease:~~
~~(b) Elimination or reduction of a patient's symptomatology;~~
~~(c) Arrest or solving of a disease process: or~~
~~(d) Prevention of a disease or symtomatology~~s or devices~~, records, and equipments used to access pharmacy records~~ are located and dispensed.

Walgreens also suggests the minor amendment as indicated below to allow for alternative forms of product verification, including video and image verification of a product consistent with many forms of technology that exist today to improve efficiency and increase patient safety.

(21~~8~~) "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.

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

References:

1. AACP Pharmacy Work Force Demand Report, 2021 Full Report (Q1, Q2, Q3, Q4.) Accessed November 15, 2022

From:	Nic Powers
To:	PHARMACY RULEMAKING * BOP
Cc:	Mike Farley
Subject:	OR Board of Pharmacy Rulemaking
Date:	Monday, November 21, 2022 5:54:53 PM
Attachments:	image.png WWC OBOP Rule Comment Nov 2022.pdf

Oregon Board of Pharmacy

RE: Proposed Draft Rule(s) 855-006-005(10), 855-115-0070 (3) (a)-(p), 855-115-0070(3)(m), 855-115-0115, 855-115-0120, 855-115-0125

Please see the attached written comments for the proposed draft rules. We would be happy to follow-up with any additional information that would be helpful.

Thank you,

Nic

Nicolas Powers, MBA, FACHE
Chief Executive Officer
Winding Waters
a non-profit community health center

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November 21, 2022

Oregon Board of Pharmacy

RE: Proposed Draft Rule(s) 855-006-005(10), 855-115-0070 (3) (a)-(p), 855-115-0070(3)(m), 855-115-0115, 855-115-0120, 855-115-0125

President Murray, Vice President Doyle and members of the Oregon Board of Pharmacy:

Winding Waters Community Health Center is located in the frontier medical setting of Wallowa County serving about 5,000 of the 7,000 patients living in the county. Our mission is simply "The Best Health For All". We have assembled a team of 9 MD's, 3 PA's, 3 RN's, 3 DMD's, 4 Behavioral Health Councilors, a Clinical Pharmacist, & 2 Community Health Workers all who band together to provide care for our patients in an effort to maximize health outcomes.

Health centers are highly regarded and trusted within their communities because they tailor their health care services and supporting programs including pharmacy operations to meet the unique needs of their patients wherever the patients are in the course of their healthcare journey. Rooted in the civil rights movement, health centers prioritize providing high quality, affordable, and accessible health care to anyone who walks through their doors.

Winding Waters wants to applaud the Oregon Board of Pharmacy's efforts to streamline how clinical pharmacists can practice in primary care. Over the last six years clinical pharmacists have helped our health center stay connected to our patients, build new patient relationships, and expand the reach of the health center program all while improving outcomes and driving down the cost of care.

Health centers are located in medically underserved areas, where 40% of our patients live in poverty and face significant social determinants of health that create barriers to affordable health care services. Given the size of Wallowa County and the remote nature of our geography, many patients have difficulty finding transportation to get to Clinic for care. Our efforts to improve care through home visits and telemedicine with a patient's Primary Care Physician facilitated by our nurses and pharmacist is an example of how we have adjusted to deliver care during and since the pandemic has eased. By virtue of this and other pharmacist co-visits we have innovated in ways that have helped us meet and exceed CCO outcome measures and improved the health status of high-risk patients. Health centers have proven highly effective at utilizing clinical pharmacist services in primary care to the most vulnerable and underserved communities. As clinical pharmacists gain more popularity, it's critical that health centers can continue to utilize this important provider type to meet the complex needs of the patients they serve.

The need for our organization to have both a collaborative drug therapy management (CDTM) and clinical pharmacy agreement (CPA) has been confusing but is presently an established

practice. It is in this context where the unintended consequences of the proposed rule changes are causing fundamental and grave concerns for the sustainability of integrated clinical pharmacy services at Oregon's community health centers. Winding Waters appreciates the opportunity to provide comments on the proposed rules and has detailed them below:

A. 855-006-005(10) Definitions for OAR Chapter 855

Winding Waters Community Health Center strongly urges the Oregon Board of Pharmacy to keep the definition of Collaborative Drug Therapy Management (CDTM)

Health Centers are required to serve "medically underserved, or special medically underserved populations", which face barriers in accessing health care services. HRSA requires health centers to address these barriers and disparities among patients' health status and through the health center's operations – including pharmacy programs. Health centers rely on the ability to bill for pharmacy services to not only meet this requirement for their insured patients but also for those who do not have health insurance.

Transitioning the authorities of CDTMs into the CPA rules alone will not permit physicians to engage in collaborative drug therapy management unless the Oregon Medical Board changes their administrative rules. OAR 847-015-0040 presently prohibits physicians from engaging in management of drug therapy pursuant to a written protocol with pharmacists without a collaborative drug therapy management protocol. Oregon Medical Board rules presently mirror the existing Pharmacy Board CDTM rules and definitions. We suggest that the Board wait to make this change until the Oregon Medical Board updates their rules from CDTM to CPA.

B. 855-115-0070 (3) (a)-(p) Pharmacist General Responsibilities

Winding Waters Community Health Center urges the Oregon Board of Pharmacy to maintain a pharmacist's ability to practice at the fullest extent of their scope.

The new OAR which replaces 855-019-0200 (3) in general removes language which may limit the dynamic utilization of pharmacists in Oregon's community health centers. **Given ongoing health care workforce challenges, it's imperative the finalized OAR recognizes how pharmacists can be a solution to increasing capacity at health centers to meet the rising needs of underserved patients.** Our Clinical Pharmacist has become a necessary asset working alongside our Primary Care Physicians to monitor and adjust medications to address chronic care conditions to achieve optimal outcomes at the lowest cost possible. It has increased our ability to innovate and be flexible to changing needs of patients particularly during the time of the pandemic. Should the current scope of their practice change this would severely impact our ability to meet patient demand and follow up for many would slip through the cracks.

Maintaining the existing scope of practice for Oregon pharmacists under 855-019-0200 (3) enables more patients to receive comprehensive and affordable care. Besides the workforce challenges that can adversely affect health center patients, they often experience challenges accessing health care services due to social determinants of health. **Health centers tailor their pharmacy services to meet the unique needs of their surrounding communities and address barriers to culturally competent and comprehensive primary health care services.**

Winding Waters Community Health Center encourages the Board of Pharmacy to retain aspects of the existing OAR by adding back the following language to 855-115-0070 (3) “but are not limited to”

C. 855-115-0070(3)(m) Pharmacist: General Responsibilities and 855-115-0115 Services: Laboratory

Winding Waters Community Health Center is concerned that this change will remove the broad ability for pharmacists to order, interpret and monitor lab tests.

The proposed OARs essentially remove the long-established ability of a pharmacist to independently order and interpret laboratory tests and limits their scope of testing to pharmacy services expressly defined and permitted in ORS 689. This is a crucial component of how community health centers utilize clinical pharmacists as a member of the primary care team. In a time when providers and care teams are stretched to capacity and the pipeline for new providers to enter practice areas is long, we are concerned that this deviation away from nationally accepted scope of practice for pharmacists will mean patients experience extended wait times, fewer touch points with their care team, and ultimately poorer outcomes. This change will only serve to further exacerbate the existing health care workforce crisis by essentially adding additional workload onto exhausted providers.

D. 855-115-0120 Clinical Pharmacy Agreement

Winding Waters Community Health Center is concerned that draft OAR 855-115-0120 does not align with the legislative intent of HB 2028 (2015). The result of this deviation in the proposed draft rule would complicate rather than simplify administrative rule obligations for pharmacists.

Clinical pharmacy agreements are synonymous with a health care providers professional services agreement and are in common use in Oregon today with this purpose. It is a contract between a physician, naturopathic physician, or health care organization permitting a pharmacist

or pharmacies to engage in the practice of pharmacy and provide patient care services. HB 2028 (2015) permits health insurers and the Oregon Health Authority to provide payment or reimbursement for services pursuant to a clinical pharmacy agreement or statewide drug therapy protocol.

Moreover, the additional requirements set forth in proposed **OAR 855-115-0120 (B)(C)** would make the administrative burden and actual ability to implement new CPA services or transition existing CDTM agreements into CPAs overwhelming and unworkable for many community-based pharmacy programs.

The bill included statutory language specific to Coordinated Care Organizations contained within ORS 414.764 (2)(a)(b). “A coordinated care organization may reimburse a pharmacist or pharmacy for any health service: a) Provided to a medical assistance recipient who is enrolled in the coordinated care organization or prepaid managed care health service organization that enters into a clinical pharmacy agreement with the pharmacist or pharmacy; and b) That is within the lawful scope of practice of a pharmacist.”

Removing the OARs for Collaborative Drug Therapy Management and adding the language to Clinical Pharmacy Agreement implies that the CCO must create an agreement that contains all requirement in OAR 855-115-0120 including the types of decisions the pharmacist is allowed to make. These proposed rule changes in 855-115-0120 would require CCOs to create protocols that define the pharmacist(s) patient care process, referral process, standards of care, and decision criteria for conditions like diabetes for the purposes of reimbursement. It was never intended for CCOs to take on the role of defining pharmacist, pharmacies, or a clinic’s scope of work for the pharmacists under their employ or have health plan physician and pharmacist staff fill the role of principle physician or pharmacist. It is not feasible or appropriate to require CCO providers to take on this level of liability without a patient-provider relationship or physician-pharmacist relationship within their health care provider contracts. This may create a situation where clinical pharmacists may have two or more different clinical pharmacy agreements dictating how they manage chronic conditions such as diabetes.

E. 855-115-0125 Medication Therapy Management (MTM)

Winding Waters Community Health Center seeks clarity around changes to Medication Therapy Management practices. New language directs pharmacists to fulfill certain requirements when performing MTM. The change from “may” to “must” in the draft OAR potentially creates a requirement that certain actions be taken during every encounter. **This shift implies MTM must include all the listed elements at every encounter for a pharmacist to be in compliance.** However, in practice all of these elements are not performed in a single visit for various reasons.

We worry about additional administrative burden on providers who are already at the breaking point.

Winding Waters Community Health Center encourages the Board to amend the proposed OAR back to the original language or to offer additional clarity to guide pharmacists in successful implementation, as we do not believe it was the Board's intention to layer on additional administrative burden in cases such as this.

Winding Waters Community Health Center thanks the Oregon Board of Pharmacy for the opportunity to comment on draft rule changes and urge the Board to consider the broader practice and policy implications of moving forward without additional public engagement. Health Center pharmacy programs have proven successful in expanding access to care and improving health outcomes for the most vulnerable patients. Our patients have become accustomed to our clinical pharmacist's involvement and would suffer if the proposed changes are instituted. We look forward to answering any questions you might have.

Nicolas Powers, MBA, FACHE, CEO
nic.powers@windingwaters.org

Michael Farley, RPh, Clinical Pharmacy Director
mike.farley@windingwaters.org

From:	Matthew Yeates
To:	PHARMACY RULEMAKING * BOP
Subject:	CDTM Feedback
Date:	Tuesday, November 15, 2022 2:36:34 PM

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern and provide feedback about the proposed changes to the Collaborative Drug Therapy Management (CDTM) rules. I am strongly opposed to removing all OARs that discuss CDTM and proposed OAR, 855-115-0120. It appears that the Board voted to send these proposed changes to rulemaking for feedback from the public; however, changes were not discussed in public comment during either the August or October Board of pharmacy meeting making thorough feedback difficult.

I urge you to use a rules advisory committee to provide feedback on the impact additional rules will have, but especially with the proposed rules for 855-115-0120. I feel there are consequences of removing CDTMs from rules and replacing them with a redefined clinical pharmacy agreement. One implication, though certainly not the least, is the ability of pharmacists to be reimbursed for and thus provide services to Medicaid recipients enrolled in Coordinated Care Organizations (CCOs). In addition, these rules impact pharmacists in all settings, not just community pharmacy. The intent of these rules is unclear, as they have not been discussed and it feels as though the intent is to limit our current scope of practice. Licensees have no idea what the intent of these rules are, because they have not been discussed, and therefore we are unclear if your intent is to limit our current scope of practice or to replace CDTM with something new.

The Oregon Medical Board does not have corresponding rules that recognize a CPA. When these draft rules go into effect, there will be no ability for pharmacists to have a way to collaboratively manage drug therapy. This will greatly affect many of the pharmacists currently working in a clinical environment and could cause patient harm. It may also disrupt care for many Oregonians without access to healthcare providers other than their pharmacist and further erode efforts made to address health equity for rural and minority populations in Oregon. Before passing these rules I urge you to press pause and let subject matter experts weigh in on what these rule changes will mean for the current practice of pharmacy, the evolution of pharmacy practice, and patient safety.

Thank you,

--
Matthew R. Yeates, PharmD
Director of Clinical Services
Grants Pass Pharmacy
414 SW 6th St.
Grants Pass, OR 97526
P: 541-476-4262 ext. 3

From:	Matthew Yeates
To:	PHARMACY RULEMAKING * BOP
Subject:	MTM Rulemaking Feedback
Date:	Tuesday, November 15, 2022 2:46:14 PM

Dear Oregon Board of Pharmacy Members,

I am writing to express my concern about the proposed rule changes to Medication Therapy Management. I urge you to reject changing the word “may” to “must” in proposed rule 855-115-0125 (2). It appears the Board voted to send these proposed changes to rulemaking for feedback from the public. However, the changes to the definition of MTM were not discussed in public comment during either the August or October Board of pharmacy meeting making the reasoning for the changes and thorough feedback difficult.

MTM encompasses a variety of services provided by pharmacists, generally for Medicare Part D plans which have their own definition. Changing the definition of MTM in this rule to require that “all elements listed be completed” is unnecessary and puts an undue burden on Oregon Pharmacists who complete MTM visits for Medicare recipients. Some Part D MTM interventions may be as simple and brief as a telephone call to determine why a patient is late for a maintenance medication refill or if an intervention or refill is needed. The proposed change would mandate the provision of services that are not indicated and increases the documentation and administrative burden of the pharmacist providing said service. This may in turn, entice Medicare plans to contract with pharmacists outside of Oregon (as they are not held to the same rules) to complete their yearly MTM visit instead of their local pharmacist who they see when filling their prescription medications. The Oregon Board of Pharmacy should be doing everything they can to develop and encourage the pharmacist-patient relationship which results in improved patient safety outcomes, not burden it with cumbersome mandates. **This proposed rule change from “may include” to “must include” is unnecessary.**

Thank you,

--
Matthew R. Yeates, PharmD
Director of Clinical Services
Grants Pass Pharmacy
414 SW 6th St.
Grants Pass, OR 97526
P: 541-476-4262 ext. 3

From:	Matthew Yeates
To:	PHARMACY RULEMAKING * BOP
Subject:	Rulemaking Hearing Nov 2022
Date:	Wednesday, October 26, 2022 5:21:05 PM

Regarding Divisions 010/019/020 - COVID-19 Antiviral (Paxlovid)
Healthcare provider name should be switch to "primary care provider"
Allergies are asked for in two different places
If patients are asked REALD questions then race/ethnicity are being collected in two different locations.
Hepatic function section B: Child-Pugh points are not labeled for each component of calculation, but the scoring is classified.
All instances of healthcare provider should be switched to primary care provider. It is unclear to read because the pharmacist rendering the service is considered a patient's healthcare provider.

--
Matthew R. Yeates, PharmD
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P: 541-476-4262 ext. 3

Division 019: Pharmacists (Duties of a Pharmacist Receiving a Prescription; 2022 HB 4034)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Duties of a Pharmacist receiving a prescription; Telemedicine; 2022 HB 4034

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Section 14 of House Bill 4034 (2022) defines "telemedicine" as "the provision of health care services to a patient by a physician or physician assistant from a distance using electronic communications, including synchronous technologies to facilitate an exchange of information between a patient and physician or physician assistant in real time or asynchronous technologies to facilitate an exchange of information between a patient and a physician or physician assistant in other than real time." Modification to OAR 855-019-0210(2)(a) is necessary to eliminate conflict in Board of Pharmacy regulations with this new statute. Pharmacists must still ensure that prescriptions are 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.

Documents to be Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034; ORS 689.525

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed amendments provide clarity, transparency for licensees/registrants and promotes patient safety, no effects on racial equity are anticipated.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal impact anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on small businesses): There are no known economic impacts to the Oregon Board of Pharmacy, 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 the proposed amendments, directive of 2022 HB 4034.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, Legislative directive of 2022 HB 4034.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments are necessary in order to remove conflict between Board of Pharmacy regulations and revised telemedicine statutes in 2022 HB 4034. Amendments include removing "not result solely from a questionnaire or an internet-based relationship" and adding "issued pursuant to a valid patient-practitioner relationship" in OAR 855-019-0210(2)(a).

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

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(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

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Division 139: Remote Dispensing Site Pharmacy (Prohibited Practices)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): 2022 HB 4034 allows a Retail Drug Outlet RDSP to deliver a prescription

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Pursuant to Section 19 of 2022 HB 4034, a Retail Drug Outlet Pharmacy may deliver a prescription; thus, a Retail Drug Outlet RDSP may deliver a prescription.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034; ORS 689.005

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed amendments provide clarity, transparency for licensees/registrants and promotes patient safety, no effects on racial equity are anticipated.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal impact anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on small businesses): There are no known economic impacts to the Oregon Board of Pharmacy, 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 the proposed amendments, directive of 2022 HB 4034.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, Legislative directive of 2022 HB 4034.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments removes language that states a Retail Drug Outlet RDSP may not "Deliver a prescription." Per 2022 HB 4034, the board may not establish standards for telepharmacy that are more restrictive than standards for the delivery of in-person pharmacy services, including standards regarding prescription and dispensation of drugs.

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet RDSP must not:

(1) Allow a Certified Oregon Pharmacy Technician or Pharmacy Technician to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;

(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the board pursuant to ORS 689.305;

(3) Compound sterile preparations; or

(4) Repackage drugs.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315, 2022 HB 4034
Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

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Division 019: Pharmacists (2022 HB 4096: Out-of-State Volunteer RPH)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Allows an out-of-state licensed pharmacist to volunteer without compensation or licensure in Oregon

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Adopts language that would allow an out-of-state licensed pharmacist to volunteer without compensation in Oregon for 30 days each calendar year without being required to apply for licensure in Oregon and provides requirements needed to qualify as an out-of-state volunteer pharmacist. These rules are necessary pursuant to directives of 2022 HB 4096, becomes operative on 1/1/2023.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4096

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 COVID-19 pandemic has exacerbated health care workforce shortages, leaving many health care facilities short-staffed. Appropriate staffing in health care facilities is essential to providing safe patient care and a safe work environment for health care providers. Volunteer health care providers provide services to people who might not otherwise have access, including rural areas bordering other states.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The agency anticipates a minimal fiscal impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses: If an out-of-state Pharmacist who is licensed in another state chooses to volunteer and qualifies, they may be subject to any fees charged by their state of residence associated with complying with the requirements.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Legislative mandate of 2022 HB 4096.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): The proposed rules create the necessary requirements for a pharmacist to practice pharmacy in Oregon without compensation for a specified amount of time without being required to obtain licensure in Oregon. The proposed rules are necessary as a directive of 2022 HB 4096.

Division 019
PHARMACISTS

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

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Division 062: Drug Distribution Agent (DDA)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Applicant for DDA renewal; annual due date

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amends the current Drug Distribution Agent registration due date from August 31 to reflect the proper due date of September 30 to provide clarity to licensees and registrants.

Documents Relied Upon per ORS 183.335(2)(b)(D): None available.

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed amendments provide clarity, transparency for licensees/registrants, no effects on racial equity are anticipated.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal impact is anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public) (Effect on Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses, or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed rule amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not consulted. Board staff recommend amending the due date for transparency and clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendment removes outdated due date of "August 31" and revises it to "September 30" in OAR 855-062-0020. DDA applicants for renewal must complete and submit the form to the board by September 30 annually.

Division 062
DRUG DISTRIBUTION AGENT

855-062-0020
Registration

(1) Any person engaged in any part of the process of manufacture or wholesale distribution of a drug into, out of, or within Oregon must be registered with the board. A person must register as either:

(a) A manufacturer under Division 60 of this chapter of rules; or

(b) A wholesaler under Division 65 of this chapter of rules; or

(c) A Drug Distribution Agent under this division of rules.

(2) A person that is required to register as a Drug Distribution Agent must be registered before commencing business in Oregon and before any drug for which they provide a manufacturing, marketing or distribution service, may be sold, distributed, dispensed or administered in Oregon.

(3) A person that is required to register as a Drug Distribution Agent must apply for registration on a form provided by the board and must provide information required by the board that includes but is not limited to:

(a) The name, business address, social security number or federal tax identification number of each owner, officer, and stockholder owning more than 10 per cent of the stock of the company, unless the stock of the company is publicly traded;

(b) Every trade or business name used by the applicant;

(c) Any disciplinary action taken by any state or federal authority against the applicant or any other distributor under common ownership or control, or any owner, principal or designated representative of the applicant, in connection with the drug laws or regulations of any state or the federal government.

(4) An applicant for renewal must complete the form provided by the board and submit it to the board with the appropriate fee by September 30 annually.

(5) An applicant that provides a manufacturing or distribution service in respect of a controlled substance as defined in Division 80 of this chapter of rules must also complete and submit the Controlled Substance registration form provided by the board, with the appropriate fee.

(6) The board may require a criminal history and financial background check of each principal, owner or officer of the applicant prior to initial registration and prior to any renewal unless the applicant is publicly traded. Any such checks will be at the applicant's expense.

(7) The board may require a physical inspection of each facility prior to initial registration and prior to any renewal.

(8) Each separate business entity and each location that does business in Oregon must be separately registered by the board.

(9) The registrant must notify the board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change includes but is not limited to:

(a) Change of ownership;

(b) Change of business address;

(c) Any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers.

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(10) The registration certificate is issued to a specific person and is non-transferable. Any addition or deletion of an owner or partner constitutes a change of ownership.

(11) 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 will only be effective when issued in writing.

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

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Division 010/019/020: Pharmacist Prescriptive Authority

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Compendia and prescribing practices amendments; incorporates Public Health and Pharmacy Formulary Advisory Committee recommendations

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Adopts rules in Division 10 related to committee requirements of the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC). Proposed amendments in Division 020 include adding language related to ensuring training and education requirements have been met prior to engaging in prescribing and requirements related to retaining copies of the training and education. Adds language that prohibits prescribing drugs or devices when the Formulary and Protocol Compendia requires a referral to another non-Pharmacist provider and language that a Pharmacist may not require but may allow a patient to schedule an appointment with the RPH for prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive. Adds PAXLOVID, and Contraception to the Protocol Compendium. Repeals OAR 855-020-0105. Repeals language in Division 019 related to contraceptives.

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

References for Pharmacist Prescriptive Authority ORS 689.689, ORS 689.645, ORS 689.649

References for each protocol are included in the protocol.

Proposed Statewide Drug Therapy Management Protocol – COVID-19 Antiviral (Paxlovid) v.12/2022

Proposed Statewide Drug Therapy Management Protocol – Travel Medications v. 12/2022

Proposed Statewide Drug Therapy Management Protocol – HIV Post-Exposure Prophylaxis (PEP) v. 12/2022.

Proposed Statewide Drug Therapy Management Protocol – HIV Pre-Exposure Prophylaxis (PrEP) v. 12.2022

Proposed Statewide Drug Therapy Management Protocol – Contraception – Oral, Transdermal Patch, Vaginal Ring and Injectable v. 12/2022

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Per the Oregon Health Authority and the Public Health and Pharmacy Formulary Advisory Committee, pharmacists need the ability to prescribe PAXLOVID via a statewide drug therapy management protocol to provide critical treatment of COVID-19 infection. Access affordable COVID-19 antiviral medication in a timely manner protects public health and safety of all Oregonians.

Approximately 45% of pregnancies in the US are unintended. In Oregon, pharmacists have prescribed birth control since 2016. In 2019, one study found that 46% of Oregon pharmacies participate in contraception prescribing. These pharmacies are located in approximately 63% of the zip codes within the state. Another 2019 study found that women receiving contraception from the pharmacist were

more likely to be younger, uninsured and have less education than women seeing traditional clinic based providers.

By making treatment for COVID-19 and contraception easily accessible to patients at their local pharmacy, it may improve access for patients who may not be able to otherwise access these services.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance: State agencies and local government are not impacted by these rules. Pharmacy stakeholders and the public may be impacted by these rules if utilized. Provision of formulary prescribing services by a pharmacist/pharmacy is voluntary. The professional time to offer these services and comply with record keeping requirements may increase costs to the outlet, which may possibly be passed on to the public for prescribing services. Outlets will be required to establish and enforce policies and procedures and pharmacists must comply with the rules if they offer the services.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of these rules. Participation is voluntary, and a pharmacist is not mandated to offer patient care and prescribing services.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): The statutorily mandated Public Health and Pharmacy Formulary Advisory Committee informed the content of the proposed draft protocols and proposed amendments to existing protocols.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Relocates rules from OAR 855-020-0105 to OAR 855-010-0018 related to defining what the Public Health and Pharmacy Formulary Advisory Committee shall consist of such as members, terms, process to submit a concept, recommendations to the board for adoption and recommendations for protocol and compendium review and revisions. Relocating these rules to board administration and policies improves rule organization.

Proposed rule amendments in Division 020 include adding language related to ensuring training and education requirements have been met prior to engaging in prescribing and requirements for retaining copies of the training and education. It also adds new language that prohibits prescribing drugs or devices when the Formulary and Protocol Compendia requires a referral to another non-Pharmacist provider and adds that a Pharmacist may not require but may allow a patient to schedule an appointment with the RPH for prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive. The proposed amendments in Division 020 are necessary for compliance, provide clarity to licensees and were recommended by the PHPFAC.

Proposed amendments to the Protocol Compendium as recommended by the PHPFAC would add COVID-19 Antiviral (PAXLOVID), and Contraception as approved items. It would also add amended versions of Travel Medications protocol, HIV Post and Pre-Exposure Prophylaxis (PEP & PrEP) as requested by the PHPFAC.

The PHPFAC reviewed proposed protocols with subject matter experts and drafted a statewide drug therapy management protocol for Contraception.

Repeals rules in Division 019 related to contraceptive training program, procedural mandates, prohibited practices and records. Striking these specific contraceptive rules in Division 019 is necessary in order to add Contraception to the Protocol Compendium.

Division 010
BOARD ADMINISTRATION AND POLICIES

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

Division 20
PHARMACIST PRESCRIPTIVE AUTHORITY

~~855-020-0105~~
~~Public Health and Pharmacy Formulary Advisory Committee~~

~~(1) The Public Health and Pharmacy Formulary Advisory Committee shall 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~~

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~~(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 shall recommend to the Board, for adoption by rule, a protocol or formulary of drugs and devices from which a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a qualified healthcare practitioner.~~

~~(4) The committee shall 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~~

855-020-0110
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:

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(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.

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(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

855-020-0300
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 (v. 06/2021)

(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 Monoclonal Antibody (mAb) (v. 12/2021);

(d) COVID-19 Antigen Self-Test (v. 12/2021);

(e) COVID-19 Antiviral (v. 12/2022).

(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. 12/2022);

(e) HIV Post-exposure Prophylaxis (PEP) (v. 12/2022);

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(f) HIV Pre-exposure Prophylaxis (PrEP) (v. 12/2022); and

(g) Contraception (v. 12/2022).

[Publications referenced are available for inspection in the office of the Board of Pharmacy per OAR 855-010-0021.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689

Division 19
PHARMACISTS

~~855-019-0400~~
~~Contraceptives Purpose~~

~~The purpose of rules OAR 855-019-0400 through 855-019-0435, is to develop standard procedures for the prescribing of injectable hormonal contraceptives and self-administered hormonal contraceptives by an Oregon licensed pharmacist, providing timely access to care. To ensure public safety and provide a consistent level of care, a pharmacist may participate upon completion of a Board approved training program. Under the rules of this section, a qualified pharmacist may prescribe hormonal contraceptives to a patient pursuant to a self-screening risk assessment questionnaire and standard procedural algorithm.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0405~~
~~Contraceptives Definitions~~

~~In OAR 855-019-0400 through 855-019-0435:~~

~~(1) "Clinical visit" means a consultation with a healthcare provider, other than a pharmacist, for women's health, which should address contraception and age-appropriate screening.~~

~~(2) "Injectable hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that a health care practitioner administers to the patient by injection.~~

~~(3) "Self-administered hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may administer to oneself.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

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~~855-019-0410~~

~~Prescriptive Practice Consultation~~

~~In an effort to clarify, improve, and support appropriate pharmacist prescribing, the Board shall periodically review prescribing standards, practices, and scope in consultation with designated representatives from the Oregon Medical Board, Oregon State Board of Nursing, and Oregon Health Authority. The Board will seek recommendations from these representatives to be considered in conjunction with American Congress of Obstetricians and Gynecologists (ACOG) guidelines and other evidence-based standards, as it seeks to evaluate and improve prescribing practices within pharmacy. To the extent that developed standards are incorporated into practice, the forms, screening tools, or requisite training materials shall be prepared by the Board in consultation with these designated representatives.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0415~~

~~Contraceptive Training Program~~

~~(1) Only a pharmacist, who has completed a Board approved Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may prescribe injectable hormonal contraceptives and self-administered hormonal contraceptives for a patient.~~

~~(2) A pharmacist must submit a copy of the certificate of completion of training to the Board within 15 days of completion.~~

~~(3) A pharmacist must maintain the certificate of completion and make available upon request.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0425~~

~~Contraceptive Procedural Mandates~~

~~(1) For each new patient requesting contraceptive services and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:~~

~~(a) Obtain a completed Oregon Self-Screening Risk Assessment Questionnaire; and~~

~~(b) Utilize and follow the Oregon Standard Procedures Algorithm to perform the patient assessment; and~~

~~(c) Prescribe, if clinically appropriate, the self-administered or injectable hormonal contraceptive, or refer to a healthcare practitioner; and~~

~~(d) Provide the patient with a Visit Summary; and~~

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~~(e) Advise the patient to consult with a primary care practitioner or women's health care practitioner; and~~

~~(f) Document the encounter and maintain records pursuant to OAR 855-019-0435.~~

~~(2) If the self-administered hormonal contraceptive is dispensed or the injectable hormonal contraceptive is administered, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.~~

~~(3) Nothing in this rule shall prohibit the partial filling or transferring of a drug prescribed pursuant to this process, per the request of the patient.~~

~~(4) A pharmacy must:~~

~~(a) Keep records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years; and~~

~~(b) Keep records of the medication dispensed for a minimum of three years; and~~

~~(c) Establish, maintain and enforce written procedures for the provision of care under this section, including, but not limited to:~~

~~(A) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and~~

~~(B) Documentation and recordkeeping.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0430~~
~~Contraceptive Prohibited Practices~~

~~A pharmacist must not:~~

~~(1) Require a patient to schedule an appointment with the pharmacist for the prescribing, administering or dispensing of a hormonal contraceptive;~~

~~(2) Continue to prescribe a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit;~~

~~(3) Prescribe in instances that the Oregon Standard Procedures Algorithm requires referral to a provider; and~~

~~(4) Prescribe to self or immediate family members.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

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~~855-019-0435~~

~~Contraceptive Records~~

~~(1) A pharmacist must document the encounter and the prescription, and maintain records.~~

~~(2) A pharmacy must maintain records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years and maintain records of the medication administered or dispensed for a minimum of three years.~~

~~(3) Prescriptions are valid for one year pursuant to OAR 855-041-1125.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

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CONDITIONS

Nirmatrelvir and Ritonavir (PAXLOVID)
TREATMENT OF COVID-19 INFECTION

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe nirmatrelvir and ritonavir (PAXLOVID).

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PAXLOVID Patient Intake Form (pg. 2-3)
  - Utilize the standardized PAXLOVID Assessment and Treatment Care Pathway (pg. 6-9)
  - Utilize the standardized PAXLOVID Provider Notification (pg. 20)

  PHARMACIST TRAINING/EDUCATION:
  - Pharmacist is familiar with how to access patient laboratory data to assess renal and hepatic function.
  - Review PAXLOVID resources for healthcare providers, available at:
    - https://www.paxlovidhcp.com/
    - FDA: PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers
  - A minimum of 1 hour of training **is recommended**
    - CDC 6/16/2022 Webinar: What Clinicians Need to Know About Available Therapeutic Options for COVID-19
    - CDC 1/12/2022 Webinar: What Clinicians Need to Know About the New Oral Antiviral Medications for COVID-19

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Nirmatrelvir and Ritonavir (PAXLOVID) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

If you have any of the following, please go directly to the emergency room or have someone call 911.

□ New confusion □ Difficulty breathing □ Pain or pressure in the chest
□ Cannot stay awake □ Gray or blue-colored skin, lips, or nail beds □ Fast heart rate or palpitations
□ If you are on oxygen and have greater oxygen needs

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Theirs, Ze/Hir/Hirs, Other_____Height_____Weight____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? □ Yes □ No Insurance Provider Name _____
Any allergies to medications? □ Yes □ No If yes, please list _____
Which of the following best describes your racial or ethnic identity? Please check **ALL** that apply.
□ Black/African American □ Hispanic or Latino/a/x □ American Indian or Alaska Native □ Asian □ Other
□ Native Hawaiian/Pacific Islander □ Middle Eastern/North African □ White □ Not specified
Are you houseless, or live in a shelter, encampment, or transitional housing? □ Yes □ No

Background Information:

1.	Have you had a positive COVID-19 (SARS-CoV-2) antigen test within the past 5 days? If yes, please indicate the date of the positive test ___/___/_____.	□ Yes □ No
2.	Have you experienced any of the following symptoms? If yes, select all that apply: □ Fever □ Chills □ Cough □ Fatigue □ Headache □ Sore throat or Laryngitis □ Difficulty breathing □ Muscle or body aches □ Loss of taste or smell □ Congestion/head cold □ Runny nose □ Nausea or Vomiting □ Diarrhea □ Loss of appetite □ Light sensitivity If yes, did the symptoms start in the past 5 days?	□ Yes □ No □ Yes □ N/A
3.	Do you have or have you had any of the following that would qualify you for COVID-19 treatment? Please ask the Pharmacist if you have any questions about this list.	
	A. Age 50 years or older	□ Yes □ No
	B. Asthma	□ Yes □ No
	C. Cancer	□ Yes □ No
	D. Cystic fibrosis	□ Yes □ No
	E. Dementia	□ Yes □ No
	F. Diabetes	□ Yes □ No
	G. Disability (e.g., mental, physicial, emotional)	□ Yes □ No
	H. Heart condition	□ Yes □ No
	I. HIV infection	□ Yes □ No
	J. Immune system problems or medications affecting the immune system	□ Yes □ No
	K. Kidney disease	□ Yes □ No
	a. If yes, are you currently on dialysis?	□ Yes □ No
	L. Liver disease	□ Yes □ No
	M. Lung disease or blood clot in the lung	□ Yes □ No
	N. Mental health condition	□ Yes □ No
	O. Unvaccinated or not up to date on COVID-19 vaccinations	□ Yes □ No
	P. Overweight or obese	□ Yes □ No
	Q. Physically inactive	□ Yes □ No
	R. Pregnancy or recent pregnancy	□ Yes □ No

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Nirmatrelvir and Ritonavir (PAXLOVID) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

	S. Sickle cell disease or thalassemia……	□ Yes □ No
	T. Smoking, current or former……	□ Yes □ No
	U. Transplant of organ or bone marrow……..	□ Yes □ No
	V. Stroke or brain bleed……	□ Yes □ No
	W. Problematic drug or alcohol use……..	□ Yes □ No
	X. Tuberculosis……	□ Yes □ No
	Y. Other: _____	□ Yes □ No
4.	Have you had bloodwork of kidney and liver function that is less than 12 months old? If yes, can you provide it to the Pharmacist now?	□ Yes □ No □ Yes □ No
5.	Do you have any known medication allergies? If yes, list them here:	□ Yes □ No
6.	Do you take any medicines, including herbs or supplements? If yes, list them here:	□ Yes □ No (notify Pharmacist if more space needed)
7.	Do you take any medicines that you do not remember the name of?	□ Yes □ No
8.	Please write the names of all pharmacies you have filled prescriptions with in the last 90 days: Pharmacy (location):_____ Pharmacy (location):_____ Pharmacy (location):_____ Pharmacy (location):_____	

Signature_____ Date ____/_____/_____

TO BE COMPLETED BY PHARMACIST:

1. Weight _____ lbs.
   a. If applicable to verify overweight/obese status as only risk factor: Height __ ft. ___ in., BMI _____
2. Renal function:
   a. Provider verified eGFR is ≥60 mL/min *or* ≥30 to <60 mL/min *or* <30 mL/min (circle one).
      Provider name (phone):_____ **-or-**
   b. SCr:_____ mg/dL (date of lab:___/___/___). eGFR using CKD-EPI formula:_____ mL/min
3. Hepatic function:
   a. Provider-verified patient has: No Cirrhosis *or* Child-Pugh Class A *or* Class B *or* Class C (circle one)
      Provider name/phone:_____ **-or-**
   b. Total Bilirubin_____ mg/dL (date of lab:___/___/___), Albumin:_____ g/dL (date of lab:___/___/___),
      INR or Prothrombin Time (sec):_____ (date of lab:___/___/___).
      Child-Pugh score:_____ (6 points added for missing ascites and encephalopathy information)
      Estimated Child-Pugh: Class A: 5-6 points *or* Class B: 7-9 points *or* Class C: 10-15 points (circle one)

IF PAXLOVID WAS PRESCRIBED, COMPLETE THE FOLLOWING:

1. EUA Fact Sheet for Patients, Parents and Caregivers was provided: Version Date____/_____
2. Dose (check one):
   □ Nirmatrelvir 300 mg (two 150 mg tablets) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days
   □ Nirmatrelvir 150 mg (one 150 mg tablet) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days
3. Healthcare Provider (if known) contacted/notified of therapy: □ Yes Date ____/_____/_____ □ Not Applicable

RPH Signature_____Date ____/_____/_____

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

REALD Data Collection Form

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____

Legal Name_____ Preferred Name _____

1. Which of the following describes your **Racial or Ethnic identity**? Please check **ALL** that apply.

Hispanic and Latino/a/x
□ Central American
□ Mexican
□ South American
□ Other Hispanic or Latino/a/x

Native Hawaiian and Pacific Islander
□ CHamoru (Chamorro)
□ Marshallese
□ Communities of the Micronesian Region
□ Native Hawaiian
□ Samoan
□ Other Pacific Islander

White
□ Eastern European
□ Slavic
□ Western European
□ Other White

American Indian and Alaska Native
□ American Indian
□ Alaska Native
□ Canadian Inuit, Metis, or First Nation
□ Indigenous Mexican, Central American, or South American

Black and African American
□ African American
□ Afro-Caribbean
□ Ethiopian
□ Somali
□ Other African (Black)
□ Other Black

Middle Eastern/North African
□ Middle Eastern
□ North African

Asian
□ Asian Indian
□ Cambodian
□ Chinese
□ Communities of Myanmar
□ Filipino/a
□ Hmong
□ Japanese
□ Korean
□ Laotian
□ South Asian
□ Vietnamese
□ Other Asian

Other Categories
□ Other (please list)
_____
□ Don't know
□ Don't want to answer

2. If you checked **more than one** category above, is there **one** you think of as your **primary** racial or ethnic identity?
   □ Yes. Please circle your primary racial or ethnic identity above.
   □ I do not have just one primary racial or ethnic identity.
   □ No. I identify as Biracial or Multiracial.
   □ N/A. I only checked one category above.
   □ Don't know
   □ Don't want to answer

Language (*Interpreters are available at no charge*)

3. What language or languages do you **use at home**? _____
   → Skip to question 9 if you indicated English only

4. In what language do you want us to communicate in **person, on the phone, or virtually** with you?

5. In what language do you want us to **write** to you? _____

6. Do you need or want an **interpreter** for us to communicate with you?
   □ Yes □ No □ Don't know □ Don't want to answer

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7. If you need or want an interpreter, what type of interpreter is preferred?
□ Spanish language interpreter □ Deaf Interpreter for DeafBlind, additional barriers, or both
□ American Sign Language interpreter □ Contact sign language (PSE) interpreter
□ Other (**please list**): _____

→ Skip to question 9 if you do not use a language other than English or sign language

8. How well do you speak English?
□ Very Well □ Well □ Not Well □ Not at all □ Don't know □ Don't want to answer

	Disability Your answers will help us find health and service differences among people with and without functional difficulties. Your answers are confidential.	Yes	***If yes**, at what age did this condition begin?	No	Don't know	Don't want to answer	Don't know what this question is asking
9.	Are you deaf or do you have serious difficulty hearing?						
10.	Are you blind or do you have serious difficulty seeing, even when wearing glasses?						
11.	Do you have serious difficulty walking or climbing stairs?						
12.	Because of a physical, mental or emotional condition, do you have serious difficulty concentrating, remembering or making decisions?						
13.	Do you have difficulty dressing or bathing?						
14.	Do you have serious difficulty learning how to do things most people your age can learn?						
15.	Using your usual (customary) language, do you have serious difficulty communicating (for example understanding or being understood by others)?						
16.	Because of a physical, mental or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping?						
17.	Do you have serious difficulty with the following: mood, intense feelings, controlling your behavior, or experiencing delusions or hallucinations?						

All health care providers must begin collecting and reporting REALD data in accordance with current REALD standards and Oregon Disease Reporting rules starting October 1, 2021.

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Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

1) Assessment Screen (Self-screening Patient Intake Form, REALD demographics and pharmacist assessment)

a. Age < 12 years → **Refer to healthcare provider**
b. Weight < 88 lbs (40 kg) → **Refer to healthcare provider**
c. Clinical Factors listed below: → **Refer immediately to local Emergency Department or call 911**

If the Pharmacist observes or the patient reports:

□ New confusion □ Difficulty breathing □ Cannot stay awake
□ Pain or pressure in the chest □ Gray or blue-colored skin, lips, or nail beds
□ Fast heart rate or palpitations □ If patient is on oxygen and has greater oxygen needs

If referral criteria not met, *proceed to Step 2*.

2) Treatment Screen (Self-screening Patient Intake Form #1-2)

a. Positive SARS-CoV-2 molecular or antigen test within past 5 days associated with current symptoms?

NOTE: Test results that are indeterminate or inconclusive results can suggest the presence of SARS-CoV2 in quantities insufficient for the molecular or antigen test to be positive. It is recommended to collect a new specimen and retest. If the results are still indeterminate or inconclusive, the patient should be referred to their healthcare provider for further evaluation.

b. Onset of mild to moderate COVID-19 symptoms within past 5 days?

NOTE: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea, vomiting; or diarrhea

If YES to *BOTH* Steps 2a **AND** 2b, *proceed to Step 3*.

3) Risk of Progression to Severe COVID-19 Screen (Self-screening Patient Intake Form #3, REALD demographics)

a. Did the patient attest to at least one risk factor in #3 on the Self-screening Patient Intake Form, which places an individual at high risk of progression to severe COVID-19?

NOTE: Pharmacist must obtain or calculate BMI to verify overweight/obese status if #3.P. is the *only* risk factor checked "Yes" on #3 of the Self-screening Patient Intake Form. A BMI ≥25 is a risk factor.

b. Does the patient identify as Black, African American, Hispanic, Latino/a/x, American Indian/Alaska Native, Asian, Asian American, or Pacific Islander, which places an individual at high risk of progression to severe COVID-19?

NOTE: Patients of color or from tribal communities are most harmed by health inequities and the risk of hospitalization and death for these groups is greater than that of white patients. These patients may face higher risk than white patients due to longstanding societal injustices including racism, discrimination, colonization, etc., which have and continue to negatively affect health outcomes. For this

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reason, people who identify as Black/African American, Hispanic, Latino/a/x, American Indian/Alaska Native, Asian/Asian American or Pacific Islander are eligible for PAXLOVID under this protocol.

c. Is the patient houseless or live in a shelter, encampment or transitional housing, which places an individual at high risk of progression to severe COVID-19?

NOTE: There is increased transmission of virus in indoor and outdoor congregate settings that do not provide protection from the environment, adequate access to hygiene and sanitation facilities, or connection to services and health care. These settings include those where people who are houseless, are sleeping outdoors or in encampments. For this reason, people who are houseless are eligible for PAXLOVID under this protocol.

If YES to *EITHER* Step 3a, 3b, **OR** 3c, *proceed to Step 4*; otherwise, *PAXLOVID is not indicated at this time → Refer as outlined in EUA.*

4) Renal Function Assessment Screen

a. Is the patient currently on dialysis as reported on the Self-Screening Patient Intake Form Question #3.K.a.?

b. Did the pharmacist verify an eGFR ≥30 mL/min after consultation with a healthcare provider who is in an established patient-provider relationship with the individual patient?

c. Did the pharmacist obtain a SCr level that is **less than 12 months** old and calculate an eGFR ≥30 mL/min using an online calculator based on the 2021 CKD-EPI equation?

Note: Patient reporting of renal function is not adequate for utilization of this protocol.

If YES to Step 4a, PAXLOVID is contraindicated. → *Refer as outlined in EUA.*
If YES to *EITHER* Step 4b **OR** 4c, *proceed to Step 5; otherwise*, → *Refer as outlined in EUA.*

5) Hepatic Function Assessment Screen

a. Did the pharmacist verify the patient does not have Child-Pugh Class C liver disease (severe, decompensated) after consultation with a healthcare provider who is in an established patient-provider relationship with the individual patient?

b. Did the pharmacist obtain a total bilirubin, albumin and INR/prothrombin time that is less than 12 months old and estimate the Child-Pugh score to be <10 points (No liver cirrhosis, or Child-Pugh Class A or B) using an online calculator?

If provider cannot be consulted to verify hepatic function, pharmacist may calculate the Child-Pugh score using 3 points for missing ascites data and 3 points for missing encephalopathy data (adds 3 points for each missing data) for most conservative estimate.

Note: Patient reporting of liver function is not adequate for utilization of this protocol.

If YES to *EITHER* Step 5a **OR** 5b, *proceed to Step* 6; otherwise, → *Refer as outlined in EUA.*

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6) Allergy Screen (Self-screening Patient Intake Form #5)

Does the patient have a known allergy/hypersensitivity to any ingredient of PAXLOVID?

If NO known allergy, *proceed to Step 7*; otherwise, PAXLOVID is contraindicated → *Refer as outlined in EUA.*

7) Assessment of Drug-Drug Interactions (Self-screening Patient Intake Form #6-8)

a. Did the pharmacist obtain a comprehensive list of current medications and supplements (prescribed and non-prescribed):
   i. Through access to health records or pharmacy records less than 12 months old **-or-**
   ii. In consultation with a healthcare provider in an established patient-provider relationship with the patient **-or-**
   iii. Through patient reporting

b. After review of the medications, did the pharmacist identify potential serious drug interactions with PAXLOVID? Tool to assess drug interactions include:
   - Databases like Micromedex, Lexicomp or the drug interaction program provided by the pharmacy and routinely used by the pharmacist
   - The Fact Sheet for Healthcare Providers (Section 7)
   - The FDA PAXLOVID Eligibility Screening Checklist Tool
   - The University of Liverpool COVID-19 Drug Interactions tool

If YES to Step 7a **AND** *NO* to Step 7b, *proceed to Step 8; otherwise,* → *Refer as outlined in EUA.*

8) Document the Patient Education

Document that you communicated to your patient or parent/caregiver, as age appropriate, information consistent with:

a. The "Fact Sheet for Patients, Parents, and Caregivers - Emergency Use Authorization (EUA) of PAXLOVID" and provided a copy of this Fact Sheet to the patient or parent/caregiver prior to the patient receiving PAXLOVID
b. Patient Counseling Information outlined in Section 17 of the Fact Sheet for Healthcare Providers.
c. Patients treated with PAXLOVID should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

9) Prescribe PAXLOVID

a. If eGFR ≥60 mL/min: nirmatrelvir 300 mg (two 150 mg tablets) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days, or
b. If eGFR ≥30 to <60 mL/min: nirmatrelvir 150 mg (one 150 mg tablet) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days.

10) Notify primary care provider (if known) within 5 days of receipt of therapy

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Adverse Reactions and Medication Errors Reporting Requirements:

Required reporting for serious adverse events and medication errors using FDA form 3500 as described in section 6.4 of EUA within 7 calendar days from the pharmacist's awareness of the event.

An Oregon-licensed pharmacist must adhere to the most current EUA when prescribing PAXLOVID.

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COVID Antiviral (Paxlovid™) Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Rx

☐ Drug: Paxlovid- Nirmatrelvir 300mg/ Ritonavir 100 mg

- Sig: Take two tablets of nirmatrelvir 150 mg tablets (300mg) and one tablet of ritonavir 100 mg twice daily for 5 days
- Quantity: #30
- Refills: none

☐ Drug: Paxlovid Renal- Nirmatrelvir 150mg/ Ritonavir 100 mg

- Sig: Take one tablet of nirmatrelvir 150 mg tablets and one tablet of ritonavir 100 mg twice daily for 5 days
- Quantity: #20
- Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

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FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF PAXLOVID FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with PAXLOVID for the treatment of mild-to-moderate coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. This Fact Sheet contains information to help you understand the risks and benefits of taking the PAXLOVID you have received or may receive. This Fact Sheet also contains information about how to take PAXLOVID and how to report side effects or problems with the appearance or packaging of PAXLOVID.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make PAXLOVID available during the COVID-19 pandemic (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). PAXLOVID is not an FDA approved medicine in the United States. Read this Fact Sheet for information about PAXLOVID. Talk to your healthcare provider about your options or if you have any questions. It is your choice to take PAXLOVID.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. You can get COVID-19 through close contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild-to-severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example seem to be at higher risk of being hospitalized for COVID-19.

What is PAXLOVID?

PAXLOVID is an investigational medicine used to treat mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. PAXLOVID is investigational because it is still being studied. There is limited information about the safety and effectiveness of using PAXLOVID to treat people with mild-to-moderate COVID-19.

The FDA has authorized the emergency use of PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with a positive test for the virus that causes COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death, under an EUA.

What should I tell my healthcare provider before I take PAXLOVID?

Tell your healthcare provider if you:

- Have any allergies
- Have liver or kidney disease
- Are pregnant or plan to become pregnant
- Are breastfeeding a child
- Have any serious illnesses

Some medicines may interact with PAXLOVID and may cause serious side effects.

- **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- Your healthcare provider can tell you if it is safe to take PAXLOVID with other medicines.
- You can ask your healthcare provider or pharmacist for a list of medicines that interact with PAXLOVID.
- Do not start taking a new medicine without telling your healthcare provider.

Tell your healthcare provider if you are taking combined hormonal contraceptive. PAXLOVID may affect how your birth control pills work. Females who are able to become pregnant should use another effective alternative form of contraception or an additional barrier method of contraception. Talk to your healthcare provider if you have any questions about contraceptive methods that might be right for you.

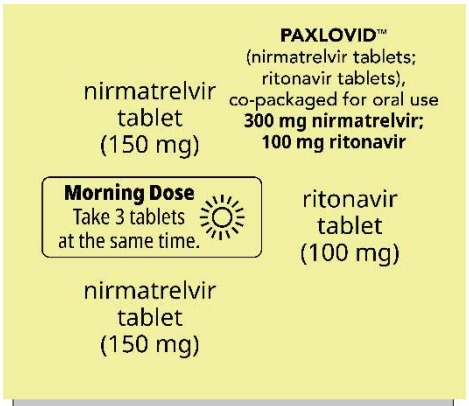
How do I take PAXLOVID?

- **PAXLOVID consists of 2 medicines: nirmatrelvir tablets and ritonavir tablets. The 2 medicines are taken together 2 times each day for 5 days.**
  - Nirmatrelvir is an oval, pink tablet.
  - Ritonavir is a white or off-white tablet.
- PAXLOVID is available in 2 Dose Packs (see **Figures A and B** below). Your healthcare provider will prescribe the PAXLOVID Dose Pack that is right for you.
- **If you have kidney disease, your healthcare provider may prescribe a lower dose (see Figure B). Talk to your healthcare provider to make sure you receive the correct Dose Pack.**

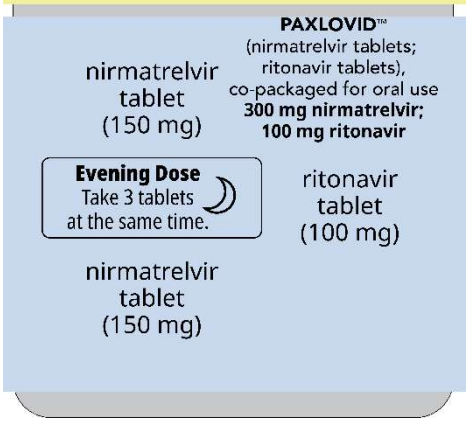
Figure A

If you have a PAXLOVID 300 mg; 100 mg **Dose Pack**: each dose contains 3 tablets.

How to take PAXLOVID 300 mg; 100 mg Dose Pack



Morning Dose:
Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together at the same time each morning.

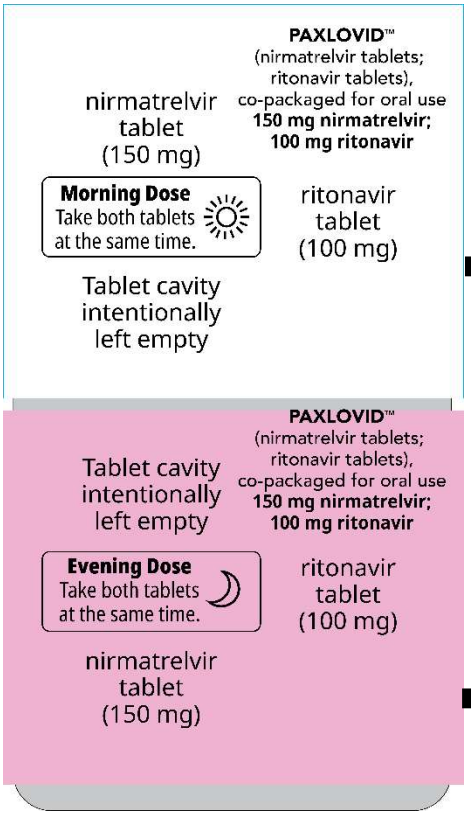


Evening Dose:
Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together at the same time each evening.

Figure B

If you have a PAXLOVID 150 mg; 100 mg **Dose Pack**: each dose contains 2 tablets.

How to take PAXLOVID 150 mg; 100 mg Dose Pack



Morning Dose:
Take the 1 pink nirmatrelvir tablet and
1 white to off-white ritonavir tablet together
at the same time each morning.

Evening Dose:
Take the 1 pink nirmatrelvir tablet and
1 white to off-white ritonavir tablet together
at the same time each evening.

- Do not remove your PAXLOVID tablets from the blister card before you are ready to take your dose.
- Take your first dose of PAXLOVID in the Morning or Evening, depending on when you pick up your prescription, or as recommended by your healthcare provider.
- Swallow the tablets whole. Do not chew, break, or crush the tablets.
- Take PAXLOVID with or without food.
- Do not stop taking PAXLOVID without talking to your healthcare provider, even if you feel better.
- If you miss a dose of PAXLOVID within 8 hours of the time it is usually taken, take it as soon as you remember. If you miss a dose by more than 8 hours, skip the missed dose and take the next dose at your regular time. Do not take 2 doses of PAXLOVID at the same time.
- If you take too much PAXLOVID, call your healthcare provider or go to the nearest hospital emergency room right away.
- If you are taking a ritonavir- or cobicistat-containing medicine to treat hepatitis C or Human Immunodeficiency Virus (HIV), you should continue to take your medicine as prescribed by your healthcare provider.

Talk to your healthcare provider if you do not feel better or if you feel worse after 5 days.

Who should generally not take PAXLOVID?

Do not take PAXLOVID if:

- You are allergic to nirmatrelvir, ritonavir, or any of the ingredients in PAXLOVID.
- You are taking any of the following medicines:
  - alfuzosin
  - amiodarone
  - apalutamide
  - carbamazepine
  - colchicine
  - dihydroergotamine
  - dronedarone
  - eletriptan
  - eplerenone
  - ergotamine
  - finerenone
  - flecainide
  - flibanserin
  - ivabradine
  - lomitapide
  - lovastatin
  - lumacaftor/ivacaftor
  - lurasidone
  - methylergonovine
  - midazolam (oral)
  - naloxegol
  - phenobarbital
  - phenytoin
  - pimozide
  - primidone
  - propafenone
  - quinidine
  - ranolazine
  - rifampin
  - St. John's Wort (*hypericum perforatum*)
  - sildenafil (Revatio®) for pulmonary arterial hypertension
  - silodosin
  - simvastatin
  - tolvaptan
  - triazolam
  - ubrogepant
  - voclosporin

Taking PAXLOVID with these medicines may cause serious or life-threatening side effects or affect how PAXLOVID works.

These are not the only medicines that may cause serious side effects if taken with PAXLOVID. PAXLOVID may increase or decrease the levels of multiple other

medicines. It is very important to tell your healthcare provider about all of the medicines you are taking because additional laboratory tests or changes in the dose of your other medicines may be necessary while you are taking PAXLOVID. Your healthcare provider may also tell you about specific symptoms to watch out for that may indicate that you need to stop or decrease the dose of some of your other medicines.

What are the important possible side effects of PAXLOVID?

Possible side effects of PAXLOVID are:

- **Allergic Reactions.** Allergic reactions can happen in people taking PAXLOVID, even after only 1 dose. Stop taking PAXLOVID and call your healthcare provider right away if you get any of the following symptoms of an allergic reaction:
  - hives
  - trouble swallowing or breathing
  - swelling of the mouth, lips, or face
  - throat tightness
  - hoarseness
  - skin rash
- **Liver Problems.** Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems: loss of appetite, yellowing of your skin and the whites of eyes (jaundice), dark-colored urine, pale colored stools and itchy skin, stomach area (abdominal) pain.
- **Resistance to HIV Medicines**. If you have untreated HIV infection, PAXLOVID may lead to some HIV medicines not working as well in the future.

- **Other possible side effects include:**
  - altered sense of taste
  - diarrhea
  - high blood pressure
  - muscle aches
  - abdominal pain
  - nausea
  - feeling generally unwell

These are not all the possible side effects of PAXLOVID. Not many people have taken PAXLOVID. Serious and unexpected side effects may happen. PAXLOVID is still being studied, so it is possible that all of the risks are not known at this time.

What other treatment choices are there?

Veklury (remdesivir) is FDA-approved for the treatment of mild-to-moderate COVID-19 in certain adults and children. Talk with your healthcare provider to see if Veklury is appropriate for you.

Like PAXLOVID, FDA may also allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for

information on the emergency use of other medicines that are authorized by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials for which you may be eligible.

It is your choice to be treated or not to be treated with PAXLOVID. Should you decide not to receive it or for your child not to receive it, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is no experience treating pregnant women or breastfeeding mothers with PAXLOVID. For a mother and unborn baby, the benefit of taking PAXLOVID may be greater than the risk from the treatment. If you are pregnant, discuss your options and specific situation with your healthcare provider.

It is recommended that you use effective barrier contraception or do not have sexual activity while taking PAXLOVID.

If you are breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects or problems with the appearance or packaging of PAXLOVID?
Contact your healthcare provider if you have any side effects that bother you or do not go away.

Report side effects or problems with the appearance or packaging of PAXLOVID (see Figures A and B above for examples of PAXLOVID Dose Packs) to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

How should I store PAXLOVID?
Store PAXLOVID tablets at room temperature, between 68°F to 77°F (20°C to 25°C).

How can I learn more about COVID-19?
- Ask your healthcare provider.
- Visit https://www.cdc.gov/COVID19.
- Contact your local or state public health department.

What is an Emergency Use Authorization (EUA)?
The United States FDA has made PAXLOVID available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to

justify the emergency use of drugs and biological products during the COVID-19 pandemic.

PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved, and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. The EUA for PAXLOVID is in effect for the duration of the COVID-19 declaration justifying emergency use of this product, unless terminated or revoked (after which the products may no longer be used under the EUA).

Additional Information
For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.COVID19oralRx.com	1-877-219-7225 (1-877-C19-PACK)

You can also go to www.pfizermedinfo.com or call 1-800-438-1985 for more information.

Distributed by
Pfizer Labs
Division of Pfizer Inc.
New York, NY 10017

LAB-1494-6.1

Revised: 26 August 2022

Provider Notification
COVID Antiviral (Paxlovid™)

Pharmacy Name:_____ Pharmacist Name: _____

Pharmacy Address:_____

Pharmacy Phone: _____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) was:

☐ **Prescribed** (Paxlovid™) at our Pharmacy noted above on ___/___/_____. The prescription issued and dispensed consisted of:

- Paxlovid- Nirmatrelvir 300mg/ Ritonavir 100 mg
  - Sig: Take two tablets of nirmatrelvir 150 mg tablets (300mg) and one tablet of ritonavir 100 mg twice daily for 5 days, #30, no refills
- Paxlovid Renal- Nirmatrelvir 150mg/ Ritonavir 100 mg
  - Sig: Take one tablet of nirmatrelvir 150 mg tablets and one tablet of ritonavir 100 mg twice daily for 5 days, #20, no refills

Your patient was:

- Provided with the FDA EUA Paxlovid™ Fact Sheet for Patients, Parents, & Caregivers https://www.fda.gov/media/155051/download
- Informed that an office visit with you or another provider on your team is recommended after taking a COVID antiviral.
- For treatment or post-exposure prevention of COVID-19, the patient was also advised that they should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

If you have further questions: Please contact the prescribing pharmacy or call the Pfizer Medical Information Department at 1-800-438-1985. Clinicians can review the NIH COVID-19 Treatment Guidelines as well as the FDA EUA for the therapy.

- NIH COVID-19 Treatment Guidelines: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management-of-adults/nonhospitalized-adults--therapeutic-management/

- FDA EUA Paxlovid™ Fact Sheet for Healthcare Providers https://www.fda.gov/media/155050/download

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Attention Pharmacy: This is a template document. Please feel free to customize it to your pharmacy, however you must retain all elements set forth by this template. The information may be transmitted electronically.

PREVENTIVE CARE

TRAVEL MEDICATIONS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe pre-travel medications.
  - Malaria prophylaxis
  - Traveler's diarrhea
  - Acute mountain sickness
  - Motion sickness

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized Travel Medications Patient Intake Form (pg. 2-3)
  - Utilize the standardized Travel Medications Assessment and Treatment Care Pathway (pg. 4-10)

PHARMACIST TRAINING/EDUCATION:

- APhA Pharmacy-Based Immunization Delivery certificate (or equivalent); and
- Minimum of 4 hour comprehensive training program related to pharmacy-based travel medicine services intended for the pharmacist (one-time requirement); and
- A minimum of 1 hour of travel medication continuing education (CE), every 24 months.

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Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

PATIENT INFORMATION

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____

Legal Name_____ Name _____

Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____

Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____

Street Address _____

Phone ( ) _____ Email Address _____

Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____

Do you have health insurance? Yes / No Insurance Provider Name _____

Any allergies to medications? Yes / No If yes, please list _____

TRAVEL SPECIFICS

Purpose of Trip: _____

Activities: _____

Departure Date: _____ Return Date: _____

Countries AND Cities to be Visited (In Order of Visits)	**Arrival Date**	**Departure Date**

Have you traveled outside the United States before? □ Yes □ No

If yes, where and when?

_____

_____

1.	Will you be ONLY using airplane as your mode of transportation If no, explain: _____	□ Yes □ No □ Not sure
2.	Will you be ONLY visiting major cities? If no, explain: _____	□ Yes □ No □ Not sure
3.	Will you be ONLY staying in hotels? If no, explain: _____	□ Yes □ No □ Not sure
4.	Will you be visiting friends and family?	□ Yes □ No □ Not sure
5.	Will you be ascending to high altitudes? (> 7,000 ft or 2,300 meters) in the mountains	□ Yes □ No □ Not sure
6.	Will you be working in the medical or dental field with exposure to blood or bodily fluids?	□ Yes □ No □ Not sure

DRAFT

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

ALLERGIES

□ No known drug allergies □ No known food allergies

Drug Allergies: _____

Food Allergies: _____

VACCINE MEDICAL INFORMATION

Please complete the table below ***(please bring your vaccination record to the pre-travel consult)***

Vaccinations	Yes – *(Enter vaccination date below)*	No	Not Sure
COVID (Manufacturer):_____	Dose 1: 2:		
Hepatitis A	Dose 1: 2:		
Hepatitis B	Dose 1: 2: 3:		
Influenza			
Japanese Encephalitis			
Meningococcal Meningitis	Dose 1: 2:		
MMR (Measles, Mumps, Rubella)	Dose 1: 2:		
Pneumonia	PPSV23: PCV13:		
Polio (Adult Booster)			
Rabies			
Shingles			
Tetanus (Tdap/Td/DTaP/DT)			
Typhoid (Oral / Shot)			
Varicella			
Yellow Fever			
Other:			
Other:			

MEDICAL HISTORY

List your current prescription medications and medical conditions treated (include birth control pills and anti-depressants):

Current Medical Conditions:_____

_____

Current Prescription Medications:_____

_____

Regularly used Non-Prescription Medications (over the counter, herbal, homeopathic, vitamins, and supplements including those purchased at health-food stores):_____

7.	Are you currently using steroids?	□ Yes □ No □ Not sure
8.	Are you currently receiving radiation therapy?	□ Yes □ No □ Not sure
9.	Are you currently receiving immunosuppressive therapy?	□ Yes □ No □ Not sure
10.	Are you pregnant or are you planning to become pregnant within the next year?	□ Yes □ No □ Not sure
11.	Are you currently breast-feeding?	□ Yes □ No □ Not sure

QUESTIONS/CONCERNS

Please list additional questions or concerns that you might have regarding your travel:

_____

_____

Signature:_____Date:_____

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Travel Medications - Assessment and Treatment Care Pathway

STEP 1: Assess routine and travel vaccinations
STEP 2: Choose and issue prescription for appropriate prophylaxis medication, in adherence to the CDC's 2020 Yellow Book: Health Information for International Travel (06/11/2019) and this protocol, to include documented screening for contraindications (see pgs. 6-7).
STEP 3: Prescribe medications and administer vaccinations.
STEP 4: Provide a written individualized care plan to each patient.

1. **Malaria Prophylaxis**
    a. **Patient assessment**
        i. Review detailed itinerary
        ii. Identify zones of resistance
        iii. Review recommendations by the CDC
        iv. Discuss planned activities
        v. Assess risk of acquiring malaria and body weight (kg)
    b. **Prophylaxis**
        i. Discuss insect precautions and review signs/symptoms of malaria with patient
        ii. Screen for contraindications
        iii. Assess travel areas for resistance:
            1. **Non-chloroquine resistant zone**
                a. *Chloroquine (Aralen®)*
                Adult dosing: Chloroquine 500 mg
                - Begin 1-2 weeks prior to travel-1 tablet weekly
                - Taken once weekly during trip and for 4 weeks after leaving

                Pediatric dosing:
                8.3 mg/kg (maximum is adult dose)
                - Begin 1-2 weeks prior to travel-1 tablet weekly
                - Taken once weekly during trip and for 4 weeks after leaving

                OR

                b. *Hydroxychloroquine (Plaquenil®)*
                Adult Dosing: Hydroxychloroquine 400 mg
                - Begin 1-2 weeks prior to travel-1 tablet weekly
                - Taken once weekly during trip and for 4 weeks after leaving

                Pediatric Dosing:
                6.5 mg/kg (maximum is adult dose)
                - Begin 1-2 weeks prior to travel-1 tablet weekly
                - Taken once weekly during trip and for 4 weeks after leaving

            2. **Chloroquine-resistant zone**
                a. Atovaquone/Proguanil (Malarone®)
                Adult Dosing: Atovaquone/Proguanil 250mg/100mg
                - Begin 1 tablet daily 1-2 days prior to travel
                - Taken daily during trip and 7 days after leaving

                Pediatric Dosing: Atovaquone/Proguanil 62.5mg/25mg
                5–8 kg: 1/2 pediatric tablet daily
                9–10 kg: 3/4 pediatric tablet daily
                11–20 kg: 1 pediatric tablet daily
                21–30 kg: 2 pediatric tablets daily
                31–40 kg: 3 pediatric tablets daily

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> 40 kg: 1 adult tablet daily

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 7 days after leaving

OR

b. *Doxycycline monohydrate (Monodox®) or hyclate (Vibramycin®) (≥8 years)*
Adult Dosing: Doxycycline 100mg
- Begin 1 tablet or capsule daily 1-2 days prior to travel
- Taken daily during trip and for 4 weeks after leaving

Pediatric Dosing:
≥8 years old: 2.2 mg/kg (maximum is adult dose) daily
- Begin 1 dose daily 1-2 days prior to travel
- Taken daily during trip and for 4 weeks after leaving

OR

c. *Mefloquine (Lariam®)*
Adult Dosing: Mefloquine 250mg
- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during and for 4 weeks after leaving

Pediatric Dosing:
≤9 kg: 5 mg/kg
10-19 kg: ¼ tablet weekly
20-30 kg: ½ tablet weekly
31-45 kg: ¾ tablet weekly
> 45 kg: 1 tablet weekly
- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during and for 4 weeks after leaving

3. Mefloquine-Resistant zone

a. *Doxycycline monohydrate (Monodox®) or hyclate (Vibramycin®) (≥8 years)*
Adult dosing: Doxycycline 100 mg
- Begin 1 tablet or capsule daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

Pediatric dosing:
≥8 years old: 2.2 mg/kg (maximum is adult dose) daily
- Begin 1 dose daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

OR

b. *Atovaquone/Proguanil (Malarone®)*
Adult dosing: Atovaquone/Proguanil 250mg/100mg
Pediatric Dosing: Atovaquone/Proguanil 62.5mg/25mg
5–8 kg: 1/2 pediatric tablet daily
9–10 kg: 3/4 pediatric tablet daily
11–20 kg: 1 pediatric tablet daily
21–30 kg: 2 pediatric tablets daily
31–40 kg: 3 pediatric tablets daily
> 40 kg: 1 adult tablet daily
- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 7 days after leaving

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2. <u>Traveler's diarrhea (TD)</u>

a. Patient assessment
   i. Review detailed itinerary and identify travel areas of increased risk
   ii. Assess patient's risk of acquiring traveler's diarrhea and body weight (kg)
   iii. Screen for contraindications
   iv. Consult CDC guidelines for list of high-risk factors for TD

b. Prophylaxis education
   i. Discuss dietary counseling, avoidance of high-risk foods, food and beverage selection and sanitary practices, oral rehydration
   ii. Educate patient on how to recognize symptoms and severity of traveler's diarrhea
      1. **Mild:** diarrhea that is tolerable, not distressing, and does not interfere with planned activities
      2. **Moderate:** diarrhea that is distressing or interferes with planned activities
      3. **Severe:** dysentery (bloody stools) and diarrhea that is incapacitating or completely prevents planned activities
   iii. Pharmacotherapy prophylaxis
      Pepto-Bismol®: Two 262-mg tablets or 2 fluid oz (60 mL) QID for up to 3 weeks
      Note: Avoid in patients <12 years old, patients taking doxycycline for malaria prophylaxis, anticoagulants, allergic to aspirin, probenecid, methotrexate

c. Treatment *(Note: while Yellow Book includes ciprofloxacin, this protocol only permits azithromycin)*
   i. First line for mild TD and adjunctive treatment for moderate TD
      1. Loperamide (OTC- Imodium® AD)
      <u>Adult Dosing:</u> Loperamide 2 mg
      - Take 4 mg at onset of diarrhea, followed by additional 2 mg after each loose stool (Max of 16 mg per day)

      <u>Pediatric Dosing:</u>
      - 22 to 26 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 4 mg per day)
      - 27 to 43 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 6 mg per day)

   ii. Antibiotic treatment (for moderate or severe TD)
      1. Consult CDC guidelines for resistance rates to antibiotics
      2. Empiric treatment for moderate TD and severe TD (age <18 requires a prescription form PCP)
         a. *Azithromycin 500mg*
         • 1 tablet daily for 1-3 days
         • 1 course/14 days, Max 2 courses for trips >14 days

OR

         b. *Azithromycin 1000mg:* Single dose of one tablet (if symptoms are not resolved after 24 hours, continue daily dosing for up to 3 days)

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3. <u>Acute Mountain Sickness</u>

a. Patient assessment/Education
   i. Review detailed itinerary and identify travel areas of increased risk
   ii. Assess patients' risk of acquiring Acute Mountain Sickness (AMS) and body weight (kg)
   iii. Review signs/symptoms of AMS, discuss safe ascent rates and tips for acclimating to higher altitudes (alcohol abstinence, limited activity)
   iv. Screen for contraindications
      1. AcetaZOLAMIDE
         a. Hypersensitivity to acetazolamide or sulfonamides

b. Prophylaxis
   i. Consult CDC guidelines for list of risk factors for AMS. If risk factors are present and warrant prophylaxis:
      1. *AcetaZOLAMIDE (Diamox®)*

         <u>Adult Dosing:</u> Acetazolamide 125 mg
         - Take 1 tablet twice daily starting 24 hours before ascent, continuing during ascent, and 2-3 days after highest altitude achieved or upon return

         <u>Pediatric Dosing:</u>

         2.5 mg/kg/dose every 12 hours before ascent, continuing during ascent, and 2-3 days after highest altitude achieved or upon return. (Maximum of 125 mg/dose)

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4. <u>Motion Sickness</u>

a. Patient assessment
   i. Review detailed itinerary and identify travel areas of increased risk
   ii. Assess patients' risk of acquiring motion sickness and body weight (kg)
   iii. Review signs/symptoms of motion sickness, discuss tips for reducing motion sickness: being aware of triggers, reducing sensory input
   iv. Screen for contraindications

b. Prophylaxis
   i. Consult CDC guidelines for list of risk factors for Motion sickness. If risk factors present and warrant pharmacologic prevention:
   ii. Adults
      1. **First-line**: *Scopolamine transdermal patches* (Age <18 Requires prescription from PCP)
      • Apply 1 patch (1.5 mg) to hairless area behind ear at least 4 hours prior to exposure; replace every 3 days as needed

      AND/OR

      2. **Second-line:**
         a. *Promethazine 25mg Tablets:* Take one tablet by mouth 30 – 60 minutes prior to exposure and then every 12 hours as needed
         b. *Promethazine 25mg Suppositories:* Unwrap and insert one suppository into the rectum 30-60 minutes prior to exposure and then every 12 hours as needed
         c. *Meclizine 12.5-25mg* (OTC/Rx):
         Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

   iii. Pediatrics
      1. **First-line**:
         a. 7-12 years old
            - *DimenhyDRINATE (OTC Dramamine®)* 1-1.5mg/kg/dose*:* Take one dose 1 hour before travel and every 6 hours during the trip. (Maximum 25 per dose)
            - *DiphenhydrAMINE (OTC Benadryl®)* 0.5-1mg/kg/dose*:* Take one dose 1 hour before travel and every 6 hours during the trip. (Maximum 25 mg per dose)
         b. ≥ 12 years old
            - *Meclizine 12.5-25mg* (OTC/Rx): Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

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Travel Medications - Assessment and Treatment Care Pathway

Screen for Contraindications:

Malaria Prophylaxis

1. Chloroquine
    c. Age < 7 years old
    d. Hypersensitivity to chloroquine, 4-aminoquinolone compounds, or any component of the formulation
    e. Presence of retinal or visual field changes of any etiology
2. Hydroxychloroquine
    a. Age < 7 years old
    b. Hypersensitivity to hydroxychloroquine, 4 aminoquinoline derivatives, or any component of the formulation
3. Atovaquone/proguanil
    a. Age < 7 years old
    b. Weight < 5 kg
    c. Hypersensitivity to atovaquone, proguanil or any component of the formulation
    d. Prophylactic use in severe renal impairment (CrCl < 30 mL/min)
4. Doxycycline
    a. Age < 8 years old
    b. Hypersensitivity to doxycycline, other tetracyclines
    c. Use in infants and children < 8 years old
    d. During second or third trimester of pregnancy
    e. Breast-feeding
5. Mefloquine
    a. Age < 7 years old
    b. Hypersensitivity to mefloquine, related compounds (i.e. quinine and quinidine)
    c. Prophylactic use in patients with history of seizures or psychiatric disorder (including active or recent history of depression, generalized anxiety disorder, psychosis, schizophrenia, or other major psychiatric disorders)

Traveler's Diarrhea

1. Loperamide
    a. Age < 7 years old
    b. Hypersensitivity to loperamide or any component of the formulation
    c. Abdominal pain without diarrhea
    d. Acute dysentery
    e. Acute ulcerative colitis
    f. Bacterial enterocolitis (caused by *Salmonella, Shigella, Campylobacter)*
    g. Pseudomembranous colitis associated with broad-spectrum antibiotic use
    h. OTC—do not use if stool is bloody of black
2. Azithromycin
    a. Age < 18 years old will require a prescription from a PCP
    b. Hypersensitivity to azithromycin, erythromycin or other macrolide antibiotics
    c. History of cholestatic jaundice/hepatic dysfunction associated with prior azithromycin use

Acute Mountain Sickness

1. AcetaZOLAMIDE
    a. Age < 7 years old
    b. Marked hepatic disease or insufficiency
    c. Decreased sodium and/or potassium levels
    d. Adrenocortical insufficiency
    e. Cirrhosis
    f. Hyperchloremic acidosis
    g. Severe renal dysfunction or disease

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h. Long term use in congestive angle-closure glaucoma

Motion Sickness

1. Scopolamine
    a. Age < 18 years old will require a prescription from a PCP
    b. Hypersensitivity to scopolamine
    c. Glaucoma or predisposition to narrow-angle glaucoma
    d. Paralytic ileus
    e. Prostatic hypertrophy
    f. Pyloric obstruction
    g. Tachycardia secondary to cardiac insufficiency or thyrotoxicosis
2. Promethazine
    a. Age < 7 years old
    b. Hypersensitivity to promethazine or other phenothiazines (i.e. prochlorperazine, chlorproMAZINE, fluPHENAZine, perphenazine, etc)
    c. Treatment of lower respiratory tract symptoms
    d. Asthma
3. Meclizine
    a. Age < 12 years old
    b. Hypersensitivity to meclizine
4. DimenhyDRINATE
    a. Age < 7 years old
    b. Hypersensitivity to dimenhyDRINATE or any component of the formulation
    c. Neonates
5. DiphenhydrAMINE
    a. Age < 7 years old
    b. Hypersensitivity to diphenhydrAMINE or other structurally related antihistamines or any component of the formulation
    c. Neonates or premature infants
    d. Breast feeding

DRAFT

PREVENTIVE CARE

HIV POST-EXPOSURE PROPHYLAXIS (PEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe post-exposure prophylaxis (PEP) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PEP Patient Intake Form (pg. 2)
  - Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-5)
  - Utilize the standardized PEP Patient Informational Handout (pg. 7)
  - Utilize the standardized PEP Provider Fax (pg. 8)

PHARMACIST TRAINING/EDUCATION:

- Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

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Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
2.	What was the date of the exposure?	___/___/___
3.	What was the approximate time of the exposure?	___:___ *AM/PM*
4.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____	□ Yes □ No □ Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
7.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	□ Yes □ No □ Not sure
8.	Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	□ Yes □ No □ Not sure
9.	Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	□ Yes □ No □ Not sure
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? □persons with known HIV infection □men who have sex with men with unknown HIV status □persons who inject drugs □sex workers	□ Yes □ No □ Not sure
11.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____	Yes □ No □ Not sure

Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
13.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
14.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like a vaccine today? *Yes/No*	□ Yes □ No □ Not sure
15.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
16.	Are you currently pregnant?	□ Yes □ No □ Not sure
17.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	□ Yes □ No □ Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

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Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

Name: _____Date of Birth:____/____/_____ Today's Date:____/____/_____

<table>
<tr><td colspan="2">1. Is the patient less than 13 years old?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic</td><td>☐ No: Go to #2</td></tr>
<tr><td colspan="2">2. Was the patient a survivor of sexual assault?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.**</td><td>☐ No: Go to #3</td></tr>
<tr><td colspan="2">3. Is the patient known to be HIV-positive?</td><td rowspan="2">Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.</td></tr>
<tr><td>☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.</td><td>☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).</td></tr>
<tr><td colspan="2">4. What time did the exposure occur?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.</td><td>☐ ≤72 hours ago: go to #5</td></tr>
<tr><td colspan="2">5. Was the exposure from a source person known to be HIV-positive?</td><td rowspan="2"></td></tr>
<tr><td>☐ Yes: Go to #6</td><td>☐ No: Go to #7</td></tr>
<tr><td colspan="2">6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids:</td><td rowspan="2">Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.</td></tr>
<tr><td>Please check any/all that apply:
☐Blood
☐Semen
☐Vaginal secretions
☐Rectal secretions
☐Breast milk
☐Any body fluid that is visibly contaminated with blood

If any boxes are checked, go to #9.</td><td>Please check any/all that apply (Note: only applicable if not visibly contaminated with blood):
☐Urine
☐Nasal Secretions
☐Saliva
☐Sweat
☐Tears
☐None of the above

Go to #7</td></tr>
<tr><td colspan="2">7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: This type of exposure puts the patient at a high risk for HIV acquisition</td></tr>
<tr><td>☐ Yes: Go to #9</td><td>☐ No: Go to #8</td></tr>
</table>

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

<table>
<tr><td colspan="2">8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.

Oregon AIDS Education and Training Center List of PEP Resources, PEP Navigation Services, STI and HIV testing and treatment sites and community organizations: https://www.oraetc.org/pep-resource-list</td></tr>
<tr><td>☐ Yes: Please check all that apply and go to #9:
☐Was the source person known to be HIV-positive?
☐Were there cuts/openings/sores/ulcers on the oral mucosa?
☐Was blood present?
☐Has this happened more than once without PEP treatment?
☐None of the above</td><td>☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.</td></tr>
<tr><td colspan="2">9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?</td><td rowspan="2">Notes: Connection to care is critical for future recommended follow-up.</td></tr>
<tr><td>☐ Yes: Go to #10</td><td>☐ No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td></tr>
<tr><td colspan="2">10. Does the patient have history of known Hepatitis B infection (latent or active)?</td><td rowspan="4">Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No. Go to #11</td></tr>
<tr><td colspan="2">11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No
Verify vaccine records or Alert-IIS.
Dates:_____</td></tr>
<tr><td>☐ Yes: Go to #13</td><td>☐ No: Go to #12</td></tr>
<tr><td colspan="2">12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.
☐Vaccine administered
Lot:_____ Exp:_____
Signature:_____</td><td></td></tr>
<tr><td colspan="2">13. Does the patient have known chronic kidney disease or reduced renal function?</td><td rowspan="2">Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.</td></tr>
</table>

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV) Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg) one tablet by mouth daily for 30 days

PLUS

Isentress® (raltegravir 400 mg) one tablet by mouth twice daily for 30 days

Notes:

- There may be other FDA-approved regimens available for treatment of PEP. Truvada® plus Isentress® is the only regimen permitted for pharmacist prescribing at this time.
- Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such.
- Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com
- If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.

COUNSELING POINTS:

- Truvada®:
  - Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset.
  - Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.
- Isentress®:
  - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
  - If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress®.
- Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.
- Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.
- Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

*Oregon licensed pharmacists are mandatory reporters of child abuse, per ORS Chapter 419B. Reports shall be made to Oregon Department of Human Services @ **1-855-503-SAFE (7233)**.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____Date____/____/_____

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PEP Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Note: RPh must refer patient if exposure occurred >72 hours prior to initiation of medication

Rx

- Drug: emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada)
  Sig: Take one tablet by mouth once daily in combination with Isentress for 30 days
  Quantity: #30
  Refills: none

AND

- Drug: raltegravir 400mg (Isentress)
  Sig: Take one tablet by mouth twice daily in combination with Truvada for 30 days.
  Quantity: #60
  Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:
Lot:_____Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

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Patient Information
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name: _____Pharmacist Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

This page contains important information for you; please read it carefully.

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are the medications and directions you have been prescribed, some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

Medications: You must start these within 72 hours of your exposure

- Truvada (emtricitabine/tenofovir disoproxil) 200 mg/300 mg – take 1 tablet by mouth daily for 30 days, **AND**
- Isentress (raltegravir) 400 mg – take 1 tablet by mouth twice daily for 30 days

Key Points

- Take every dose. If you miss a dose, take it as soon as you remember.
  - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking either medication without first asking your doctor or pharmacist.
- Truvada and Isentress don't have side effects most of the time. The most common side effects (if they do happen) are stomach upset. Taking Truvada and Isentress with food can help with stomach upset. Over-the-counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you.
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
   - ☐ HIV antigen/antibody 4th generation
   - ☐ Hepatitis B surface antigen and surface antibody
   - ☐ Hepatitis C antibody
   - ☐ Treponema pallidum antibody
   - ☐ Comprehensive metabolic panel
4. If you think that you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

Provider Notification
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____ Pharmacist Name: _____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) has been prescribed HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

This regimen consists of:

- Truvada (emtricitabine/tenofovir disoproxil) 200/300mg tablets - one tab by mouth daily for 30 days AND
- Isentress (raltegravir) 400mg tablets - one tab by mouth twice daily for 30 days.

This regimen was initiated on _____(Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

Provider pearls for HIV PEP:

- Truvada needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Truvada and Isentress are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs at **6 weeks** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis B surface antigen and surface antibody
- ☐ Hepatitis C antibody
- ☐ Comprehensive metabolic panel
- ☐ Treponema pallidum antibody as appropriate
- ☐ Pregnancy test as appropriate
- ☐ STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis C antibody

If you have further questions, please contact the prescribing pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.

PREVENTIVE CARE

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe pre-exposure prophylaxis (PrEP) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PrEP Patient Intake Form (pg. 2-3)
  - Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-8)
  - Utilize the standardized PrEP Provider Fax (pg.10)

  PHARMACIST TRAINING/EDUCATION:
  - Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

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Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

Do you answer yes to any of the following? □ yes □ no

1. Do you want to start or continue PrEP?
2. Do you sexually partner with men, women, transgender, or non-binary people?
3. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom. _____% of the time __/__/__ last sex without a condom
4. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
5. Do you have vaginal sex? • Receptive- you have a vagina and you use it for vaginal sex • Insertive- you have a penis and you use it for vaginal sex
6. Do you have anal sex? • Receptive- someone uses their penis to perform anal sex on you • Insertive- you use your penis to perform anal sex on someone else
7. Do you inject drugs?
8. Are you in a relationship with an HIV-positive partner?
9. Do you exchange sex for money or goods? (includes paying for sex)
10. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex?

Medical History: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)?	□ yes □ no
2. Have you had any of the following in the last 4 weeks: fever, feeling very tired, muscle or joint aches or pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, general flu-like symptoms?	□ yes □ no
3. When was your last possible HIV exposure?	□ < 72 hrs ago □ 72 hrs – 4 weeks ago □ > 4 weeks ago
4. Have you ever had Hepatitis B Infection?	□ yes □ no
5. Have you ever received an immunization for Hepatitis B? If yes, when: • If no, would you like a Hepatitis B immunization today? □ yes □ no	□ yes □ no Date of vaccine __/__/__

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Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

6. Have you ever been told you have a bone disease (e.g. osteoporosis, low bone mineral density, etc.)?	□ yes □ no
7. Do you see a healthcare provider for problems with your kidneys?	□ yes □ no
8. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? • Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)	□ yes □ no
9. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no
10. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	□ yes □ no

Testing and Treatment:

1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription. • I may be able to have tests performed at the pharmacy. • I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks. o I brought my labs in today □ Yes □ No I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV. I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate.
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.

Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.

Please list any questions you have for the pharmacy staff:

Patient Signature: _____ **Date:** _____

DRAFT

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

Risk Factor:	Notes and considerations
1. Patient requests PrEP	• Patient may not be comfortable sharing detailed sexual history per CDC PrEP guidelines, if a patient requests PrEP, the recommendation is to prescribe it regardless of identified HIV exposure risk.
2. Sexual partners	• MSM activity is highest risk for HIV. • Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present.
3. Estimated condom use _____% of the time __/__/__ last sex without a condom	• Condomless sex greatly increases risk of HIV and STIs. • For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP). • Condomless sex within last 14 days, repeat HIV test in one month.
4. Oral sex	• Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals. • STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex.
5. Vaginal sex	• Receptive vaginal sex can be high risk for HIV. • Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present.
6. Anal sex	• Receptive anal sex has the most risk of HIV of any sex act. • Insertive anal sex has high risk for HIV. • STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex.
7. Injection drug use	• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
8. HIV-positive partner	• People living with HIV who have undetectable viral loads will not transmit HIV. • For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP.
9. Exchanging sex for money or goods	• People who buy or sell sex are at high risk for HIV.
10. Popper or methamphetamine use	• Popper (inhaled nitrates) and methamphetamine use is associated with an increased risk of HIV. • Recommend adequate lubrication in persons who use poppers for sex.

1. Is one or More Risk Factor Present? □ **yes** □ ***no***

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

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Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Testing:

The pharmacist must verify appropriate labs are complete. *Italics* below indicate need for referral.

Test Name	Date of Test	Result	Needs referral
• HIV Ag/Ab (4th gen) test:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• HIV RNA test:	____/____/_____	□ *detected* □ *indeterminate* □ not detected	□ *Yes*

Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing. NOTE: HIV Ag/Ab test must be performed within the 7 days prior to prescribing and dispensing. Order lab at initial intake and every 90 days thereafter.

- Syphilis/Treponemal antibody: ____/____/_____ □ *reactive* □ *indeterminate* □ non-reactive □ *Yes*

Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing. Order lab at initial intake and every 90-180 days depending on risk.

- Hepatitis B surface antigen: ____/____/_____ □ *reactive* □ non-reactive □ *Yes*

Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician. Confirmation of being fully vaccinated for hepatitis B via ALERT or medical record may meet criteria for negative Hepatitis B surface antigen. If records of vaccination are not available, order lab at initial intake only.

- *Hepatitis C antibody (recommended, optional):* ____/____/_____ □ *reactive* □ non-reactive □ *Yes*

Recommended for men who have sex with men, transgender women who have sex with men, and persons with illicit or injection drug use. At least annual screenings and every 3 to 6 months for those with injection drug use.

Positive antibody indicates exposure to Hepatitis C virus. The pharmacist will refer this person for confirmatory testing and treatment. It is permissible to proceed with PrEP prescribing in this scenario.

- Gonorrhea/Chlamydia: ____/____/_____ □ *Yes*

Urinalysis result:	Pharyngeal test result:	Rectal test result:
□ *reactive* □ *indeterminate*	□ *reactive* □ *indeterminate*	□ *reactive* □ *indeterminate*
□ non-reactive	□ non-reactive	□ non-reactive

Patients can determine which sites need to be screened. All reactive or indeterminate chlamydia or gonorrhea results must be reported to the County Health Department and Oregon Health Authority and will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment. Order lab at initial intake and every 90-180 days depending on risk.

- Renal function (CrCl): ____/____/_____ _____ mL/min □ CrCl > 60 mL/min □ *Yes*

SCr _____mg/dL □ CrCl 30-60 mL/min

□ *CrCl < 30 mL/min*

CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy.* Order lab at initial intake and annually thereafter; if over 50 years old and on emtricitabine/tenofovir DF (Truvada) PrEP order every 6 months.

- HCG: ____/____/_____ □ positive □ *indeterminate* □ negative □ *Yes*

Applies to anyone who may become pregnant; frequency can be from every 3 to 12 months per patient preference and pharmacist clinical judgment. Refer to healthcare provider if positive.

- Signs/symptoms of acute retroviral syndrome (□ *Present* □ Not Present) AND potential HIV exposure (□ *Yes* □ No) in the last 4 weeks AND not on PrEP (□ *Yes* □ No) □ *Yes*

If signs/symptoms present and answered yes to potential HIV exposure and not on PrEP, do NOT prescribe PrEP; ***Urgently refer*** *to PCP, HIV specialist, or PrEP specialist or community organization[1] to link to care and evaluation*

- Signs/symptoms of acute retroviral syndrome and potential exposure *while on PrEP*. □ *Yes*

□ *Present* □ Not Present

If present, eligible for PrEP for up to a 30-day supply. Order HIV RNA and repeat HIV Ag/Ab within 7 days of the next prescription or refer to PrEP provider or Infectious Disease provider for further evaluation.

- Exposure risk less than 72 hours ago? □ *Yes* □ No □ *Yes*

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

2. Is HIV Ab/Ag 4th gen test resulted? □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes and non-reactive: Proceed to question #3
- *If yes and reactive or indeterminate: Do NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, do NOT prescribe PrEP, obtain HIV Ab/Ag 4th gen test. Repeat question #2 once results are available.*

3a. If initial visit: Are syphilis, gonorrhea, chlamydia, Hepatitis B serologies (if no documentation of complete vaccination), and serum creatinine resulted? □ **yes** □ ***no***

- If yes, RPH may prescribe PrEP for up to a 90 day supply. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP for up to a 30 day supply and the patient needs to complete all required labs and bring them in within 30 days before next refill. Proceed to next section: Medical History.

→ *See next page for follow-up visit lab requirements and sample language for reactive (indeterminate) HIV and STI tests.*

3b. If follow-up visit: Are required follow-up labs resulted? □ **yes** □ ***no***

- □ Every 90 days- HIV
- □ Every 90-180 days- Syphilis/Treponemal antibody and Gonorrhea/Chlamydia; Renal function if > 50 yrs old and on emtricitabine/tenofovir DF (Truvada)
- □ Annually - Renal function

- If yes, RPH may prescribe PrEP for up to a 90 day supply. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP for up to a 30 day supply; patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

Sample language for reactive or indeterminate tests:

Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.

Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

Oregon AIDS Education and Training Center List of PrEP and PEP Resources, PrEP Navigation Services, STI and HIV testing and treatment sites and community organizations: https://www.oraetc.org/prep https://www.oraetc.org/pep-resource-list

Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA.

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Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Medical History: The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

Medical history factor	Notes and considerations
	REFERRAL CONDITIONS
1. Positive HIV test *Needs Referral:* □ *yes* □ no	• A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. • Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management.
2. Symptoms of acute retroviral syndrome in last 4 weeks □ *yes* □ no	• Could have acute HIV with negative screening HIV Ag/Ab result. • Order HIV RNA and refer to PrEP provider or Infectious Disease provider for further evaluation.
3. Exposure risk was: < 72 hrs ago □ *yes* □ no >72 hours to 4 weeks ago □ *yes* □ no	• If exposure <72 hours ago, screen for eligibility for PEP (see OBOP Protocol for PEP Prescribing) OR refer to urgent care or ED for further evaluation and possible PEP initiation. • If exposure 72 hours to 4 weeks ago, eligible for up to a 30-day supply of PrEP. Order HIV RNA test now and repeat HIV Ag/Ab within 7 days of next assessment; review symptoms of acute retroviral syndrome and need for urgent evaluation should symptoms develop.
4. Presence of Hepatitis B infection *Needs Referral:* □ *yes* □ no	• Truvada and Descovy are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare. • People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.
5. Presence of Hepatitis C exposure *Needs Referral:* □ *yes* □ no	• People with HepC exposure must be referred to primary care or other appropriate community health outreach organization (see Oregon AIDS Education and Training Center website for list above). Pharmacist may proceed with prescribing PrEP.
6. Impaired kidney function (<30mL/min) *Needs Referral:* □ *yes* □ no	• Truvada is approved for patients with a CrCl >60mL/min. • Consider Descovy in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease.
7. Other medications *Needs Referral:* □ *yes* □ no	• Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density. • For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Descovy over Truvada.
	CONSIDERATIONS
8. NSAID use Precaution- Counseled on limiting use: □ yes □ no	• Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.
9. Hepatitis B vaccinated If not, would the patient like to be vaccinated? □ yes □ no	• Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP. • Counsel on risk factors for Hepatitis B and recommend vaccination. • If patient would like to be vaccinated, proceed according to OAR 855-019-0280.
10. Pregnant or breastfeeding	• Pregnancy and breastfeeding are not contraindications for PrEP. • Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence. • Truvada is preferred due to better data in these populations.

4. Are One or More Referral Condition(s) Present? □ *yes* □ no

- *If yes, HIV PrEP is recommended but pharmacists are not authorized to prescribe in accordance with this RPH protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.*
- If no, HIV PrEP is recommended and pharmacists are authorized to prescribe and dispense PrEP in accordance with this RPH protocol. Proceed to next sections: Regimen Selection and Prescription.

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Regimen Selection:

Considerations*	**Preferred regimen**
Cis-gender male or male to female transgender woman. • Both Truvada and Descovy are FDA approved in these populations. May prescribe based on patient preference.	May choose Truvada or Descovy
Cis-gender female or female to male transgender man. • Only Truvada is FDA approved in these populations. • If patient has low bone mineral density or renal function that would preclude Truvada use, but has risk factors for HIV, refer the patient to a specialist for PrEP management.	Truvada
NSAID use • If patient is male or a male to female transgender woman, consider Descovy	Descovy
Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist. • If patient is male or male to female transgender woman, consider Descovy	Descovy
Patient has decreased bone mineral density or on medications that affect bone mineral density. • If patient is male or male to female transgender woman, consider Descovy.	Descovy
Patient is pregnant or breastfeeding • Descovy has not been studied in these populations. Truvada is approved in these populations.	Truvada

*generic versions are acceptable in all cases if available.

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PrEP Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Note: RPh may not prescribe and must refer patient if HIV test reactive or indeterminate

Rx

☐ **Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

-or-

☐ **Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

Written Date: _____

Expiration Date: (This prescription expires 90 days from the written date) _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:

Lot:_____ Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____

_____

_____

_____

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Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	

Provider Notification
Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____ Pharmacist Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been prescribed HIV Pre-Exposure Prophylaxis (PrEP) by _____, RPH. This regimen was filled on _____/_____/_____ (Date) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

This regimen consists of the following (check one):

☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
- Take one tablet by mouth daily

☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
- Take one tablet by mouth daily

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• HIV RNA	___/____/_____	□ *detected* □ *indeterminate* □ not detected	□ *Yes*
• Syphilis/Treponemal antibody:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• Hepatitis B surface antigen:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
• Hepatitis C antibody:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
• Gonorrhea/Chlamydia:	____/____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ non-reactive	Pharyngeal test result: □ *reactive* □ *indeterminate* □ non-reactive	Rectal test result: □ *reactive* □ *indeterminate* □ non-reactive	
• Renal function (CrCl): □ CrCl >60mL/min	____/____/_____ _____ mL/min □ CrCl 30mL/min - 60mL/min	□ *CrCl <30mL/min*	□ *Yes*
• HCG:	____/____/_____	□ *positive* □ *indeterminate* □ negative	□ *Yes*
• Signs/symptoms of acute retroviral syndrome (□ *Present* □ Not Present) AND potential HIV exposure (□ *Yes* □ No) in the last 4 weeks and not on PrEP (□ *Yes* □ No).			□ *Yes*
• Exposure risk less than 72 hours ago? □ *Yes* □ No			□ *Yes*

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

Provider pearls for HIV PrEP:

- PrEP is prescribed for up to a 90 day supply for each prescription to align with appropriate lab monitoring guidelines.
- Truvada is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada and Descovy are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacist monitoring of HIV PrEP and transition of care:

- The pharmacist prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and other baseline and treatment monitoring lab results as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

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PREVENTIVE CARE

CONTRACEPTION – Oral, Transdermal Patch, Vaginal Ring and Injectable

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.689, a pharmacist may prescribe and administer injectable hormonal contraceptives and prescribe and dispense self-administered hormonal contraceptives. Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe oral, vaginal ring, transdermal patch or injectable hormonal contraceptives for the prevention of pregnancy.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Contraception Patient Intake Form (pg. 2-3)
- Utilize the standardized Contraception Assessment and Treatment Care Pathway Form (pg. 4-8)
- Utilize the standardized Contraception Provider Notification Form (pg. 10)
- Utilize the standardized Contraception Patient Visit Summary Form (pg. 11)

PHARMACIST TRAINING/EDUCATION:

- Completed a Board-approved and Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist.

REFERENCES:

- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2016). US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016. Retrieved from https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf
- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2020). Summary Chart of US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2020. Retrieved from https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf
- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2016). US Selected Practice Recommendations (US SPR) for Contraceptive Use, 2016. Retrieved from https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf

RESOURCES:

- CDC US MEC & US SPR App
- National Family Planning and Reproductive Health Association. (2020). Self-Administration of Injectable Contraception Retrieved from https://www.nationalfamilyplanning.org/file/documents---service-delivery-tools/NFPRHA---Depo-SQ-Resource-guide---FINAL-FOR-DISTRIBUTION.pdf

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Contraception Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____
Any allergies to foods (ex. soy, lactose)? Yes / No If yes, please list _____

Background Information:

1.	Have you previously had a contraceptive prescribed to you by a pharmacist? If yes, when was the last time a pharmacist prescribed a contraceptive to you?	□ Yes □ No ___/___/___
2.	What was the date of your last reproductive or sexual health clinical visit with a non-pharmacist?	___/___/___

Contraception History:

3.	Have you ever been told by a healthcare professional not to take hormones? -If yes, what was the reason? _____	□ Yes □ No
4.	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection?	□ Yes □ No
5.	Did you ever experience a bad reaction to using hormonal birth control? - If yes, what kind of reaction occurred? _____	□ Yes □ No
6.	Are you currently using any method of birth control including pills, patch, ring or shot/injection? - If yes, which one do you use? _____	□ Yes □ No
7.	Do you have a preferred method of birth control that you would like to use? - If yes, please check one: □ Oral pill □ Skin patch □ Vaginal ring □ Injection □ Other (IUD, implant)	□ Yes □ No

Pregnancy Screen:

8.	Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have you had no menstrual period since the delivery?	□ Yes □ No
9.	Have you had a baby in the last 4 weeks?	□ Yes □ No
10.	Did you have a miscarriage or abortion in the last 7 days?	□ Yes □ No
11.	Did your last menstrual period start within the past 7 days?	□ Yes □ No
12.	Have you abstained from sexual intercourse since your last menstrual period or delivery?	□ Yes □ No
13.	Have you been using a reliable contraceptive method consistently and correctly?	□ Yes □ No

Medical Health & History:

14.	What was the first day of your last menstrual period?	___/___/___
15.	Have you had a recent change in vaginal bleeding that worries you?	□ Yes □ No
16.	Have you given birth within the past 21 days? If yes, how long ago? _____	□ Yes □ No
17.	Are you currently breastfeeding?	□ Yes □ No
18.	Do you smoke cigarettes?	□ Yes □ No
19.	Do you have diabetes?	□ Yes □ No
20.	Do you get migraine headaches? If yes, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	□ Yes □ No □ Yes □ No □ N/A
21.	Are you being treated for inflammatory bowel disease?	□ Yes □ No
22	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	□ Yes □ No
23.	Have you ever had a heart attack or stroke, or been told you had any heart disease?	□ Yes □ No

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Contraception Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

24.	Have you ever had a blood clot?	□ Yes □ No
25.	Have you ever been told by a healthcare professional that you are at risk of developing a blood clot?	□ Yes □ No
26.	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	□ Yes □ No
27	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	□ Yes □ No
28.	Have you had bariatric surgery or stomach reduction surgery?	□ Yes □ No
29.	Do you have or have you ever had breast cancer?	□ Yes □ No
30.	Have you had an organ transplant?	□ Yes □ No
31.	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	□ Yes □ No
32.	Do you have lupus, rheumatoid arthritis, or any blood disorders?	□ Yes □ No
33.	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)? - If yes, list them here: _____	□ Yes □ No
34.	Do you have any other medical problems or take any medications, including herbs or supplements? - If yes, list them here: _____ _____ _____	□ Yes □ No

Patient Signature_____Date_____

To Be Completed by a Pharmacist:

1. Blood Pressure Reading _____/_____ mmHg

2a. If contraception was prescribed/dispensed, please complete the following:

Drug: _____

Directions: _____

Quantity: _____

Refills:_____

Healthcare Provider (if known) contacted/notified of therapy Date _____/_____/_____

2b. If contraception was administered, please complete the following:

Drug: _____

Directions: _____

Quantity: _____

Product/Lot: _____ Expiration: ___/___/_____

Injection Sites:

□ Depo-Provera CI - IM □ R deltoid or □ L deltoid

□ Depo-SubQ Provera- SQ in □ R anterior thigh or □ L anterior thigh or □ abdomen

Administration Time: ____:_____ AM/PM

3. Healthcare Provider (if known) contacted/notified of therapy Date _____/_____/_____

If contraception was not prescribed/dispensed/administered, please indicate reason(s) for referral:

_____

_____

_____

RPH Signature_____Date_____

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Standardized Assessment and Treatment Care Pathway - Contraception

Algorithm A: Oral, Vaginal and Transdermal Contraception with Combined Hormonal Contraceptives (CHC) and Progestin Only Pills (POP). RPH must utilize Summary US MEC (v. 2020) & Full US MEC (v. 2016) to make determinations below. In Full US MEC, Appendix D contains classifications for CHCs and Appendix C contains classifications for POPs.

1) Background Information – Review Patient Intake Form Questions #1-2. Each patient must complete a new Patient Intake Form a minimum of every twelve months.

-Never prescribed contraception by RPH **-or-**
-Previously prescribed contraception by RPH **-and-**
had clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years

-Previously prescribed contraception by RPH **-and-**
has not had clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years

No Exclusion Criteria

Any Exclusion Criteria → Refer

2) Pregnancy Screen- Review Patient Intake Form #8-13

- If YES to AT LEAST ONE and is free of pregnancy symptoms

- If NO to ALL of these questions, pregnancy can NOT be ruled out

Patient is not pregnant

Patient is possibly pregnant → Refer

3) Medical and Medication History - Review Patient Intake Form #14-34 (and med list in pharmacy record). Evaluate medical health & history utilizing the US MEC. Evaluate medications utilizing the US MEC and any current references for drug-drug interactions with contraceptives.

- If ALL boxes are labeled 1 or 2 (green) on the US MEC for the type of contraception that RPH plans to prescribe (e.g., CHC, POP)

-If ANY boxes are labeled 3 or 4 (pink/red) on the US MEC or a significant drug-drug or drug-disease interaction exists for the type of contraception that RPH plans to prescribe (e.g., CHC, POP)

No Contraindicated Condition(s) or Medication(s)

Any Contraindicated Condition(s) or Medication(s) → Refer

4) Blood Pressure Screen:
Assess the patient's self-reported blood pressure or document the pharmacist's measurement of the patient's current blood pressure. Note: RPH may choose to take a second reading if initial report or measurement is **≥** 140/90

CHC + BP < 140/90 **-or-**
POP + Any BP

CHC + BP ≥ 140/90 → Refer or consider POP or DMPA

5) Evaluate patient contraception history, preference, and current therapy for selection of treatment.

Not currently on birth control

Currently on birth control

6a) Choose Contraception

- ***Initiate*** contraception based on patient preferences, adherence, and history for new therapy

6b) Choose Contraception

- ***Continue*** current form of pills, ring or patch, if no change is necessary **-or-**
- ***Alter*** therapy based on patient concerns, such as side effects patient may be experiencing; or refer, if appropriate

- ***Prescribe and dispense*** up to 12 months of desired contraception product. This must be done as soon as practicable after the pharmacist issues the prescription and must include any relevant educational materials.
  ORS 743A.066 requires prescription drug benefit programs to reimburse for 3 months for the first dispensing and 12 months for subsequent dispensing of the same contraceptive.

7) Provide Counseling

- Address any unexplained vaginal bleeding that worries patient (Patient Intake Form #15) – Refer for further evaluation
- Address any high blood pressure - Refer for further evaluation
- Discuss the management and expectations of side effects (bleeding irregularities, etc.)
- Discuss initiation strategy for initial treatment/change in treatment (as applicable). For quick start - instruct patient they can begin contraceptive today; use backup method for 7 days
- Discuss adherence and opportunities for follow-up visits
- Encourage routine health screenings and STI prevention

8) Discuss and provide visit summary to patient and advise the patient to consult with a primary care practitioner or women's health care practitioner per ORS 689.689(2)(b)(D).

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Standardized Assessment and Treatment Care Pathway - Contraception

Algorithm B: Injectable Contraception- Depot Medroxyprogesterone (DMPA). RPH must utilize Summary US MEC (v. 2020) & Full US MEC (v. 2016) to make determinations below. In Full US MEC, Appendix C contains classifications for DMPA.

1) Background Information – Review Patient Intake Form (Questionnaire) #1-2. Each patient must complete a new Patient Intake Form a minimum of every twelve months.

No Exclusion Criteria	Any Exclusion Criteria
	Refer

2) Pregnancy Screen- Review questionnaire #8-13

- If YES to AT LEAST ONE and is free of pregnancy symptoms	- If NO to ALL of these questions, pregnancy can NOT be ruled out
Patient is not pregnant	Patient is possibly pregnant → Refer

3) Medical and Medication History - Review Patient Intake Form #14-34 (and med list in pharmacy record). Evaluate medical health & history utilizing the US MEC. Any unexplained vaginal bleeding that worries patient (Patient Intake Form #15) – requires a referral. Evaluate medications utilizing the US MEC and any current references for drug-drug interactions with contraceptives.

- If ALL boxes are labeled 1 or 2 (green) on the US MEC for the type of contraception that RPH plans to prescribe (e.g., CHC, POP)	-If ANY boxes are labeled 3 or 4 (pink/red) on the US MEC or a significant drug-drug or drug-disease interaction exists for the type of contraception that RPH plans to prescribe (e.g., CHC, POP)
No Contraindicated Condition(s) or Medication(s)	Any Contraindicated Condition(s) or Medication(s) → Refer

4) Blood Pressure Screen: Assess the patient's self-reported blood pressure or document the pharmacist's measurement of the patient's current blood pressure. Note: RPH may choose to take a second reading if initial report or measurement is ≥ 160/100.

BP < 160/100	BP ≥ 160/100 → Refer or consider POP

5) Discuss DMPA therapy and provide counseling

- Discuss the management and expectations of side effects (bleeding irregularities, etc.)
- Discuss plans for follow-up visits, particularly for every 3-month administration of DMPA.
  - Stress importance of returning for next injection within 11-13 weeks of previous injection.
  - Provide patient with specific calendar date range for next injection.
- Caution with use of DMPA > 2 years (due to loss of bone mineral density). For therapy > 2 years, consultation with healthcare provider is indicated.
- Encourage routine health screenings and STI prevention

Initial dose of DMPA IM or SQ	Follow-up (every) 3-month dose of DMPA IM or SQ

6a) *Prescribe* and *administer (IM or SQ) or dispense (SQ)* DMPA to the patient.

- Instruct patient that if this injection is not within 7 days of start of their period, then abstain or use backup method for 7 days
- If *administering* DMPA IM or SQ, observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device. **-or-**
- If *dispensing* DMPA SQ for self-administration, the first self-administration must be observed by RPH after providing the patient with educational materials that include step-by-step instructions for self-injection, as well as guidance on the proper disposal of needles. The patient may complete self-administration at home after the initial observation.

6b) *Continue* current form of contraception, DMPA, if no change is necessary.

- Confirm that date of last injection or dispensing was within 11-15 weeks.
  - If > 15 weeks ago, then pharmacist must rule out pregnancy (repeat Step 2, and document), and instruct patient to abstain or use backup method for 7 days.
  - If between 11-15 weeks ago, administer or dispense the medication.
  - Do not administer or dispense if < 11 weeks ago.

-or-

***Alter* therapy based on patient concerns (see Algorithm A), such as side effects patient may be experiencing; or refer, if appropriate.**

Prescribe and administer up to 3 months ***or dispense*** up to 12 months of desired contraception product. This must be done as soon as practicable after the pharmacist issues the prescription and must include any relevant educational materials.

ORS 743A.066 requires prescription drug benefit programs to reimburse for 3 months for the first dispensing and 12 months for subsequent dispensing of the same contraceptive.

7) *Discuss* and *provide* visit summary to patient and *refer* the patient to the patient's primary care practitioner or women's health care practitioner per ORS 689.689(2)(b)(C).

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Standardized Assessment and Treatment Care Pathway - Contraception

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

This summary sheet only contains a subset of the recommendations from the USMEC. It is color coded in the left column to match the corresponding question of the Contraception Patient Intake Form
For complete guidance, see: Summary US MEC (v. 2020) & Full US MEC (v. 2016)
Note: Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condom reduces the risk of STDs and HIV

Key:

1	No restriction (method can be used)	
2	Advantages generally outweigh theoretical or proven risks	
3	Theoretical or proven risks usually outweigh the advantages	
4	Unacceptable health risk (method not to be used)	

Corresponding to the Contraception Patient Intake Form:

Condition	Sub-condition	Combined pill, patch (CHC)		Progestin-only Pill (POP)		DMPA (Inj)		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	Initiating	Continuing	
a. Age		Menarche to <40=1		Menarche to <18=1		Menarche to <18=2		Yes
		≥40=2		18-45=1		18-45=1		Yes
				>45=1		>45=2		Yes
b. Smoking	a) Age < 35	2		1		1		Yes
	b) Age ≥ 35, < 15 cigarettes/day	3		1		1		Yes
	c) Age ≥ 35, ≥15 cigarettes/day	4		1		1		Yes
c. Pregnancy	(Not Eligible for contraception)	NA*		NA*		NA		NA*
d. Vaginal Bleeding	Unexplained or worrisome vaginal bleeding	2		2		3		Yes
e. Postpartum (see also Breastfeeding)	a) < 21 days	4		1		1		Yes
	b) 21 days to 42 days:							
	(i) with other risk factors for VTE	3*		1		1		Yes
	(ii) without other risk factors for VTE	2		1		1		Yes
	c) > 42 days	1		1		1		Yes
f. Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3/4*		2*		2*		Yes
	b) 30 days to 42 days							
	(i) with other risk factors for VTE	3*		2*		2*		Yes
	(ii) without other risk factors for VTE	2*		1*		1*		Yes
	c)> 42 days postpartum	2*		1*		1*		Yes
g. Diabetes mellitus (DM)	a) History of gestational DM only	1		1		1		Yes
	b) Non-vascular disease							
	(i) non-insulin dependent	2		2		2		Yes
	(ii) insulin dependent‡	2		2		2		Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		3		Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		3		Yes
h. Headaches	a) Non-migrainous	1*		1		1		Yes
	b) Migraine:							
	i) without aura (includes menstrual migraines)	2*		1		1		Yes
	iii) with aura	4*		1		1		Yes
i. Inflammatory Bowel Disease	a) Mild; no risk factors	2		2		2		
	b) IBD with increased risk for VTE	3						
j. Hypertension	a) Adequately controlled hypertension	3*		1*		2*		Yes
	b) Elevated blood pressure levels (properly taken measurements):							
	(i) systolic 140-159 or diastolic 90-99	3*		1*		2*		Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4*		2*		3*		Yes
	c) Vascular disease	4*		2*		3*		Yes
k. History of high blood pressure during pregnancy		2		1		1		Yes
l. Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function:							
	(i) < 6 months	4		1		1		Yes
	(ii) ≥ 6 months	3		1		1		Yes
	b) Moderately or severely impaired cardiac function	4		2		2		Yes
m. Multiple risk factors for arterial CVD	(such as older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	3/4*		2*		3*		Yes
n. Ischemic heart disease‡	Current and history of	4		2	3	3		Yes
o. Valvular heart disease	a) Uncomplicated	2		1		1		Yes
	b) Complicated‡	4		1		1		Yes
p. Stroke‡	History of cerebrovascular accident	4		2	3	3		Yes
q. Known Thrombogenic mutations‡		4*		2*		2*		Yes

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable
* Please see the complete guidance for a clarification to this classification: Full US MEC (v. 2016)
‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

CONTINUES NEXT PAGE

Standardized Assessment and Treatment Care Pathway - Contraception

Condition	Sub-condition	Combined pill, patch (CHC)		Progestin-only Pill (POP)		DMPA (Inj)		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	Initiating	Continuing	
r. Deep venous thrombosis (DVT) & Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoag therapy							
	i) higher risk for recurrent DVT/PE	4		2		2		Yes
	ii) lower risk for recurrent DVT/PE	3		2		2		Yes
	b) Acute DVT/PE	4		2		2		Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months							
	i) higher risk for recurrent DVT/PE	4*		2		2		Yes
	ii) lower risk for recurrent DVT/PE	3*		2		2		Yes
	d) Family history (first-degree relatives)	2		1		1		Yes
	e) Major surgery							
	(i) with prolonged immobilization	4		2		2		Yes
	(ii) without prolonged immobilization	2		1		1		Yes
	f) Minor surgery without immobilization	1		1		1		Yes
s. Superficial venous disorders	a) Varicose veins	1		1		1		
	b) Superficial venous thrombosis (acute or history)	3*		1		1		
ll. Multiple Sclerosis	a) With prolonged immobility	3		1		2		Yes
	b)Without prolonged immobility	1		1		2		Yes
t. History of bariatric surgery‡	a) Restrictive procedures	1		1		1		Yes
	b) Malabsorptive procedures	COCs: 3	P/R: 1	3		1		Yes
u. Breast Disease & Breast Cancer	a) Undiagnosed mass	2*		2*		2*		Yes
	b) Benign breast disease	1		1		1		Yes
	c) Family history of cancer	1		1		1		Yes
	d) Breast cancer:‡							
	i) current	4		4		4		Yes
	ii) past/no evidence current disease x 5yr	3		3		3		Yes
v. Solid Organ Transplant	a) Complicated – graft failure, rejection, etc.	4		2		2		Yes
	b) Uncomplicated	2*		2		2		Yes
w. Viral hepatitis	a) Acute or flare	3/4*	2 C	1		1		Yes
	b) Carrier/Chronic	1	1	1		1		Yes
x. Cirrhosis	a) Mild (compensated)	1		1		1		Yes
	b) Severe‡ (decompensated)	4		3		3		Yes
y. Liver tumors	a) Benign:							
	i) Focal nodular hyperplasia	2		2		2		Yes
	ii) Hepatocellular adenoma‡	4		3		3		Yes
	b) Malignant‡ (hepatoma)	4		3		3		Yes
z. Gallbladder disease	a) Symptomatic:							
	(i) treated by cholecystectomy	2		2		2		Yes
	(ii) medically treated	3		2		2		Yes
	(iii) current	3		2		2		Yes
	b) Asymptomatic	2		2		2		Yes
aa. History of Cholestasis	a) Pregnancy-related	2		1		1		Yes
	b) Past COC-related	3		2		2		Yes
bb. Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4*		3*		3*	3*	Yes
	b) Severe thrombocytopenia	2*		2*		3*	2*	Yes
	c) Immunosuppressive treatment	2*		2*		2*	2*	Yes
	d) None of the above	2*		2*		2*	2*	Yes
cc. Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		2*		Yes
	(i) Long-term corticosteroid therapy					3		Yes
	b) Not on immunosuppressive therapy	2		1		2		Yes
dd. Blood Conditions & Anemias	a) Thalassemia	1		1		1		Yes
	b) Sickle Cell Disease‡	2		1		1		Yes
	c) Iron-deficiency anemia	1		1		1		Yes
ee. Epilepsy‡	(see also Drug Interactions)	1*		1*		1*		Yes
ff. Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*		1*		1*		Yes
	b) Pelvic	1*		1*		1*		Yes
gg. HIV	a) High risk for HIV	1		1		1*		Yes
	b) HIV infection	1*		1*		1*		Yes
	(i) On ARV therapy	If on treatment, see Drug Interactions						Yes
hh. Antiretroviral therapy (All other ARVs are a 1 or 2)	a) Fosamprenavir (FPV)	3		2		2		Yes
	(i) Fosamprenavir + Ritonavir (FPV/r)	2		2		1		Yes
ii. Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		1*		Yes
	b) Lamotrigine	3*		1		1		Yes
jj. Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		Yes
	b) Antifungals	1		1		1		Yes
	c) Antiparasitics	1		1		1		Yes
	d) Rifampin or rifabutin therapy	3*		3*		1*		Yes
kk. Supplements	a) St. John's Wort	2		2		1		Yes

Standardized Assessment and Treatment Care Pathway - Contraception

Condition	Sub-condition	Combined pill, patch (CHC)		Progestin-only Pill (POP)		DMPA (Inj)		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	Initiating	Continuing	

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable
* Please see the complete guidance for a clarification to this classification: Full US MEC (v. 2016)
‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

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Contraception Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Rx

☐ **Drug:** _____

- Directions: _____
- Quantity: _____
- Refills:_____

Written Date: _____

Prescriber Name:_____Prescriber Signature: _____

Pharmacy Address:_____Pharmacy Phone: _____

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Provider Notification
Contraception

Pharmacy Name:_____ Pharmacist Name: _____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____
Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) was:

☐ **Prescribed and dispensed** contraception at our Pharmacy on ____/_____/_____ noted above. The prescription issued and dispensed consisted of:

- Drug: _____
  - Directions: _____
  - Quantity: _____
  - Refills:_____

☐ **Prescribed and administered** contraception at our Pharmacy on ____/_____/_____ noted above. The prescription issued and administered consisted of:

- Drug: _____
  - Directions: _____
  - Quantity: _____
  - Refills:_____

☐ **NOT prescribed, dispensed or administered** contraception at our Pharmacy noted above, because:

□ Pregnancy cannot be ruled out.

Notes: _____

□ The patient indicated they have a health condition than requires further evaluation.

Notes: _____

□ The patient indicated they take medication(s) or supplements that may interfere with contraception.

Notes: _____

□ Their blood pressure reading was _____/_____ :

□ ≥140/90 mmHg and I am unable to prescribe any combined hormonal contraceptive (estrogen + progesterone) pill, patch, or ring

□ ≥160/100 mmHg and I am unable to prescribe any injectable (progesterone only)

□ The patient did not have a clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years.

The prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-020-0300.

- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2016). US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016. Retrieved from https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf
- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2020). Summary Chart of US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2020. Retrieved from https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf
- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2016). US Selected Practice Recommendations (US SPR) for Contraceptive Use, 2016. Retrieved from https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf

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CONTRACEPTION – Oral, Transdermal Patch, Vaginal Ring or Injectable

Pharmacy Name:_____ Pharmacist Name:_____

Pharmacy Address:_____

Pharmacy Phone: _____ Pharmacy Fax: _____

□ Today you were prescribed (and □ administered) the following hormonal contraception:

_____

Notes: _____

If you have a question, my name is _____.

Please review this information with your healthcare provider.

-- or --

□ I am not able to prescribe hormonal contraception to you today, because:

□ Pregnancy cannot be ruled out.

Notes: _____

□ You have a health condition than requires further evaluation.

Notes: _____

□ You take medication(s) or supplements that may interfere with contraception.

Notes: _____

□ Your blood pressure reading is _____/_____ :

□ ≥140/90 mmHg and I am unable to prescribe any combined hormonal contraceptive (estrogen + progesterone) pill, patch, or ring

□ ≥160/100 mmHg and I am unable to prescribe any injectable (progesterone only)

Each checked box requires additional evaluation by another healthcare provider. Please share this information with your provider.

□ You have not had a clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years.

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Attention Pharmacy: This is a template document. Please feel free to customize it to your pharmacy, however you must retain all elements set forth by this template.

Divisions 021/135- Continuing Pharmacy Education CPE(Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Continuing Pharmacy Education procedural rule review; creates new Division 135

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 135 that includes definitions, requirements for applicants, instructors, renewal requirements for licensees and audits to reflect current requirements and standards related to continued pharmacy education. Repeals Division 021 Continuing Pharmacy Education rules in their entirety.

Documents Relied Upon per ORS 183.335(2)(b)(D): Rules Advisory Committee- Continuing Pharmacy Education: May 2021 minutes, October 2021 minutes, and January 2022 minutes.

Resources: Other State Regulations: CA: CCR 1732**,** OH: OAC 4729:1-5**,**TX: TAC 295.8 Continuing Education Requirements, WA: WAC 246-861 Pharmacists—Professional Pharmaceutical Education

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (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): It is anticipated that state agencies, units of local government, licensees or the public will not be financially impacted by the proposed rules. Applicants and licensees are currently required by statute and rule to complete certain CE based on their license type.

Effect on Small Businesses? No effect anticipated for small businesses.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): Yes, a RAC was consulted at three separate RAC meetings.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Adopting the proposed rules may increase patient safety for all Oregonians in every community by ensuring that all licensees continue to develop, maintain and enhance their competence in the practice or assistance of the practice of pharmacy.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): The proposed rules clarify definitions, incorporates universally acceptable CPE standards, removes outdate language from existing CPE rules and streamlines the process and requirements for providers and licensees applying for continuing pharmacy education credit. Creates new Division 135 Continuing Pharmacy Education and repeals Division 021 in its entirety.

Division 135
CONTINUING PHARMACY EDUCATION

855-135-0001
Continuing Pharmacy Education: Definitions

(1) "Accredited program" means a structured continuing pharmacy education (CPE) program which has been reviewed and approved by a provider of continuing pharmacy education that is accredited by the Accreditation Council on Pharmaceutical Education (ACPE) (v. 06/01/2022) or continuing medical education (CME) accredited by the Accreditation Council for Continuing Medical Education (ACCME) or an ACCME-recognized State Medical Society (v. 6/2022) as an American Medical Association (AMA) Category 1 CME program.

(2) "Board-approved program" means a structured continuing pharmacy education program which has been reviewed and approved by the board.

(3) “Certificate of completion” means a certificate or other official document issued to a participant certifying the successful completion of a continuing pharmacy education program.

(4) “Continuing Pharmacy Education” or “CPE” means an accredited or board-approved program designed to support the continuing development of Pharmacists, Interns, Certified Oregon Pharmacy Technicians or Pharmacy Technicians to maintain and enhance their competence applicable to the practice of pharmacy or the assistance of the practice of pharmacy.

(5) “Contact hour” means sixty minutes of continuing pharmacy education.

(6) “CPE Monitor” means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy (NABP) for monitoring continuing pharmacy education that Pharmacists, Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians receive from participating providers;

(7) “Cultural competence” means the lifelong process of examining the values and beliefs and developing and applying an inclusive approach to health care practice in a manner that recognizes the content and complexities of provider-patient communication and interaction and preserves the dignity of individuals, families, and communities.

(a) Cultural competence applies to all patients.

(b) Culturally competent providers do not make assumptions on the basis of an individual’s actual or perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital status, socio-economic status, veteran’s status, sexual orientation, gender identity, gender expression, gender transition status, level of formal education, physical or mental disability, medical condition or any consideration recognized under federal, state and local law.

(8) “Medication error prevention” means the prevention of events that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer.

(9) “Patient safety” means the prevention of healthcare related errors or the elimination or mitigation of patient injury caused by healthcare related errors.

(10) "Pain management education program" means a specific one-hour web-based program developed by the Pain Management Commission of the Oregon Health Authority.

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(11) “Pharmacy law” means the body of laws relating to pharmacy practice.

(12) “Structured continuing pharmacy education” or “Structured CPE” means education that includes defined learning objectives, qualified instructors, learning assessment, and a program evaluation.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 413.450, ORS 413.590, ORS 689.255, ORS 689.285, ORS 689.486, ORS 689.490

855-135-0010
Continuing Pharmacy Education Programs: General Requirements

(1) CPE programs must consist of subject matter pertinent to pharmacy including:

(a) Socioeconomic aspects of healthcare;

(b) Legal aspects of healthcare;

(c) Properties and actions of drugs and dosage forms;

(d) Etiology, characteristics, therapeutics, and prevention of disease states; or

(e) General topics related to pharmacy.

(2) Time spent in the following activities may be included in the calculation of CPE credit:

(a) A program delivered by an instructor or a panel of instructors;

(b) A structured CPE discussion, workshop or demonstration;

(c) A structured CPE question and answer session;

(d) An ACPE accredited program or board-approved program;

(e) An ACCME AMA Category 1 accredited program up to the following limits per renewal cycle:

(A) 10 hours of CPE for Pharmacists;

(B) 6 hours of CPE for Certified Oregon Pharmacy Technicians and Pharmacy Technicians.

(f) A policy discussion at an Oregon Board of Pharmacy meeting up to a maximum of 2 hours of law CPE per renewal cycle.

(3) Time spent in the following activities must not be included in the calculation of CPE credit:

(a) Welcoming remarks;

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(b) Meals or social functions;

(c) Business sessions (e.g. voting, treasury report, strategic plan);

(d) Unstructured discussion, workshops, and demonstrations;

(e) Unstructured question and answer sessions;

(f) Degree programs;

(g) Non-ACPE approved certificate programs;

(h) Licensing or certification examinations;

(i) Skills training programs;

(j) Software training programs;

(k) Learning assessments;

(l) Program evaluations; and

(m) Attending CPE programs for which credit was not granted by the provider.

(4) For each accredited or board-approved program, the licensee must retain a certificate of completion for each completed program that includes:

(a) Licensee name;

(b) Title, activity date, and activity number of the program;

(c) Topic designation (e.g. law, patient safety, pain);

(d) Name of the program provider;

(e) Number of contact hours earned by topic designation; and

(f) Statement of credit granted to the participant.

(5) For each accredited or board-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or a certificate of completion is uploaded to the licensee's electronic licensing record with the board prior to submission of the license renewal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.255, ORS 689.285, ORS 689.490

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855-135-0030

Continuing Pharmacy Education Programs: Applications for Approval

(1) An application for approval of a CPE program which is not an accredited program may apply for board approval using a form supplied for this purpose. A complete application includes:

(a) Program provider or sponsor name;

(b) Program name;

(c) Program topic designation(s);

(d) Licensee type(s);

(e) Total number of contact hours offered by topic designation;

(f) Description of program goal(s) and learning objective(s);

(g) Program format (e.g. interactive discussion, panel, speaker);

(h) Name and qualification(s) of each instructor;

(i) Date(s) and location(s) of program;

(j) Learning assessment; and

(k) Program evaluation.

(2) The provider must submit an application form a minimum of forty-five days prior to the date the program will be held. Applications submitted less than forty-five days prior to the date the program will be held will not be approved.

(3) Incomplete applications will not be approved.

(4) An application for post-approval of a CPE program will not be approved.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285

855-135-0040

Continuing Pharmacy Education Programs: Instructors' Credit Toward CPE Hours

(1) Any Pharmacist whose primary responsibility is not the education of health professionals, who instructs a group of health professionals on pharmacy-related topics according to OAR 855-135-0010(1)(a)-(e) in structured CPE may be granted two hours of CPE credit for each hour spent in presenting the course or program which has been approved for CPE credit.

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(2) Any Pharmacist whose primary responsibility is the education of health professionals may be granted CPE credit as in (1) when instructing a group of health professionals on pharmacy-related topics unrelated to their formal course responsibilities in a learning institution.

(3) An instructor will only be granted credit for one presentation of the same course or program.

(4) An instructor may earn a maximum of 10 hours of CPE for instruction per renewal cycle.

(5) An instructor must submit an application form a minimum of forty-five days prior to the date the program will be held to apply for instructor credit toward CPE hours using a form provided for this purpose by the board. Applications submitted less than forty-five days prior to the date of the program will not be approved.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285

855-135-0050
Continuing Pharmacy Education: Requirements for Pharmacist License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a pharmacist must have satisfactorily completed at least 30 hours of CPE. These hours must include at least:

(a) Two hours of CPE in pharmacy law;

(b) Two hours of CPE in patient safety or medication error prevention;

(c) Two hours of CPE in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(d) One hour of CPE in pain management, provided by the Pain Management Commission of the Oregon Health Authority; and

(e) Twenty-three additional hours of CPE in subjects pertinent to pharmacy per OAR 855-135-0010(1)(a)-(e).

(2) Pharmacists applying for the first renewal of their license if they have been licensed by the board for at least one year prior to July 1 of the renewal period, must complete the requirement listed in (1).

(3) Pharmacists applying for the first renewal of their license if they have not been licensed by the board for at least one year prior to July 1 of the renewal period, must have satisfactorily completed the following hours of CPE in any topic area. If the initial license is issued between:

(a) July 1 to September 30 of an even year, the Pharmacist must complete 16 hours of CPE.

(b) October 1 to December 31 of an even year, the Pharmacist must complete 12 hours of CPE.

(c) January 1 to March 31 of an odd year, the Pharmacist must complete 8 hours of CPE.

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(d) April 1 to June 30 of an odd year, the Pharmacist must complete 4 hours of CPE.

(4) A Pharmacist must register with the CPE Monitor for tracking completed ACPE credit hours.

(5) For each ACPE-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor.

(6) For each board-approved or ACCME accredited program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or uploaded to the licensee's electronic licensing record with the board.

(7) A Pharmacist must retain documentation of completed CPE for 6 years and must provide this documentation if requested by the board.

(8) CPE credit accumulated in excess of the required 30 contact hours for biennial license renewal cannot be carried forward.

(9) A Pharmacist 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, must complete the CPE requirement in (1) prior to renewal.

(10) A Pharmacist who is applying for reinstatement must provide certification of completion of the continuing pharmacy education requirement in (1) for all licensing cycles in which the license was lapsed, and complete reinstatement requirements listed in OAR 855-019.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 413.450, ORS 413.590, ORS 689.285, ORS 689.486,

855-135-0060
Continuing Pharmacy Education: Requirements for Intern License Renewal

(1) During each license renewal cycle, an Intern must have satisfactorily completed 2 contact hours of approved CPE in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(2) An Intern must retain documentation of completed CPE for 6 years and must provide this documentation if requested by the board.

(3) An Intern must register with the CPE Monitor for tracking completed ACPE credit hours.

(4) For each ACPE-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor.

(5) For each board-approved or ACCME accredited program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or uploaded to the licensee's electronic licensing record with the board.

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Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 413.450, ORS 676.850, ORS 689.151, ORS 689.255, ORS 689.285

855-135-0070
Continuing Pharmacy Education: Requirements for Certified Oregon Pharmacy Technician or Pharmacy Technician License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, Certified Oregon Pharmacy Technician or Pharmacy Technician must have satisfactorily completed 20 contact hours of CPE. These hours must include:

(a) Two hours of CPE in pharmacy law;

(b) Two hours of CPE in patient safety or medication error prevention;

(c) Two hours of CPE in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency effective July 1, 2023; and

(d) Fourteen additional hours of CPE in subjects pertinent to pharmacy per OAR 855-135-0010(1)(a)-(e).

(2) Certified Oregon Pharmacy Technicians or Pharmacy Technicians applying for the first renewal of their license, if they have not been licensed by the board for at least one year prior to July 1 of the renewal period., only need to complete cultural competency as required by (1)(c).

(3) Certified Oregon Pharmacy Technicians and Pharmacy Technicians must register with the CPE Monitor for tracking completed ACPE credit hours.

(4) For each ACPE-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor.

(5) For each board-approved or ACCME accredited program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or uploaded to the licensee's electronic licensing record with the board prior to submission of the license renewal.

(6) A Certified Oregon Pharmacy Technician or Pharmacy Technician must retain documentation of completed CPE for 6 years and must provide this documentation if requested by the board.

(7) CPE credit accumulated in excess of the required 20 contact hours for biennial license renewal cannot be carried forward.

(8) A Certified Oregon Pharmacy Technician or Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license and must complete the CPE requirements in (1) prior to renewal.

(9) Section (1)(a)(b) and (d) do not apply to a Pharmacy Technician applying for the first renewal of their license prior to July 1, 2023. Section (1)(c) is required.

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Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 413.450, ORS 676.850, ORS 689.285, ORS 689.486

855-135-0080
Continuing Pharmacy Education: Requirements for Licensees Licensed in Other Health Professions

A Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician who is licensed to practice another health profession must meet the same CPE requirements in the same manner as all other board licensees and must otherwise comply with this chapter.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.255, ORS 689.285, ORS 689.490

855-135-0085
Continuing Pharmacy Education: Notification of Biennial License Renewal

The board will send a biennial renewal notice to be issued to all licensed Pharmacists, Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians at least 60 days prior to the license expiration date that states the biennial license fee, CPE requirements and other information necessary for renewal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.255, ORS 689.275 & ORS 689.486, ORS 689.490

855-135-0090
Continuing Pharmacy Education: Audits

(1) The biennial renewal application must be submitted to the board with the appropriate fee and the licensee must attest that they have satisfactorily completed the CPE requirements prior to submission of the license renewal.

(2) The board may select and audit applications for renewal to verify completion of CPE by Pharmacists, Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians reported on the application for renewal.

(3) The board may utilize the National Association of Boards of Pharmacy CPE Monitor service or the licensee's electronic licensing record with the board when auditing licensees for CPE compliance.

(4) If the board is unable to confirm compliance, the licensee must comply with board requests to provide documentation.

(5) A licensee who fails to provide the requested documentation to the board within the time allowed or who fails to complete the biennial CPE requirement may be disciplined for unprofessional conduct.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.275

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~~Division 021~~
~~CONTINUING PHARMACY EDUCATION~~

~~855-021-0001~~
~~Definitions~~

~~(1) "Continuing Pharmacy Education" or "CPE" means classes of post graduate studies, informal study group participation, institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, planned and professional meetings, self-study courses, cassette or audio visual tape/slides or materials, and other self-instruction units applicable to the practice of pharmacy.~~

~~(2) "Contact hour" means fifty minutes of continuing pharmacy education.~~

~~(3) "Patient safety" means systems, procedures and processes that ensure that the correct patient receives the correct drug in the correct dose and is counseled appropriately.~~

~~(4) "Medication error prevention" means systems, procedures and processes to prevent and avoid adverse events and to ensure that the correct patient receives the correct drug in the correct dose.~~

~~(5) "Pain management education program" means a specific one hour web-based program developed by the Pain Management Commission of the Oregon Health Authority.~~

~~(6) "Cultural competence" means the lifelong process of examining the values and beliefs and developing and applying an inclusive approach to health care practice in a manner that recognizes the content and complexities of provider-patient communication and interaction and preserves the dignity of individuals, families, and communities.~~

~~(a) Cultural competence applies to all patients.~~

~~(b) Culturally competent providers do not make assumptions on the basis of an individual's actual or perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital status, socio-economic status, veteran's status, sexual orientation, gender identity, gender expression, gender transition status, level of formal education, physical or mental disability, medical condition or any consideration recognized under federal, state and local law.~~

~~Statutory/Other Authority: ORS 689.205 & ORS 676.850~~
~~Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 413.590~~

~~855-021-0005~~
~~Continuing Pharmacy Education Required for Pharmacist License Renewal~~
~~(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a pharmacist must have satisfactorily completed at least 30 hours of continuing pharmacy education. These hours must include at least:~~

~~(a) Two hours of continuing pharmacy education in pharmacy law;~~

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~~(b) Two hours of continuing pharmacy education in patient safety or medication error prevention;~~

~~(c) Two hours 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) One hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority; and~~

~~(e) Twenty three additional hours of continuing pharmacy education.~~

~~(2) Section (1) does not apply to pharmacists applying for the first renewal of their license if they have not been licensed by the board for at least one year prior to July 1 of the renewal period.~~

~~(3) A pharmacist must retain documentation of completed continuing pharmacy education for six years and must provide this documentation if requested by the board.~~

~~(4) Continuing pharmacy education credit accumulated in excess of the required 30 contact hours for biennial license renewal cannot be carried forward.~~

~~Statutory/Other Authority: ORS 689.205 & ORS 676.850~~
~~Statutes/Other Implemented: ORS 689.285, ORS 413.450, ORS 413.590 & 2021 HB 2078~~

~~855-021-0007~~
~~Continuing Pharmacy Education Required for Intern License Renewal~~

~~(1) During each license renewal cycle, an intern must have satisfactorily completed 2 contact hours of approved continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and~~

~~(2) An intern must retain documentation of completed continuing pharmacy education for six years and must provide this documentation if requested by the board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.285, ORS 676.850, ORS 413.450 & ORS 689.151~~

~~855-021-0009~~
~~Continuing Pharmacy Education Required for Pharmacy Technician or Certified Oregon Pharmacy Technician License Renewal~~

~~(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a Pharmacy Technician or Certified Oregon Pharmacy Technician must have satisfactorily completed 20 contact hours of continuing pharmacy education. These hours must include:~~
~~(a) Two hours of continuing pharmacy education in pharmacy law;~~

~~(b) Two hours of continuing pharmacy education in patient safety or medication error prevention;~~

~~(c) Two hours of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency effective July 1, 2023; and~~

~~(d) Fourteen additional hours of continuing pharmacy education or documented onsite training approved by the board.~~

~~(2) Section (1)(a)(b) and (d) do not apply to a Pharmacy Technician or Certified Oregon Pharmacy Technician applying for the first renewal of their license if they have not been licensed by the board for at least one year prior to July 1 of the renewal period. Section (1)(c) is required.~~

~~(3) A Pharmacy Technician or Certified Oregon Pharmacy Technician must retain documentation of completed continuing pharmacy education for six years and must provide this documentation if requested by the board.~~

~~(4) Continuing pharmacy education credit accumulated in excess of the required 20 contact hours for biennial license renewal cannot be carried forward.~~

~~(5) If a license renewal is submitted after June 30th of the license renewal cycle, continuing pharmacy education must be completed prior to submission of the license renewal.~~

~~(6) Section (1)(a)(b) and (d) do not apply to a Pharmacy Technician applying for the first renewal of their license prior to July 1, 2023. Section (1)(c) is required.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 676.850~~

~~855-021-0010~~
~~Continuing Pharmacy Education Programs~~

~~(1) A continuing pharmacy education program must consist of therapeutics, or pharmacy and drug law or other aspects of health care applicable to the practice of pharmacy.~~

~~(2) Programs must provide for examinations or other methods of evaluation to assure satisfactory completion by participants.~~

~~(3) The person or persons who are to instruct or who are responsible for the delivery or content of the program must be qualified in the subject matter by education and experience.~~

~~(4) Continuing pharmacy education programs must be approved by the Board of Pharmacy. Application for approval must be made on and in accordance with forms established by the board. The forms must require information relating to:~~

~~(a) Name of provider or sponsor;~~

~~(b) Type of program offered;~~

~~(c) Description of subject matter;~~

~~(d) Number of contact hours offered;~~

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~~(e) Total number of contact hours in therapeutics or pharmacy and drug law or other aspects of health care applicable to the practice of pharmacy;~~

~~(f) Method of determining satisfactory completion of program;~~

~~(g) Dates and location of program;~~

~~(h) Name and qualification of instructors or other persons responsible for the delivery or content of the program.~~

~~(5) CE programs are not required to carry approval of American Council on Pharmaceutical Education (ACPE). Programs presented by providers approved by the American Council on Pharmacy Education (ACPE) are accepted.~~

~~(6) Providers must provide attendees with proof of attendance that shows the date and number of contact hours provided. Providers must maintain attendance lists for six years.~~

~~(7) A maximum of 10 contact hours may be earned in any licensing cycle by preparing and presenting CE programs. Pharmacists and Certified Oregon Pharmacy Technicians presenting CE programs may earn one contact hour for preparation time of one hour or more, plus credit for the actual contact hour time of the presentation. A pharmacist or Certified Oregon Pharmacy Technician must show content of the course, and a description of the intended audience (e.g., pharmacists, technicians, physicians, nurses). Public service programs, such as presentations to school children or service clubs, are not eligible for continuing education credit.~~

~~(8) Pharmacists or Certified Oregon Pharmacy Technicians taking post graduate studies applicable to graduate or professional degrees may submit the course syllabus and evidence of satisfactory completion of the course for continuing education credit approval by the board.~~

~~(9) The board may approve up to 26 contact hours of CE credit for pharmacists who have successfully completed nationally certified Disease State Management courses.~~

~~(10) Board members or staff may attend CE programs for the purpose of evaluating content, format and appropriateness of material for Continuing Pharmacy Education credit. Subsequent programs by CE providers whose current programs are deemed deficient by on-site evaluation may be required to obtain prior approval by the board. The board will provide feedback to CE providers regarding evaluated CE presentations.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.285~~

~~855-021-0045~~
~~Notification of Biennial License Renewal~~

~~The board will send a biennial renewal notice to be issued to all licensed pharmacists, interns, and Certified Oregon Pharmacy Technicians at least 60 days prior to the license expiration date that states the biennial license fee, continuing pharmacy education requirements and other information necessary for renewal.~~

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~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.275 & ORS 689.486~~

~~855-021-0050~~
~~Continuing Pharmacy Education Audits~~

~~(1) The biennial renewal application must be submitted to the board with the appropriate fee and the licensee must attest that they have satisfactorily completed the continuing pharmacy education requirements.~~

~~(2) The Board may randomly select and audit applications for renewal to verify completion of continuing pharmacy education by pharmacists, interns and Certified Oregon Pharmacy Technicians or documented on-site training by Certified Oregon Pharmacy Technicians reported on the application for renewal.~~

~~(a) Pharmacists whose applications for renewal are selected for audit must provide documentation of completion of the continuing pharmacy education programs reported. A pharmacist who fails to provide the requested documentation to the board or who fails to complete the biennial continuing pharmacy education requirement may be disciplined for unprofessional conduct.~~

~~(b) Interns whose applications for renewal are selected for audit must provide documentation of completion of the cultural competency continuing pharmacy education. An intern who fails to provide the requested documentation to the board or who fails to complete the biennial continuing education requirement may be disciplined for unprofessional conduct.~~

~~(c) Certified Oregon Pharmacy Technicians whose applications for renewal are selected for audit must provide documentation of completion of the continuing pharmacy education or documented onsite training reported. A Certified Oregon Pharmacy Technician who fails to provide the requested documentation to the board or who fails to complete the biennial continuing education requirement may be disciplined for unprofessional conduct.~~

~~(3) The board may utilize the National Association of Boards of Pharmacy CPE Monitor service when auditing licensees.~~

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

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Division 019/141: Pharmacists/Pharmacy Prescription Kiosk (PPK)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Pharmacy Prescription Kiosk; Establishes new Division 141 and new registration type

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed rules would establish a new registration type for Pharmacy Prescription Kiosk. Adds new Division 141 which contains requirements for the operation of a Pharmacy Prescription Kiosk by a PPK Affiliated Pharmacy.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): The proposed rules may positively impact Oregonian's ability to access and pick up prescriptions without having to physically visit an open pharmacy.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): On 9/6/2022 the agency sent out a fiscal impact request for estimated costs associated with compliance, implementation and operation of a PPK. On The request was sent via GovDelivery to 5,004 Drug Outlet, PIC and Pharmacy email addresses and to 2,813 bd. mtg/rulemaking interested party email addresses. The agency received 1 response from MedAvail who stated that their pricing is proprietary and based on project size and scope.

Pharmacies are not required to operate a PPK. If a pharmacy chooses to operate a PPK, the PPK Affiliated Pharmacy will be required to apply and pay a registration fee of $225 for the PPK and be required to comply with all Oregon Administrative Rules and Oregon Revised Statutes. We do anticipate that licensed drug outlets may be financially impacted in order to comply with the proposed rules.

Pharmacies that choose to deploy kiosks will generate revenue from prescription and over-the-counter drug sales to help offset the cost of compliance with these proposed rules. Presumably, Pharmacy Prescription kiosk owners will achieve revenues in excess of expenses in the deployment of this technology.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses): OBOP- Fiscal impact is estimated to be minimal for the agency and limited to administrative and compliance costs. There is no anticipated fiscal impact to other state agencies, units of local government or the public. There are approximately 113 small business drug outlet pharmacies registered with the board. It is not anticipated that the cost of compliance for small business would be different from that of a non-small business.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The board held a technology forum during the August 2020 board meeting where vendors presented information and resources for the board's consideration prior to drafting proposed rules.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

Division 019
PHARMACISTS

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.

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(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 inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained 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 Report;

(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

Division 141
PHARMACY PRESCRIPTION KIOSK

855-141-0001
Purpose and Scope

The purpose of OAR 855-141 is to provide minimum requirements for the operation of a Pharmacy Prescription Kiosk (PPK) by a PPK Affiliated Pharmacy.

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Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0005
Definitions

(1) “Pharmacy Prescription Kiosk Affiliated Pharmacy” or “PPK Affiliated Pharmacy” means a Retail Drug Outlet Pharmacy registered in Oregon that operates a Pharmacy Prescription Kiosk.

(2) “Pharmacy Prescription Kiosk” or “PPK” means an Oregon location registered as a Retail Drug Outlet Pharmacy Prescription Kiosk using a mechanical system that stores and dispenses patient-specific prescription and non-prescription drugs, devices, and related supplies.

(3) “Telepharmacy system” means a system of telecommunications technologies that enables documenting and recording of the delivery of pharmacy services at a remote location by an electronic method.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0010
Registration: General

(1) Each PPK located in Oregon must be registered as a Retail Drug Outlet PPK.

(2) A controlled substance registration will not be issued for a Retail Drug Outlet PPK.

(3) A Retail Drug Outlet PPK application must specify the PPK Affiliated Pharmacy and cannot operate without a PPK Affiliated Pharmacy that is registered by the board as a Retail Drug Outlet Pharmacy.

(4) Each registration renewal application must be accompanied by the annual fee and must contain the same information required in OAR 855-141-0015(2) and additional information requested by the board.

(5) The initial and annual registration fee for a PPK is set out in OAR 855-110.

(6) A Retail Drug Outlet PPK registration expires March 31, annually. If the annual registration fee in OAR 855-110 is not paid by March 31 of the current year, a late fee as set out in OAR 855-110 must be included with the application for registration renewal.

(7) The registration is not transferable.

(8) The registration fee cannot be prorated.

(9) A PPK must not operate until a certificate of registration has been issued by the board.

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(10) The PPK Affiliated Pharmacy registration and the PPK registration must be on display at both the PPK Affiliated Pharmacy and at the PPK.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.305 & ORS 689.527

855-141-0015
Registration: Application

(1) An application for registration of a PPK may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of:

(a) A completed application including;

(A) Payment of the fee prescribed in OAR 855-110;

(B) A floor plan drawn to scale with the location of the:

(i) PPK within the building;

(ii) Surveillance system cameras; and

(iii) Alarm system panel; and

(C) A detailed explanation and supporting documentation relating to the PPK Affiliated Pharmacy regarding all conduct that is required to be disclosed;

(b) The PPK Affiliated Pharmacy name, Retail Drug Outlet registration number and Pharmacist-in-Charge; and

(c) Indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application must indicate the owner and the applicant's affiliation with the owner:

(A) If the owner is a partnership or other multiple owners, the names of the partners or persons holding the five largest interests must be indicated on the application; and

(B) If the owner is a corporation, the name filed must be the same as filed with the Secretary of State. The name of the corporation, the names of the corporation officers and the names of the stockholders, if applicable, who own the five largest interests must be indicated on the application.

(3) Upon request by the board, the applicant must furnish such information as required by the board regarding the partners, stockholders, or other persons not named in the application.

(4) A registration may be denied for any of the following:

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(a) Failure to completely and accurately answer all questions on the application for registration or renewal of registration;

(b) Failure to disclose any requested information on the application or requests resulting from the application; or

(c) Any other grounds found in ORS 689.405.

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

(6) The certificate of registration for a PPK must be issued prior to opening.

(7) The registration for a PPK expires March 31 in each year and may be renewed annually.

Statutory/Other Authority: ORS 475.035 & ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 689.527

855-141-0020
Registration: Change of Physical Address or Location

(1) A change of physical address of the PPK requires:

(a) Submission of a new PPK application a minimum of 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the board; and

(d) Issuance of a new certificate of registration.

(2) A change of location at the same physical address of the PPK requires the submission of an updated floor plan drawn to scale a minimum of 15 days prior to the change with the new location of the:

(a) PPK within the building;

(b) Surveillance system cameras; and

(c) Alarm system panel.

Statutory/Other Authority: ORS 475.035 & ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 689.527

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855-141-0030
Non-Resident PPK Affiliated Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes a PPK Affiliated Pharmacy located outside of Oregon and providing pharmacy services under OAR 855-141 with a PPK located in Oregon.

(2) Each non-resident PPK Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy as a Retail Drug Outlet Pharmacy.

(3) To qualify for registration under these rules, every non-resident PPK Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) The Pharmacist-in-Charge (PIC) of the non-resident PPK Affiliated Pharmacy is the PIC for each PPK.

(5) The PIC is responsible for ensuring that the PPK PIC self-inspection form is correctly completed prior to February 1 each year.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225 & ORS 689.527

855-141-0050
Personnel

(1) A PPK must have a PIC at all times.

(2) Prior to utilizing a PPK, a Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician must have completed a training program on the proper use of the PPK.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.527

855-141-0100
Security

(1) The PPK Affiliated Pharmacy, the PPK, PIC of the PPK Affiliated Pharmacy and each Pharmacist supervising the PPK is responsible for the security of the PPK including provisions for adequate safeguards against loss, theft or diversion of prescription and non-prescription drugs, devices, and related supplies, and records for such drugs, devices and related supplies.

(2) The PPK Affiliated Pharmacy must ensure the PPK:

(a) Is placed in a secure indoor location that is climate controlled and protected from the elements;

(b) Is securely fastened to a permanent structure so that it cannot be removed;

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(c) Stores prescription and non-prescription drugs, devices, and related supplies in compliance with the provisions of OAR 855-141-0125;

(3) The PPK must be secured to prevent access when:

(a) There is no Pharmacist supervising and authorizing access in real-time to the PPK; or

(b) There is no Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician employed by the PPK Affiliated Pharmacy present at the PPK; or

(c) Any component of the PPK is not functioning.

(4) A record must be maintained with the name and Oregon license number of each person accessing the PPK.

(5) An Intern, Certified Oregon Pharmacy Technician, and Pharmacy Technician must only access the PPK when a Pharmacist is supervising the licensee and has authorized access to the PPK in real-time.

(6) Unlicensed personnel (e.g. service or repair personnel) must only access the PPK when escorted and continuously observed by a licensee who is authorized by the Pharmacist who is supervising and authorizing access to the PPK in real-time.

(7) Minimum security methods must include a properly functioning:

(a) Alarm system at the PPK and real-time notification to a Pharmacist from the PPK Affiliated Pharmacy if unauthorized access occurs;

(b) Electronic entry system that is controlled by a Pharmacist and records the:

(A) Identification of the Pharmacist authorizing each access and securing the PPK;

(B) Identification of the Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician accessing and securing the PPK; and

(C) Date and time of each activity; and

(c) Surveillance system that utilizes continuously accessible and recorded video between the PPK Affiliated Pharmacy and the PPK. The system must provide a clear view of the entire PPK including its access points.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

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855-141-0120

Drug: Procurement

A PPK must only receive prescription and non-prescription drugs, devices, and related supplies from the PPK Affiliated Pharmacy.

Statutory/Other Authority: ORS 475.035 & ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0125

Drug: Storage

(1) A PPK must maintain proper storage of all drugs. This includes, but is not limited to the following:

(a) All drugs must be stored according to manufacturer's published or USP guidelines.

(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.

(d) A PPK must quarantine drugs which are outdated, adulterated, misbranded or suspect.

(2) A PPK must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).

(a) All drug refrigeration systems must:

(A) Maintain refrigerated products between 2 to 8 °C (35.6 to 46.4°F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.

(B) Utilize a centrally placed, accurate, and calibrated thermometer;

(C) Be dedicated to pharmaceuticals only;

(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.

(b) A PPK must adhere to a monitoring plan, which includes, but is not limited to:

(A) Documentation of training of all personnel;

(B) Maintenance of manufacturer recommended calibration of thermometers;

(C) Maintenance of records of temperature logs for a minimum of three years;

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(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;

(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination by a Pharmacist that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan;

(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment; and

(H) Documentation and review of temperature recordings at least once every 28 days by the Pharmacist at the time of in person physical inspection.

Statutory/Other Authority: ORS 689.205 & ORS 689.325
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0130
Drug: Loss

A PPK and its PPK Affiliated Pharmacy must:

(1) Ensure that disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices are reported to the board immediately.

(2) Ensure that confirmed significant drug loss or any loss related to suspected drug theft is reported to the board within one business day.

Statutory/Other Authority: ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0145
Outlet: Closure

A PPK Affiliated Pharmacy must notify the board a minimum of 15 days prior to discontinuing operation of a PPK. Notification must include the:

(1) Final disposition of drugs stored in the PPK including:

(a) Name and location where the drugs are transferred;

(b) Name and location where destruction occurred; and

(c) Name and location of the site that will store all records;

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(2) Provide the board with:

(a) Oregon Board of Pharmacy state license(s); and

(b) Signed statement giving the effective date of closure.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 689.527

855-141-0150
Outlet: Sanitation

A PPK and its PPK Affiliated Pharmacy must ensure the PPK is kept clean.

Statutory/Other Authority: ORS 689.305
Statutes/Other Implemented: ORS 689.305 & ORS 689.527

855-141-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon PPK must have the following:

(a) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the PPK outlet;

(b) Appropriate equipment to maintain the proper storage of drugs;

(c) Signage in a location easily seen by the public at the PPK where prescription and non-prescription drugs, devices, and related supplies are dispensed:

(A) Stating “The (insert name of PPK Affiliated Pharmacy) may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve.” The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-141-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Stating "This location is a Pharmacy Prescription Kiosk, supervised by a Pharmacist from (insert name of PPK Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and

(D) Providing notification of accurate hours of operation at the PPK; and

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(d) Additional equipment and supplies that are determined as necessary by the PPK Affiliated Pharmacy or PIC.

(e) As an alternative to posting the required signage, PPK's that utilize an electronic video monitor that the patient is required to acknowledge prior to retrieving medication from the PPK may display the information required by sub-paragraphs (1)(c)(A) - (D) electronically.

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

Statutory/Other Authority: ORS 689.205 & ORS 689.654
Statutes/Other Implemented: ORS 689.155, ORS 689.515, ORS 689.654 & ORS 689.527

855-141-0200
Outlet: General Requirements

(1) The PPK Affiliated Pharmacy and its PIC are responsible for all operations and enforcing all policies and procedures of the PPK.

(2) A PPK Affiliated Pharmacy may operate more than one PPK.

(3) A PPK Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the PPK.

(4) A PPK and its PPK Affiliated Pharmacy must:

(a) Have the same owner; or

(b) Have a written contract that specifies:

(A) The services to be provided by each licensee and registrant;

(B) The responsibilities of each licensee and registrant; and

(C) The accountabilities of each licensee and registrant;

(c) Ensure prescription and non-prescription drugs, devices, and related supplies are dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, OAR 855-041 and OAR 855-141;

(d) Ensure that the PPK Affiliated Pharmacy prevents duplicate dispensing of a prescription;

(e) Comply with all applicable federal and state laws and rules;

(f) Ensure that there is an PIC who is responsible for all operations and enforcing all policies and procedures of the PPK;

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(g) Designate in writing the Pharmacists, Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians authorized to access the PPK;

(h) Utilize complete chain of custody tracking;

(i) Train the Pharmacists, Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians in the operation of the telepharmacy system and PPK and document the training;

(j) Develop, implement and enforce a continuous quality improvement program for dispensing services from a PPK 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;

(k) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Pharmacist from the PPK Affiliated Pharmacy; and

(l) Develop, implement and enforce a process for an in person physical inspection of the PPK by a Pharmacist at least once every 28 days or more frequently as deemed necessary by the PIC of the PPK Affiliated Pharmacy. The inspection must utilize the PPK self-inspection form, be documented, and records retained.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0205
Outlet: Technology

A PPK and its PPK Affiliated Pharmacy must:

(1) Utilize a shared telepharmacy system and have appropriate technology or interface to allow access to information required to dispense prescription and non-prescription drugs, devices, and related supplies and counsel the patient or patient's agent;

(2) Utilize barcode, radio-frequency identification or quick response code technology for stocking, destocking and dispensing at the PPK;

(3) Test the telepharmacy system and PPK and verify the unit is operable and functioning in all aspects in accordance with minimum acceptable system or unit design specifications before dispensing prescription and non-prescription drugs, devices, and related supplies and after an upgrade or change is made to the system. The PPK Affiliated Pharmacy must make the results of such testing available to the board upon request; and

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(4) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system and PPK.

(5) Develop, implement and enforce a plan for responding to and recovering from an interruption of service where the PPK is not fully operational and functioning.

(6) For verification of prescriptions, use still image capture or store and forward with a camera that is of sufficient quality and resolution so that the Pharmacist from the PPK Affiliated Pharmacy can visually identify each:

(a) Source container including manufacturer, name, strength, lot, and expiration;

(c) Dispensed product including the imprint and physical characteristics if applicable;

(d) Completed prescription container including the label; and

(7) Utilize barcode, radio-frequency identification or quick response code technology to record information in (6) if available.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0210
Outlet: Supervision

A PPK and its PPK Affiliated Pharmacy must:

(1) Ensure prescription and non-prescription drugs, devices, and related supplies are only dispensed at the PPK if a Pharmacist is available for patient consultation and the PPK is fully operational.

(2) Ensure that stocking and destocking of prescription and non-prescription drugs, devices, and related supplies in a PPK is completed under the supervision, direction, and control of a Pharmacist.

(3) Ensure that a Pharmacist verifies and documents that:

(a) All prescription and non-prescription drugs, devices, and related supplies were correctly stocked into the PPK;

(b) All prescription and non-prescription drugs, devices, and related supplies destocked from the PPK were returned to the PPK Affiliated Pharmacy;

(c) Proper storage conditions were maintained during transfer per OAR 855-141-0125; and

(d) Records are maintained per OAR 855-141-0550.

(4) Drugs and devices destocked from a PPK that satisfy the requirements of this section may be returned to stock at the PPK Affiliated Pharmacy.

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Statutory/Other Authority: ORS 689.205 & ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305 & ORS 689.527

855-141-0215
Outlet: Pharmacist Utilization

A PPK and its PPK Affiliated Pharmacy must ensure that a prescription drug or device is not released from the PPK until the Pharmacist or Intern has:

(1) Provided counseling when required under OAR 855-019-0230 or when requested by the patient or patient's agent; and

(2) Documented the interaction.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0225
Outlet: Controlled Substances

Controlled substances must not be stored in the PPK.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0300
Prescription: General Requirements

(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization.

(2) Each PPK Affiliated Pharmacy must document the following information for each prescription:

(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal.

(b) If for an animal, the name of the patient, name the owner and the species of the animal.

(c) The full name, address, and contact phone number of the practitioner.

(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

(e) The directions for use, if given by the practitioner; and

(f) The date of filling, and the total number of refills authorized by the prescribing practitioner.

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(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, instruction must use one of the following phrases or notations:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words with similar meaning.

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent must clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

(c) Such instructions must not be default values on the prescription.

(4) A PPK or Pharmacist filling a prescription or order for a biological product must not substitute a biosimilar product for the prescribed biological product unless:

(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;

(d) The PPK Affiliated Pharmacy or Pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar product; and

(5) The PPK must dispense prescriptions accurately and to the correct party.

Statutory/Other Authority: ORS 689.205 & ORS 689.522
Statutes/Other Implemented: ORS 689.505, ORS 689.515 & ORS 689.522

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855-141-0305
Prescription: Tamper-resistant

When the use of a tamper-resistant prescription is required by any federal or state law or rule, the term "tamper-resistant" has the meaning as defined in OAR 855-006-0015.

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

855-141-0310
Prescription: Verification of Authenticity

Alteration of a written prescription, other than by a Pharmacist's or practitioner's authorization, in any manner constitutes an invalid order unless verified with the prescriber.

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

855-141-0315
Prescription: Refills

(1) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable.

(2) If the practitioner is not available and in the reasonable professional judgment of the Pharmacist from the PPK Affiliated Pharmacy an emergency need for the refill of a prescription drug has been demonstrated, the Pharmacist may authorize the PPK to prepare for Pharmacist verification a sufficient quantity of the drug consistent with the dosage regimen, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner must be promptly notified of the emergency refill.

(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years by the PPK Affiliated Pharmacy. This record must include;

(a) Date, time and identification of each individual and activity or function performed;

(b) Name of the patient;

(c) Name of the medication;

(d) Date of refill; and

(e) Quantity dispensed.

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(4) Refill quantities may be combined into a single filling if the prescription is not for a psychotherapeutic drug and the prescriber is notified of the change.

(5) A PPK may only dispense a prescription refill upon request of the patient or patient's agent. A request specific to each prescription medication is required.

(6) A prescription must be refilled in context with the approximate dosage schedule unless specifically authorized by the prescriber.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-141-0320
Prescription: Expiration

This section of rule addresses the expiration date of the prescription and not the expiration date of the drug.

(1) After one year from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber.

(2) When "PRN" is used as a prescription refill designation:

(a) The abbreviation means that the prescription can be refilled in proper context for a period of one year.

(b) In conjunction with a definite time period, or a specific number of refills, the prescription can be refilled in proper context for a period not to exceed one year.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-141-0325
Prescription: Transfers

(1) Prescriptions may be transferred between pharmacies for the purpose of an initial or refill dispensing provided that:

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

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.

(2) Prescriptions for controlled substances can only be transferred one time.

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(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.

(4) An Oregon registered pharmacy must transfer a prescription:

(a) To a pharmacy requesting a transfer on behalf of the patient or patient's agent unless the transfer would compromise patient safety or violate state or federal laws or rules; and

(b) By the end of the next business day of the request.

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

855-141-0345
Dispensing: General Requirements

The PPK Affiliated Pharmacy must:

(1) Ensure each prescription, prescription refill, and drug order is correctly dispensed from the PPK in accordance with the prescribing practitioner's authorization; and

(2) Ensure the PPK dispenses prescriptions accurately and to the correct party.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0350
Dispensing: Containers

Each PPK must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2021), 16 CFR 1701 (01/01/2021), and 16 CFR 1702 (01/01/2021).

[Publications: Publications referenced are available from the agency.]

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

855-141-0400
Labeling: General Requirements

Prescriptions must be labeled with the following information:

(1) Name and address of the PPK.

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(2) Date;

(3) Identifying number;

(4) Name of patient;

(5) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(6) Directions for use by the patient;

(7) Name of practitioner;

(8) Such other and further accessory cautionary information as required for patient safety;

(9) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier. Any drug expiring before the expected length of time for course of therapy must not be dispensed.

(10) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules; and

(11) Name, address and telephone number of the PPK Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-141-0405
Labeling: Prescription Reader Accessibility

(1) A PPK must notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request; a prescription reader is a device designed to audibly convey labeling information.

(2) If a person informs the PPK Affiliated Pharmacy that the person identifies as a person who is blind, the pharmacy must provide to the person a prescription reader that is available to the person for at least the duration of the prescription, must confirm it is appropriate to address the person's visual impairment, and must ensure that prescription labels are compatible with the prescription reader. This requirement does not apply to an institutional drug outlet, dispensing a drug intended for administration by a healthcare provider.

(3) The PPK Affiliated Pharmacy must ensure a Pharmacist verifies and documents that the correct electronic label was placed on each prescription container and that the audio information produced by the prescription reader is accurate prior to dispensing the prescription.

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Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.561

855-141-0410
Labeling: Limited English Proficiency and Accessibility

(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by the PPK for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), the PPK must provide labels and informational inserts in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

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Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

855-141-0450
Drugs and Devices: Disposal

Drugs and devices that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-141-0455
Drug and Devices: Return

A PPK or PPK Affiliated Pharmacy may accept the return of a drug or device as defined by ORS 689.005 once the drug or device have been dispensed from the PPK if they were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, or are subject of a drug or device recall only if:

(1) A Pharmacist has approved the return;

(2) The drugs or devices are accepted for destruction or disposal; and

(3) A Pharmacist verifies the destruction or disposal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

855-141-0500
Policies and Procedures

(1) The PIC of the PPK Affiliated Pharmacy and the PPK Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the PPK. The written policies and procedures must be maintained at the PPK Affiliated Pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the responsibilities of the PPK Affiliated Pharmacy and each PPK including;

(a) Security;

(b) Operation, testing and maintenance of the telepharmacy system and the PPK;

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(c) Sanitation and cleaning;

(d) Storage of drugs;

(e) Stocking and destocking;

(f) Dispensing;

(g) Preventing duplicate dispensing;

(h) Pharmacist supervision, direction and control of and licensed personnel accessing the PPK;

(i) Documenting the identity, function, location, date and time of licensees engaging in telepharmacy and licensed personnel accessing the PPK;

(j) Utilization of Interns, Certified Oregon Pharmacy Technicians or Pharmacy Technicians;

(k) Utilization of Pharmacist (e.g. Counseling);

(l) Drug and/or device procurement

(m) Receiving of drugs and/or devices;

(n) Delivery of drugs and/or devices;

(o) Recordkeeping;

(p) Patient confidentiality;

(q) On-site inspection by a Pharmacist;

(r) Continuous quality improvement;

(s) Plan for discontinuing and recovering services if PPK disruption occurs;

(t) Training: initial and ongoing; and

(u) Interpretation, translation and prescription reader services.

(3) A PPK Affiliated Pharmacy that provides prescription and non-prescription drugs, devices, and related supplies through a PPK must review its written policies and procedures every 12 months, revise them if necessary, and document the review.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

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855-141-0550

Records: General Requirements

(1) The recordkeeping requirements OAR 855-141 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) All required records for the PPK must be maintained by the PPK Affiliated Pharmacy.

(3) Records retained by the PPK Affiliated Pharmacy must include, but are not limited to:

(a) Date, time and identification of each individual and activity or function performed via the PPK;

(b) Pharmacist physical inspection of the PPK;

(c) Telepharmacy system testing;

(d) Licensee training on the proper use of the PPK;

(e) Still image capture and store and forward images must be retained according to (1);

(f) Data and surveillance system data must be retained for 6 months; and

(g) Any errors or irregularities identified by the quality improvement program.

(4) Records of dispensing from a PPK must include the:

(a) Physical location of the PPK;

(b) Identification of the patient or patient's agent retrieving the prescription, non-prescription drugs, and supplies;

(c) A digital image of the individual to whom the prescription was dispensed.

(d) Date and time of transaction;

(e) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;

(f) Each non-prescription drug and supply name, UPC or NDC number, and quantity; and

(g) Name of Pharmacist or Intern who provided counseling to the patient or patient's agent, if required, documentation that the counseling was performed or that the Pharmacist or Intern accepted the patient or patient's agent request not to be counseled.

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(5) Records of stocking and destocking of prescriptions into or from a PPK must include the:

(a) Date and time;

(b) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;

(c) Each non-prescription drug and supply name, UPC or NDC number, and quantity;

(d) Name and Oregon license number of the person stocking or destocking prescription, non-prescription drugs and supplies from the system; and

(e) Identity of the Pharmacist who verifies that the system has been accurately stocked or destocked.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508 & ORS 689.527

855-141-0555
Records: Patient

A patient record system must be maintained by the PPK Affiliated Pharmacy for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing Pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing. The Pharmacist must make a reasonable effort to obtain, record, and maintain the following information:

(1) Full name of the patient for whom the drug is intended;

(2) Address and telephone number of the patient;

(3) Patient's age or date of birth;

(4) Patient's gender;

(5) Patient's preferred language for communication and prescription labeling;

(6) Chronic medical conditions;

(7) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(8) Known allergies, drug reactions, and drug idiosyncrasies; and

(9) If deemed relevant in the Pharmacist's reasonable professional judgment:

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

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

855-141-0600
Prohibited Practices: General

A PPK must not:

(1) Allow unlicensed personnel, Certified Oregon Pharmacy Technicians or Pharmacy Technicians to ask questions of a patient or patient's agent which screen and/or limit interaction with the Pharmacist;

(2) Utilize a person to dispense or deliver a prescription and non-prescription drug, device, and any related supply directly to the patient from the PPK;

(3) Dispense drugs that require further manipulation prior to administration or dispensing (e.g. reconstitution, compounding, vaccines); and

(4) Store or dispense controlled substances.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0602
Prohibited Practices: Disclosure of Patient Information

A PPK must not:

(1) Allow a licensee or registrant of the board who obtains any patient information to disclose that information to a third party without the consent of the patient except as provided in (a)-(e) of this rule. A licensee can disclose patient information:

(a) To the board;

(b) To a practitioner, Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, if disclosure is authorized by a Pharmacist who reasonably believes that disclosure is necessary to protect the patient's health or wellbeing; or

(c) To a third party when disclosure is authorized or required by law; or

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(d) As permitted pursuant to federal and state patient confidentiality laws; or

(e) To the patient or to persons as authorized by the patient.

(2) Allow a licensee or registrant of the board to access or obtain any patient information unless it is accessed or obtained for the purpose of patient care except as provided in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0650
Grounds for Discipline

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(1) Any of the grounds listed in ORS 689.405.

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:

(a) Is false, fraudulent, deceptive, or misleading; or

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.

Statutory/Other Authority: ORS 689.151, ORS 689.155, ORS 689.205 & ORS 689.225
Statutes/Other Implemented: ORS 689.155, ORS 689.405 & ORS 689.527

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Division 006/019/031/: Definitions

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds multiple new Definitions to Division 006

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments to Division 006 will add definitions for "board approved school or college of pharmacy", amends clinical pharmacy agreement definition by adding appropriate statute references and "naturopathic physician". It also adds definitions for "counseling", "Drug Regimen Review" (DRR), "Drug Utilization Review" (DUR), "Good Standing", "Independent Practice of Pharmacy", "Intern", Pharmacist" "Pharmacy Area" and "Preceptor". Repeals language related to oral counseling, participation in drug selection and DUR and language related to responsibility for advising. Repeals OAR 855-019-0110. Adds "board approved" and rule reference to OAR 855-031-0005.

Documents Relied Upon per ORS 183.335(2)(b)(D): None available.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal impact is anticipated.

Cost of Compliance (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): There are no known economic impacts to the agency, other state or local government, small businesses, or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of the proposed rule amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommends adopting the proposed amendments for transparency and clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments include adding "board approved school or college of pharmacy", amends clinical pharmacy agreement definition by adding references to ORS 677.010 and 685.010 and adds "naturopathic physician". Adds definitions for "counseling", "Drug Regimen Review" (DRR), "Drug Utilization Review" (DUR), "Good Standing", "Independent Practice of Pharmacy", "Intern", "Pharmacist", "Pharmacy Area" and "Preceptor". Repeals language in 006-0005(33) related to participation in drug selection and DUR and language related to responsibility for advising in 006-0005(46). Repeals 855-019-0010. Amends 855-031-0005 by removing outdated language related to Interns and adds a reference to new definition in Division 006 related to "board approved". Proposed amendments will ensure clarity by informing licensees that these definitions apply across all Divisions in OAR 855.

Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR Chapter 855:

(1) “Adulterated” has the same meaning as set forth in 21 USC 351 (v. 3/15/2022).

(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) (03/15/2022).

(6) “Board” means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(7) “Board-approved school or college of pharmacy” means an ACPE accredited, accredited with probation, pre-candidate or candidate status (v. 6/2022) or a Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program (v. 6/2022) with a curriculum taught in English;

(8) “Certified health care interpreter” has the meaning given that term in ORS 413.550.

(9) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the Pharmacist are not considered Certified Oregon Pharmacy Technicians or Pharmacy Technicians.

(10) “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.

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

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

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

(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.

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(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) “Independent Practice of Pharmacy” means the provision of clinical pharmacy services not related to the dispensing, distribution and delivery of drugs or devices.

(26) “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.

(27) “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) (03/15/2022).

(28) “Intern” means a person who is enrolled in or has completed a course of study at a school or college of pharmacy approved by the board and who is licensed with the board as an Intern.

(29) "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.

(30) "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.

(31) “Misbranded” has the same definition as set forth in 21 USC 352 (v. 03/15/2022).

(32) "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.

(33) "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.

(34) "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.

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

(36) "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.

(37) “Official compendium” means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP NF 2022, Issue 1), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2022), or any supplement to any of these.

(38) "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.

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

(40) "Pharmacy Area" means each area where prescription drugs or devices, records, and equipment used to access pharmacy records are located.

(41) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board but has not completed the specialized education program pursuant to OAR 855-025-0012.

(42) “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

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(c) The practice of pharmacy by a Pharmacist pursuant to a clinical pharmacy agreement.

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

(44) “Preceptor” means a Pharmacist or a person licensed by the board to supervise the internship training of a licensed Intern.

(45) “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.

(46) "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.

(47) “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.

(48) "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.

(49) “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.

(50) “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.

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(51) “Reference biological product” means the biological product licensed pursuant to 42 USC 262(a) (03/15/2022) 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.

(52) “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.

(53) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as Certified Oregon Pharmacy Technicians or Pharmacy Technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or

(b) A structured program approved by the board and designed to educate Certified Oregon Pharmacy Technicians or Pharmacy Technicians in one or more specific issues of patient health and safety that is offered by:

(A) An organization recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians;

(B) An employer recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians; or

(C) A trade association recognized by the board as representing pharmacies.

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

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

(56) "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.

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

(58) "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.

(59) "Verification" means the confirmation by the Pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed an Intern, a Certified Oregon Pharmacy Technician, or a Pharmacy Technician.

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

Division 19
PHARMACISTS

~~855-019-0110~~
~~Definitions~~

~~In this Division of Rules:~~

~~(1) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a health care organization or a physician 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.~~

~~(2) "Collaborative Drug Therapy Management (CDTM)" has the same meaning as defined in OAR 855-006-0005.~~

~~(3) "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.~~

~~(4) "Drug Regimen Review (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.~~

~~(5) "Drug Utilization Review (DUR)" has the same meaning as defined in OAR 855-006-0005.~~

~~(6) "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.~~

~~(7) "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.~~

~~(8) "Practice of Pharmacy" is as defined in ORS 689.005.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005, 689.151 & 689.155~~

Division 31
INTERNS

855-031-0005
Definitions

(1) "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.

(2) “School of pharmacy”: In this division of rules, “school of pharmacy” means a Board-approved school or college of pharmacy as defined in OAR 855-006-0005.

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

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Division 041: Operation of Pharmacies (Labeling)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Retail Drug Outlet Pharmacy Prescription Labeling; Expiration date requirements

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Permanently adopts temporary rule related to expiration date requirements.

Documents Relied Upon per ORS 183.335(2)(b)(D): None available.

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rule language will increase patient access, especially for life saving medications such as naloxone and inhalers for asthma. The rule provides clarity and transparency to licensees and registrants.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal impact is anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public) Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government, small businesses, or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed rule amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not consulted. Board staff recommend amending the labeling requirements to increase patient access and for transparency and clarity for licensees/registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments allow prescription drugs dispensed in manufacturer's container to be labeled with the expiration date on the container and not limited to one year. Includes striking language in (10) and adding (a) (b) (A) (B), and (11). Adds clarifying language related to expiration date requirements on prescription labels including manufacturer's expiration date or one year from the date the drug was repackaged and dispensed. The current rule as written may limit patient access due to prescription medication expiration dates being limited to one year. Amendments are necessary to allow licensees and registrants the ability to label prescriptions dispensed in the manufacturer's container with the manufacturer's expiration date and not being limited to one year from dispensing.

Division 041
OPERATION OF PHARMACIES

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling

Prescriptions must be labeled with the following information:

(1) Name, address and telephone number of the pharmacy;

(2) Date of fill;

(3) Identifying number;

(4) Name of patient;

(5) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(6) Directions for use by the patient;

(7) Name of practitioner;

(8) Required precautionary information regarding controlled substances;

(9) Such other and further accessory cautionary information as required for patient safety;

(10) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must not exceed:

(a) That on the manufacturer's container if dispensed in the manufacturer's container; or

(b) The earliest date of either:

(A) The manufacturer's expiration date; or

(B) One year from the date the drug was repackaged and dispensed.

(11) Any drug expiring before the expected length of time for the course of therapy must not be dispensed.

(12) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

DRAFT

Division 019/041: Safe Pharmacy Practice Conditions (RPH Autonomy)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Incorporates rules to address safe pharmacy practice conditions

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amends general responsibilities for Pharmacist. Amends outlet personnel and grounds for discipline.

Documents Relied Upon per ORS 183.335(2)(b)(D): Safe Pharmacy Practice Conditions Workgroup meeting minutes: January 2022, March 2022, May 2022, July 2022 and September 2022.

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Adopting the proposed amendments may increase patient safety for all Oregonians in every community by ensuring that licensees have a properly staffed working environment to improve pharmacy practice conditions. A properly staffed working environment may create fewer opportunities for medication errors and increase the availability of the Pharmacist to provide necessary patient services such as counseling and immunizations.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): Effect on Small Businesses: Number/Type, Reporting, Recordkeeping, Administrative Activities Cost, Professional Services, Equipment/Supplies, Labor Cost: None anticipated. The rulemaking imposes no additional mandatory reporting, recordkeeping, or other administrative requirements on small businesses.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. A Workgroup was convened per the board's direction.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments in Division 019 will clarify that the Pharmacist has autonomy to control each aspect of the practice of pharmacy which includes shutting down touchpoints and services if understaffed and that the Pharmacist is responsible for the conduct, operation, management and control of the pharmacy. Proposed amendments were recommended by the Safe Pharmacy Practice Conditions workgroup to help address staffing issues and practice conditions in pharmacies as recognized in the February 2022 Safe Pharmacy Practice Conditions Survey results.

Proposed amendments in Division 041 will add drug outlet staffing requirements and amends grounds for discipline to include overriding or interfering with the Pharmacist on duty's control of all aspects of the practice of pharmacy. Proposed amendments were recommended by the Safe Pharmacy Practice Conditions workgroup to help address the drug outlet working environment, insufficient personnel issues, lack of rest and meal periods and lack of adequate time for the Pharmacist to perform essential duties to ensure safe and timely patient care.

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NOTES:

- History of rule package review
  - This rule package was included on the agenda for the August 2022 and October 2022 board meetings, but the board did not discuss the package during those meetings.
  - The December 2022 meeting is the 1st review of this package.

Division 19
PHARMACISTS

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;

PROPOSED

(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;

POLICY DISCUSSION: Pharmacist Autonomy

(~~b~~**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;

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

(~~d~~**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** ~~When supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, determine how many licensed individuals the Pharmacist is capable of supervising, directing and controlling~~ based on the **workload and** services being provided.

POLICY DISCUSSION: May/Must, Temporary/Permanent, Dispensing/Non-Dispensing, Discretion/Determines, Examples (e.g.,), Notification

(g1) Ensure there is sufficient staff to provide services in a safe and timely manner. The Pharmacist on duty may temporarily shut down touchpoints and services at the discretion of the Pharmacist, if determined in their reasonable professional judgment, that there is insufficient staff to provide services in a safe and timely manner.

(g2) Ensure there is sufficient staff to provide services in a safe and timely manner. The Pharmacist on duty must shut down touchpoints and non-dispensing services if the Pharmacist determines, in their reasonable professional judgment, that there is insufficient staff to provide services in a safe and timely manner.

(g3) Ensure there is sufficient staff to provide services in a safe and timely manner.

(g3a1) The Pharmacist on duty ~~may~~ must temporarily shut down
(g3a2) The Pharmacist on duty may ~~must~~ temporarily shut down

(g3b1) touchpoints and ~~non-dispensing~~ services
(g3b1) touchpoints and non-dispensing services

PROPOSED

(g3c1) touchpoints (e.g. drive-thru, registers, etc.) and ~~non-dispensing~~ services (e.g., vaccinations, dispensing)
(g3c2) touchpoints (e.g. drive-thru, registers, etc.) and non-dispensing services (e.g., vaccinations, testing)

(g3d1) during each timeframe of insufficient staffing as determined by the Pharmacist using their reasonable professional judgment.
(g3d2) if the Pharmacist determines, in their reasonable professional judgment, that there is insufficient staff to provide services in a safe and timely manner.

(g3e1) The Pharmacist must provide notification to the PIC by the end of the business day that touchpoint and service limits were applied.

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

(~~f~~**i**) 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;

(~~g~~**j**) 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:

PROPOSED

(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

Division 41
OPERATION OF PHARMACIES

855-041-1010
Outlet (RP & IP): Personnel ~~(Both Retail and Institutional Drug Outlets)~~

Each pharmacy must:

(1) ~~Each pharmacy must h~~**H**ave one **P**~~p~~harmacist-in-charge employed on a regular basis at that location who shall be responsible for the daily operation of the pharmacy. The **P**~~p~~harmacist-in-charge shall be indicated on the application for a new or relocated pharmacy and for pharmacy renewal registration.

(2) ~~A resident pharmacy that~~ **Report** terminat**inge**~~s~~ or allow**ing**~~s~~ a **b**~~B~~oard licensee to resign in lieu of termination ~~must report the termination or resignation~~ to the **b**~~B~~oard within 10 working days.

(3) ~~A pharmacy must e~~**E**nsure that it is in compliance with all state and federal laws and rules governing the practice of pharmacy.

(4) Provide a working environment that protects the health, safety and welfare of a patient which includes but not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

(c) Adequate time for a Pharmacist to complete professional duties and responsibilities including, but not limited to:

(A) Drug Utilization Review;

(B) Immunization;

PROPOSED

(C) Counseling;

(D) Verification of the accuracy of a prescription; and

(E) All other duties and responsibilities of a Pharmacist as specified in OAR 855-019.

(d) Adequate staffing to provide safe and timely patient care based on workload volume and services provided. If conditions exist that could cause a clinical delay in patient care or patient care to be conducted in an unsafe manner, the outlet must take timely corrective action, document, and retain records of the corrective action. Determination of adequate staffing must be based on the following:

POLICY DISCUSSION: Clinical delay, Corrective action

(A) Volume of prescriptions handled by staff to include:

(i) Prescriptions filled, dispensed, and sold;

(ii) Prescriptions placed on hold;

(iii) Prescriptions returned to stock; and

(iv) Any other prescription related metrics utilized by the outlet.

(B) Volume of non-dispensing services provided by staff to include;

(i) Vaccinations offered and provided

(ii) Prescribing services offered and provided (e.g., hormonal contraceptive, statewide drug therapy management protocols or formulary drugs and devices)

(iii) CDTM services offered and provided

(iv) MTM offered and provided; and

(v) Laboratory testing offered and provided;

(C) Security needs of the pharmacy and pharmacy staff; and

(D) Staff experience and competency related to the practice of pharmacy;

POLICY DISCUSSION: Factors

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, 689.155 & 689.305

855-041-1170
Outlet (RP & IP): Grounds for Discipline

PROPOSED

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(1) Unprofessional conduct as defined in OAR 855-006-0020;

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:

(a) Is false, fraudulent, deceptive, or misleading; or

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.

(3) Fail**ing**~~ure~~ to provide a working environment that protects the health, safety and welfare of a patient ~~which includes but is not limited to:~~ **as required in OAR 855-041-1010.**

~~(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.~~

~~(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.~~

~~(c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:~~

~~(A) Drug Utilization Review;~~

~~(B) Immunization;~~

~~(C) Counseling;~~

~~(D) Verification of the accuracy of a prescription; and~~

~~(E) All other duties and responsibilities of a pharmacist as specified in Division 19 of this chapter of rules.~~

(4) Incent**iviz**ing or inducing the transfer of a prescription ~~absent professional rationale~~.

POLICY DISCUSSION: Professional rationale, New prescriptions

(5) Overriding or interfering with the Pharmacist on duty's control of all aspects of the practice of pharmacy.

(6) Any other grounds found in ORS 689.405 or ORS 689.490.

Statutory/Other Authority: ORS 689.151, **ORS** 689.155~~(2)~~, **ORS** 689.205 & **ORS** 689.225~~(4)~~
Statutes/Other Implemented: ORS 689.155

PROPOSED

Division 019/020/041/115: Pharmacists (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 115 for Pharmacists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): The proposed rules create a new Division 115 for Pharmacists, relocates and reorganizes existing Pharmacists rules from Division 019, Division 020, Division 031 and Division 041 into this new division. If the board adopts Division 115, existing rules related to Pharmacists would be repealed in Division's 019, 020, 031 and 041.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): To be determined.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed revisions to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed rule adoption includes relocating and reorganizing existing Pharmacist rules from Division's 019, 020, 031 and 041 to newly created Division 115 in alignment with the board's strategy to systematically organize all Divisions. Proposed amendments include revising titles, clarifying requirements for applicability, definitions, general qualifications for all Pharmacists license types, licensure requirements for all Pharmacist license types, licensure application, license renewal, license reinstatement, licensure lapse, licensure retirement, licensure voluntary surrender, Pharmacist Preceptor registration, in-state and out-of-state volunteer Pharmacist, and Nuclear Pharmacist. General responsibilities, confidentiality responsibilities, duty to report responsibilities, training responsibilities, Drug Utilization Review (DUR), Counseling, PIC qualifications, limitations and duties. Services such as independent practice, Pharmacist consulting practice, and administration of vaccines, drugs or devices.

Other health care boards in Oregon and other states consider counseling to patients who are located in Oregon to require licensure. This would bring us in alignment with other boards and ensure that the Board is following statutory mandates regarding licensure requirements for those practicing pharmacy in Oregon.

Repeals Division 019.

Would amend OAR 855-041-3000 by repealing (4). Proposes repealing Division 020.
Proposes repealing OAR 855-041-3300, 041-3305, 041-3310, 041-3315, 041-3320, 041-3325, 041-3330, 041-3335 and 041-3340. A few rules in Division 041 are related specifically to a pharmacist and need to be relocated to the newly created Division 115 Pharmacists.

NOTES:

- History of rule package review
  - The board completed a 1st review the licensing rules of this package in June 2022.
  - The board completed a 2nd review of the licensing rules and a 1st review of the responsibilities rules (ending with 855-115-0086(1)) of this package at the August 2022 board meeting.
  - The board completed a 3rd review of the licensing rules and a 2nd review of the responsibilities rules (ending with 855-115-0086(1)) of this package at the October 2022 board meeting.
  - The December 2022 meeting is the 4th review of licensing rules, 3rd review of responsibilities rules (ending with 855-115-0086(1) and 1st review of services rules of this package.
- Highlights
  - Rules highlighted in yellow denote staff proposed amendments between the August 2022 and October 2022 board meeting that were not discussed at the October 2022 meeting
  - Rule language highlighted in blue denote staff proposed amendments made between the board's review of this package at the October 2022 board meeting and the December 2022 board meeting.
  - Rules highlighted in green are part of the SPPC rule package in mailing #C.

---------- LICENSING (4th REVIEW) ----------

Division ~~19~~**115**
PHARMACISTS

~~855-019-0100~~ **855-115-0001**
~~Application~~ **Applicability**

(1) This Division applies to any ~~p~~**P**harmacist **who engages in the practice of pharmacy** ~~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~~**2**) ~~Any pharmacist who engages in the~~ **Only persons licensed with the board as a Pharmacist may** practice ~~of~~ pharmacy ~~in Oregon~~ **and** must ~~be licensed by the Board in accordance with the following~~ **act in compliance with statutes and** rules.

PROPOSED

(4**3**) A **P**~~p~~harmacist 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 ~~B~~**b**oard in accordance with the following rules, except that a **P**~~p~~harmacist **located in another state who is** working ~~in~~ **for** an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, ~~counseling~~ and verification associated with the~~ir~~ **out-of-state pharmacy** dispensing of a drug **in**to ~~a patient in~~ Oregon, is not required to be licensed by the ~~B~~**b**oard ~~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~~ **855-115-0005**
Definitions
Note: Placeholder- No definitions specific to Division 115 at this time.

~~In this Division of Rules:~~

~~(1) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a health care organization or a physician 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.~~

~~(2) "Collaborative Drug Therapy Management (CDTM)" has the same meaning as defined in OAR 855-006-0005.~~

~~(3) "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.~~

~~(4) "Drug Regimen Review (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.~~

~~(5) "Drug Utilization Review (DUR)" has the same meaning as defined in OAR 855-006-0005.~~

~~(6) "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.~~

~~(7) "Practice of Clinical Pharmacy" means:~~

PROPOSED

~~(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.~~

~~(8) "Practice of Pharmacy" is as defined in ORS 689.005.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005, 689.151 & 689.155~~

855-115-0010
Licensure: Qualifications: General

(1) Before licensure as a Pharmacist, an applicant must meet the qualifications required that are applicable to their method of licensure;

(a) Examination or Score Transfer in OAR 855-115-0020; or

(b) Reciprocity in OAR 855-115-0025.

(2) If residing in the United States, proof of citizenship, legal permanent residency or qualifying visa, as required by 8 USC 1621

(3) Foreign pharmacy graduates must also meet the requirements of OAR 855-115-0013 prior to applying for a Pharmacist license.

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

~~855-019-0150~~ **855-115-0013**
Licensure: Qualifications: Pharmacist 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~~**1**) Provide a copy of the original certificate issued by the NABP Foreign Pharmacy Graduate Examination Committee (FPGEC); and

PROPOSED

~~(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~~ **Submit evidence of** 1440 hours in pharmacy practice as an ~~i~~**I**ntern**.** ~~that must be certified to the Board by the preceptors.~~ **An applicant must not count internship hours or practice as a Pharmacist toward Oregon's internship requirement that was completed:**

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

(a) Outside the United States; or

~~(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.~~

(b) Before obtaining the FPGEC certification.

~~(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.~~

(3) Graduates from a Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program with a curriculum taught in English are exempt from (1) and (2). These graduates must be:

(a) Licensed as a Pharmacist in a US state or jurisdiction with a minimum of 1440 hours in pharmacy practice in a US state or jurisdiction; and

(b) The license is not suspended, revoked, canceled or otherwise completely restricted from the practice of pharmacy for any reason.

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

~~855-019-0120~~ **855-115-0016**
Licensure: Qualifications: Pharmacist Examination or Score Transfer

(1) ~~Before~~ **To receive** licensure as a ~~p~~**P**harmacist **by examination or score transfer**, an applicant must meet the following requirements:

(a) Provide evidence from a **board-approved** school or college of pharmacy ~~approved by the board~~ that**:** ~~they have successfully completed all the requirements for graduation and, starting with the graduating~~

PROPOSED

~~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**) ~~a~~**A** degree ~~will be~~ **has been** conferred; **and**

(B) The applicant has completed a minimum of 1440 hours of School-based Rotational Internships as that term is defined in OAR 855-120-0005.

(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam**.** ~~with a score of not less than 75. This score~~ **A passing result** is valid for ~~only one year~~ **12 months** ~~unless the board grants an extension~~. A candidate who does not ~~attain this score~~ **pass** may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 **failed attempts** ~~times~~;

(c) Pass the **Oregon** Multistate Pharmacy Jurisprudence Examination (MPJE) exam**. A passing result is valid for 12 months** ~~The applicant may not take the MPJE until they have graduated from a school or college of pharmacy.~~ A candidate who does not ~~attain this score~~ **pass** may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 **failed attempts**. ~~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~~**d**) 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.~~

(2) An applicant who has obtained their professional degree outside the United States is not eligible for licensure via examination or score transfer until they have met the requirements of OAR 855-115-0013.

(3) An applicant applying via score transfer must request the National Association of Boards of Pharmacy to transfer their NAPLEX score to Oregon.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151**, ORS 413.590** ~~& 2021 HB 2078~~ **ORS 689.285**

~~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.~~

PROPOSED

~~(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~~

~~855-019-0130~~ **855-115-0019**
Licensure**: Qualifications: Pharmacist** ~~by~~ Reciprocity

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

(a) Be a graduate of a **board-approved** 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 **Oregon** MPJE**.** ~~with a score of not less than 75;~~ **A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;**

(d) ~~Be licensed and in good standing in the state from which the applicant bases the reciprocity application;~~ **Provide proof that each Pharmacist license granted to the applicant is not suspended, revoked, canceled or otherwise completely restricted from the practice of pharmacy for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the practice of pharmacy.**

(e) Have either:

(A) Been engaged in the practice of pharmacy for period of at least ~~one year~~ **12 months** including a minimum of 1440 hours of work experience as a licensed ~~p~~**P**harmacist. Evidence supporting this work experience ~~shall~~ **must** be provided at time of application; or

PROPOSED

(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~~ **must** 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~~**2**) An applicant who has obtained their professional degree outside the United States **and jurisdiction** is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-~~019-0150~~**115-0013**.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151**,** ~~&~~ **ORS** 689.265**, ORS 689.405**

855-115-0020
Licensure: Application- Pharmacist

(1) An application for licensure as a Pharmacist may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of:

(a) Official transcript from a board-approved school or college of pharmacy;

(b) Passing result from NABP for the NAPLEX and MPJE;

(c) A completed application including:

(A) Payment of the fee prescribed in OAR 855-110;

(B) A current, passport regulation size photograph (full front, head to shoulders);

(C) Personal identification or proof of identity;

(D) Certificate of completion for the one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority;

(d) A completed national fingerprint-based background check; and

(e) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(3) Penalties may be imposed for:

PROPOSED

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405.

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

(5) The license of a Pharmacist expires June 30 in odd numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.225, ORS 689.285

~~855-019-0122~~ **855-115-0030**
~~Renewal of~~ **Licensure: Renewal or Reinstatement-** ~~as a~~ Pharmacist

(1) An applica**nt**~~tion~~ for renewal of a ~~p~~**P**harmacist license must ~~include documentation of~~:

~~(a) Completion of continuing pharmacy education requirements as outlined in OAR 855-021; and~~

(~~b~~**a**) Pay~~ment of~~ the biennial license fee required in OAR 855-110;~~.~~

(b) Complete the continuing pharmacy education requirements as outlined in OAR 855-135; and

(~~2~~**c**) ~~A pharmacist will b~~**B**e subject to an ~~annual~~ criminal background check**; and**

(d) Provide a completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(2) A Pharmacist who fails to renew their license by the expiration date and whose license has been lapsed for 12 months or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A person who fails to renew their license by the expiration date and whose license has been lapsed for greater than 12 months may apply to reinstate their Pharmacist license as follows:

~~855-019-0170~~
~~Reinstatement of License~~

PROPOSED

~~(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~~ **Apply per OAR 855-115-0020;**

(b) ~~By p~~**P**rovid~~e~~**e**~~ing~~ certification of completion of the continuing pharmacy education requirement in OAR 855-~~021~~**135** for all years in which the license was lapsed ~~and for the current year;~~ and;

(c) Meet the requirements below, if applicable.

(~~d~~**4**) **A person must pass the Oregon MPJE** ~~I~~**i**f their **pharmacist** license has been lapsed for more than ~~one~~ **three** year**s**~~, pass the MPJE.~~ ~~With a score of not less than 75; and~~ **A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;**

(~~d~~**5**) ~~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.~~**If the Pharmacist license has been lapsed for more than five years and the person has not maintained an active pharmacist license in another US state or jurisdiction, a person must comply with (4) and take and pass the NAPLEX. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts.**

(6) In lieu of reinstatement, a person may apply for licensure via reciprocity if the person has maintained an active pharmacist license in good standing in another US state or jurisdiction.

(~~2~~**7**) ~~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 855-021 for all years since their retirement and pass the MPJE with a score of not less than 75.~~ **A person whose Pharmacist license has been retired for more than 12 months need only pay the annual license fees for the year in which they seek a license, however they must also complete the requirements in (3).**

~~855-019-0171~~
~~Reinstatement of a Revoked or Surrendered License~~

(8) A person whose **P**~~p~~pharmacist license has been **suspended,** revoked or **restricted** ~~surrendered~~ ~~shall have~~ **has** the right, at reasonable intervals, to petition to the ~~B~~**b**oard ~~in writing~~ for reinstatement of such license **pursuant to ORS 689.445**. ~~The written petition to the Board shall be made~~ **and** in conjunction with the application process identified in OAR 855-~~019-0120~~**115-0020**.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151**,** ~~&~~ **ORS** 689.275**, ORS 689.445**

855-115-0040

PROPOSED

Licensure: Lapse

(1) A Pharmacist may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person must not practice pharmacy if their license is lapsed.

(d) A person may apply for renewal or reinstatement of their license according to OAR 855-115-0030.

(2) If a Pharmacist requests to lapse their license prior to the expiration date, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board will not accept the lapse if an investigation of or disciplinary action against the licensee is pending.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0043
Licensure: Retire

(1) A Pharmacist may request that the board retire their license if the Pharmacist is in good standing, has been licensed as a Pharmacist for at least 20 years and is no longer practicing pharmacy.

(a) A retired license is not considered discipline;

(b) The board has continuing authority under ORS 689.153;

(c) A person must not practice pharmacy if the license is retired.

(d) A person may apply for renewal or reinstatement according to OAR 855-115-0030.

(2) If a Pharmacist requests to retire their license prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the request to retire the license.

PROPOSED

(b) If the board accepts the request to retire the license, the board will notify the licensee of the date the license is no longer active.

(c) The board will not accept the request to retire the license if an investigation of or disciplinary action against the licensee is pending.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0046
Licensure: Voluntary Surrender

A Pharmacist may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date the licensee is sent the executed final order.

(4) The licensee must cease practicing pharmacy from the date the license terminates.

(5) A voluntarily surrendered license cannot be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-115-0030 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

~~855-031-0045~~ **855-115-0055**
~~School and Preceptor Registration and Responsibilities~~ **Registration: Pharmacist Preceptor**

NOTE: Will be updated for future board review. No changes proposed at this time.
(1) A preceptor license may be issued by the board upon receipt of a completed application.

(2) A ~~p~~**P**harmacist preceptor must have been an actively practicing **P**~~p~~harmacist for at least ~~one year~~ **12 months** immediately prior to supervising an **I**~~i~~ntern.

PROPOSED

(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 **I**~~i~~ntern under the preceptor's supervision, or must do so upon request of the board.

(5) The preceptor ~~must be~~ **is** responsible for supervision of the majority of the **I**~~i~~ntern's SRI hours and must provide the **I**~~i~~ntern with internship experiences, which in the preceptor's judgment will increase the **I**~~i~~ntern's competency in the practice of pharmacy.

(6) Before supervising an **I**~~i~~ntern 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 **I**~~i~~ntern is currently licensed with the board.

(9) A **P**~~p~~harmacist acting as a preceptor in a federal facility is not required to be licensed as a **P**~~p~~harmacist 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 **I**~~i~~ntern'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

~~855-019-0123~~ **855-115-0060**
~~Liability Limitations for Volunteers~~ **Registration: In-State Volunteer Pharmacist**

(1) A **P**~~p~~harmacist may register with the ~~B~~**b**oard 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 ~~B~~**b**oard upon receipt of a completed application. Registration requires submission of a signed form provided by the ~~B~~**b**oard in accordance with ORS 676.345(2).

PROPOSED

(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 ~~B~~**b**oard regulations and still may be subject to disciplinary actions.

(5) Pharmacists providing care under the provisions of ORS 676.340 and **ORS** 676.345 remain subject to the ~~B~~**b**oard complaint investigation process articulated in ORS 676.175.

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

~~855-019-0124~~ **855-115-0063**
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, a Pharmacist practicing under this section is subject to the laws and rules governing the pharmacy profession that the Pharmacist is authorized to practice and to disciplinary action by the appropriate health professional regulatory board.

Statutory/Other Authority: ORS 689.205, ORS 689.315, 2022 HB 4096
Statutes/Other Implemented: ORS 689.151, 2022 HB 4096

PROPOSED

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

NOTE: Moving rule to Division 10: Board Administration and Policies

~~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~~

~~855-019-0160~~ **855-115-0066**
Notification: Nuclear Pharmacists

NOTE: Will be updated for future board review. No changes proposed at this time.

In order to qualify under these rules as a nuclear **P**~~p~~harmacist, a **P**~~p~~harmacist ~~shall~~ **must** :

(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 **P**~~p~~harmacist 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 Pharmac**y**~~eutical~~ 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 **P**~~p~~harmacist 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 ~~B~~**b**oard.

(4) Receive a letter of notification from the ~~B~~**b**oard that the evidence submitted by the **P**~~p~~harmacist meets the above requirements and has been accepted by the ~~B~~**b**oard.

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

PROPOSED

~~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~~

---------- RESPONSIBILITIES (3rd REVIEW)----------
~~855-019-0200~~ **855-115-0070**
Pharmacist: General Responsibilities

PROPOSED

~~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 **and prudent** Pharmacist in the same or similar circumstances.

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

(2) ~~A~~ **Each** Pharmacist and **each** ~~pharmacy~~ **drug outlet** are responsible for the actions of **each** Intern~~s~~, Certified Oregon Pharmacy Technician~~s~~, Pharmacy Technician~~s~~ **and non-licensed pharmacy personnel.**

(3) **With the exception of healthcare providers working within the scope of their licensure,** ~~O~~**o**nly a Pharmacist~~, may~~ **is permitted to:**

(a) ~~p~~**P**ractice 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: to include the provision of patient care services. Activities that only a Pharmacist is permitted to do require reasonable professional judgment of a Pharmacist include but are not limited to:~~

(b) Evaluate and interpret a prescription;

(~~a~~**c**) **Conduct a** Drug Utilization Review **or Drug Regimen Review**;

(d) Consult with any prescriber, other healthcare professional or authorized agent;

(~~b~~**e**) Counsel~~ing~~ **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) Drug Regimen Review;~~

(f) Advise on therapeutic values, content, hazards and use of drugs and devices;

(g) Interpret the clinical data in a patient record system or patient chart.

(~~d~~**h**) **Conduct** Medication Therapy Management;

(~~e~~**i**) **Practice pursuant to a Clinical Pharmacy Agreement** ~~Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement~~;

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

(~~g~~**k**) Prescrib**e**~~ing~~ a drug or device, as authorized by statute**s and rules**;

(l) Administer a drug or device;

PROPOSED

(~~h~~**m**) Order~~ing~~, interpret~~ing~~ and monitor~~ing of~~ a laboratory test **within the scope of pharmacy practice as authorized under ORS 689**;

(~~i~~**n**) **Receive** ~~Oral receipt or~~ **a new ~~refill~~ or** transfer**red** ~~of a~~ prescription **orally**~~; and~~

(~~j~~**o**) Verify the work performed by those under their supervision**; and**

(p) Delegate tasks to other healthcare providers who are appropriately trained and authorized to perform the delegated tasks.

(4) A Pharmacist may permit an Intern under their supervision to perform any task listed in (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.

(5) A Pharmacist must not permit a Certified Oregon Pharmacy Technician or Pharmacy Technician under their supervision, direction and control to perform any task listed in (3).

(4**6**) 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 prescription contains all the elements required in OAR 855-041, or OAR 855-139.

(d) Ensure the patient record contains the elements required in OAR 855-041 or OAR 855-139.

(e) Perform appropriately the duties of a Pharmacist while engaging in the practice of pharmacy as defined in ORS 689.005;

(f) Ensure prescriptions, prescription refills, and drug orders are dispensed:

(A) Accurately;

(B) To the correct party;

(C) Pursuant to a valid prescription;

(D) Pursuant to a valid patient-practitioner relationship; and

(E) For a legitimate medical purpose.

PROPOSED

(g) Ensure each Intern only practices pharmacy under the supervision of a Pharmacist;

(~~b~~**h**) 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;

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

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

(~~e~~**k) Ensure that the supervision of non-Pharmacist personnel does not exceed their capacity to safely supervise** ~~When supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, determine how many licensed individuals the Pharmacist is capable of supervising, directing and controlling~~ based on the **workload and** services being provided.

(l) Ensure there is sufficient staff to provide services in a safe and timely manner. The Pharmacist on duty may temporarily shut down touchpoints and services at the discretion of the Pharmacist, if determined in their reasonable professional judgment, that there is insufficient staff to provide services in a safe and timely manner.

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

(~~f~~**n**) ~~Ensure~~ **Review, adhere to,** and enforce the drug outlet written **policies and** procedures**.** ~~for use of Certified Oregon Pharmacy Technicians and Pharmacy Technicians as required by OAR 855-025-0035~~;
The review must:

(A) Occur upon employment and with each update; and

(B) Be documented and records retained by the outlet; and

(~~g~~**o**) Ensure the security of ~~the~~ **each** 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~~.~~**; and**

(~~5~~**7**) 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;

PROPOSED

(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.

(8) 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

855-115-0072
Responsibilities: Confidentiality

(1) No licensee of the board who obtains any patient information can disclose that information to a third-party without the consent of the patient except as provided in except as provided in (a)-(e) of this rule.

(2) A licensee can disclose patient information:

(a) To the board;

(b) To a practitioner, Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, if disclosure is authorized by a Pharmacist and disclosure is necessary to protect the patient's health or well-being;

(c) To a third-party when disclosure is authorized or required by law;

(d) As permitted pursuant to federal and state patient confidentiality laws or;

(e) To the patient or to persons as authorized by the patient.

(3) A licensee or registrant of the board must not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

PROPOSED

~~855-019-0205~~ **855-115-0074**

Responsibilities: 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~~**1**) **Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each** ~~A p~~**P**harmacist must report to the board **without undue delay, but** within: ~~10 days if they:~~

(a) 1 business day:

(A) Confirmed significant drug loss; or

(B) Any loss related to suspected drug theft of a controlled substance.

(b) 10 days if they:

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

(~~b~~**B**) ~~If they a~~**A**re arrested for a felony~~.~~**; or**

(C) Have reasonable cause to believe that any suspected violation of ORS 475, ORS 689 or OAR 855 has occurred.

(c) 10 working days if they:

(4**A**) ~~A pharmacist who has~~ **Have** reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct ~~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.~~ **to that licensee's board; or**

(B) Suspect records are lost or stolen.

(d) 15 days of any change in:

(A) Legal name;

(B) Name used when practicing pharmacy;

(C) Preferred email address;

PROPOSED

(D) Personal phone number;

(E) Personal physical address;

(F) Personal mailing address; or

(G) Employer.

(~~5~~**2**) A ~~p~~**P**harmacist who reports to a board in good faith as required by **ORS 676.150** ~~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 676.150,** ORS 689.151, ORS 689.155 & ORS 689.455

855-115-0076
Responsibilities: Training

(1) Pharmacists must complete:

(a) Initial training that includes on-the-job and related education that is commensurate with the tasks that the Pharmacist will perform, prior to the performance of those tasks; and

(b) Ongoing training to ensure continued competency in tasks that are performed.

(2) The outlet must retain records of training in (1).

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

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

NOTE: Moving elements of (1)-(2) to OAR 855-115-0200, Repealing (3), moving elements of (4)-(7) to a new rule in OAR 855-041 and (8) to OAR 855-041-2115.

~~(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.~~

PROPOSED

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

~~(a) Using professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall 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 shall include 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 not result solely from a questionnaire or an internet-based 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 shall 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:~~

PROPOSED

~~(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 be confident 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, 689.155 & 689.508~~

~~855-019-0220~~ **855-115-0082**
Drug Utilization Review (DUR)

(1) A Pharmacist must complete a drug utilization review (DUR) by reviewing the patient record prior to dispensing each prescription drug or device for the purpose of identifying the following:

PROPOSED

(a) Over-utilization or under-utilization;

(b) Therapeutic duplication;

(c) Drug-disease contraindications;

(d) Drug-drug interactions;

(e) Incorrect drug dosage or formulation;

(f) Inappropriate duration of treatment;

(g) Drug-allergy interactions; and

(h) Drug abuse or misuse.

(2) Upon recognizing a concern with any of the items in (1)(a)-(h), the Pharmacist must take steps to mitigate or resolve the problem and document the steps taken and outcome.

~~(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.~~

PROPOSED

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

~~855-019-0230~~ **855-115-0084**
Counseling

(1) The ~~p~~**P**harmacist ~~or intern~~ must ~~orally~~ counsel the patient or patient's agent on the use of a drug or device ~~as appropriate~~:

(a) **Upon request;** ~~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) When the drug or device has not been previously dispensed to the patient by the pharmacy;

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

(d) When the prescription has been transferred to the drug outlet by oral, written or electronic means; or

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

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

(~~b~~**a**) Only the Pharmacist ~~or Intern may~~ **can** accept a patient's or patient's agent's request not to be counseled**, when counseling is required**;

(b) ~~If, in their reasonable professional judgment, the pharmacist or intern believes that the patient's safety may be affected, t~~**T**he Pharmacist ~~or Intern~~ may choose not to release the prescription until counseling has been completed;

(~~c~~**3**) The Pharmacist ~~or Intern~~ that provides counseling or accepts the request not to be counseled must document **their identity and** the **provision or declination of counseling at the time of the** interaction;

(~~d~~**4**) A Pharmacist must not allow ~~non-Pharmacist personnel~~ **a prescription** to **be** release**d from the drug outlet when** ~~a prescription that requires~~ counseling **is required**, **prior to the counseling** or accept**ance of** the request not to be counseled **by a Pharmacist**;

~~(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;~~

PROPOSED

(~~f~~**5**) For each **prescription** ~~patient~~, the Pharmacist ~~or Intern~~ must determine the **manner and** amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(~~g~~**6**) 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.

(7) Counseling on a new prescription may include, but is not limited to, the following elements:

(a) Name and description of the drug;

(b) Dosage form, dose, route of administration, and duration of drug therapy;

(c) Intended use of the drug and expected action;

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) Techniques for adherence and self-monitoring drug therapy;

(g) Proper storage and appropriate disposal method(s) of unwanted or unused medication;

(h) Refill information;

(i) Action to be taken in the event of a missed dose; and

(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(~~2~~**8**) Counseling on a refill prescription **may include, but is not limited to, the following elements:** ~~must be such as a reasonable and prudent pharmacist would provide including but not limited to changes in strength or directions.~~

(a) Name and purpose of the medication;

(b) Directions for use, including technique;

(c) Perceived side effects; and

(d) Adherence.

PROPOSED

~~(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.~~

(9) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.

(4**10**) A Pharmacist ~~or Intern shall~~ **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
Statutes/Other Implemented: ORS 689.151 & 689.155

~~855-019-0300~~ **855-115-0086**
~~Duties of a~~ Pharmacist-in-Charge**: Qualifications, Limitations, and Duties**

~~(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~~**1**) In order to be a **Pharmacist-in-Charge (**PIC**)**, a Pharmacist must ~~have~~:

(a) Complete~~d~~ at least ~~one year~~ **2000 hours** of pharmacy practice **as a Pharmacist within the last 2 years in a US state or jurisdiction**; ~~or~~ **and**

(b) Complete~~d~~ a board ~~approved~~**provided** PIC training course either before the appointment or within ~~30~~ **90** days after the appointment **and every 5 years thereafter effective July 1, 2025** ~~With the approval of the board, this course may be employer provided and may qualify for continuing education credit~~.

(c) Be employed by the outlet; and

(d) Be actively engaged in pharmacy activities at the drug outlet and be physically present at the drug outlet for a sufficient amount of time as needed to effectively supervise drug outlet activities, be responsible for the daily operation of the drug outlet and ensure drug outlet compliance.

---------- RESPONSIBILITIES (2nd REVIEW)----------

(~~3~~**2**) A Pharmacist m**ust**~~ay~~ 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.~~ **The following drug outlet types do not count towards this limit**:

(a) Pharmacy Prescription Kiosk in OAR 855-141;

(b) ~~A~~ Pharmacy Prescription Locker in OAR 855-143 ~~does not count toward this limit~~.

PROPOSED

(4**3)** The PIC must perform **all of** the following ~~the duties and responsibilities~~:

(a) **Notify the board of becoming the PIC** ~~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;

POLICY DISCUSSION: PIC vs Outlet

(b) Be responsible for the daily conduct, operation, management and control of the drug outlet;

(c) Establish, maintain, and enforce written policies and procedures governing the practice of pharmacy in coordination with the outlet;

(d) Ensure maintenance of accurate records governing the practice of pharmacy in coordination with the outlet;

(e) Ensure compliance with all federal and state laws and rules governing the practice of pharmacy;

(f) Assess and approve personnel who may access the areas where drugs and records are stored;

(g) Ensure personnel with access to ~~the areas where~~ drugs and records ~~are stored~~ are trained and that training records are retained;

POLICY DISCUSSION: Security of pharmacy, prescription areas, open vs closed

(h) Ensure personnel that require licensure have been granted and maintain licensure with the board;

(i) Ensure licensed personnel work within the duties permitted by their licensure;

(j) Ensure non-licensed personnel only perform work that does not require licensure;

(k) Ensure the pharmacy is operated in a professional manner at all times;

(l) Ensure adequate staffing to provide safe and timely patient care based on workload volume and services provided in coordination with the drug outlet;

(m) Ensure the drug outlet contains the reference material and equipment needed;

(n) Enforce a continuous quality improvement program for dispensing services;

(o) Submit a plan of correction for observations noted on an inspection within the time allowed by the board;

(~~b~~**p**) ~~The new PIC must c~~**C**omplete an inspection on the PIC Annual Self-Inspection Form **by July 1 each year and** within 15 days of becoming PIC. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion; ~~Such training should include an annual review of the PIC Self-Inspection Report;~~

PROPOSED

(q) Complete and document a controlled substance inventory with discrepancy reconciliation as follows:

(A) Within 15 days of a change in PIC, an inventory of all controlled drugs as required by OAR 855-080;

(B) Annually (within 367 days) for all controlled drugs as required by OAR 855-080;

(C) Monthly (within 31 days) for Schedule II controlled drugs.

POLICY DISCUSSION: Frequency schedule II

(r) Ensure the drug outlet reports data as required by the Oregon Health Authority for PDMP, ALERT, Death with Dignity and communicable diseases.

(s) Ensure the drug outlet delivers prescriptions accurately;

(t) Notify the board of ceasing to be the PIC within 15 days of the occurrence, on a form provided by the board.

~~(c) The PIC may 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 30 days of receiving notice.~~

~~(A) 15 days of receiving a deficiency notice; or~~

~~(B) 30 days of receiving a non-compliance notice.~~

~~(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;~~

PROPOSED

~~(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 inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained 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 Report;~~

~~(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

----------SERVICES (1st LOOK)----------

855-115-0100
Services: Independent Practice of Pharmacy

(1) A Pharmacist engaged in the independent practice of pharmacy must:

(a) Be responsible for the daily conduct, operation, management and control of their practice;

(b) Ensure compliance with all federal and state laws and rules governing the practice of pharmacy;

(c) Document services provided and maintain a record of such services including the date, time and identification of the licensee and the specific activity or function.

(d) Ensure the Pharmacist and personnel have access to reference material and equipment needed based on the services provided;

(e) Ensure services are provided with required interpretation and translation per ORS 689.564

PROPOSED

(f) Ensure services occur in a sanitary, secure and confidential environment;

(g) Ensure all computer equipment used for the independent practice of pharmacy:

(A) Establishes and maintains a secure connection to patient information including but not limited to patient demographics, medical records, pharmacy records and clinical visit documentation;

(B) Prevents unauthorized access to patient information; and

(C) Is configured so information from any patient records are not duplicated, downloaded, or removed from the electronic database when an electronic database is accessed remotely;

(h) Ensure patient records are stored at a health care organization, practitioner, pharmacy, or Pharmacist office and must be maintained in a secure manner that ensures only those authorized have access to such records; and

(i) Register as a drug outlet if involved in the dispensing, distribution or delivery of drugs.

(2) A Pharmacist who personally possesses or stores drugs or devices when acting in the usual course of business and within their scope of practice, must comply with (1) and the following:

(a) Be responsible for drugs and devices in their possession;

(b) Only receive drugs from an Oregon Registered Drug Outlet (e.g. Wholesaler, Manufacturer or Pharmacy);

(c) Restrict access to such drugs and devices;

(d) Ensure security including provisions for adequate safeguards against loss, theft or diversion of such drugs and devices;

(e) Comply with the drug storage rules for pharmacies in OAR 855-041-1036.

(f) Ensure drugs and devices that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or identified as suspect or illegitimate, or otherwise unfit for dispensing must be documented, quarantined and physically separated from other drugs and devices until they are destroyed or returned to the supplier.

(g) Maintain records pertaining to the acquisition, storage, administration, and disposal of such drugs and devices.

(3) A Pharmacist who utilizes an Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician, must comply with (1) and the following:

(a) Only utilize Interns when under the Pharmacist's supervision;

PROPOSED

(b) Only utilize Certified Oregon Pharmacy Technicians and Pharmacy Technicians when under the Pharmacist's supervision, direction and control; and

(c) Ensure licensed personnel work within the duties permitted by their licensure;

(4) A Pharmacist who utilizes licensees remotely, must comply with (1), (3) and the following:

(a) Utilize a fully operational audiovisual communication system and have appropriate technology or interface to allow access to information required to complete assigned duties;

(b) Ensure telephone audio is recorded and stored for all patient interactions completed by Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians;

(c) Supervise each Intern and supervise, direct and control each Certified Oregon Pharmacy Technician, and Pharmacy Technician via an audiovisual communication system;

(d) Use reasonable professional judgment to determine the frequency of "check-ins" for each non-Pharmacist personnel being supervised via the audiovisual communication system with a minimum of at least once per work shift to ensure patient safety, compliance with federal and state laws, and documents the interaction;

(e) Be readily available to answer questions and fully responsible for the conduct and accuracy of the licensees; and

(f) Ensure each Intern knows the identity of the Pharmacist who is providing supervision at all times.

(g) Ensure each Certified Oregon Pharmacy Technician and Pharmacy Technician knows the identity of the Pharmacist who is providing supervision, direction, and control at all times.

(h) Use reasonable professional judgment to determine the percentage of patient interactions for each licensee that must be observed or reviewed to ensure public health and safety with a minimum of 5% of patient interactions observed or reviewed;

(i) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a Pharmacist upon request;

(j) Document the following within 24 hours of the observation or review in (i):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions Pharmacist has observed or reviewed;

(C) Date and time of licensee patient interaction Pharmacist has observed or reviewed;

(D) Date and time of Pharmacist observation or review of licensee's patient interaction; and

PROPOSED

(E) Pharmacist notes of each interaction observed or reviewed; and

(k) Reports any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of discovery and to the board within 10 days.

(5) All documentation and records required by this rule must be retained and made available to the board per 855-102-0050.

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

~~855-019-0240~~ **855-115-0105**
~~Consulting~~ Pharmacist **Consulting** 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~~**1**) A ~~consulting~~ **P**~~p~~harmacist **who provides services to** ~~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.

(2) A Pharmacist who provides services to a correctional facility, long term care facility, community-based care facility, hospital drug room, or charitable pharmacy that does not have additional Pharmacist service requirements under the terms of its licensure with any other state agency, must provide services that include but are not limited to the following:

(a) Provide the facility with policies and procedure relating to security, storage and distribution of drugs within the facility;

(b) Provide guidance on the proper documentation of drug administration or dispensing;

(c) Provide educational materials or programs as requested.

(3) A Pharmacist who provides services to an Oregon licensed healthcare provider must follow all state and federal laws and rules related to the practice of pharmacy.

(~~3~~**4**) A ~~consulting~~ **P**~~p~~harmacist must maintain appropriate records of their ~~consulting activities~~ services **in (2) - (4)** 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~~**5**) A ~~consulting~~ **P**~~p~~harmacist may store health protected records outside an Oregon licensed facility ~~if~~ **as permitted in OAR 855-115-0100** ~~registered as an Oregon Consulting or Drugless Pharmacy outlet as defined by OAR Chapter 855, division 41.~~

PROPOSED

~~(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.~~

(6) Records and documents must be retained according to OAR 855-102-0050.

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

~~855-019-0265~~ **855-115-0110**
Administration of **Vaccines,** Drugs**, or Devices**

(1) In accordance with **ORS 689.645 and** ORS 689.655, a **P**~~p~~harmacist may administer a **vaccine,** drug or device as specified in this rule.

(2) A **P**~~p~~harmacist who administers a **vaccine,** drug or device must:

(a) Document that they have received practical training on the vaccine, drug or device, injection site and administration technique that is to be utilized:

(A) For vaccines, the training must be at least 20 hours and approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. Records of such training must be retained according to OAR 855-102-0050.

POLICY DISCUSSION: Course criteria

(B) For non-vaccine drugs or devices, the training may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board.

(C) For orally administered drugs, training is not required;

(b) Hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years. The most current CPR certification record must be retained according to OAR 855-102-0050.

PROPOSED

(c) Ensure that any drugs administered to a patient were stored in accordance with the drug storage rules for pharmacies in ORS 855-041-1036. For vaccines, the Pharmacist must also follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022).

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

(e) Ensure that vaccine, drug or device administration is documented in the patient's permanent record.

(~~b~~**f**) Ensure **records and documents are retained according to OAR 855-102-0050.** ~~a record is kept for three years of such activities~~. ~~This r~~**R**ecords **of administration** ~~shall~~ **must** include but ~~is~~ **are** not limited to:

(A) Patient identifier;

(B) **Vaccine,** ~~D~~**d**rug or device and strength;

(C) Route and site of administration;

(D) Date and time of administration;

(E) Pharmacist identifier.

(3) For vaccines only, the requirements in (2) and the following apply, the Pharmacist must:

(a) Have access to a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);

(b) Give the appropriate Vaccine Information Statement (VIS) to the patient or patient's agent with each dose of vaccine covered by these forms. The Pharmacist must ensure that the patient or patient's agent is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine.

(c) Report all vaccinations administered to the ALERT IIS in accordance with OAR 333-049-0050, or for COVID-19 immunizations, in accordance with OAR 333-047-1000.

(d) Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.

(~~3~~**4**) The **P**~~p~~harmacist 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~~;~~

PROPOSED

(b) In accordance with a ~~written~~ **statewide drug therapy management** protocol **per OAR 855-020-0300 or** ~~collaborative~~ **clinical pharmacy agreement** ~~drug therapy agreement with a licensed practitioner~~ **per OAR 855-115-0120; or**

(c) In accordance with a written administration protocol issued by the Oregon Health Authority and approved by the board.

~~(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 **P**~~p~~harmacist may administer a drug or device in conjunction with training the patient or the patient's ~~caregiver~~ **agent** how to administer or self-administer the drug or device. **Injectable vaccines must not be dispensed to the patient or the patient's agent for self-administration.**

POLICY DISCUSSION: Injectable vaccines

(6) Except as required in (2), records and documents must be retained according to OAR 855-102-0050.

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

~~855-019-0270~~
~~Immunization Qualifications~~

~~(1) In this rule and in OAR 855-019-0280, an intern who is appropriately trained and qualified in accordance with Section (3) of this rule may perform the same duties as a pharmacist, provided that the intern is supervised by an appropriately trained and qualified pharmacist.~~

~~(2) A pharmacist may administer vaccines to persons who are at least 7 years of age as provided by these rules. For the purposes of this rule, a person is at least 7 years of age on the day of the person's seventh birthday.~~

~~(3) A pharmacist may administer vaccines under section (1) or section (2) of this rule only if:~~

~~(a) The pharmacist has completed a course of training approved by the Board and maintained competency;~~

~~(b) The pharmacist training includes, injection site, and Cardiopulmonary Resuscitation (CPR) specific to the age and population the pharmacist treats;~~

~~(c) The pharmacist holds active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that contains a hands-on training component and is valid for not more than three years, and documentation of the certification is placed on file in the pharmacy;~~

PROPOSED

~~(d) The vaccines are administered in accordance with an administration protocol written and approved by the Oregon Health Authority (OHA); and~~

~~(e) The pharmacist has a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."~~

~~(4) A pharmacist otherwise in compliance with section three of this rule may, during a declared emergency, administer a vaccine to a person who is at least three (3) years of age when;~~

~~(a) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or~~

~~(b) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.~~

~~(5) A pharmacist may not delegate the administration of vaccines to another person.~~

~~Statutory/Other Authority: ORS 689.205 433.441, 433.443 & 2015 OL Ch 295~~
~~Statutes/Other Implemented: ORS 689.151, 689.155, 689.645 & 2015 OL Ch 295~~

~~855-019-0280~~
~~Immunization Protocols, Policies and Procedures~~

~~(1) Prior to administering a vaccine to a person who is at least 7 years of age a pharmacist must follow protocols written and approved by the Oregon Health Authority (OHA) for administration of vaccines and the treatment of severe adverse events following administration of a vaccine.~~

~~(2) A pharmacist during a declared emergency may administer a vaccine to a person who is at least three~~

~~(3) years of age when;~~

~~(a) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or~~

~~(b) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.~~

~~(3) The pharmacy must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.~~

~~(4) The pharmacist must give the appropriate Vaccine Information Statement (VIS) to the patient or legal representative with each dose of vaccine covered by these forms. The pharmacist must ensure that the patient or legal representative is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine.~~

~~(5) The pharmacist must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.~~

PROPOSED

~~(6) The pharmacist may prescribe, administer or dispense immunizations, including oral vaccines, as established by written protocols approved by OHA.~~

~~Statutory/Other Authority: ORS 689.205, 433.441, 433.443 & 2015 OL Ch 295~~
~~Statutes/Other Implemented: ORS 689.151, 689.155, 689.645 & 2015 OL Ch 295~~

~~855-019-0290~~
~~Immunization Record Keeping and Reporting~~

~~(1) A pharmacist who administers a vaccine to a patient must fully document the administration in the patient's permanent record.~~

~~(2) A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider.~~

~~(a) The name, address, gender and date of birth of the patient;~~

~~(b) The date of administration of the vaccine;~~

~~(c) The NDC number of the vaccine, or other acceptable standardized vaccine code set;~~

~~(d) The address of the pharmacy where vaccine was administered unless automatically embedded in the electronic report provided to the OHA ALERT Immunization System;~~

~~(e) The phone number of the patient when available;~~

~~(f) The dose amount, manufacturer, site of administration, lot number and expiration date of the vaccine when available;~~

~~(3) A pharmacist who administers any vaccine will keep documentation of current CPR training. This documentation will be kept on site and available for inspection.~~

~~(4) A pharmacist who administers any vaccine will follow storage and handling guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC).~~

~~(5) For the purpose of participation in the Oregon Vaccines for Children program,~~

~~(a) The vaccine eligibility code for each dose must be reported to the ALERT Immunization Information System in the manner prescribed by OHA, and~~

~~(b) The pharmacist is recognized as a prescriber.~~

~~(6) If providing state or federal vaccines during a pandemic as determined by the CDC, the event and priority code as specified by OHA must be provided upon request in the manner prescribed by OHA.~~

PROPOSED

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, 689.155 & 689.645~~

855-115-0115
Services: Laboratory

NOTE: A corresponding rule will be added in Division 041 concerning when a drug outlet may perform a laboratory test.

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

(a) Managing drug therapy pursuant to the terms of a clinical pharmacy agreement with a provider under OAR 855-115-0120;

(b) Providing patient care services pursuant to the terms of the post diagnostic formulary listed in OAR 855-115-1140 that is developed under ORS 689.645 and adopted by the board under ORS 689.649;

(c) Providing patient care services pursuant to and as allowed by the terms of a protocol listed in OAR 855-115-1145 that is developed under ORS 689.645 and adopted by the board under ORS 689.649;

(d) Permitted under a Health Screen Testing Permit pursuant to ORS 438.010(8); ORS 438.060; ORS 438.130(2); ORS 438.150(5), (6) and (7); OAR 333-024-0370, OAR 333-024-0375, OAR 333-024-0380, OAR 333-024-0385, OAR 333-024-0390, OAR 333-024-0395 and OAR 333-024-0400; or

(e) Monitoring a therapeutic response or adverse effect to drug therapy under ORS 689.005.

(2) A pharmacy may perform a laboratory test as permitted under ORS 689.661.

(3) Records and documents must be retained according to OAR 855-102-0050.

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

~~855-019-0260~~ **855-115-0120**
Services: ~~Collaborative Drug Therapy Management~~ **Clinical Pharmacy Agreement**

~~(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~~

PROPOSED

~~(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.~~

(**1**~~2~~) A **P**~~p~~harmacist **or pharmacy** ~~shall~~ **may** engage in ~~collaborative drug therapy management~~ **a Clinical Pharmacy Agreement** with a ~~practitioner~~ **health care organization, physician or naturopathic physician** only under a written ~~arrangement~~ **agreement** that includes:

(a) The identification, either by name or by description, of each ~~of the~~ participating **P**~~p~~harmacists~~;~~

(b) The identification, **either** by name or description, of each ~~practitioner~~ **participating physician, naturopathic physician, or providers of a healthcare organization** ~~of the participating practitioners or group of practitioners~~;

(c) The name of the principal **P**~~p~~harmacist and ~~practitioner~~ **physician, naturopathic physician or provider on behalf of the healthcare organization** who are responsible for development, training, administration, and quality assurance of the ~~arrangement~~ **agreement**;

POLICY DISCUSSION: Provider in a healthcare organization

(d) The types of decisions that the **P**~~p~~harmacist is allowed to make, which ~~may~~ **must include a detailed description of the:**

(A) Methods by which a physician or naturopathic physician or a provider on behalf of a healthcare organization enters a patient into the agreement;

(B) ~~A detailed description of the types of~~ ~~d~~**D**iagnoses, drugs, or drug categories involved, and the activities allowed ~~in each case~~; **The drug information must include the dosage, frequency, duration and route of administration of the drug.**

(C) ~~A detailed description of the m~~**M**ethods, procedures, decision criteria, and plan the ~~p~~**P**harmacist is to follow when conducting allowed activities;

(D) ~~A detailed description of the~~ **Documentation the Pharmacist is to complete** ~~activities the pharmacist is to follow including documentation of~~ **concerning** 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~~ **must** occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;

(E) Circumstances which will cause the **P**~~p~~harmacist 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 **P**~~p~~harmacist participation and ongoing assessment of competency, if necessary;

PROPOSED

(f) Quality ~~assurance~~ **improvement** and periodic review by a panel of the participating **P**~~p~~harmacists and practitioners;

(g) Authorization by the practitioner for the **P**~~p~~harmacist to participate in collaborative drug therapy; and

(h) A requirement for the ~~collaborative drug therapy arrangement~~ **Clinical Pharmacy Agreement** to be reviewed and updated, or discontinued at least every two years;

(3) **The Pharmacist must document and keep a record of each patient encounter where the clinical pharmacy agreement is utilized.** ~~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) **Records and documents must be retained according to OAR 855-102-0050.**~~Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.~~

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

~~855-019-0250~~ **855-115-0125**
Services: Medication Therapy Management

(1) Medication Therapy Management (MTM) is a distinct service or group of services that is intended to optimize the therapeutic outcomes of a patient. Medication Therapy Management can be an independent service provide by a **P**~~p~~harmacist 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 **P**~~p~~harmacist; and

(e) Improving outcomes.

(2) A **P**~~p~~harmacist that provides MTM services ~~shall~~ **must** ensure that they are provided according to the individual needs of the patient and ~~may~~ **must** 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;

PROPOSED

(c) Monitoring the safety and effectiveness of the medication therapy;

(d) Selecting, initiating, modifying or administering medication therapy in consultation with the practitioner where appropriate;

(e) Performing a medication review to identify, prevent or resolve medication related problems;

(f) Monitoring the patient for adverse drug events;

(g) Providing education and training to the patient or the patient's agent on the use or administration of the medication **where appropriate**;

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

(A) **Be accurate;** ~~Provide accountability and an audit trail; and~~

(B) Identify the person who completed each action;

(~~B~~**C**) **Records and documents must be retained according to OAR 855-102-0050.** ~~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; **and**

(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**,** ~~&~~ **ORS** 689.155

~~855-020-0105~~
~~Public Health and Pharmacy Formulary Advisory Committee~~

~~(1) The Public Health and Pharmacy Formulary Advisory Committee shall 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~~

PROPOSED

~~(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 shall recommend to the Board, for adoption by rule, a protocol or formulary of drugs and devices from which a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a qualified healthcare practitioner.~~

~~(4) The committee shall 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~~

~~855-020-0110~~ **855-115-0130**
Services: Prescribing Practices**- Formulary or Protocol Compendia**

(1) A **P**~~p~~harmacist 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.

(2) A **P**~~p~~harmacist **must**~~ay~~ 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 **P**~~p~~harmacist 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.

PROPOSED

(4) For each drug or device the **P**~~p~~harmacist prescribes **via the Formulary or Protocol Compendia**, the **P**~~p~~harmacist must:

(a) Ensure training and education requirements have been met prior to engaging in prescribing activities. A copy of all required training and education must retained according to OAR 855-102-0050;

(~~a~~**b**) ~~Assess patient and c~~**C**ollect subjective and objective information~~, including the diagnosis for Formulary Compendia items,~~ about the patient's health history and clinical status. **If prescribing pursuant to the Formulary Compendia in OAR 855-115-0140, a diagnosis from the patient's healthcare provider is required.** ~~The pharmacist's physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means; and~~

(c) Assess the information collected in (b). Any physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means.

(~~b~~**d**) **Create an individualized patient-centered care plan that** ~~U~~**u**tilize**s** information obtained in the assessment to evaluate and develop ~~an individualized patient-centered~~ **a** care plan~~, pursuant to the protocol listed in the statewide drug therapy management protocol and policies and procedures~~; and

(~~c~~**e**) Implement the care plan, to include ~~appropriate treatment goals, monitoring parameters, and follow-up; and~~**:**

(A) Addressing medication and health-related problems and engaging in preventive care strategies;

(B) Initiating, modifying, discontinuing, or administering medication therapy as permitted by the Formulary or Protocol Compendia;

(C) Providing education and self-management training to the patient or caregiver;

(D) Contributing to coordination of care, including the referral or transition of the patient to another health care professional; and

(E) Scheduling follow-up care as needed to achieve goals of therapy;

(~~d~~**f**) Monitor and evaluate the effectiveness of the care plan and make modifications to the plan ~~pursuant to a protocol listed in a statewide drug therapy management protocol.~~**;**

~~(f) Refer the patient to another health care provider as required by the protocol.~~

(g) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a **Formulary or Protocol** Compendia drug or device.

~~(5) The pharmacist must maintain all records associated with prescribing and other related activities performed for a minimum of 10 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~~

PROPOSED

~~location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.~~

(~~6~~**5**) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.

(6) All records and documents must be retained according to OAR 855-102-0050 and must be made available to the patient and provider upon request.

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

~~855-020-0120~~ **855-115-0135**
Prescribing**:** **Prohibited** Practices

(1) A **P**~~p~~harmacist may not prescribe a **vaccine,** drug or device**:**

(a) ~~t~~**T**o 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 **P**~~p~~harmacist's personal or emotional involvement may render the **P**~~p~~harmacist unable to exercise detached professional judgment in prescribing ~~pursuant to the Formulary and Protocol Compendia.~~**; and**

(b) When the Formulary or Protocol Compendia requires referral to non-Pharmacist provider.

(2) An **I**~~i~~ntern m**ust**~~ay~~ not prescribe a **vaccine,** 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

~~855-020-0200~~ **855-115-0140**
Formulary Compendium

A **P**~~p~~harmacist may prescribe, according to **OAR 855-115-1130 and OAR 855-115-0135**, a~~n~~ 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;

PROPOSED

(3) Nebulizers and associated supplies;

(4) Inhalation spacers;

(5) Peak flow meters;

(6) International Normalized Ratio (INR) testing supplies;

(7) Enteral nutrition supplies;

(8) Ostomy products and supplies; and

(9) Non-invasive blood pressure monitors

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

~~855-020-0300~~ **855-115-0145**
Protocol Compendium

A Pharmacist may prescribe, **according to 855-115-1130 and OAR 855-115-0135**, ~~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, **pursuant to a statewide drug therapy management protocol.** ~~listed in the following compendium~~:

(1) Continuation of therapy (v. 06/2021)

(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) Protocol (v. 06/2021);

(c) COVID-19 Monoclonal Antibody (mAb) Protocol (v. 12/2021); ~~and~~

(d) COVID-19 Antigen Self-Test Protocol (v. 12/2021)~~.~~**;**

(e) COVID-19 Antiviral Protocol (v. 12/2022); and

PROPOSED

(f) Shingles (v. 12/2022).

(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 Protocol (v. 06/2022);

(d) Travel Medications Protocol (v. ~~6~~**12**/202~~1~~**2**);

(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 12/202~~1~~**2**);~~ and~~

(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. ~~06~~**12**/2022)~~.~~**; and**

(g) Contraception (v. 12/2022).

[Publications referenced are available for inspection in the office of the Board of Pharmacy per OAR 855-010-0021.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645 ~~&~~ ORS 689.649**, ORS 689.689**

~~855-019-0400~~
~~Contraceptives - Purpose~~

~~The purpose of rules OAR 855-019-0400 through 855-019-0435, is to develop standard procedures for the prescribing of injectable hormonal contraceptives and self-administered hormonal contraceptives by an Oregon licensed pharmacist, providing timely access to care. To ensure public safety and provide a consistent level of care, a pharmacist may participate upon completion of a Board approved training program. Under the rules of this section, a qualified pharmacist may prescribe hormonal contraceptives to a patient pursuant to a self-screening risk assessment questionnaire and standard procedural algorithm.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0405~~
~~Contraceptives - Definitions~~

~~In OAR 855-019-0400 through 855-019-0435:~~

~~(1) "Clinical visit" means a consultation with a healthcare provider, other than a pharmacist, for women's health, which should address contraception and age-appropriate screening.~~

PROPOSED

~~(2) "Injectable hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that a health care practitioner administers to the patient by injection.~~

~~(3) "Self-administered hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may administer to oneself.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.005 & 689.683

~~855-019-0410~~
~~Prescriptive Practice Consultation~~

~~In an effort to clarify, improve, and support appropriate pharmacist prescribing, the Board shall periodically review prescribing standards, practices, and scope in consultation with designated representatives from the Oregon Medical Board, Oregon State Board of Nursing, and Oregon Health Authority. The Board will seek recommendations from these representatives to be considered in conjunction with American Congress of Obstetricians and Gynecologists (ACOG) guidelines and other evidence-based standards, as it seeks to evaluate and improve prescribing practices within pharmacy. To the extent that developed standards are incorporated into practice, the forms, screening tools, or requisite training materials shall be prepared by the Board in consultation with these designated representatives.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0415~~
~~Contraceptive - Training Program~~

~~(1) Only a pharmacist, who has completed a Board approved Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may prescribe injectable hormonal contraceptives and self-administered hormonal contraceptives for a patient.~~

~~(2) A pharmacist must submit a copy of the certificate of completion of training to the Board within 15 days of completion.~~

~~(3) A pharmacist must maintain the certificate of completion and make available upon request.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0425~~
~~Contraceptive - Procedural Mandates~~

PROPOSED

~~(1) For each new patient requesting contraceptive services and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:~~

~~(a) Obtain a completed Oregon Self-Screening Risk Assessment Questionnaire; and~~

~~(b) Utilize and follow the Oregon Standard Procedures Algorithm to perform the patient assessment; and~~

~~(c) Prescribe, if clinically appropriate, the self-administered or injectable hormonal contraceptive, or refer to a healthcare practitioner; and~~

~~(d) Provide the patient with a Visit Summary; and~~

~~(e) Advise the patient to consult with a primary care practitioner or women's health care practitioner; and~~

~~(f) Document the encounter and maintain records pursuant to OAR 855-019-0435.~~

~~(2) If the self-administered hormonal contraceptive is dispensed or the injectable hormonal contraceptive is administered, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.~~

~~(3) Nothing in this rule shall prohibit the partial filling or transferring of a drug prescribed pursuant to this process, per the request of the patient.~~

~~(4) A pharmacy must:~~
~~(a) Keep records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years; and~~

~~(b) Keep records of the medication dispensed for a minimum of three years; and~~

~~(c) Establish, maintain and enforce written procedures for the provision of care under this section, including, but not limited to:~~

~~(A) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and~~

~~(B) Documentation and recordkeeping.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0430~~
~~Contraceptive - Prohibited Practices~~

~~A pharmacist must not:~~

PROPOSED

~~(1) Require a patient to schedule an appointment with the pharmacist for the prescribing, administering or dispensing of a hormonal contraceptive;~~

~~(2) Continue to prescribe a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit;~~

~~(3) Prescribe in instances that the Oregon Standard Procedures Algorithm requires referral to a provider; and~~

~~(4) Prescribe to self or immediate family members.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0435~~
~~Contraceptive - Records~~

~~(1) A pharmacist must document the encounter and the prescription, and maintain records.~~

~~(2) A pharmacy must maintain records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years and maintain records of the medication administered or dispensed for a minimum of three years.~~

~~(3) Prescriptions are valid for one year pursuant to OAR 855-041-1125.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005 & 689.683~~

~~855-019-0460~~ **855-115-0180**
Naloxone - Delivery of Care and Prescribing

NOTE: Plan to move to formulary or protocol compendia

(1) A **P**~~p~~harmacist, having determined that there is an identified medical need, can prescribe naloxone and the necessary medical supplies to administer naloxone for opiate overdose:

(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME);

(b) To an individual seeking naloxone;

(c) To an entity seeking naloxone.

(2) The **P**~~p~~harmacist ~~shall~~ **must** determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.

PROPOSED

(3) The **P**~~p~~harmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.

(4) The **P**~~p~~harmacist ~~shall~~ **must** dispense the naloxone product in a properly labeled container.

(5) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.

(6) The **P**~~p~~harmacist must document the encounter and the prescription, and maintain records for three years.

(7) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.684, ORS 689.305, ORS 689.681, ORS 689.682 ~~& 2019 OL Ch. 470~~

~~855-019-0470~~ **855-115-0185**
Emergency Insulin
NOTE: Plan to move to formulary or protocol compendia

Emergency Insulin. A **P**~~p~~harmacist ~~who has completed a Board approved ACPE accredited training program~~ may prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies, not including insulin pump devices, to a person who has evidence of a previous prescription from a licensed health care provider; in such cases, a **P**~~p~~harmacist ~~shall~~ **must** prescribe the lesser of a 30-day supply or the smallest available package size, and not more than three emergency refills and supplies in a calendar year.

Statutory/Other Authority: ORS 689.205, **ORS 689.696**
Statutes/Other Implemented: **ORS 689.696, ORS 689.645** ~~2019 OL Ch. 95~~

Division 41
OPERATION OF PHARMACIES

855-041-3000
Central Fill and Remote Processing Outlet Designations ~~and Consulting/Drugless Pharmacy Outlets~~ - Purpose and Scope

(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.

PROPOSED

(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.

~~(4) 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 consulting or drugless pharmacy. Prior to initiating this model, a description of how the model will be utilized to improve patient safety 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~~

PROPOSED

~~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~~

PROPOSED

~~(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~~

PROPOSED

~~(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;~~

PROPOSED

~~(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~~

PROPOSED

Division 001/102: Procedural and Universal Rules

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Procedural and Universal Rules; Adopts new Division 102, repeals Division 001

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 102 and adopts existing procedural rules related to rulemaking, model rules of procedure, time for requesting a contested case hearing, filing exceptions to the board, petition for reconsideration or rehearing as condition for judicial review, duty to cooperate, inspections and records and document retention requirements. Repeals Division 001.

Documents Relied Upon per ORS 183.335(2)(b)(D): None available.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Proposed rules provide clarity for licensees, and registrants. It is anticipated that the proposed rules will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): Reporting, Recordkeeping and Administrative Activities Cost: Professional Services, Equipment/ Supplies, Labor Cost, Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of the proposed rule amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommends adopting the proposed rules for transparency and clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Creates new Division 102 for procedural and universal rules. Proposed rules relocate existing procedural rules from Division 001 and adds rules related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public. Repeals Division 001.

Repeals Division 001. Relocates existing rules from Division 001 to newly created Division 102 Procedural and Universal Rules. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

NOTES:

- Highlights
  - Rule language highlighted in blue denote staff proposed amendments made between the board's review of this package at the October 2022 board meeting and the December 2022 board meeting.

Division 102
PROCEDURAL AND UNIVERSAL RULES

~~855-001-0000~~ **855-102-0005**
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 ORS 183.341(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 ORS 183.335(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~~ **855-102-0010**
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

PROPOSED

~~855-001-0012~~ **855-102-0015**
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~~ **855-102-0020**
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~~ **855-102-0025**
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

~~855-001-0030~~ **855-102-0035**
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

PROPOSED

~~855-001-0040~~ **855-102-0040**

Inspections

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

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

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

(b) Inspecting all drugs and devices;

(c) Taking photographs, recording video and audio; and

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

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

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

Statutory/Other Authority: ORS 475.125 & ORS 689.205

Statutes/Other Implemented: ORS 689.155

855-102-0050

Record and Document Retention

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

(a) Must be retained for 3 years except that:

(A) Clinical pharmacy records must be retained for 7 years;

(B) Training records for patient care services, when required, must be retained for 3 years after ceasing participation in the activity requiring training;

(b) Must be stored ~~on site~~ at the Drug Outlet for 12 months and must be provided to the board immediately upon request at the time of inspection;

(c) 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;

(d) May be in written or electronic format; and

(e) Made available to the board upon request.

PROPOSED

~~(2) Records must be stored at the Drug Outlet for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days.~~

(2) Records generated under Independent Pharmacy Practice, must be stored at a health care organization, practitioner, pharmacy, or pharmacist office or in a secure location by the Pharmacist according to OAR 855-115-0100 for at least 12 months and may be stored, after 12 months, in a secured off-site location if retrievable within three business days.

~~(4) Records must be written, electronic or a combination of the two.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

PROPOSED

Division 025/125: Pharmacy Technicians (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 125 for Pharmacy Technicians

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 125 for Certified Oregon Pharmacy Technicians (COPT) and Pharmacy Technicians (PT). Proposes relocating and reorganizing existing COPT and PT rules from Division 025. If the board adopts Division 125, existing rules related to COPT and PT would be repealed in Division 025.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed revisions to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed rule adoption includes relocating and reorganizing existing COPT and PT rules from Division 025 to newly created Division 125 in alignment with the board's strategy to systematically organize all Divisions. Proposed amendments include revising titles, clarifying requirements for COPT and PT applicability, licensure qualifications, licensure application, licensure renewal and reinstatement, licensure lapse and voluntary surrender of license. Amendments also clarify general responsibilities, confidentiality, duty to report, training responsibilities and permitted and prohibited practices.

Repeals Division 025. Existing COPT and PT rules from Division 025 are being reorganized and relocated to new Division 125 Certified Oregon Pharmacy Technicians and Pharmacy Technicians.

NOTES:

- History of rule package review
  - The board completed a 1st review of this package in June 2022.
  - The board completed a 2nd review of this package in August 2022

- The December 2022 meeting is the 3rd review of this package.
- Highlights
  - Rule language highlighted in blue denote staff proposed amendments made between the board's review of this package at the August 2022 board meeting and the December 2022 board meeting.

----------3rd REVIEW----------

Division **1**25
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

~~855-025-0001~~**855-125-0001**
~~**Purpose and Scope**~~ **Applicability**

~~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.~~

(1) This Division applies to any individual who assists a Pharmacist in the practice of pharmacy.

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

(3) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification when delegated to do so by a Pharmacist and done in compliance with all applicable statutes and rules and under the supervision, direction, and control of that Pharmacist.

(4) Only a person licensed as a Certified Oregon Pharmacy Technician may use the titles "Certified Oregon Pharmacy Technician" and "COPT".

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-125-0005
Definitions

Note: Placeholder- No definitions specific to Division 125 at this time.

PROPOSED

~~855-025-0005~~**855-125-0010**

Licensure: Qualifications - ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) To qualify for licensure as a ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **or Pharmacy Technician,** an applicant must demonstrate that the applicant is at least 18 years of age and has completed high school (or equivalent).

(2) To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must also demonstrate that the applicant has taken and passed a national pharmacy technician certification examination offered by:

(a) Pharmacy Technician Certification Board (PTCB); or

(b) National Healthcareer Association (NHA).

~~(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~~**855-125-0020**

Licensure: Application- Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) An application for licensure as a **Certified Oregon Pharmacy Technician or** Pharmacy Technician may be accessed on the board website.

~~(2) 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~~**2**) The board may issue a license to a qualified applicant after the receipt of:

(a) A completed application **including:**~~;~~

(~~b~~**A**) Payment of the fee prescribed in OAR 855-110;

(~~c~~**B**) A current, passport regulation size photograph (full front, head to shoulders);

(~~d~~**C**) Personal identification or proof of identity; ~~and~~

PROPOSED

(~~e~~**D**) A completed national fingerprint-based background check~~.~~**; and**

(E) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(b) An applicant for a Certified Oregon Pharmacy Technician license, must provide a passing result from PTCB or NHA on a national pharmacy technician certification examination.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application or requests resulting from the application;

(c) Any other grounds found in ORS 689.405 or ORS 689.490.

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

(5) The license of a **Certified Oregon Pharmacy Technician or** Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

~~855-025-0012~~
~~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;~~

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~~(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~~

~~855-025-0011~~**855-125-0030**
Licensure: Renewal or Reinstatement **Applications**- **Certified Oregon Pharmacy Technician or** Pharmacy Technician

(1) An applicant for renewal of a **Certified Oregon Pharmacy Technician or** Pharmacy Technician license must:

(a) Pay the biennial license fee required in OAR 855-110.

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-021;

(c) Be subject to an annual criminal background check; **and**

(d) Provide a completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(2) A **Certified Oregon Pharmacy Technician or** Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A **Certified Oregon Pharmacy Technician or** Pharmacy Technician or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-**125-0020**; and

(b) Provide certification of completion of 10 continuing education hours earned in the prior 12 months. These hours may not be counted toward a future renewal; and must include:

(A) One hour of continuing pharmacy education in pharmacy law;

(B) One hour of continuing pharmacy education in patient safety or error prevention; and

PROPOSED

(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.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405 or ORS 689.490.

(5) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.

(6) Any person whose Certified Oregon Pharmacy Technician or Pharmacy Technician license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition the board for reinstatement of such license pursuant to ORS 689.445 and in conjunction with the application process identified in OAR 855-125-0020.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, **ORS 689.445,** ORS 689.486 & ORS 413.450

~~855-025-0015~~
~~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 855-021; 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.~~

PROPOSED

~~(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 855-025-0010; 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~~

855-125-0040
Licensure: Lapse

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not assist in the practice of pharmacy if the license is lapsed.

(d) A person may apply for renewal or reinstatement according to OAR 855-125-0030.

(2) If a person requests lapse prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board will not accept the lapse if an investigation of, or disciplinary action against the licensee is pending.

PROPOSED

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-125-0046
Licensure: Voluntary Surrender

A Certified Oregon Pharmacy Technician or Pharmacy Technician may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date the licensee is sent the executed final order.

(4) The licensee must cease assisting in the practice of pharmacy from the date the license terminates.

(5) A voluntarily surrendered license may not be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-125-0030 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation, action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

~~855-025-0023~~**855-125-0070**
~~Certified Oregon Pharmacy Technician and Pharmacy Technician: General~~ **Responsibilities: General- Certified Oregon Pharmacy Technician and Pharmacy Technician**

(1) ~~A~~ **Each** Certified Oregon Pharmacy Technician ~~or~~ **and** Pharmacy Technician is responsible for their own actions; however, this does not absolve the Pharmacist and the pharmacy from responsibility for the Certified Oregon Pharmacy Technician or Pharmacy Technician's actions.

(~~3~~**2**) A Certified Oregon Pharmacy Technician or Pharmacy Technician may not engage in the practice of pharmacy as defined in ORS 689.005.

(~~2~~**3**) A Certified Oregon Pharmacy Technician ~~or~~ **and** Pharmacy Technician must:

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

PROPOSED

(b) Only assist in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;

(c) Know the identity of the Pharmacist who is providing supervision, direction and control at all times;

(d) Only work within the scope of duties permitted by their license;

(e) Only work within the scope of duties permitted by the Pharmacist providing supervision, direction and control;

(~~e~~**f**) Only perform duties they are trained to perform~~; and~~

(g) Appropriately perform the tasks permitted;

(~~f~~**h**) Only access the pharmacy area when a Pharmacist is ~~on duty~~ **physically present or when the outlet is operating under a Remote Dispensing Site Pharmacy (RDSP) registration and following the requirements in OAR 855-139;**

(i) Be clearly identified as a Certified Oregon Pharmacy Technician or Pharmacy Technician in all interactions and communications (e.g., nametag, phone interaction, chart notations);

(j) Review and adhere to drug outlet written policies and procedures. The review must:

(A) Occur upon employment and with each update; and

(B) Be documented and records retained by the outlet;

(k) Dispense and deliver prescriptions accurately and to the correct party; and

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

(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

PROPOSED

~~855-025-0030~~**855-125-0072**
Responsibilities: Confidentiality

~~(1)~~ No licensee of the ~~B~~**b**oard who obtains any patient information ~~shall~~ **may** disclose that information to a third-party without the consent of the patient except as provided in ~~section two~~ **except as provided in (a)-(e)** of this rule.

(**1**~~2~~) A licensee may disclose patient information:

(a) To the ~~B~~**b**oard;

(b) To a practitioner, Pharmacist, **Intern,** ~~Pharmacy Technician, or~~ Certified Oregon Pharmacy Technician **or Pharmacy Technician**, if disclosure is authorized by a Pharmacist ~~who reasonably believes that~~ **and** disclosure is necessary to protect the patient's health or well-being; or

(c) To a third-party when disclosure is authorized or required by law; or

(d) As permitted pursuant to federal and state patient confidentiality laws~~.~~**or;**

(e) To the patient or to persons as authorized by the patient.

(2) A licensee or registrant of the board may not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, **ORS 689.305, ORS 689.315**
Statutes/Other Implemented: ORS 689.155

~~855-025-0020~~**855-125-0074**
Responsibilities: 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~~**1**) **Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each** ~~A~~ ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **and Pharmacy Technician** must report to the board **without undue delay, but** within

(a) 10 days if they:

(~~a~~**A**) Are ~~c~~**C**onvicted of a misdemeanor or a felony; or

(~~b~~**B**) ~~If they a~~**A**re arrested for a felony~~.~~**; or**

PROPOSED

(C) Have reasonable cause to believe that any suspected violation of ORS 475, ORS 689 or OAR 855 has occurred.

(b) 10 working days if they:

(4**A**) ~~A Pharmacy Technician or Certified Oregon Pharmacy Technician who has~~ **Have** reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct ~~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.~~ **to that licensee's board; or**

(B) Suspect records are lost or stolen.

(c) 15 days, any change in:

(A) Legal name;

(B) Name used when assisting in the practice of pharmacy;

(C) Preferred email address;

(D) Personal phone number;

(E) Personal physical address;

(F) Personal mailing address; or

(G) Employer.

(5**2**) A ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **or Pharmacy Technician** who reports to a board in good faith as required by:

(a) ORS 676.150 ~~section (4) of this rule~~ is immune from civil liability for making the report~~.~~**; and**

(b) ORS 689.455 is not subject to an action for civil damages as a result thereof.

~~(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.~~

PROPOSED

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: **ORS 676.150,** ORS 689.155**, ORS 689.455**~~, &~~ ORS 689.486

855-125-0076
Responsibilities: Training

Certified Oregon Pharmacy Technicians and Pharmacy Technicians must:

(1) Complete and document initial training that includes on-the-job and related education that is commensurate with the tasks that the Certified Oregon Pharmacy Technician or Pharmacy Technician will perform, prior to the performance of those tasks.

(2) Complete ongoing training to ensure continued competency in tasks that are performed.

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

~~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.~~

PROPOSED

~~(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~~

~~855-025-0035~~
~~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~~**855-125-0080**
~~Certified Oregon Pharmacy Technician and Pharmacy Technician: Tasks and Guidelines~~
Responsibilities: Permitted Practices

(1) Non-licensed pharmacy personnel may **perform any function that does not constitute the practice of pharmacy as defined in ORS 689 or assistance in the practice of pharmacy. Non-licensed personnel may only perform functions permitted by the Pharmacist providing supervision, direction, and control** ~~enter non-prescription information into a computer record system and may perform clerical duties such~~

PROPOSED

~~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**s** or Pharmacy Technician**s**~~:, 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) May only assist in the practice of pharmacy as authorized by the rules of the board and as permitted by the Pharmacist providing supervision, direction, and control.

(b) Must ensure that work is verified by a Pharmacist if independent judgment is utilized when assisting in the practice of pharmacy.

(c) May perform final verification as allowed under OAR 855-125-0070(4).

~~(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.~~

PROPOSED

~~(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 reasonable 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~~

855-125-0090
Prohibited Practices

Certified Oregon Pharmacy Technicians and Pharmacy Technicians may not:

(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0070(5).

(2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.

PROPOSED

(3) Perform any task while assisting in the practice of pharmacy that requires independent judgment ~~without~~ unless it is verified by a Pharmacist ~~verification;~~.

(4) Perform any task listed in OAR 855-115-0070(3); or

(5) Ask questions of a patient or patient's agent which screen or limit interaction with the Pharmacist;

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

~~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;~~

PROPOSED

~~(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~~

PROPOSED

Division 019/041/139 – Demographics

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Patient records; Includes patient's sex assigned at birth current gender identification, and current chosen name

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Modifies patient records requirements regarding gender, sex, and name.

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

Providing Inclusive Care and Services for the Transgender and Gender Diverse Community: A Pharmacy Resource Guide March 2021

Omnibus Reconciliation Act of 1990 (OBRA 90)

Suchy, N. Presentation to OBOP 8/12/2022. Sex, Gender, Identity & Terminology. https://www.oregon.gov/pharmacy/Documents/Sex_Gender_Identity_and_Terminology.pdf

Redfern, Jan S., Jann, Michael W. "The evolving role of pharmacists in transgender health care." Transgender health 4.1 (2019): 118-130.https://www.liebertpub.com/doi/epdf/10.1089/trgh.2018.0038

Cleveland Clinic: Why Deadnaming is Harmful

EPIC: More Inclusive Care for Transgender Patients Using Epic

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): To be determined

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): To be determined

OBOP/Other State Agencies/Units of Local Government/Public: No anticipated fiscal impact is expected for the agency, other state agencies, units of local government or the public.

Cost of Compliance (including small businesses): To be determined

Number/Type: To be determined

Reporting, Recordkeeping and Administrative Activities Cost: To be determined

Professional Services, Equipment/ Supplies, Labor Cost: To be determined

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, A RAC was not consulted, proposed rules are also designed to provide more inclusive care for transgender and gender diverse patients.

Rules Summary per ORS 183.335(2)(a)(B) (Indicates the change to the rule and why): Procedural rule review modifying patient records requirements to provide pharmacists with hormonal history and anatomy for accurate drug dosing and interaction screening. Also provides pharmacies with the ability to identify patients by their chosen name and gender identification.

NOTES:

- History of rule package review

- At the February 2022 board meeting, the board provided guidance for board staff to bring back educational materials addressing rule edits for assigned sex, gender identification, and chosen names.
- A speaker presented on this topic at the August 2022 board meeting.
- This rule package was included on the agenda for the August 2022 and October 2022 board meetings, but the board did not discuss the package during those meetings.
- The December 2022 meeting is the 3rd review of this package.

- Highlights
  - Language highlighted in yellow denotes sections of rule that contemplate sex, gender, and name.

POLICY DISCUSSION: Name, Gender, Sex

Division 19
PHARMACISTS

855-019-0220
Drug Utilization Review (DUR)

NOTE: Revisions to this rule are also included in the Div 019/115 RPH Procedural Rule Review package

(1) A **P**~~p~~harmacist **must** ~~shall~~ maintain a record for each patient that contains easily retrievable information necessary for the **P**~~p~~harmacist 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 **P**~~p~~harmacist **must** ~~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.

PROPOSED

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

(3) The **P**~~p~~harmacist or intern ~~shall~~ **must** 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

855-019-0290
Immunization Record Keeping and Reporting

NOTE: Revisions to this rule are also included in the Div 019/115 RPH Procedural Rule Review package

(1) A **P**~~p~~harmacist who administers a vaccine to a patient must fully document the administration in the patient's permanent record.

(2) A **P**~~p~~harmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A **P**~~p~~harmacist is not required to notify the primary health care provider.

(a) The name, address, gender and date of birth of the patient;

(b) The date of administration of the vaccine;

(c) The NDC number of the vaccine, or other acceptable standardized vaccine code set;

(d) The address of the pharmacy where vaccine was administered unless automatically embedded in the electronic report provided to the OHA ALERT Immunization System;

(e) The phone number of the patient when available;

(f) The dose amount, manufacturer, site of administration, lot number and expiration date of the vaccine when available;

(3) A **P**~~p~~harmacist who administers any vaccine will keep documentation of current CPR training. This documentation will be kept on site and available for inspection.

(4) A **P**~~p~~harmacist who administers any vaccine will follow storage and handling guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC).

(5) For the purpose of participation in the Oregon Vaccines for Children program,

(a) The vaccine eligibility code for each dose must be reported to the ALERT Immunization Information System in the manner prescribed by OHA, and

PROPOSED

(b) The **P**~~p~~harmacist is recognized as a prescriber.

(6) If providing state or federal vaccines during a pandemic as determined by the CDC, the event and priority code as specified by OHA must be provided upon request in the manner prescribed by OHA.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645

Division 41
OPERATION OF PHARMACIES

855-041-1165
Records: Patient

NOTE: Base language below is effective 9/1/2022 and includes amendments adopted at the June 2022 board meeting.

A patient record system shall be maintained by pharmacies for all patients for whom prescription drug orders are dispensed. The patient record system must provide for readily retrievable information necessary for the dispensing **P**~~p~~harmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The **P**~~p~~harmacist must make a reasonable effort to obtain, record, and maintain the following information:

(1) Full name of the patient for whom the drug is intended;

(2) Address and telephone number of the patient;

(3) Patient's date of birth;

(4) Patient's gender;

(5) Patient's preferred language for communication and prescription labeling;

(6) Chronic medical conditions;

(7) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(8) Known allergies, drug reactions, and drug idiosyncrasies; and

(9) If deemed relevant in the pharmacist's reasonable professional judgment:

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

PROPOSED

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

855-041-6510
In-patient Drug Profile

(1) Each **P**~~p~~harmacist must ensure that a drug order for a patient requiring continuous drug therapy is entered into the patient's drug profile. The profile must contain:

(a) The patient's name, location and important clinical data such as age, height, weight, sex, chronic disease states, problem list and allergies;

(b) The drug name, strength, dosage form, route of administration and directions for administration;

(c) The drug therapy start and end date as applicable;

(d) The name or ID of the **P**~~p~~harmacist responsible for entry or verification of the drug order.

(2) Prior to the drug being released for access by the nurse, a **P**~~p~~harmacist must enter the drug order into a drug profile and perform a DUR except when:

(a) The drug is being dispensed from an after-hours cabinet in the absence of a **P**~~p~~harmacist;

(b) The drug is from an emergency drug kit; or

(c) A system override is being used by a LIP or nurse to treat the emergency needs of a patient. Subject to a prescriber's order, a sufficient quantity to meet the emergency needs of the patient may be used until a **P**~~p~~harmacist is available to review and confirm the drug order.

(3) The **P**~~p~~harmacist must continue to monitor the appropriateness of the patient's drug utilization throughout the patient's stay in the hospital.

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

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0555
Records: Patient

PROPOSED

NOTE: Base language below is effective 9/1/2022 and includes amendments adopted at the June 2022 board meeting.

A patient record system must be maintained by pharmacies for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing Oregon licensed Pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing. The **P**~~p~~harmacist must make a reasonable effort to obtain, record, and maintain the following information:

(1) Full name of the patient for whom the drug is intended;

(2) Address and telephone number of the patient;

(3) Patient's date of birth;

(4) Patient's gender;

(5) Patient's preferred language for communication and prescription labeling;

(6) Chronic medical conditions;

(7) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(8) Known allergies, drug reactions, and drug idiosyncrasies; and

(9) If deemed relevant in the **P**~~p~~harmacist's professional judgment:

(a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

PROPOSED

Division 110: Fees – Pharmacy Prescription Kiosk (PPK)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Registration Fee for Pharmacy Prescription Kiosk (PPK)

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new registration fee for the new registration type of Pharmacy Prescription Kiosk.

Documents Relied Upon per ORS 183.335(2)(b)(D): None available.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) It is anticipated that these amendments will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal or economic impact is known; pharmacies are not required to operate a Pharmacy Prescription Kiosk (PPK). If a pharmacy chooses to operate a PPK, the PPK Affiliated Pharmacy will be required to apply and pay a registration fee of $120 for the PPK and be required to comply with all Oregon Administrative Rules and Oregon Revised Statutes. We do anticipate that registered drug outlets will be financially impacted in order to comply with the proposed rules. Pharmacies that choose to deploy kiosks will generate revenue from prescription and over-the-counter drug sales to help offset the cost of compliance with these proposed rules.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public) Effect on Small Businesses: OBOP- Fiscal impact is estimated to be minimal for the agency and limited to administrative and compliance costs. There is no anticipated fiscal impact to other state agencies, units of local government or the public. There are approximately 113 small business drug outlet pharmacies registered with the board. It is not anticipated that the cost of compliance for small business would be different from that of a non-small business.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed amendments to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. New registration type requires appropriate registration fee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments add "Prescription Kiosks Retail Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually." as new registration types require appropriate registration fees.

NOTES:

- History of rule package review
  - The December 2022 meeting is the 1st review of this package.

Division 110
FEES

855-110-0007
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) Manufacturers (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) Consulting ”Drugless” Drug Outlet Pharmacy

(B) Home Dialysis Retail Drug Outlet Pharmacy

(C) Institutional Drug Outlet Pharmacy

(D) Remote Dispensing Site Retail Drug Outlet Pharmacy

(E) Retail Drug Outlet Pharmacy

PROPOSED

(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) ~~Reserved.~~ **Prescription Kiosks Retail Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.**

(E) Prescription Lockers 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) Wholesalers (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

PROPOSED

Division 019: Pharmacists – Duties of a Pharmacist-in-Charge – Deficiency/Non-Compliance Notifications

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Updates days to respond to receiving a deficiency or non-compliance notifications

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amends the number of days for which a Pharmacist-in-Charge (PIC) must submit a plan of correction if a discrepancy is noted on a board inspection related to deficiency or non-compliance notification.

Documents Relied Upon per ORS 183.335(2)(b)(D): None available

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): There are no known economic impacts to the agency, other state or local government, small businesses, or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of the proposed rule amendments.

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

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments revise (4)(f)(A) by striking "15" and adding "30" and revises (4)(f)(B) by striking "30" and adding "15". Non-compliance notifications are more concerning related to patient safety and require a quicker response to address patient safety issues observed.

Division 19
PHARMACISTS

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 may 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. A Pharmacy Prescription Locker in OAR 855-143 does 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 may 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:

(A) ~~15~~**30** days of receiving a deficiency notific**ation**~~e~~; or

(B) ~~30~~**15** days of receiving a non-compliance notific**ation**e.

(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;

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(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained 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 Report;

(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

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OREGON BOARD OF PHARMACY
DELEGATION OF AUTHORITY

The following tasks and functions are delegated to the staff of the Oregon Board of Pharmacy, under the Executive Director's supervision, in accordance with ORS 689.195:

General:

1. Executive Director is responsible for all administrative matters related to the operation of the board, the agency, and board staff.

2. Executive Director is responsible for all financial matters related to the operation of the board office except for approving the board's biennial operating budget.

3. Authorize Executive Director to exercise managerial oversight of board employees, accounting, and payroll.

4. Authorize staff per Policy (AD-010) to make reasonable efforts to collect all monies owed using appropriate practices in the management and collection of accounts receivable, to include debt collection procedures for all liquidated and delinquent accounts as outlined in ORS 293 and the Oregon Accounting Manual, Chapter 35.

5. Authorize staff per Policy (AD-009) to respond to public records request. (ORS 192)

6. Authorize staff to complete surveys. [e.g. National Association of Boards of Pharmacy (NABP) Survey of Pharmacy Law]

7. Authorize staff to write and submit Newsletter articles to NABP.

8. Authorize Executive Director and authorized staff to respond to lawfully issued subpoenas.

9. Authorize Pharmacist Consultant, Executive Director, or a staff member directed by the Executive Director, to review and approve board-approved Continuing Pharmacy Education (CPE).

Licensing:

1. To review, process, and determine if an application is complete.

2. Review, process, and verify credentials related to license or registration type through primary source verification for all applications. Refer to the Compliance Department, as necessary.

3. Facilitate national fingerprint background checks and review results. (OAR 855-010-0100(3))

4. Review and process applications. Refer applications to the Compliance Department if a record or discipline is self-reported on the application, identified on the national fingerprint background check results, or identified on an inspection report.

5. Expire incomplete applications 6 months from the date received or as the application directs.

6. Approve extensions of MPJE / NAPLEX score expiration dates (OAR 855-019-0120(1)(b) & (c))

7. Respond to NABP requests regarding eligibility for examinations or licensure.

8. To issue a license or registration to applicants who satisfy all requirements.

9. Conduct LEDS background check on all renewing licensees. (OAR 855-019-0122(2), OAR 855-025-0015(2)(c), OAR 855-031-0016(2))

10. Approve voluntary registration and license lapse requests not connected to any pending investigation or disciplinary action.

11. Conduct CPE audits. (OAR 855-021-0050)

12. Review and approve CPE certificates and documentation submitted by licensees or obtained through the review of the NABP CPE Monitor. Refer to Compliance if requirements set in rule are not demonstrated. (OAR 855-021-0010)

Compliance

1. Authorize Compliance staff to review, assess, and act on applicant's or licensee's/registrant's reported state, US Territory or federal disciplinary action.
    - Staff will present, in Case Review, discipline related to probations, surrenders, suspensions, denials, and revocations; and
    - Staff to approve license or registration, or take no action for licensees, for other self-reported discipline (e.g. civil penalties, reprimand, letter of admonishment).

2. Authorize Compliance staff to approve the issuance of a license for an applicant or licensee that discloses the following arrests, convictions, or history, that are **not a felony**:

- Harassment, Assault 4th degree, Vandalism, Criminal mischief, Hit and run, Disorderly conduct, Corporal injury, Battery, Domestic violence, Misuse ID, Marijuana possession, Violation of restraining order, Failure to appear, MIPs, or similar charges where staff is unable to establish a nexus to the practice.
- A history of one DUI > 5 years.
- A history of one Theft II or lower > 5 years

3. Authorize Compliance staff to review and close case for licensees that discloses the following arrests, convictions or history, that are **not a felony**:
    - Harassment, Assault 4th degree, Vandalism, Criminal mischief, Hit and run, Disorderly conduct, Corporal injury, Battery, Domestic violence, Misuse ID, Marijuana possession, Violation of restraining order, Failure to appear, MIPs, or similar charges where staff is unable to establish a nexus to the practice.
    - A history of one DUI > 5 years.
    - A history of one Theft II or lower > 5 years

4. Authorize Compliance staff to review complaints and ensure that all complaints of alleged violations, are fully investigated and that necessary action is taken for board review. (ORS 689.155(6))

5. Authorize Executive Director and Compliance Director to issue subpoenas. (ORS 689.135(12))

6. Authorize Compliance staff to initiate a case for licensees that are non-compliant with order sanctions.

7. For Pharmacist CPE Audit failure cases, authorize Compliance staff to close case with Board direction and issue case closure letter of education if the following parameters are met:
    - Licensee takes and passes OR MPJE; and
    - Licensee completes CPE deficient from audit.
    - Board to approve at next applicable Board meeting in the Consent Agenda.

8. Authorize Compliance staff to draft and issue Notices and Orders.

9. Authorize Compliance staff to refer hearing requests to the Department of Justice General Counsel Division to initiate hearing process with the Office of Administrative Hearings.

10. Authorize staff or AAG to accept request for virtual hearing when possible.

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11. Authorize Compliance Director and Executive Director to execute modified and negotiated consent orders as directed by the board, including the following:
    - Default Orders;
    - Stipulated Orders of license surrender; and
    - Orders within Board pre-specified parameters.

12. Authorize staff to review conditions of probation orders for early termination of probation and authorize staff to give licensee early termination if conditions are met

13. Authorize Compliance Staff to review and accept CPE to satisfy disciplinary orders and license renewal requirements. (OAR 855-021-0010)

14. Authorize Compliance staff to report discipline to the National Practitioner Databank (NPDB).

15. Authorize Compliance staff to post final orders on BOP website via license verification.

16. Authorize Compliance staff to respond to record requests for information from another government agency. (ORS 676.177 and ORS 676.175)

17. Authorize staff to provide outlet notification of registration requirements for unregistered Non-Prescription Drug Outlet (A, B, C, D, E). (OAR 855-035)

18. Authorize staff to provide notification to a person for advertising or using the title of pharmacist or the title of druggist or apothecary, or any other title or description of like import in their business name unless the person is licensed to practice pharmacy under ORS 689. (ORS 689.225(2))

19. All applicants, licensees, registrants, and unregistered or unlicensed activity that is not approved in this document, will be provided to the board for review.

20. Authorize Compliance Officer to issue the following response times for inspections:

    - 15 days for a Non-Compliance Notification
    - 30 days for a Deficiency Notification

21. Authorize Compliance staff to provide appropriate deadline extensions to requests.

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Oregon Board of Pharmacy

Budget Report: September 2022 (Month 15)

Revenue:

Through September, revenue is $5,525,507 (-2.8%) **under** budget

Expenditures:

Through September, **total expenditures** are $5,603,498 (7.5%) **under** budget

Personal services are $3,965,745 (5.4%) **under** budget

Services and Supplies are $1,637,754 (13.3%) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: ($77,991)

Cash Balance:

Cash balance through September is $4,035,855 which represents (9.99) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through September 2022. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,835,586, which represents (12.77) months of operating expense*)

Cash balance target is 2,271,950, (6.0 months of operating expense)

*Note: The end of biennium projected cash balance is calculated based on the biennium to date plus the remaining months projections for 2021-23.

Oregon Board of Pharmacy				
Total All Funds - LAB 2021-2023				
Actuals through September 2022				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**3,679,852**	**4,714,145**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	8,716,500.00	8,841,006.99	(124,506.99)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	295,108.00	(102,113.00)
505	FINES AND FORFEITS	410,000.00	394,912.66	15,087.34
605	INTEREST AND INVESTMENTS	131,250.00	66,686.07	64,563.93
975	OTHER REVENUE	84,335.00	61,361.08	22,973.92
	TOTAL REVENUE	**9,535,080.00**	**9,659,074.80**	**(123,994.80)**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	443,120.00	449,834.00	(6,714.00)
	TOTAL TRANSFER OUT	**443,120.00**	**449,834.00**	**(6,714.00)**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,283,003.00	4,202,416.41	80,586.59
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	10,141.79	(10,141.79)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	198,616.00	173,647.47	24,968.53
3210	ERB ASSESSMENT	1,276.00	1,240.80	35.20
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	768,173.96	(7,436.96)
3221	PENSION BOND CONTRIBUTION	236,241.00	236,450.21	(209.21)
3230	SOCIAL SECURITY TAX	334,236.00	323,524.84	10,711.16
3240	UNEMPLOYMENT ASSESSMENT	-	86.40	(86.40)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	926.36	85.64
3260	MASS TRANSIT	27,053.00	26,052.76	1,000.24
3270	FLEXIBLE BENEFITS	841,104.00	780,613.82	60,490.18
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,525,474.37**	**185,109.63**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	42,120.90	73,773.10
4125	OUT-OF-STATE TRAVEL	17,024.00	3,625.77	13,398.23
4150	EMPLOYEE TRAINING	22,320.00	18,320.63	3,999.37
4175	OFFICE EXPENSES	134,566.00	65,746.16	68,819.84
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	59,968.51	(9,038.51)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	202,541.00	-
4250	DATA PROCESSING	318,678.00	356,981.57	(38,303.57)
4275	PUBLICITY & PUBLICATIONS	43,329.00	14,249.39	29,079.61
4300	PROFESSIONAL SERVICES	339,713.00	255,858.78	83,854.22
4315	IT PROFESSIONAL SERVICES	134,467.00	36,850.00	97,617.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	557,877.98	63,957.02
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,804.00	1,614.00
4425	FACILITIES RENT & TAXES	229,042.00	284,945.83	(55,903.83)
4475	FACILITIES MAINTENANCE	55.00	1,851.13	(1,796.13)
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	500.00	702.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	208,192.19	42,286.81
4650	OTHER SERVICES AND SUPPLIES	411,285.00	428,445.31	(17,160.31)
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	5,423.49	8,684.51
4715	IT EXPENDABLE PROPERTY	45,228.00	15,023.40	30,204.60
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,562,326.04**	**396,468.96**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,691,342.00**	**9,087,800.41**	**603,541.59**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**4,835,586**	
	End of biennium projected cash balance in months		12.77	
	Cash balance target of 6.0 months (working capital)		2,271,950	

Oregon Board of Pharmacy

Budget Report: October 2022 (Month 16)

Revenue:

Through October, revenue is $5,709,653 (-5.8%) **under** budget

Expenditures:

Through October, **total expenditures** are $5,947,259 (7.9%) **under** budget

Personal services are $4,235,080 (5.3%) **under** budget

Services and Supplies are $1,712,179 (15.6%) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: ($237,606)

Cash Balance:

Cash balance through October is $4,035,855 which represents (9.99) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through October 2022. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,816,456, which represents (12.74 months of operating expense*)

Cash balance target is $2,268,406, (6.0 months of operating expense)

*Note: The end of biennium projected cash balance is calculated based on the biennium to date plus the remaining months projections for 2021-23.

Oregon Board of Pharmacy				
Total All Funds - LAB 2021-2023				
Actuals through October 2022				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**3,679,852**	**4,714,145**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	8,716,500.00	8,811,627.74	(95,127.74)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	295,909.00	(102,914.00)
505	FINES AND FORFEITS	410,000.00	384,156.33	25,843.67
605	INTEREST AND INVESTMENTS	131,250.00	71,942.65	59,307.35
975	OTHER REVENUE	84,335.00	62,135.08	22,199.92
	TOTAL REVENUE	**9,535,080.00**	**9,625,770.80**	**(90,690.80)**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	443,120.00	449,834.00	(6,714.00)
	TOTAL TRANSFER OUT	**443,120.00**	**449,834.00**	**(6,714.00)**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,283,003.00	4,185,277.17	97,725.83
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	10,179.64	(10,179.64)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	198,616.00	173,647.47	24,968.53
3210	ERB ASSESSMENT	1,276.00	1,240.80	35.20
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	764,291.87	(3,554.87)
3221	PENSION BOND CONTRIBUTION	236,241.00	235,325.29	915.71
3230	SOCIAL SECURITY TAX	334,236.00	319,016.51	15,219.49
3240	UNEMPLOYMENT ASSESSMENT	-	86.40	(86.40)
3241	PAID LEAVE OREGON-EMPLOYER	-	4,106.26	(4,106.26)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	919.02	92.98
3260	MASS TRANSIT	27,053.00	25,944.52	1,108.48
3270	FLEXIBLE BENEFITS	841,104.00	780,613.82	60,490.18
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,502,848.32**	**207,735.68**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	42,617.91	73,276.09
4125	OUT-OF-STATE TRAVEL	17,024.00	3,625.77	13,398.23
4150	EMPLOYEE TRAINING	22,320.00	18,246.77	4,073.23
4175	OFFICE EXPENSES	134,566.00	66,278.94	68,287.06
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	59,734.40	(8,804.40)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	203,248.00	(707.00)
4250	DATA PROCESSING	318,678.00	356,146.22	(37,468.22)
4275	PUBLICITY & PUBLICATIONS	43,329.00	13,866.18	29,462.82
4300	PROFESSIONAL SERVICES	339,713.00	264,703.78	75,009.22
4315	IT PROFESSIONAL SERVICES	134,467.00	32,850.00	101,617.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	551,065.38	70,769.62
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,869.00	1,549.00
4425	FACILITIES RENT & TAXES	229,042.00	284,945.83	(55,903.83)
4475	FACILITIES MAINTENANCE	55.00	1,851.13	(1,796.13)
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	500.00	702.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	216,545.29	33,933.71
4650	OTHER SERVICES AND SUPPLIES	411,285.00	431,535.92	(20,250.92)
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	5,423.49	8,684.51
4715	IT EXPENDABLE PROPERTY	45,228.00	13,723.40	31,504.60
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,570,777.41**	**388,017.59**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,691,342.00**	**9,073,625.73**	**617,716.27**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**4,816,456**	
	End of biennium projected cash balance in months		12.74	
	Cash balance target of 6.0 months (working capital)		2,268,406	