Oregon Board of Pharmacy
*REVISED BOARD MEETING AGENDA
October 12-14, 2022

Public Attendance Options:

1. **In-person: 800 NE Oregon St. Conference Room 1A, Portland, OR**
2. **Virtually via Microsoft Teams: Link**
3. **Audio only: (503) 446-4951 Phone Conference ID: 512 750 453#**

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, October 12, 2022 @ 8:30AM
Thursday, October 13, 2022 @ 8:30AM
Friday, October 14, 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 10/14/2022**.

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, OCTOBER 12, 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*

THURSDAY, OCTOBER 13, 2022

I. OPEN SESSION, Michelle Murray RPh, Presiding

a. Roll Call

II. GENERAL ADMINISTRATION

b. Consider Adoption of Rules – *None*

c. Consider Adoption of Temporary Rules – *Melvin/Schnabel*
   i. **Div 020** – COVID-19 Antiviral Protocol **#A,Aa** *Action Necessary*
   ii. **Div 041** – Prescription Labeling Expiration Date **#A1** *Action Necessary*

d. Rulemaking Policy Discussion Items – *Melvin/Schnabel*
   i. **Div 019** – 2022 HB 4034 Duties of a Pharmacist **#B,Ba** *Action Necessary*
   ii. **Div 139** – 2022 HB 4034 Prohibited Practices **#B1,B1a** *Action Necessary*
   iii. **Div 019** – 2022 HB 4096 Out-of-State Volunteer Pharmacist **#B2,B2a** *Action Necessary*
   iv. **Div 062** – Drug Distribution Agent **#B3** *Action Necessary*
   v. **Div 010/019/020** – Pharmacist Prescriptive Authority – Paxlovid, Shingles Travel Medications, PEP, PrEP & Contraception Protocols **#B4,B4a, B4b, B4c, B4d,B4e,B4f** *Action Necessary*
   vi. **Div 021/135** – CPE Procedural Rule Review **#B5** *Action Necessary*
   vii. **Div 019/141** – Pharmacy Prescription Kiosk (PPK) **#B6** *Action Necessary*
   viii. **Div 019/041** – Safe Pharmacy Practice Conditions **#B7** *Action Necessary*
   ix. **Div 025/125** – Pharmacy Technician Procedural Rule Review **#B8** *Action Necessary*
   x. **Div 019/020/031/041/115/001/102** – RPH Procedural Rule Review/Procedural & Universal Rules **#B9,B9a** *Action Necessary*
   xi. **Div 031/120** – Intern Procedural Rule Review **#B10**
   xii. **Div 019/041/139** – Patient Demographics **#B11**
   xiii. **Div 006/019/031** – Definitions **#B12** *Action Necessary*
   xiv. **Div 041** – Prescription Labeling Expiration Date **#B13** *Action Necessary*

Adjourn *Action Necessary*

FRIDAY, OCTOBER 14, 2022

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

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

III. GENERAL ADMINISTRATION
   b. Resume Rulemaking Policy Discussion Items
   c. Discussion Items
      i. Waiver/Exemption Requests
         1. Deschutes County Health Services **#C**- *Efremoff* *Action Necessary*
         2. Murray's Pharmacy (Condon) **#C1**- *Efremoff* *Action Necessary*
         3. NAPLEX Score Extension Request SBAR **#C2**- *Hennigan* *Action Necessary*
      ii. Public Health and Pharmacy Formulary Advisory Committee Update - *Schnabel*
      iii. Workgroup Update
         1. Safe Pharmacy Practice Conditions Workgroup – *Schnabel*
      iv. Strategic Plan Update – *Schnabel*
      v. Pharmacy Workforce – *Schnabel* **#D**
      vi. Financial/Budget Report – *MacLean* **#E**
         1. 2022 Annual Performance Progress Report **#E1**

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

2022 Board Meeting Dates

- November 10, 2022 Portland (Strategic Planning)
- December 14-16, 2022 Portland

2023 Board Meeting Dates

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

- November 22, 2022
- May 23, 2023

Conferences/Meetings – *Schnabel*

- OSPA Annual Convention – October 22, 2022, Portland OR
- OSHP Fall Seminar – November 19, 2022, Portland, OR
- 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 – August 2022 **# CONSENT-2**
c. Strategic Planning Meeting Minutes – November 2021 **# CONSENT-3**

VI. PUBLIC COMMENT

Adjourn *Action Necessary*

Division 020: Pharmacist Prescriptive Authority (COVID-19 Antiviral Protocol)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Compendia updated to include COVID-19 Antiviral protocol

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Temporarily adopts COVID-19 Antiviral protocol.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): 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. Oregon pharmacists are more familiar using statewide protocols for prescribing services than an FDA Emergency Use Authorization. Access affordable COVID-19 antiviral medication in a timely manner protects public health and safety.

Optional: Documents Relied Upon per ORS 183.335(2)(b)(D): Temporary Statewide Drug Therapy Management COVID-19 Antiviral protocol v.10/2022. ORS 689.689

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Temporarily adopts a COVID-19 Antiviral Protocol and amends the current protocol compendia by adding "COVID-19 Antiviral Protocol". Increases equitable access and reduces barriers for patients seeking treatment for COVID-19.

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) Protocol (v. 06/2021);

(c) COVID-19 Monoclonal Antibody (mAb) Protocol (v. 12/2021);

(d) COVID-19 Antigen Self-Test Protocol (v. 12/2021); **and**

(e) COVID-19 Antiviral Protocol (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. 6/2021);

(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 12/2021); and

(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. 06/2022).

[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

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 or continuing education (CE) on PAXLOVID.
    - 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

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____
Preferred Pronouns (circle) She/Her, He/Him, They/Them, Ze/Hir, 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 _____
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

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
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 ____/_____/_____

4. Follow-up with patient completed within 7 days of prescription on: Date ____/_____/_____
5. FDA Form 3500 submitted because adverse event occurred: □ Yes Date ____/_____/_____ □ Not Applicable

RPH Signature_____Date ____/_____/_____

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 **<u>one</u>** 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

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.

Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

1) Immediate Physical Assessment Screen (Self-screening Patient Intake Form, REALD demographics and pharmacist physical 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 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

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.*

Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

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

11) Document follow-up with patient within 7 days, phone consultation permitted

Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

Adverse Reactions and Medication Errors Reporting Requirements:

Required reporting for serious adverse events and medication errors 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.

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:_____
_____
_____
_____

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.

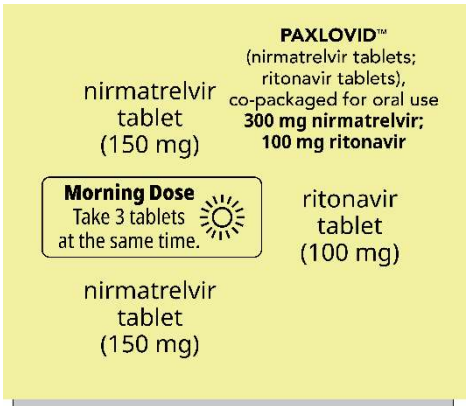
How do I take PAXLOVID?

- **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.**

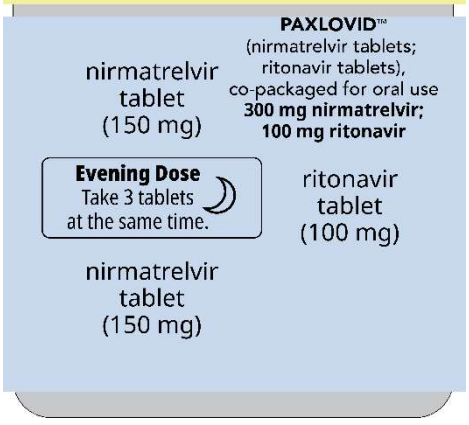
Figure A

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.

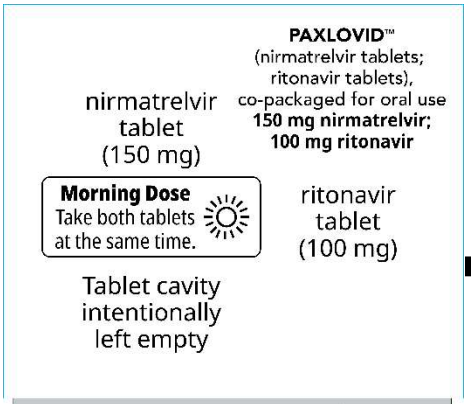


Evening Dose:
Take the 2 pink nirmatrelvir tablets and
1 white to off-white ritonavir tablet together
at the same time each evening.

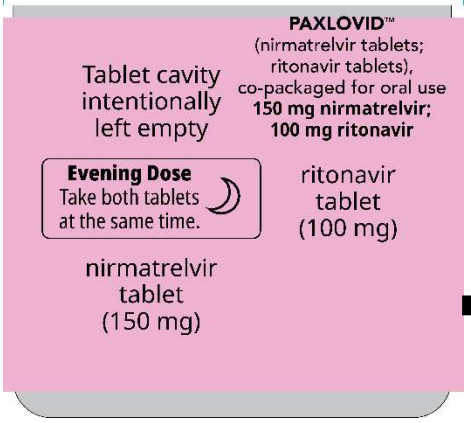
Figure B

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:_____

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

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): Prescription Labeling; Expiration date requirements

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Temporarily amends current rule by clarifying prescription expiration date requirements.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): 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.

Documents Relied Upon per ORS 183.335(2)(b)(D): None available.

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.

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 ~~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~~ **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.

(1~~1~~**2**) 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

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 **P**~~p~~harmacist 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 **P**~~p~~harmacist receiving a prescription is responsible for:

(a) Using professional judgment in dispensing only pursuant to a valid prescription. A **P**~~p~~harmacist shall not dispense a prescription if the **P**~~p~~harmacist, 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 **issued pursuant to a valid patient-practitioner relationship** ~~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 **P**~~p~~harmacist 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 **P**~~p~~harmacist 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 **D**~~d~~ivision 41 and **D**~~d~~ivision 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 **D**~~d~~ivision 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 P~~p~~harmacist must ~~be confident~~ **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 **P**~~p~~harmacist 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 **P**~~p~~harmacist 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 **P**~~p~~harmacist 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

81st OREGON LEGISLATIVE ASSEMBLY--2022 Regular Session

Enrolled
House Bill 4034

Introduced and printed pursuant to House Rule 12.00. Presession filed (at the request of House Interim Committee on Health Care for Representative Rachel Prusak)

CHAPTER .....

AN ACT

Relating to health care; creating new provisions; amending ORS 435.205, 442.015, 475.230, 677.135, 689.005, 689.225, 689.522, 689.700, 743A.067 and 807.750 and section 4, chapter 92, Oregon Laws 2021, and sections 1, 2 and 5, chapter 619, Oregon Laws 2021; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

PSEUDOEPHEDRINE

SECTION 1. ORS 475.230 is amended to read:

475.230. (1) As used in this section, **"intern,"** "pharmacist," "pharmacy" and "pharmacy technician" have the meanings given those terms in ORS 689.005.

(2) A pharmacist**, intern** or pharmacy technician may transfer a drug containing pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine without a prescription from a practitioner to a person who is 18 years of age or older and who provides to the pharmacist**, intern** or pharmacy technician the person's valid government-issued photo identification.

(3) Prior to the transfer of a drug described in subsection (2) of this section, a pharmacist**, intern** or pharmacy technician shall submit the following information to the electronic system described in subsection (6) of this section:

(a) The date and time of the transfer;

(b) The name, address and date of birth of the person to whom the transfer will be made;

(c) The form of government-issued photo identification and identification number of the person to whom the transfer will be made;

(d) The name of the government agency that issued the photo identification; and

(e) The name of the drug that will be transferred and the amount of pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine, specified in grams, to be transferred.

(4) If, after receiving the information submitted under subsection (3) of this section, the electronic system generates an alert to not proceed with the transfer, the pharmacist**, intern** or pharmacy technician may not transfer the drug described in subsection (2) of this section to the person, except as provided in subsection (6) of this section.

(5)(a) Upon transferring a drug described in subsection (2) of this section, the pharmacist**, intern** or pharmacy technician shall require the person to whom the drug is transferred to sign an electronic or written log that shows the date of the transfer, the name of the person to whom the

transfer is made and the amount transferred of pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine, specified in grams.

(b) The log described in this subsection must be retained at the pharmacy where the transfer was made for at least two years from the date of the transaction.

(c) A law enforcement agency may obtain information contained in a log described in this subsection through a lawfully issued subpoena accepted by the State Board of Pharmacy. The board shall accept a lawfully issued subpoena under this paragraph, and shall adopt rules to carry out this paragraph. The board may designate a third party vendor as the custodian of records, including of a log described in this subsection.

(6)(a) For purposes of tracking the transfer of drugs described in subsection (2) of this section, a pharmacy shall use an electronic system designed to prevent illegal transfer of drugs described in subsection (2) of this section. The electronic system must:

(A) Be capable of tracking transfers nationwide in real time;

(B) Be capable of generating an alert described in subsection (4) of this section;

(C) Allow a pharmacist to override an alert described in subsection (4) of this section if, in the discretion of the pharmacist, the transfer is necessary to protect the person to whom the transfer will be made from imminent bodily harm;

(D) Be able to communicate in real time with similar systems operated in other states and the District of Columbia, including with similar systems that contain information submitted by more than one state;

(E) For each transfer, allow for the recording of:

(i) The information described in subsection (3) of this section;

(ii) The number of packages of the drug transferred;

(iii) The total amount of pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine transferred, specified in grams;

(iv) The name of the drug transferred;

(v) Either the signature of the person to whom the drug is transferred or a unique number connecting the transfer transaction to an electronic or written log described in subsection (5) of this section; and

(vi) The name or initials of the pharmacist**, intern** or pharmacy technician who transferred the drug;

(F) Be free of charge to a pharmacy;

(G) Be accessible at no charge to law enforcement and to other authorized personnel, as determined by the board, through an online portal or at the pharmacy;

(H) Retain information submitted for at least two years from the date of transaction; and

(I) Be accompanied by training, 24-hour online support and a toll-free support telephone hotline.

(b) A pharmacist who uses the override function described in this subsection shall record in the electronic system the use of the override.

(7) A drug described in subsection (2) of this section must be:

(a) Transferred from behind a pharmacy counter; and

(b) Stored behind the pharmacy counter in an area that is closed to the public.

(8) A person, other than a pharmacy, may not receive more than 3.6 grams per transfer, or more than nine grams in a 30-day period, of pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine.

(9) This section does not apply to a drug that contains pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine when the drug is transferred pursuant to a prescription.

(10) In addition to rules adopted under subsection (5) of this section, the board may adopt other rules as necessary to carry out this section.

(11) Violation of this section, or a rule adopted pursuant to this section, is a Class A misdemeanor.

SECTION 2. ORS 807.750 is amended to read:

807.750. (1) As used in this section:

(a) "Driver license" means a license or permit issued by this state or any other jurisdiction as evidence of a grant of driving privileges.

(b) "Financial institution" has the meaning given that term in ORS 706.008.

(c) "Identification card" means the card issued under ORS 807.400 or a comparable provision in another state.

(d) "Personal information" means an individual's name, address, date of birth, photograph, fingerprint, biometric data, driver license number, identification card number or any other unique personal identifier or number.

(e) "Private entity" means any nongovernmental entity, such as a corporation, partnership, company or nonprofit organization, any other legal entity or any natural person.

(f) "Swipe" means the act of passing a driver license or identification card through a device that is capable of deciphering, in an electronically readable format, the information electronically encoded in a magnetic strip or bar code on the driver license or identification card.

(2) Except as provided in subsection (6) of this section, a private entity may not swipe an individual's driver license or identification card, except for the following purposes:

(a) To verify the authenticity of a driver license or identification card or to verify the identity of the individual if the individual pays for a good or service with a method other than cash, returns an item or requests a refund.

(b) To verify the individual's age when providing an age-restricted good or service to any person about whom there is any reasonable doubt of the person's having reached 21 years of age.

(c) To prevent fraud or other criminal activity if an individual returns an item or requests a refund and the private entity uses a fraud prevention service company or system.

(d) To transmit information to a check services company for the purpose of approving negotiable instruments, electronic funds transfers or similar methods of payment.

(e) To collect information about the individual for the purpose of processing an application for a deposit account or loan for the individual, if the private entity is a financial institution.

(f) To enable a pharmacist, pharmacy technician or intern, as those terms are defined in ORS 689.005, to submit information to the electronic system described in ORS 475.230 for the purpose of transferring a drug containing pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine without a prescription from a practitioner to a person who is 18 years of age or older.

(3) A private entity that swipes an individual's driver license or identification card under subsection (2)(a) or (b) of this section may not store, sell or share personal information collected from swiping the driver license or identification card.

(4) A private entity that swipes an individual's driver license or identification card under subsection (2)(c) or (d) of this section may store or share the following information collected from swiping an individual's driver license or identification card for the purpose of preventing fraud or other criminal activity against the private entity:

(a) Name;

(b) Address;

(c) Date of birth; and

(d) Driver license number or identification card number.

(5)(a) A person other than an entity regulated by the federal Fair Credit Reporting Act, 15 U.S.C. 1681 et seq., who receives personal information from a private entity under subsection (4) of this section may use the personal information received only to prevent fraud or other criminal activity against the private entity that provided the personal information.

(b) A person who is regulated by the federal Fair Credit Reporting Act and who receives personal information from a private entity under subsection (4) of this section may use or provide the personal information received only to effect, administer or enforce a transaction or prevent fraud or other criminal activity, if the person provides or receives personal information under contract from the private entity.

(6)(a) Subject to the provisions of this subsection, a private entity that is a commercial radio service provider that provides service nationally and that is subject to the Telephone Records and Privacy Protection Act of 2006 (18 U.S.C. 1039) may swipe an individual's driver license or identification card if the entity obtains permission from the individual to swipe the individual's driver license or identification card.

(b) The private entity may swipe the individual's driver license or identification card only for the purpose of establishing or maintaining a contract between the private entity and the individual. Information collected by swiping an individual's driver license or identification card for the establishment or maintenance of a contract shall be limited to the following information from the individual:

(A) Name;

(B) Address;

(C) Date of birth; and

(D) Driver license number or identification card number.

(c) If the individual does not want the private entity to swipe the individual's driver license or identification card, the private entity may manually collect the following information from the individual:

(A) Name;

(B) Address;

(C) Date of birth; and

(D) Driver license number or identification card number.

(d) The private entity may not withhold the provision of goods or services solely as a result of the individual requesting the collection of the following information from the individual through manual means:

(A) Name;

(B) Address;

(C) Date of birth; and

(D) Driver license number or identification card number.

(7) A governmental entity may swipe an individual's driver license or identification card only if:

(a) The individual knowingly makes the driver license or identification card available to the governmental entity;

(b) The governmental entity lawfully confiscates the driver license or identification card;

(c) The governmental entity is providing emergency assistance to the individual who is unconscious or otherwise unable to make the driver license or identification card available; or

(d) A court rule requires swiping of the driver license or identification card to facilitate accurate linking of court records pertaining to the individual.

(8) In addition to any other remedy provided by law, an individual may bring an action to recover actual damages or $1,000, whichever is greater, and to obtain equitable relief, if equitable relief is available, against an entity that swipes, stores, shares, sells or otherwise uses the individual's personal information in violation of this section. A court shall award a prevailing plaintiff reasonable costs and attorney fees. If a court finds that a violation of this section was willful or knowing, the court may increase the amount of the award to no more than three times the amount otherwise available.

(9) Any waiver of a provision of this section is contrary to public policy and is void and unenforceable.

SECTION 3. The amendments to ORS 807.750 by section 2 of this 2022 Act apply to conduct occurring on or after January 1, 2022.

COVID-19 DATA COLLECTION

SECTION 4. Section 4, chapter 92, Oregon Laws 2021, is amended to read:

Sec. 4. (1) Section 1 [*of this 2021 Act*]**, chapter 92, Oregon Laws 2021,** is repealed [*on June 30, 2022*] **one year after the date on which the state of emergency declared by the Governor on March 8, 2020, for the COVID-19 pandemic, and any extension of the state of emergency, is no longer in effect**.

(2) The amendments to ORS 433.008 by section 3 [*of this 2021 Act*]**, chapter 92, Oregon Laws 2021,** become operative on June 30, 2022.

BIOLOGICAL PRODUCTS

SECTION 5. ORS 689.522 is amended to read:

689.522. (1) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biological product for the prescribed biological product unless:

(a) The substitute biological 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 in a manner reasonable under the circumstances; and

(d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

(2) Not later than five business days after the dispensing of a biological product, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, by making an entry into an electronic system that the prescribing practitioner can access electronically and that is:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing technology;

(c) A pharmacy benefit management system; or

(d) A pharmacy record.

(3) If the pharmacy or pharmacist, or the pharmacist's designee, does not have access to an electronic system described in subsection (2) of this section, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate not later than five business days to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The communication may be by facsimile, electronic mail, telephone or another method.

(4) If the biological product is dispensed to a patient in a clinic, community-based care facility, hospital or long term care facility, an entry made to the patient's medical record of the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, satisfies the communication requirements of subsection (2) of this section.

(5) Notwithstanding subsections (2) and (3) of this section, the pharmacy or pharmacist, or the pharmacist's designee, is not required to communicate to the prescribing practitioner the specific biological product dispensed to the patient if:

(a) The United States Food and Drug Administration has not approved an interchangeable biological product for the prescribed biological product;

(b) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is dispensing the same biological product that was dispensed the last time the pharmacy or pharmacist filled or refilled the patient's prescription; or

(c) The pharmacy or pharmacist is filling a prescription for a vaccine.

(6) The entries described in subsections (2) and (4) of this section or the communication described in subsection (3) of this section provides notice to the prescribing provider of the dispensation of a biological product to a patient.

[*(2)*] **(7)** The State Board of Pharmacy shall, on a website maintained by the board, maintain a link to the current list, if available, of biological products determined by the United States Food and Drug Administration to be interchangeable.

[*(3)(a)*] **(8)(a)** For purposes of this section, the board shall adopt by rule definitions for the terms "biological product" and "interchangeable."

(b) The rule defining the term "biological product" must be consistent with 42 U.S.C. 262(i)(1).

(c) The rule defining the term "interchangeable" must:

(A) For biological products licensed under the Public Health Service Act, define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

(B) For biological products approved by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

SECTION 6. ORS 689.522, as amended by section 5 of this 2022 Act, is amended to read:

689.522. (1) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biological product for the prescribed biological product unless:

(a) The substitute biological 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 in a manner reasonable under the circumstances; and

(d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

[*(2) Not later than five business days after the dispensing of a biological product, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, by making an entry into an electronic system that the prescribing practitioner can access electronically and that is:*]

[*(a) An interoperable electronic medical records system;*]

[*(b) An electronic prescribing technology;*]

[*(c) A pharmacy benefit management system; or*]

[*(d) A pharmacy record.*]

[*(3) If the pharmacy or pharmacist, or the pharmacist's designee, does not have access to an electronic system described in subsection (2) of this section, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate not later than five business days to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The communication may be by facsimile, electronic mail, telephone or another method.*]

[*(4) If the biological product is dispensed to a patient in a clinic, community-based care facility, hospital or long term care facility, an entry made to the patient's medical record of the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, satisfies the communication requirements of subsection (2) of this section.*]

[*(5) Notwithstanding subsections (2) and (3) of this section, the pharmacy or pharmacist, or the pharmacist's designee, is not required to communicate to the prescribing practitioner the specific biological product dispensed to the patient if:*]

[*(a) The United States Food and Drug Administration has not approved an interchangeable biological product for the prescribed biological product;*]

[*(b) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is dispensing the same biological product that was dispensed the last time the pharmacy or pharmacist filled or refilled the patient's prescription; or*]

[*(c) The pharmacy or pharmacist is filling a prescription for a vaccine.*]

[*(6) The entries described in subsections (2) and (4) of this section or the communication described in subsection (3) of this section provides notice to the prescribing provider of the dispensation of a biological product to a patient.*]

[*(7)*] **(2)** The State Board of Pharmacy shall, on a website maintained by the board, maintain a link to the current list, if available, of biological products determined by the United States Food and Drug Administration to be interchangeable.

[*(8)(a)*] **(3)(a)** For purposes of this section, the board shall adopt by rule definitions for the terms "biological product" and "interchangeable."

(b) The rule defining the term "biological product" must be consistent with 42 U.S.C. 262(i)(1).

(c) The rule defining the term "interchangeable" must:

(A) For biological products licensed under the Public Health Service Act, define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

(B) For biological products approved by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

SECTION 7. The amendments to ORS 689.522 by section 5 of this 2022 Act apply to prescriptions filled on and after the effective date of this 2022 Act.

SECTION 8. The amendments to ORS 689.522 by section 6 of this 2022 Act become operative on January 1, 2026.

REPRODUCTIVE HEALTH AND FAMILY PLANNING SERVICES

SECTION 9. Section 10 of this 2022 Act is added to and made a part of ORS 435.205 to 435.235.

SECTION 10. (1) The Oregon Health Authority may, subject to available funds, implement reproductive health services and education programs and provide funding for reproductive health services and education in this state.

(2) In order to receive state or federal funding or reimbursement from the authority for the provision of reproductive health services, a health care provider must be certified by the authority pursuant to rules adopted under subsection (3) of this section.

(3) The authority may adopt rules necessary to carry out this section, including but not limited to rules to:

(a) Establish the programs described in subsection (1) of this section;

(b) Establish a health care provider certification process; and

(c) Adopt fees.

SECTION 11. ORS 435.205 is amended to read:

435.205. (1) The Oregon Health Authority and every local health department shall offer family planning and birth control services within the limits of available funds. Both agencies jointly may offer [*such*] **the** services **described in this subsection**. The Director of the Oregon Health Authority or a designee shall initiate and conduct discussions of family planning with each person who might have an interest in and benefit from [*such service*] **the services**. The authority shall furnish consultation and assistance to local health departments.

(2) Family planning and birth control services may include**, but are not limited to:**

(a) Interviews with trained personnel;

(b) Distribution of literature;

(c) Referral to a [*licensed*] physician **licensed under ORS chapter 677**, physician assistant licensed under ORS 677.505 to 677.525, naturopathic physician licensed under ORS chapter 685 or

nurse practitioner licensed under ORS 678.375 to 678.390 for consultation, examination, medical treatment and prescription; and[,]

(d) To the extent so prescribed, the distribution of rhythm charts, the initial supply of a drug or other medical preparation, contraceptive devices and similar products.

(3) Any literature, charts or other family planning and birth control information offered under this section in counties in which a significant segment of the population does not speak English [*shall*] **must** be made available in the appropriate [*foreign*] language for that segment of the population.

(4) In carrying out its duties under this section, and with the consent of the local public health authority as defined in ORS 431.003, the local health department may adopt a fee schedule for services provided by the local health department. The fees shall be reasonably calculated not to exceed costs of services provided and may be adjusted on a sliding scale reflecting ability to pay.

(5) The local health department shall collect fees according to the schedule adopted under subsection (4) of this section. [*Such*] **Moneys from** fees **collected** may be used to meet the expenses of providing the services authorized by this section.

SECTION 12. ORS 743A.067 is amended to read:

743A.067. (1) As used in this section:

(a) "Contraceptives" means health care services, drugs, devices, products or medical procedures to prevent a pregnancy.

(b) "Enrollee" means an insured individual and the individual's spouse, domestic partner and dependents who are beneficiaries under the insured individual's health benefit plan.

(c) "Health benefit plan" has the meaning given that term in ORS 743B.005, excluding Medicare Advantage Plans and including health benefit plans offering pharmacy benefits administered by a third party administrator or pharmacy benefit manager.

(d) "Prior authorization" has the meaning given that term in ORS 743B.001.

(e) "Religious employer" has the meaning given that term in ORS 743A.066.

(f) "Utilization review" has the meaning given that term in ORS 743B.001.

(2) A health benefit plan offered in this state must provide coverage for all of the following services, drugs, devices, products and procedures:

(a) Well-woman care prescribed by the Department of Consumer and Business Services by rule consistent with guidelines published by the United States Health Resources and Services Administration.

(b) Counseling for sexually transmitted infections, including but not limited to human immunodeficiency virus and acquired immune deficiency syndrome.

(c) Screening for:

(A) Chlamydia;

(B) Gonorrhea;

(C) Hepatitis B;

(D) Hepatitis C;

(E) Human immunodeficiency virus and acquired immune deficiency syndrome;

(F) Human papillomavirus;

(G) Syphilis;

(H) Anemia;

(I) Urinary tract infection;

(J) Pregnancy;

(K) Rh incompatibility;

(L) Gestational diabetes;

(M) Osteoporosis;

(N) Breast cancer; and

(O) Cervical cancer.

(d) Screening to determine whether counseling related to the BRCA1 or BRCA2 genetic mutations is indicated and counseling related to the BRCA1 or BRCA2 genetic mutations if indicated.

(e) Screening and appropriate counseling or interventions for:

(A) Tobacco use; and

(B) Domestic and interpersonal violence.

(f) Folic acid supplements.

(g) Abortion.

(h) Breastfeeding comprehensive support, counseling and supplies.

(i) Breast cancer chemoprevention counseling.

(j) Any contraceptive drug, device or product approved by the United States Food and Drug Administration, subject to all of the following:

(A) If there is a therapeutic equivalent of a contraceptive drug, device or product approved by the United States Food and Drug Administration, a health benefit plan may provide coverage for either the requested contraceptive drug, device or product or for one or more therapeutic equivalents of the requested drug, device or product.

(B) If a contraceptive drug, device or product covered by the health benefit plan is deemed medically inadvisable by the enrollee's provider, the health benefit plan must cover an alternative contraceptive drug, device or product prescribed by the provider.

(C) A health benefit plan must pay pharmacy claims for reimbursement of all contraceptive drugs available for over-the-counter sale that are approved by the United States Food and Drug Administration.

(D) A health benefit plan may not infringe upon an enrollee's choice of contraceptive drug, device or product and may not require prior authorization, step therapy or other utilization review techniques for medically appropriate covered contraceptive drugs, devices or other products approved by the United States Food and Drug Administration.

(k) Voluntary sterilization.

(L) As a single claim or combined with other claims for covered services provided on the same day:

(A) Patient education and counseling on contraception and sterilization.

(B) Services related to sterilization or the administration and monitoring of contraceptive drugs, devices and products, including but not limited to:

(i) Management of side effects;

(ii) Counseling for continued adherence to a prescribed regimen;

(iii) Device insertion and removal; and

(iv) Provision of alternative contraceptive drugs, devices or products deemed medically appropriate in the judgment of the enrollee's provider.

(m) Any additional preventive services for women that must be covered without cost sharing under 42 U.S.C. 300gg-13, as identified by the United States Preventive Services Task Force or the Health Resources and Services Administration of the United States Department of Health and Human Services as of January 1, 2017.

(3) A health benefit plan may not impose on an enrollee a deductible, coinsurance, copayment or any other cost-sharing requirement on the coverage required by this section. A health care provider shall be reimbursed for providing the services described in this section without any deduction for coinsurance, copayments or any other cost-sharing amounts.

(4) Except as authorized under this section, a health benefit plan may not impose any restrictions or delays on the coverage required by this section.

(5) This section does not exclude coverage for contraceptive drugs, devices or products prescribed by a provider, acting within the provider's scope of practice, for:

(a) Reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause; or

(b) Contraception that is necessary to preserve the life or health of an enrollee.

(6) This section does not limit the authority of the Department of Consumer and Business Services to ensure compliance with ORS 743A.063 and 743A.066.

(7) This section does not require a health benefit plan to cover:

(a) Experimental or investigational treatments;

(b) Clinical trials or demonstration projects, except as provided in ORS 743A.192;

(c) Treatments that do not conform to acceptable and customary standards of medical practice;

(d) Treatments for which there is insufficient data to determine efficacy; or

(e) Abortion if the insurer offering the health benefit plan excluded coverage for abortion in all of its individual, small employer and large employer group plans during the 2017 plan year.

(8) If services, drugs, devices, products or procedures required by this section are provided by an out-of-network provider, the health benefit plan must cover the services, drugs, devices, products or procedures without imposing any cost-sharing requirement on the enrollee if:

(a) There is no in-network provider to furnish the service, drug, device, product or procedure that is geographically accessible or accessible in a reasonable amount of time, as defined by the Department of Consumer and Business Services by rule consistent with the requirements for provider networks in ORS 743B.505; or

(b) An in-network provider is unable or unwilling to provide the service in a timely manner.

(9) An insurer may offer to a religious employer a health benefit plan that does not include coverage for contraceptives or abortion procedures that are contrary to the religious employer's religious tenets only if the insurer notifies in writing all employees who may be enrolled in the health benefit plan of the contraceptives and procedures the employer refuses to cover for religious reasons.

(10) If the Department of Consumer and Business Services concludes that enforcement of this section may adversely affect the allocation of federal funds to this state, the department may grant an exemption to the requirements but only to the minimum extent necessary to ensure the continued receipt of federal funds.

(11) An insurer that is subject to this section shall make readily accessible to enrollees and potential enrollees, in a consumer-friendly format, information about the coverage of contraceptives by each health benefit plan and the coverage of other services, drugs, devices, products and procedures described in this section. The insurer must provide the information:

(a) On the insurer's website; and

(b) In writing upon request by an enrollee or potential enrollee.

(12) This section does not prohibit an insurer from using reasonable medical management techniques to determine the frequency, method, treatment or setting for the coverage of services, drugs, devices, products and procedures described in subsection (2) of this section, other than coverage required by subsection (2)(g) and (j) of this section, if the techniques:

(a) Are consistent with the coverage requirements of subsection (2) of this section; and

(b) Do not result in the wholesale or indiscriminate denial of coverage for a service.

(13) This section is exempt from ORS 743A.001.

TELEMEDICINE

SECTION 13. Section 14 of this 2022 Act is added to and made a part of ORS chapter 677.

SECTION 14. (1) As used in this section, "telemedicine" means 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.

(2) A physician licensed under ORS 677.100 to 677.228, a physician assistant licensed under ORS 677.505 to 677.525 or a physician or physician assistant licensed under ORS 677.139 may use telemedicine to provide health care services, including the establishment of a patient-

provider relationship, the diagnosis or treatment of a medical condition or the prescription of drugs, to a patient physically located in this state. The physician or physician assistant is not required to be physically located in this state when providing health care services through telemedicine.

SECTION 15. ORS 442.015 is amended to read:

442.015. As used in ORS chapter 441 and this chapter, unless the context requires otherwise:

(1) "Acquire" or "acquisition" means obtaining equipment, supplies, components or facilities by any means, including purchase, capital or operating lease, rental or donation, for the purpose of using such equipment, supplies, components or facilities to provide health services in Oregon. When equipment or other materials are obtained outside of this state, acquisition is considered to occur when the equipment or other materials begin to be used in Oregon for the provision of health services or when such services are offered for use in Oregon.

(2) "Affected persons" has the same meaning as given to "party" in ORS 183.310.

(3)(a) "Ambulatory surgical center" means a facility or portion of a facility that operates exclusively for the purpose of providing surgical services to patients who do not require hospitalization and for whom the expected duration of services does not exceed 24 hours following admission.

(b) "Ambulatory surgical center" does not mean:

(A) Individual or group practice offices of private physicians or dentists that do not contain a distinct area used for outpatient surgical treatment on a regular and organized basis, or that only provide surgery routinely provided in a physician's or dentist's office using local anesthesia or conscious sedation; or

(B) A portion of a licensed hospital designated for outpatient surgical treatment.

(4) "Delegated credentialing agreement" means a written agreement between an originating-site hospital and a distant-site hospital that provides that the medical staff of the originating-site hospital will rely upon the credentialing and privileging decisions of the distant-site hospital in making recommendations to the governing body of the originating-site hospital as to whether to credential a telemedicine provider, practicing at the distant-site hospital either as an employee or under contract, to provide telemedicine services to patients in the originating-site hospital.

(5) "Develop" means to undertake those activities that on their completion will result in the offer of a new institutional health service or the incurring of a financial obligation, as defined under applicable state law, in relation to the offering of such a health service.

(6) "Distant-site hospital" means the hospital where a telemedicine provider, at the time the telemedicine provider is providing telemedicine services, is practicing as an employee or under contract.

(7) "Expenditure" or "capital expenditure" means the actual expenditure, an obligation to an expenditure, lease or similar arrangement in lieu of an expenditure, and the reasonable value of a donation or grant in lieu of an expenditure but not including any interest thereon.

(8) "Extended stay center" means a facility licensed in accordance with ORS 441.026.

(9) "Freestanding birthing center" means a facility licensed for the primary purpose of performing low risk deliveries.

(10) "Governmental unit" means the state, or any county, municipality or other political subdivision, or any related department, division, board or other agency.

(11) "Gross revenue" means the sum of daily hospital service charges, ambulatory service charges, ancillary service charges and other operating revenue. "Gross revenue" does not include contributions, donations, legacies or bequests made to a hospital without restriction by the donors.

(12)(a) "Health care facility" means:

(A) A hospital;

(B) A long term care facility;

(C) An ambulatory surgical center;

(D) A freestanding birthing center;

(E) An outpatient renal dialysis facility; or

(F) An extended stay center.

(b) "Health care facility" does not mean:

(A) A residential facility licensed by the Department of Human Services or the Oregon Health Authority under ORS 443.415;

(B) An establishment furnishing primarily domiciliary care as described in ORS 443.205;

(C) A residential facility licensed or approved under the rules of the Department of Corrections;

(D) Facilities established by ORS 430.335 for treatment of substance abuse disorders; or

(E) Community mental health programs or community developmental disabilities programs established under ORS 430.620.

(13) "Health maintenance organization" or "HMO" means a public organization or a private organization organized under the laws of any state that:

(a) Is a qualified HMO under section 1310(d) of the U.S. Public Health Services Act; or

(b)(A) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services:

(i) Usual physician services;

(ii) Hospitalization;

(iii) Laboratory;

(iv) X-ray;

(v) Emergency and preventive services; and

(vi) Out-of-area coverage;

(B) Is compensated, except for copayments, for the provision of the basic health care services listed in subparagraph (A) of this paragraph to enrolled participants on a predetermined periodic rate basis; and

(C) Provides physicians' services primarily directly through physicians who are either employees or partners of such organization, or through arrangements with individual physicians or one or more groups of physicians organized on a group practice or individual practice basis.

(14) "Health services" means clinically related diagnostic, treatment or rehabilitative services, and includes alcohol, drug or controlled substance abuse and mental health services that may be provided either directly or indirectly on an inpatient or ambulatory patient basis.

(15) "Hospital" means:

(a) A facility with an organized medical staff and a permanent building that is capable of providing 24-hour inpatient care to two or more individuals who have an illness or injury and that provides at least the following health services:

(A) Medical;

(B) Nursing;

(C) Laboratory;

(D) Pharmacy; and

(E) Dietary; or

(b) A special inpatient care facility as that term is defined by the authority by rule.

(16) "Institutional health services" means health services provided in or through health care facilities and the entities in or through which such services are provided.

(17) "Intermediate care facility" means a facility that provides, on a regular basis, health-related care and services to individuals who do not require the degree of care and treatment that a hospital or skilled nursing facility is designed to provide, but who because of their mental or physical condition require care and services above the level of room and board that can be made available to them only through institutional facilities.

(18)(a) "Long term care facility" means a permanent facility with inpatient beds, providing:

(A) Medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the Director of Human Services; and

(B) Treatment for two or more unrelated patients.

(b) "Long term care facility" includes skilled nursing facilities and intermediate care facilities but does not include facilities licensed and operated pursuant to ORS 443.400 to 443.455.

(19) "New hospital" means:

(a) A facility that did not offer hospital services on a regular basis within its service area within the prior 12-month period and is initiating or proposing to initiate such services; or

(b) Any replacement of an existing hospital that involves a substantial increase or change in the services offered.

(20) "New skilled nursing or intermediate care service or facility" means a service or facility that did not offer long term care services on a regular basis by or through the facility within the prior 12-month period and is initiating or proposing to initiate such services. "New skilled nursing or intermediate care service or facility" also includes the rebuilding of a long term care facility, the relocation of buildings that are a part of a long term care facility, the relocation of long term care beds from one facility to another or an increase in the number of beds of more than 10 or 10 percent of the bed capacity, whichever is the lesser, within a two-year period.

(21) "Offer" means that the health care facility holds itself out as capable of providing, or as having the means for the provision of, specified health services.

(22) "Originating-site hospital" means a hospital in which a patient is located while receiving telemedicine services.

(23) "Outpatient renal dialysis facility" means a facility that provides renal dialysis services directly to outpatients.

(24) "Person" means an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), a state, or a political subdivision or instrumentality, including a municipal corporation, of a state.

(25) "Skilled nursing facility" means a facility or a distinct part of a facility, that is primarily engaged in providing to inpatients skilled nursing care and related services for patients who require medical or nursing care, or an institution that provides rehabilitation services for the rehabilitation of individuals who are injured or sick or who have disabilities.

(26) "Telemedicine" means the provision of health services to patients by physicians and health care practitioners from a distance using electronic communications**, including synchronous technologies to facilitate an exchange of information between a patient and physician or health care practitioner in real time or asynchronous technologies to facilitate an exchange of information between a patient and a physician or health care practitioner in other than real time**.

SECTION 16. ORS 677.135 is amended to read:

677.135. As used in ORS 677.135 to 677.141, "the practice of medicine across state lines" means:

(1) The rendering directly to a person of a written or otherwise documented medical opinion concerning the diagnosis or treatment of that person located within this state for the purpose of patient care by a physician or physician assistant located outside this state as a result of the transmission of individual patient data by [*electronic or other means*] **telemedicine, as defined in section 14 of this 2022 Act,** from within this state to that physician, the physician's agent or a physician assistant; or

(2) The rendering of medical treatment directly to a person located within this state by a physician or a physician assistant located outside this state as a result of the outward transmission of individual patient data by [*electronic or other means*] **telemedicine** from within this state to that physician, the physician's agent or a physician assistant.

TELEPHARMACY

SECTION 17. Section 18 of this 2022 Act is added to and made a part of ORS chapter 689.

SECTION 18. (1) A pharmacist, pharmacy technician or intern, or an individual similarly licensed or otherwise authorized by another state, who is contracted or employed by a pharmacy may access the pharmacy's electronic database regardless of whether the pharmacist, pharmacy technician or intern or other individual described in this subsection is physically located inside the pharmacy if:

(a) The pharmacy has established standards and controls to protect the confidentiality and integrity of any patient information contained in the electronic database when the electronic database is accessed from inside the pharmacy or remotely; and

(b) No information from the electronic database is duplicated, downloaded or removed from the electronic database when the electronic database is accessed remotely.

(2) The State Board of Pharmacy may adopt rules to carry out this section. In adopting rules under this subsection, the board may not establish standards for the remote access of a pharmacy's electronic database that are more restrictive than standards for accessing the electronic database from inside the pharmacy. This subsection may not be construed to limit the authority of the board to adopt rules to require compliance with any applicable federal law.

SECTION 19. ORS 689.700 is amended to read:

689.700. (1) As used in this section, "telepharmacy" means the delivery of pharmacy services by a pharmacist, through the use of a variety of electronic and telecommunications technologies, to a patient at a remote location staffed by a pharmacy technician.

(2) The pharmacy services for which a pharmacist may use telepharmacy include the supervision of the dispensation of prescription drugs to a patient.

(3) The remote location at which a patient receives pharmacy services through the use of telepharmacy must be affiliated with the pharmacy where the pharmacist providing the pharmacy services through telepharmacy regularly engages in the practice of pharmacy.

(4)**(a)** The State Board of Pharmacy shall adopt rules to carry out this section. The rules adopted under this section must include rules:

[*(a)*] **(A)** Regarding remote supervision of a pharmacy technician in order to facilitate the use of telepharmacy; and

[*(b)*] **(B)** Describing the pharmacy services that a pharmacist may provide through telepharmacy.

(b) In adopting rules under this section, 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. This paragraph may not be construed to limit the authority of the board to adopt rules to require compliance with any applicable federal law.

SCHOOL-BASED HEALTH SERVICES

SECTION 20. Section 1, chapter 619, Oregon Laws 2021, is amended to read:

Sec. 1. (1) As used in this section:

(a) "School-based health center" has the meaning given that term in ORS 413.225.

(b) "School nurse model" means a model for providing school-based health services that is in accord with guidance from the division of the Oregon Health Authority that addresses adolescent health.

(2) The authority, in consultation with the Department of Education, shall select **up to** 10 school districts or education service districts to receive planning grants for district planning and technical assistance. Each district receiving a grant, beginning on or after July 1, 2021, and concluding before July 1, 2023, shall:

(a) Evaluate the need for school-based health services in their respective communities; and

(b) Develop a school-based health services plan that addresses the need identified in paragraph (a) of this subsection.

(3) The authority shall contract with a nonprofit organization with experience in facilitating school health planning initiatives and supporting school-based health centers to facilitate and oversee the planning process and to provide technical assistance to grantees to reduce costs and ensure better coordination and continuity statewide. To the greatest extent practicable, the nonprofit organization shall engage with culturally specific organizations, in the grantees' communities, that

have experience providing culturally and linguistically specific services in schools or after-school programs.

(4) Each grantee shall solicit community participation in the planning process, including the participation of the local public health authority, any federally qualified health centers located in the district, a regional health equity coalition, if any, serving the district and every coordinated care organization with members residing in the district.

(5) At the conclusion of the two-year planning process each grantee shall receive funding to operate a school-based health center or school nurse model in each respective grantee school district or education service district.

SECTION 21. Section 2, chapter 619, Oregon Laws 2021, is amended to read:

Sec. 2. (1) As used in this section, "mobile school-linked health center" means a mobile medical van that:

(a) Provides primary care services, and may provide other services, to children on or near school grounds by licensed or certified health care providers; and

(b) Is sponsored by a school district or an [*educational*] **education** service district.

(2) The Oregon Health Authority shall develop grant requirements and ongoing operations criteria for mobile school-linked health centers and may award up to [*three*] **four** grants to school districts or education service districts for planning, technical assistance and operations to implement a mobile school-linked health center.

(3) A mobile school-linked health center operated using grants provided under this section shall comply with the billing, electronic medical records and data reporting requirements established for grantees under section 1 (5), chapter 601, Oregon Laws 2019, but is not subject to the school-based certification requirements or funding formulas established for school-based health centers under ORS 413.225.

SECTION 22. Section 5, chapter 619, Oregon Laws 2021, is amended to read:

Sec. 5. There is appropriated to the Oregon Health Authority, for the biennium beginning July 1, 2021, out of the General Fund, the amount of $2,555,000 to be used as follows:

[*(1) $995,000 for grants to school districts or education service districts and for technical assistance under section 1 of this 2021 Act.*]

[*(2) $285,000 for grants to school districts and education service districts under section 2 of this 2021 Act.*]

[*(3) $975,000 for grants and technical assistance to school-based health centers under section 3 of this 2021 Act.*]

(1) $2,255,000 to be used for the grants described in sections 1 to 3, chapter 619, Oregon Laws 2021.

[*(4)*] **(2)** $300,000 for the costs of the authority in carrying out sections 1 to 3 [*of this 2021 Act*]**, chapter 619, Oregon Laws 2021**.

PHARMACY

SECTION 23. Section 24 of this 2022 Act is added to and made a part of ORS chapter 689.

SECTION 24. (1) As used in this section, "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.

(2) A pharmacist may delegate, and a pharmacy technician may perform under the supervision of the pharmacist, final verification. In delegating final verification under this section, a pharmacist shall use the pharmacist's reasonable professional judgment and shall ensure that the final verification does not require the exercise of discretion by the pharmacy technician.

(3) The State Board of Pharmacy may adopt rules to carry out this section. In adopting rules under this section, the board may not impose standards or requirements stricter than those specified in this section.

SECTION 25. ORS 689.005 is amended to read:

689.005. As used in this chapter:

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(a) A practitioner or the practitioner's authorized agent; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Approved continuing pharmacy education program" means those seminars, classes, meetings, workshops and other educational programs on the subject of pharmacy approved by the board.

(3) "Board of pharmacy" or "board" means the State Board of Pharmacy.

(4) "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, physician or naturopathic physician.

(5) "Continuing pharmacy education" means:

(a) Professional, pharmaceutical post-graduate education in the general areas of socio-economic and legal aspects of health care;

(b) The properties and actions of drugs and dosage forms; and

(c) The etiology, characteristics and therapeutics of the disease state.

(6) "Continuing pharmacy education unit" means the unit of measurement of credits for approved continuing education courses and programs.

(7) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device other than by administration from one person to another, whether or not for a consideration.

(8) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

(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.

(10) "Distribute" means the delivery of a drug other than by administering or dispensing.

(11) "Drug" means:

(a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendium or any supplement to any of them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in a human or other animal;

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and

(d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subsection.

(12) "Drug order" means a written order, in a hospital or other inpatient care facility, for an ultimate user of any drug or device issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, that is immediately reduced to writing by a pharmacist, licensed nurse or other practitioner.

(13) "Drug outlet" means a pharmacy, nursing home, shelter home, convalescent home, extended care facility, drug abuse treatment center, penal institution, hospital, family planning clinic, student health center, retail store, wholesaler, manufacturer, mail-order vendor or other establishment with facilities located within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state.

(14) “Drug room” means a secure and lockable location within an inpatient care facility that does not have a licensed pharmacy.

(15) “Electronically transmitted” or “electronic transmission” means a communication sent or received through technological apparatuses, including computer terminals or other equipment or mechanisms linked by telephone or microwave relays, or similar apparatus having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities.

(16) “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.

(17) “Institutional drug outlet” means hospitals and inpatient care facilities where medications are dispensed to another health care professional for administration to patients served by the hospitals or facilities.

(18) “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.

(19) “Internship” means a professional experiential program approved by the board under the supervision of a licensed pharmacist registered with the board as a preceptor.

(20) “Itinerant vendor” means a person who sells or distributes nonprescription drugs by passing from house to house, or by haranguing the people on the public streets or in public places, or who uses the customary devices for attracting crowds, recommending their wares and offering them for sale.

(21) “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 nonprescription drug or commercially packaged legend drug or device.

(22) “Manufacture” means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for their own use or the preparation, compounding, packaging or labeling of a drug:

(a) By a practitioner as an incident to administering or dispensing of a drug in the course of professional practice; or

(b) By a practitioner or by the practitioner’s authorization under supervision of the practitioner for the purpose of or as an incident to research, teaching or chemical analysis and not for sale.

(23) “Manufacturer” means a person engaged in the manufacture of drugs.

(24) “Nonprescription drug outlet” means shopkeepers and itinerant vendors registered under ORS 689.305.

(25) “Nonprescription drugs” means drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government.

(26) “Person” means an individual, corporation, partnership, association or other legal entity.

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

(28) “Pharmacy” means a place that meets the requirements of rules of the board, is licensed and approved by the board where the practice of pharmacy may lawfully occur and includes apothecaries, drug stores, dispensaries, hospital outpatient pharmacies, pharmacy departments and prescription laboratories but does not include a place used by a manufacturer or wholesaler.

(29) “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.

(30) “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.

(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[.]**; and**

(o) The delegation of tasks to other health care providers who are appropriately trained and authorized to perform the delegated tasks.

(32) "Practitioner" means a person licensed and operating within the scope of such license to prescribe, dispense, conduct research with respect to or administer drugs in the course of professional practice or research:

(a) In this state; or

(b) In another state or territory of the United States if the person does not reside in Oregon and is registered under the federal Controlled Substances Act.

(33) "Preceptor" means a pharmacist or a person licensed by the board to supervise the internship training of a licensed intern.

(34) "Prescription drug" or "legend drug" means a drug which is:

(a) Required by federal law, prior to being dispensed or delivered, to be labeled with either of the following statements:

(A) "Caution: Federal law prohibits dispensing without prescription"; or

(B) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; 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.

(35) "Prescription" or "prescription drug order" means a written, oral or electronically transmitted direction, given by a practitioner authorized to prescribe drugs, for the preparation and use

of a drug. When the context requires, "prescription" also means the drug prepared under such written, oral or electronically transmitted direction.

(36) "Retail drug outlet" means a place used for the conduct of the retail sale, administering or dispensing or compounding of drugs or chemicals or for the administering or dispensing of prescriptions and licensed by the board as a place where the practice of pharmacy may lawfully occur.

(37) "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. "Self-administered hormonal contraceptive" includes, but is not limited to, hormonal contraceptive patches and hormonal contraceptive pills.

(38) "Shopkeeper" means a business or other establishment, open to the general public, for the sale or nonprofit distribution of drugs.

(39) "Unit dose" means a sealed single-unit container so designed that the contents are administered to the patient as a single dose, direct from the container. Each unit dose container must bear a separate label, be labeled with the name and strength of the medication, the name of the manufacturer or distributor, an identifying lot number and, if applicable, the expiration date of the medication.

(40) "Wholesale drug outlet" means a person who imports, stores, distributes or sells for resale drugs, including legend drugs and nonprescription drugs.

SECTION 26. ORS 689.225 is amended to read:

689.225. (1) A person may not engage in the practice of pharmacy unless the person is licensed under this chapter. Nothing in this section prevents physicians, dentists, veterinarians or other practitioners of the healing arts who are licensed under the laws of this state from dispensing and administering prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law of this state.

(2) A person may not take, use or exhibit the title of pharmacist or the title of druggist or apothecary, or any other title or description of like import unless the person is licensed to practice pharmacy under this chapter.

(3) A pharmacist may not possess personally or store drugs other than in a licensed pharmacy except for those drugs legally prescribed for the personal use of the pharmacist or when the pharmacist possesses or stores the drugs in the usual course of business and within the pharmacist's scope of practice. An employee, agent or owner of any registered manufacturer, wholesaler or pharmacy may lawfully possess legend drugs if the person is acting in the usual course of the business or employment of the person.

(4) The State Board of Pharmacy shall adopt rules relating to the use of pharmacy technicians [*working under the supervision, direction and control of a pharmacist*]. For retail and institutional drug outlets, the board shall adopt rules [*which*] **that** include requirements for training, including provisions for appropriate on-the-job training, guidelines for adequate supervision, standards and appropriate ratios for the use of pharmacy technicians. Improper use of pharmacy technicians is subject to the reporting requirements of ORS 689.455.

(5) The mixing of intravenous admixtures by pharmacy technicians working under the supervision, direction and control of a pharmacist is authorized and does not constitute the practice of pharmacy by the pharmacy technicians.

(6) Any person who is found to have unlawfully engaged in the practice of pharmacy is guilty of a Class A misdemeanor.

CAPTIONS

SECTION 27. The unit captions used in this 2022 Act are provided only for the convenience of the reader and do not become part of the statutory law of this state or express any legislative intent in the enactment of this 2022 Act.

EFFECTIVE DATE

SECTION 28. This 2022 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2022 Act takes effect on its passage.

Passed by House March 2, 2022

.....
Timothy G. Sekerak, Chief Clerk of House

.....
Dan Rayfield, Speaker of House

Passed by Senate March 3, 2022

.....
Peter Courtney, President of Senate

Received by Governor:

.....M.,....., 2022

Approved:

.....M.,....., 2022

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M.,....., 2022

.....
Shemia Fagan, Secretary of State

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 may 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**3**) Compound sterile preparations; or

(~~5~~**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

81st OREGON LEGISLATIVE ASSEMBLY--2022 Regular Session

Enrolled
House Bill 4034

Introduced and printed pursuant to House Rule 12.00. Presession filed (at the request of House Interim Committee on Health Care for Representative Rachel Prusak)

CHAPTER .....

AN ACT

Relating to health care; creating new provisions; amending ORS 435.205, 442.015, 475.230, 677.135, 689.005, 689.225, 689.522, 689.700, 743A.067 and 807.750 and section 4, chapter 92, Oregon Laws 2021, and sections 1, 2 and 5, chapter 619, Oregon Laws 2021; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

PSEUDOEPHEDRINE

SECTION 1. ORS 475.230 is amended to read:

475.230. (1) As used in this section, **"intern,"** "pharmacist," "pharmacy" and "pharmacy technician" have the meanings given those terms in ORS 689.005.

(2) A pharmacist**, intern** or pharmacy technician may transfer a drug containing pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine without a prescription from a practitioner to a person who is 18 years of age or older and who provides to the pharmacist**, intern** or pharmacy technician the person's valid government-issued photo identification.

(3) Prior to the transfer of a drug described in subsection (2) of this section, a pharmacist**, intern** or pharmacy technician shall submit the following information to the electronic system described in subsection (6) of this section:

(a) The date and time of the transfer;

(b) The name, address and date of birth of the person to whom the transfer will be made;

(c) The form of government-issued photo identification and identification number of the person to whom the transfer will be made;

(d) The name of the government agency that issued the photo identification; and

(e) The name of the drug that will be transferred and the amount of pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine, specified in grams, to be transferred.

(4) If, after receiving the information submitted under subsection (3) of this section, the electronic system generates an alert to not proceed with the transfer, the pharmacist**, intern** or pharmacy technician may not transfer the drug described in subsection (2) of this section to the person, except as provided in subsection (6) of this section.

(5)(a) Upon transferring a drug described in subsection (2) of this section, the pharmacist**, intern** or pharmacy technician shall require the person to whom the drug is transferred to sign an electronic or written log that shows the date of the transfer, the name of the person to whom the

transfer is made and the amount transferred of pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine, specified in grams.

(b) The log described in this subsection must be retained at the pharmacy where the transfer was made for at least two years from the date of the transaction.

(c) A law enforcement agency may obtain information contained in a log described in this subsection through a lawfully issued subpoena accepted by the State Board of Pharmacy. The board shall accept a lawfully issued subpoena under this paragraph, and shall adopt rules to carry out this paragraph. The board may designate a third party vendor as the custodian of records, including of a log described in this subsection.

(6)(a) For purposes of tracking the transfer of drugs described in subsection (2) of this section, a pharmacy shall use an electronic system designed to prevent illegal transfer of drugs described in subsection (2) of this section. The electronic system must:

(A) Be capable of tracking transfers nationwide in real time;

(B) Be capable of generating an alert described in subsection (4) of this section;

(C) Allow a pharmacist to override an alert described in subsection (4) of this section if, in the discretion of the pharmacist, the transfer is necessary to protect the person to whom the transfer will be made from imminent bodily harm;

(D) Be able to communicate in real time with similar systems operated in other states and the District of Columbia, including with similar systems that contain information submitted by more than one state;

(E) For each transfer, allow for the recording of:

(i) The information described in subsection (3) of this section;

(ii) The number of packages of the drug transferred;

(iii) The total amount of pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine transferred, specified in grams;

(iv) The name of the drug transferred;

(v) Either the signature of the person to whom the drug is transferred or a unique number connecting the transfer transaction to an electronic or written log described in subsection (5) of this section; and

(vi) The name or initials of the pharmacist**, intern** or pharmacy technician who transferred the drug;

(F) Be free of charge to a pharmacy;

(G) Be accessible at no charge to law enforcement and to other authorized personnel, as determined by the board, through an online portal or at the pharmacy;

(H) Retain information submitted for at least two years from the date of transaction; and

(I) Be accompanied by training, 24-hour online support and a toll-free support telephone hotline.

(b) A pharmacist who uses the override function described in this subsection shall record in the electronic system the use of the override.

(7) A drug described in subsection (2) of this section must be:

(a) Transferred from behind a pharmacy counter; and

(b) Stored behind the pharmacy counter in an area that is closed to the public.

(8) A person, other than a pharmacy, may not receive more than 3.6 grams per transfer, or more than nine grams in a 30-day period, of pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine.

(9) This section does not apply to a drug that contains pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine when the drug is transferred pursuant to a prescription.

(10) In addition to rules adopted under subsection (5) of this section, the board may adopt other rules as necessary to carry out this section.

(11) Violation of this section, or a rule adopted pursuant to this section, is a Class A misdemeanor.

SECTION 2. ORS 807.750 is amended to read:

807.750. (1) As used in this section:

(a) "Driver license" means a license or permit issued by this state or any other jurisdiction as evidence of a grant of driving privileges.

(b) "Financial institution" has the meaning given that term in ORS 706.008.

(c) "Identification card" means the card issued under ORS 807.400 or a comparable provision in another state.

(d) "Personal information" means an individual's name, address, date of birth, photograph, fingerprint, biometric data, driver license number, identification card number or any other unique personal identifier or number.

(e) "Private entity" means any nongovernmental entity, such as a corporation, partnership, company or nonprofit organization, any other legal entity or any natural person.

(f) "Swipe" means the act of passing a driver license or identification card through a device that is capable of deciphering, in an electronically readable format, the information electronically encoded in a magnetic strip or bar code on the driver license or identification card.

(2) Except as provided in subsection (6) of this section, a private entity may not swipe an individual's driver license or identification card, except for the following purposes:

(a) To verify the authenticity of a driver license or identification card or to verify the identity of the individual if the individual pays for a good or service with a method other than cash, returns an item or requests a refund.

(b) To verify the individual's age when providing an age-restricted good or service to any person about whom there is any reasonable doubt of the person's having reached 21 years of age.

(c) To prevent fraud or other criminal activity if an individual returns an item or requests a refund and the private entity uses a fraud prevention service company or system.

(d) To transmit information to a check services company for the purpose of approving negotiable instruments, electronic funds transfers or similar methods of payment.

(e) To collect information about the individual for the purpose of processing an application for a deposit account or loan for the individual, if the private entity is a financial institution.

(f) To enable a pharmacist, pharmacy technician or intern, as those terms are defined in ORS 689.005, to submit information to the electronic system described in ORS 475.230 for the purpose of transferring a drug containing pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine without a prescription from a practitioner to a person who is 18 years of age or older.

(3) A private entity that swipes an individual's driver license or identification card under subsection (2)(a) or (b) of this section may not store, sell or share personal information collected from swiping the driver license or identification card.

(4) A private entity that swipes an individual's driver license or identification card under subsection (2)(c) or (d) of this section may store or share the following information collected from swiping an individual's driver license or identification card for the purpose of preventing fraud or other criminal activity against the private entity:

(a) Name;

(b) Address;

(c) Date of birth; and

(d) Driver license number or identification card number.

(5)(a) A person other than an entity regulated by the federal Fair Credit Reporting Act, 15 U.S.C. 1681 et seq., who receives personal information from a private entity under subsection (4) of this section may use the personal information received only to prevent fraud or other criminal activity against the private entity that provided the personal information.

(b) A person who is regulated by the federal Fair Credit Reporting Act and who receives personal information from a private entity under subsection (4) of this section may use or provide the personal information received only to effect, administer or enforce a transaction or prevent fraud or other criminal activity, if the person provides or receives personal information under contract from the private entity.

(6)(a) Subject to the provisions of this subsection, a private entity that is a commercial radio service provider that provides service nationally and that is subject to the Telephone Records and Privacy Protection Act of 2006 (18 U.S.C. 1039) may swipe an individual's driver license or identification card if the entity obtains permission from the individual to swipe the individual's driver license or identification card.

(b) The private entity may swipe the individual's driver license or identification card only for the purpose of establishing or maintaining a contract between the private entity and the individual. Information collected by swiping an individual's driver license or identification card for the establishment or maintenance of a contract shall be limited to the following information from the individual:

(A) Name;

(B) Address;

(C) Date of birth; and

(D) Driver license number or identification card number.

(c) If the individual does not want the private entity to swipe the individual's driver license or identification card, the private entity may manually collect the following information from the individual:

(A) Name;

(B) Address;

(C) Date of birth; and

(D) Driver license number or identification card number.

(d) The private entity may not withhold the provision of goods or services solely as a result of the individual requesting the collection of the following information from the individual through manual means:

(A) Name;

(B) Address;

(C) Date of birth; and

(D) Driver license number or identification card number.

(7) A governmental entity may swipe an individual's driver license or identification card only if:

(a) The individual knowingly makes the driver license or identification card available to the governmental entity;

(b) The governmental entity lawfully confiscates the driver license or identification card;

(c) The governmental entity is providing emergency assistance to the individual who is unconscious or otherwise unable to make the driver license or identification card available; or

(d) A court rule requires swiping of the driver license or identification card to facilitate accurate linking of court records pertaining to the individual.

(8) In addition to any other remedy provided by law, an individual may bring an action to recover actual damages or $1,000, whichever is greater, and to obtain equitable relief, if equitable relief is available, against an entity that swipes, stores, shares, sells or otherwise uses the individual's personal information in violation of this section. A court shall award a prevailing plaintiff reasonable costs and attorney fees. If a court finds that a violation of this section was willful or knowing, the court may increase the amount of the award to no more than three times the amount otherwise available.

(9) Any waiver of a provision of this section is contrary to public policy and is void and unenforceable.

SECTION 3. The amendments to ORS 807.750 by section 2 of this 2022 Act apply to conduct occurring on or after January 1, 2022.

COVID-19 DATA COLLECTION

SECTION 4. Section 4, chapter 92, Oregon Laws 2021, is amended to read:

Sec. 4. (1) Section 1 [*of this 2021 Act*]**, chapter 92, Oregon Laws 2021,** is repealed [*on June 30, 2022*] **one year after the date on which the state of emergency declared by the Governor on March 8, 2020, for the COVID-19 pandemic, and any extension of the state of emergency, is no longer in effect**.

(2) The amendments to ORS 433.008 by section 3 [*of this 2021 Act*]**, chapter 92, Oregon Laws 2021,** become operative on June 30, 2022.

BIOLOGICAL PRODUCTS

SECTION 5. ORS 689.522 is amended to read:

689.522. (1) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biological product for the prescribed biological product unless:

(a) The substitute biological 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 in a manner reasonable under the circumstances; and

(d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

(2) Not later than five business days after the dispensing of a biological product, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, by making an entry into an electronic system that the prescribing practitioner can access electronically and that is:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing technology;

(c) A pharmacy benefit management system; or

(d) A pharmacy record.

(3) If the pharmacy or pharmacist, or the pharmacist's designee, does not have access to an electronic system described in subsection (2) of this section, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate not later than five business days to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The communication may be by facsimile, electronic mail, telephone or another method.

(4) If the biological product is dispensed to a patient in a clinic, community-based care facility, hospital or long term care facility, an entry made to the patient's medical record of the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, satisfies the communication requirements of subsection (2) of this section.

(5) Notwithstanding subsections (2) and (3) of this section, the pharmacy or pharmacist, or the pharmacist's designee, is not required to communicate to the prescribing practitioner the specific biological product dispensed to the patient if:

(a) The United States Food and Drug Administration has not approved an interchangeable biological product for the prescribed biological product;

(b) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is dispensing the same biological product that was dispensed the last time the pharmacy or pharmacist filled or refilled the patient's prescription; or

(c) The pharmacy or pharmacist is filling a prescription for a vaccine.

(6) The entries described in subsections (2) and (4) of this section or the communication described in subsection (3) of this section provides notice to the prescribing provider of the dispensation of a biological product to a patient.

[*(2)*] **(7)** The State Board of Pharmacy shall, on a website maintained by the board, maintain a link to the current list, if available, of biological products determined by the United States Food and Drug Administration to be interchangeable.

[*(3)(a)*] **(8)(a)** For purposes of this section, the board shall adopt by rule definitions for the terms "biological product" and "interchangeable."

(b) The rule defining the term "biological product" must be consistent with 42 U.S.C. 262(i)(1).

(c) The rule defining the term "interchangeable" must:

(A) For biological products licensed under the Public Health Service Act, define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

(B) For biological products approved by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

SECTION 6. ORS 689.522, as amended by section 5 of this 2022 Act, is amended to read:

689.522. (1) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biological product for the prescribed biological product unless:

(a) The substitute biological 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 in a manner reasonable under the circumstances; and

(d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

[*(2) Not later than five business days after the dispensing of a biological product, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, by making an entry into an electronic system that the prescribing practitioner can access electronically and that is:*]

[*(a) An interoperable electronic medical records system;*]

[*(b) An electronic prescribing technology;*]

[*(c) A pharmacy benefit management system; or*]

[*(d) A pharmacy record.*]

[*(3) If the pharmacy or pharmacist, or the pharmacist's designee, does not have access to an electronic system described in subsection (2) of this section, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate not later than five business days to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The communication may be by facsimile, electronic mail, telephone or another method.*]

[*(4) If the biological product is dispensed to a patient in a clinic, community-based care facility, hospital or long term care facility, an entry made to the patient's medical record of the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, satisfies the communication requirements of subsection (2) of this section.*]

[*(5) Notwithstanding subsections (2) and (3) of this section, the pharmacy or pharmacist, or the pharmacist's designee, is not required to communicate to the prescribing practitioner the specific biological product dispensed to the patient if:*]

[*(a) The United States Food and Drug Administration has not approved an interchangeable biological product for the prescribed biological product;*]

[*(b) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is dispensing the same biological product that was dispensed the last time the pharmacy or pharmacist filled or refilled the patient's prescription; or*]

[*(c) The pharmacy or pharmacist is filling a prescription for a vaccine.*]

[*(6) The entries described in subsections (2) and (4) of this section or the communication described in subsection (3) of this section provides notice to the prescribing provider of the dispensation of a biological product to a patient.*]

[*(7)*] **(2)** The State Board of Pharmacy shall, on a website maintained by the board, maintain a link to the current list, if available, of biological products determined by the United States Food and Drug Administration to be interchangeable.

[*(8)(a)*] **(3)(a)** For purposes of this section, the board shall adopt by rule definitions for the terms "biological product" and "interchangeable."

(b) The rule defining the term "biological product" must be consistent with 42 U.S.C. 262(i)(1).

(c) The rule defining the term "interchangeable" must:

(A) For biological products licensed under the Public Health Service Act, define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

(B) For biological products approved by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

SECTION 7. The amendments to ORS 689.522 by section 5 of this 2022 Act apply to prescriptions filled on and after the effective date of this 2022 Act.

SECTION 8. The amendments to ORS 689.522 by section 6 of this 2022 Act become operative on January 1, 2026.

REPRODUCTIVE HEALTH AND FAMILY PLANNING SERVICES

SECTION 9. Section 10 of this 2022 Act is added to and made a part of ORS 435.205 to 435.235.

SECTION 10. (1) The Oregon Health Authority may, subject to available funds, implement reproductive health services and education programs and provide funding for reproductive health services and education in this state.

(2) In order to receive state or federal funding or reimbursement from the authority for the provision of reproductive health services, a health care provider must be certified by the authority pursuant to rules adopted under subsection (3) of this section.

(3) The authority may adopt rules necessary to carry out this section, including but not limited to rules to:

(a) Establish the programs described in subsection (1) of this section;

(b) Establish a health care provider certification process; and

(c) Adopt fees.

SECTION 11. ORS 435.205 is amended to read:

435.205. (1) The Oregon Health Authority and every local health department shall offer family planning and birth control services within the limits of available funds. Both agencies jointly may offer [*such*] **the** services **described in this subsection**. The Director of the Oregon Health Authority or a designee shall initiate and conduct discussions of family planning with each person who might have an interest in and benefit from [*such service*] **the services**. The authority shall furnish consultation and assistance to local health departments.

(2) Family planning and birth control services may include**, but are not limited to:**

(a) Interviews with trained personnel;

(b) Distribution of literature;

(c) Referral to a [*licensed*] physician **licensed under ORS chapter 677**, physician assistant licensed under ORS 677.505 to 677.525, naturopathic physician licensed under ORS chapter 685 or

nurse practitioner licensed under ORS 678.375 to 678.390 for consultation, examination, medical treatment and prescription; and[,]

(d) To the extent so prescribed, the distribution of rhythm charts, the initial supply of a drug or other medical preparation, contraceptive devices and similar products.

(3) Any literature, charts or other family planning and birth control information offered under this section in counties in which a significant segment of the population does not speak English [*shall*] **must** be made available in the appropriate [*foreign*] language for that segment of the population.

(4) In carrying out its duties under this section, and with the consent of the local public health authority as defined in ORS 431.003, the local health department may adopt a fee schedule for services provided by the local health department. The fees shall be reasonably calculated not to exceed costs of services provided and may be adjusted on a sliding scale reflecting ability to pay.

(5) The local health department shall collect fees according to the schedule adopted under subsection (4) of this section. [*Such*] **Moneys from** fees **collected** may be used to meet the expenses of providing the services authorized by this section.

SECTION 12. ORS 743A.067 is amended to read:

743A.067. (1) As used in this section:

(a) "Contraceptives" means health care services, drugs, devices, products or medical procedures to prevent a pregnancy.

(b) "Enrollee" means an insured individual and the individual's spouse, domestic partner and dependents who are beneficiaries under the insured individual's health benefit plan.

(c) "Health benefit plan" has the meaning given that term in ORS 743B.005, excluding Medicare Advantage Plans and including health benefit plans offering pharmacy benefits administered by a third party administrator or pharmacy benefit manager.

(d) "Prior authorization" has the meaning given that term in ORS 743B.001.

(e) "Religious employer" has the meaning given that term in ORS 743A.066.

(f) "Utilization review" has the meaning given that term in ORS 743B.001.

(2) A health benefit plan offered in this state must provide coverage for all of the following services, drugs, devices, products and procedures:

(a) Well-woman care prescribed by the Department of Consumer and Business Services by rule consistent with guidelines published by the United States Health Resources and Services Administration.

(b) Counseling for sexually transmitted infections, including but not limited to human immunodeficiency virus and acquired immune deficiency syndrome.

(c) Screening for:

(A) Chlamydia;

(B) Gonorrhea;

(C) Hepatitis B;

(D) Hepatitis C;

(E) Human immunodeficiency virus and acquired immune deficiency syndrome;

(F) Human papillomavirus;

(G) Syphilis;

(H) Anemia;

(I) Urinary tract infection;

(J) Pregnancy;

(K) Rh incompatibility;

(L) Gestational diabetes;

(M) Osteoporosis;

(N) Breast cancer; and

(O) Cervical cancer.

(d) Screening to determine whether counseling related to the BRCA1 or BRCA2 genetic mutations is indicated and counseling related to the BRCA1 or BRCA2 genetic mutations if indicated.

(e) Screening and appropriate counseling or interventions for:

(A) Tobacco use; and

(B) Domestic and interpersonal violence.

(f) Folic acid supplements.

(g) Abortion.

(h) Breastfeeding comprehensive support, counseling and supplies.

(i) Breast cancer chemoprevention counseling.

(j) Any contraceptive drug, device or product approved by the United States Food and Drug Administration, subject to all of the following:

(A) If there is a therapeutic equivalent of a contraceptive drug, device or product approved by the United States Food and Drug Administration, a health benefit plan may provide coverage for either the requested contraceptive drug, device or product or for one or more therapeutic equivalents of the requested drug, device or product.

(B) If a contraceptive drug, device or product covered by the health benefit plan is deemed medically inadvisable by the enrollee's provider, the health benefit plan must cover an alternative contraceptive drug, device or product prescribed by the provider.

(C) A health benefit plan must pay pharmacy claims for reimbursement of all contraceptive drugs available for over-the-counter sale that are approved by the United States Food and Drug Administration.

(D) A health benefit plan may not infringe upon an enrollee's choice of contraceptive drug, device or product and may not require prior authorization, step therapy or other utilization review techniques for medically appropriate covered contraceptive drugs, devices or other products approved by the United States Food and Drug Administration.

(k) Voluntary sterilization.

(L) As a single claim or combined with other claims for covered services provided on the same day:

(A) Patient education and counseling on contraception and sterilization.

(B) Services related to sterilization or the administration and monitoring of contraceptive drugs, devices and products, including but not limited to:

(i) Management of side effects;

(ii) Counseling for continued adherence to a prescribed regimen;

(iii) Device insertion and removal; and

(iv) Provision of alternative contraceptive drugs, devices or products deemed medically appropriate in the judgment of the enrollee's provider.

(m) Any additional preventive services for women that must be covered without cost sharing under 42 U.S.C. 300gg-13, as identified by the United States Preventive Services Task Force or the Health Resources and Services Administration of the United States Department of Health and Human Services as of January 1, 2017.

(3) A health benefit plan may not impose on an enrollee a deductible, coinsurance, copayment or any other cost-sharing requirement on the coverage required by this section. A health care provider shall be reimbursed for providing the services described in this section without any deduction for coinsurance, copayments or any other cost-sharing amounts.

(4) Except as authorized under this section, a health benefit plan may not impose any restrictions or delays on the coverage required by this section.

(5) This section does not exclude coverage for contraceptive drugs, devices or products prescribed by a provider, acting within the provider's scope of practice, for:

(a) Reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause; or

(b) Contraception that is necessary to preserve the life or health of an enrollee.

(6) This section does not limit the authority of the Department of Consumer and Business Services to ensure compliance with ORS 743A.063 and 743A.066.

(7) This section does not require a health benefit plan to cover:

(a) Experimental or investigational treatments;

(b) Clinical trials or demonstration projects, except as provided in ORS 743A.192;

(c) Treatments that do not conform to acceptable and customary standards of medical practice;

(d) Treatments for which there is insufficient data to determine efficacy; or

(e) Abortion if the insurer offering the health benefit plan excluded coverage for abortion in all of its individual, small employer and large employer group plans during the 2017 plan year.

(8) If services, drugs, devices, products or procedures required by this section are provided by an out-of-network provider, the health benefit plan must cover the services, drugs, devices, products or procedures without imposing any cost-sharing requirement on the enrollee if:

(a) There is no in-network provider to furnish the service, drug, device, product or procedure that is geographically accessible or accessible in a reasonable amount of time, as defined by the Department of Consumer and Business Services by rule consistent with the requirements for provider networks in ORS 743B.505; or

(b) An in-network provider is unable or unwilling to provide the service in a timely manner.

(9) An insurer may offer to a religious employer a health benefit plan that does not include coverage for contraceptives or abortion procedures that are contrary to the religious employer's religious tenets only if the insurer notifies in writing all employees who may be enrolled in the health benefit plan of the contraceptives and procedures the employer refuses to cover for religious reasons.

(10) If the Department of Consumer and Business Services concludes that enforcement of this section may adversely affect the allocation of federal funds to this state, the department may grant an exemption to the requirements but only to the minimum extent necessary to ensure the continued receipt of federal funds.

(11) An insurer that is subject to this section shall make readily accessible to enrollees and potential enrollees, in a consumer-friendly format, information about the coverage of contraceptives by each health benefit plan and the coverage of other services, drugs, devices, products and procedures described in this section. The insurer must provide the information:

(a) On the insurer's website; and

(b) In writing upon request by an enrollee or potential enrollee.

(12) This section does not prohibit an insurer from using reasonable medical management techniques to determine the frequency, method, treatment or setting for the coverage of services, drugs, devices, products and procedures described in subsection (2) of this section, other than coverage required by subsection (2)(g) and (j) of this section, if the techniques:

(a) Are consistent with the coverage requirements of subsection (2) of this section; and

(b) Do not result in the wholesale or indiscriminate denial of coverage for a service.

(13) This section is exempt from ORS 743A.001.

TELEMEDICINE

SECTION 13. Section 14 of this 2022 Act is added to and made a part of ORS chapter 677.

SECTION 14. (1) As used in this section, "telemedicine" means 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.

(2) A physician licensed under ORS 677.100 to 677.228, a physician assistant licensed under ORS 677.505 to 677.525 or a physician or physician assistant licensed under ORS 677.139 may use telemedicine to provide health care services, including the establishment of a patient-

provider relationship, the diagnosis or treatment of a medical condition or the prescription of drugs, to a patient physically located in this state. The physician or physician assistant is not required to be physically located in this state when providing health care services through telemedicine.

SECTION 15. ORS 442.015 is amended to read:

442.015. As used in ORS chapter 441 and this chapter, unless the context requires otherwise:

(1) "Acquire" or "acquisition" means obtaining equipment, supplies, components or facilities by any means, including purchase, capital or operating lease, rental or donation, for the purpose of using such equipment, supplies, components or facilities to provide health services in Oregon. When equipment or other materials are obtained outside of this state, acquisition is considered to occur when the equipment or other materials begin to be used in Oregon for the provision of health services or when such services are offered for use in Oregon.

(2) "Affected persons" has the same meaning as given to "party" in ORS 183.310.

(3)(a) "Ambulatory surgical center" means a facility or portion of a facility that operates exclusively for the purpose of providing surgical services to patients who do not require hospitalization and for whom the expected duration of services does not exceed 24 hours following admission.

(b) "Ambulatory surgical center" does not mean:

(A) Individual or group practice offices of private physicians or dentists that do not contain a distinct area used for outpatient surgical treatment on a regular and organized basis, or that only provide surgery routinely provided in a physician's or dentist's office using local anesthesia or conscious sedation; or

(B) A portion of a licensed hospital designated for outpatient surgical treatment.

(4) "Delegated credentialing agreement" means a written agreement between an originating-site hospital and a distant-site hospital that provides that the medical staff of the originating-site hospital will rely upon the credentialing and privileging decisions of the distant-site hospital in making recommendations to the governing body of the originating-site hospital as to whether to credential a telemedicine provider, practicing at the distant-site hospital either as an employee or under contract, to provide telemedicine services to patients in the originating-site hospital.

(5) "Develop" means to undertake those activities that on their completion will result in the offer of a new institutional health service or the incurring of a financial obligation, as defined under applicable state law, in relation to the offering of such a health service.

(6) "Distant-site hospital" means the hospital where a telemedicine provider, at the time the telemedicine provider is providing telemedicine services, is practicing as an employee or under contract.

(7) "Expenditure" or "capital expenditure" means the actual expenditure, an obligation to an expenditure, lease or similar arrangement in lieu of an expenditure, and the reasonable value of a donation or grant in lieu of an expenditure but not including any interest thereon.

(8) "Extended stay center" means a facility licensed in accordance with ORS 441.026.

(9) "Freestanding birthing center" means a facility licensed for the primary purpose of performing low risk deliveries.

(10) "Governmental unit" means the state, or any county, municipality or other political subdivision, or any related department, division, board or other agency.

(11) "Gross revenue" means the sum of daily hospital service charges, ambulatory service charges, ancillary service charges and other operating revenue. "Gross revenue" does not include contributions, donations, legacies or bequests made to a hospital without restriction by the donors.

(12)(a) "Health care facility" means:

(A) A hospital;

(B) A long term care facility;

(C) An ambulatory surgical center;

(D) A freestanding birthing center;

(E) An outpatient renal dialysis facility; or

(F) An extended stay center.

(b) "Health care facility" does not mean:

(A) A residential facility licensed by the Department of Human Services or the Oregon Health Authority under ORS 443.415;

(B) An establishment furnishing primarily domiciliary care as described in ORS 443.205;

(C) A residential facility licensed or approved under the rules of the Department of Corrections;

(D) Facilities established by ORS 430.335 for treatment of substance abuse disorders; or

(E) Community mental health programs or community developmental disabilities programs established under ORS 430.620.

(13) "Health maintenance organization" or "HMO" means a public organization or a private organization organized under the laws of any state that:

(a) Is a qualified HMO under section 1310(d) of the U.S. Public Health Services Act; or

(b)(A) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services:

(i) Usual physician services;

(ii) Hospitalization;

(iii) Laboratory;

(iv) X-ray;

(v) Emergency and preventive services; and

(vi) Out-of-area coverage;

(B) Is compensated, except for copayments, for the provision of the basic health care services listed in subparagraph (A) of this paragraph to enrolled participants on a predetermined periodic rate basis; and

(C) Provides physicians' services primarily directly through physicians who are either employees or partners of such organization, or through arrangements with individual physicians or one or more groups of physicians organized on a group practice or individual practice basis.

(14) "Health services" means clinically related diagnostic, treatment or rehabilitative services, and includes alcohol, drug or controlled substance abuse and mental health services that may be provided either directly or indirectly on an inpatient or ambulatory patient basis.

(15) "Hospital" means:

(a) A facility with an organized medical staff and a permanent building that is capable of providing 24-hour inpatient care to two or more individuals who have an illness or injury and that provides at least the following health services:

(A) Medical;

(B) Nursing;

(C) Laboratory;

(D) Pharmacy; and

(E) Dietary; or

(b) A special inpatient care facility as that term is defined by the authority by rule.

(16) "Institutional health services" means health services provided in or through health care facilities and the entities in or through which such services are provided.

(17) "Intermediate care facility" means a facility that provides, on a regular basis, health-related care and services to individuals who do not require the degree of care and treatment that a hospital or skilled nursing facility is designed to provide, but who because of their mental or physical condition require care and services above the level of room and board that can be made available to them only through institutional facilities.

(18)(a) "Long term care facility" means a permanent facility with inpatient beds, providing:

(A) Medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the Director of Human Services; and

(B) Treatment for two or more unrelated patients.

(b) "Long term care facility" includes skilled nursing facilities and intermediate care facilities but does not include facilities licensed and operated pursuant to ORS 443.400 to 443.455.

(19) "New hospital" means:

(a) A facility that did not offer hospital services on a regular basis within its service area within the prior 12-month period and is initiating or proposing to initiate such services; or

(b) Any replacement of an existing hospital that involves a substantial increase or change in the services offered.

(20) "New skilled nursing or intermediate care service or facility" means a service or facility that did not offer long term care services on a regular basis by or through the facility within the prior 12-month period and is initiating or proposing to initiate such services. "New skilled nursing or intermediate care service or facility" also includes the rebuilding of a long term care facility, the relocation of buildings that are a part of a long term care facility, the relocation of long term care beds from one facility to another or an increase in the number of beds of more than 10 or 10 percent of the bed capacity, whichever is the lesser, within a two-year period.

(21) "Offer" means that the health care facility holds itself out as capable of providing, or as having the means for the provision of, specified health services.

(22) "Originating-site hospital" means a hospital in which a patient is located while receiving telemedicine services.

(23) "Outpatient renal dialysis facility" means a facility that provides renal dialysis services directly to outpatients.

(24) "Person" means an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), a state, or a political subdivision or instrumentality, including a municipal corporation, of a state.

(25) "Skilled nursing facility" means a facility or a distinct part of a facility, that is primarily engaged in providing to inpatients skilled nursing care and related services for patients who require medical or nursing care, or an institution that provides rehabilitation services for the rehabilitation of individuals who are injured or sick or who have disabilities.

(26) "Telemedicine" means the provision of health services to patients by physicians and health care practitioners from a distance using electronic communications**, including synchronous technologies to facilitate an exchange of information between a patient and physician or health care practitioner in real time or asynchronous technologies to facilitate an exchange of information between a patient and a physician or health care practitioner in other than real time**.

SECTION 16. ORS 677.135 is amended to read:

677.135. As used in ORS 677.135 to 677.141, "the practice of medicine across state lines" means:

(1) The rendering directly to a person of a written or otherwise documented medical opinion concerning the diagnosis or treatment of that person located within this state for the purpose of patient care by a physician or physician assistant located outside this state as a result of the transmission of individual patient data by [*electronic or other means*] **telemedicine, as defined in section 14 of this 2022 Act,** from within this state to that physician, the physician's agent or a physician assistant; or

(2) The rendering of medical treatment directly to a person located within this state by a physician or a physician assistant located outside this state as a result of the outward transmission of individual patient data by [*electronic or other means*] **telemedicine** from within this state to that physician, the physician's agent or a physician assistant.

TELEPHARMACY

SECTION 17. Section 18 of this 2022 Act is added to and made a part of ORS chapter 689.

SECTION 18. (1) A pharmacist, pharmacy technician or intern, or an individual similarly licensed or otherwise authorized by another state, who is contracted or employed by a pharmacy may access the pharmacy's electronic database regardless of whether the pharmacist, pharmacy technician or intern or other individual described in this subsection is physically located inside the pharmacy if:

(a) The pharmacy has established standards and controls to protect the confidentiality and integrity of any patient information contained in the electronic database when the electronic database is accessed from inside the pharmacy or remotely; and

(b) No information from the electronic database is duplicated, downloaded or removed from the electronic database when the electronic database is accessed remotely.

(2) The State Board of Pharmacy may adopt rules to carry out this section. In adopting rules under this subsection, the board may not establish standards for the remote access of a pharmacy's electronic database that are more restrictive than standards for accessing the electronic database from inside the pharmacy. This subsection may not be construed to limit the authority of the board to adopt rules to require compliance with any applicable federal law.

SECTION 19. ORS 689.700 is amended to read:

689.700. (1) As used in this section, "telepharmacy" means the delivery of pharmacy services by a pharmacist, through the use of a variety of electronic and telecommunications technologies, to a patient at a remote location staffed by a pharmacy technician.

(2) The pharmacy services for which a pharmacist may use telepharmacy include the supervision of the dispensation of prescription drugs to a patient.

(3) The remote location at which a patient receives pharmacy services through the use of telepharmacy must be affiliated with the pharmacy where the pharmacist providing the pharmacy services through telepharmacy regularly engages in the practice of pharmacy.

(4)**(a)** The State Board of Pharmacy shall adopt rules to carry out this section. The rules adopted under this section must include rules:

[*(a)*] **(A)** Regarding remote supervision of a pharmacy technician in order to facilitate the use of telepharmacy; and

[*(b)*] **(B)** Describing the pharmacy services that a pharmacist may provide through telepharmacy.

(b) In adopting rules under this section, 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. This paragraph may not be construed to limit the authority of the board to adopt rules to require compliance with any applicable federal law.

SCHOOL-BASED HEALTH SERVICES

SECTION 20. Section 1, chapter 619, Oregon Laws 2021, is amended to read:

Sec. 1. (1) As used in this section:

(a) "School-based health center" has the meaning given that term in ORS 413.225.

(b) "School nurse model" means a model for providing school-based health services that is in accord with guidance from the division of the Oregon Health Authority that addresses adolescent health.

(2) The authority, in consultation with the Department of Education, shall select **up to** 10 school districts or education service districts to receive planning grants for district planning and technical assistance. Each district receiving a grant, beginning on or after July 1, 2021, and concluding before July 1, 2023, shall:

(a) Evaluate the need for school-based health services in their respective communities; and

(b) Develop a school-based health services plan that addresses the need identified in paragraph (a) of this subsection.

(3) The authority shall contract with a nonprofit organization with experience in facilitating school health planning initiatives and supporting school-based health centers to facilitate and oversee the planning process and to provide technical assistance to grantees to reduce costs and ensure better coordination and continuity statewide. To the greatest extent practicable, the nonprofit organization shall engage with culturally specific organizations, in the grantees' communities, that

have experience providing culturally and linguistically specific services in schools or after-school programs.

(4) Each grantee shall solicit community participation in the planning process, including the participation of the local public health authority, any federally qualified health centers located in the district, a regional health equity coalition, if any, serving the district and every coordinated care organization with members residing in the district.

(5) At the conclusion of the two-year planning process each grantee shall receive funding to operate a school-based health center or school nurse model in each respective grantee school district or education service district.

SECTION 21. Section 2, chapter 619, Oregon Laws 2021, is amended to read:

Sec. 2. (1) As used in this section, "mobile school-linked health center" means a mobile medical van that:

(a) Provides primary care services, and may provide other services, to children on or near school grounds by licensed or certified health care providers; and

(b) Is sponsored by a school district or an [*educational*] **education** service district.

(2) The Oregon Health Authority shall develop grant requirements and ongoing operations criteria for mobile school-linked health centers and may award up to [*three*] **four** grants to school districts or education service districts for planning, technical assistance and operations to implement a mobile school-linked health center.

(3) A mobile school-linked health center operated using grants provided under this section shall comply with the billing, electronic medical records and data reporting requirements established for grantees under section 1 (5), chapter 601, Oregon Laws 2019, but is not subject to the school-based certification requirements or funding formulas established for school-based health centers under ORS 413.225.

SECTION 22. Section 5, chapter 619, Oregon Laws 2021, is amended to read:

Sec. 5. There is appropriated to the Oregon Health Authority, for the biennium beginning July 1, 2021, out of the General Fund, the amount of $2,555,000 to be used as follows:

[*(1) $995,000 for grants to school districts or education service districts and for technical assistance under section 1 of this 2021 Act.*]

[*(2) $285,000 for grants to school districts and education service districts under section 2 of this 2021 Act.*]

[*(3) $975,000 for grants and technical assistance to school-based health centers under section 3 of this 2021 Act.*]

(1) $2,255,000 to be used for the grants described in sections 1 to 3, chapter 619, Oregon Laws 2021.

[*(4)*] **(2)** $300,000 for the costs of the authority in carrying out sections 1 to 3 [*of this 2021 Act*]**, chapter 619, Oregon Laws 2021**.

PHARMACY

SECTION 23. Section 24 of this 2022 Act is added to and made a part of ORS chapter 689.

SECTION 24. (1) As used in this section, "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.

(2) A pharmacist may delegate, and a pharmacy technician may perform under the supervision of the pharmacist, final verification. In delegating final verification under this section, a pharmacist shall use the pharmacist's reasonable professional judgment and shall ensure that the final verification does not require the exercise of discretion by the pharmacy technician.

(3) The State Board of Pharmacy may adopt rules to carry out this section. In adopting rules under this section, the board may not impose standards or requirements stricter than those specified in this section.

SECTION 25. ORS 689.005 is amended to read:

689.005. As used in this chapter:

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(a) A practitioner or the practitioner's authorized agent; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Approved continuing pharmacy education program" means those seminars, classes, meetings, workshops and other educational programs on the subject of pharmacy approved by the board.

(3) "Board of pharmacy" or "board" means the State Board of Pharmacy.

(4) "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, physician or naturopathic physician.

(5) "Continuing pharmacy education" means:

(a) Professional, pharmaceutical post-graduate education in the general areas of socio-economic and legal aspects of health care;

(b) The properties and actions of drugs and dosage forms; and

(c) The etiology, characteristics and therapeutics of the disease state.

(6) "Continuing pharmacy education unit" means the unit of measurement of credits for approved continuing education courses and programs.

(7) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device other than by administration from one person to another, whether or not for a consideration.

(8) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

(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.

(10) "Distribute" means the delivery of a drug other than by administering or dispensing.

(11) "Drug" means:

(a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendium or any supplement to any of them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in a human or other animal;

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and

(d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subsection.

(12) "Drug order" means a written order, in a hospital or other inpatient care facility, for an ultimate user of any drug or device issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, that is immediately reduced to writing by a pharmacist, licensed nurse or other practitioner.

(13) "Drug outlet" means a pharmacy, nursing home, shelter home, convalescent home, extended care facility, drug abuse treatment center, penal institution, hospital, family planning clinic, student health center, retail store, wholesaler, manufacturer, mail-order vendor or other establishment with facilities located within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state.

(14) “Drug room” means a secure and lockable location within an inpatient care facility that does not have a licensed pharmacy.

(15) “Electronically transmitted” or “electronic transmission” means a communication sent or received through technological apparatuses, including computer terminals or other equipment or mechanisms linked by telephone or microwave relays, or similar apparatus having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities.

(16) “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.

(17) “Institutional drug outlet” means hospitals and inpatient care facilities where medications are dispensed to another health care professional for administration to patients served by the hospitals or facilities.

(18) “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.

(19) “Internship” means a professional experiential program approved by the board under the supervision of a licensed pharmacist registered with the board as a preceptor.

(20) “Itinerant vendor” means a person who sells or distributes nonprescription drugs by passing from house to house, or by haranguing the people on the public streets or in public places, or who uses the customary devices for attracting crowds, recommending their wares and offering them for sale.

(21) “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 nonprescription drug or commercially packaged legend drug or device.

(22) “Manufacture” means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for their own use or the preparation, compounding, packaging or labeling of a drug:

(a) By a practitioner as an incident to administering or dispensing of a drug in the course of professional practice; or

(b) By a practitioner or by the practitioner’s authorization under supervision of the practitioner for the purpose of or as an incident to research, teaching or chemical analysis and not for sale.

(23) “Manufacturer” means a person engaged in the manufacture of drugs.

(24) “Nonprescription drug outlet” means shopkeepers and itinerant vendors registered under ORS 689.305.

(25) “Nonprescription drugs” means drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government.

(26) “Person” means an individual, corporation, partnership, association or other legal entity.

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

(28) “Pharmacy” means a place that meets the requirements of rules of the board, is licensed and approved by the board where the practice of pharmacy may lawfully occur and includes apothecaries, drug stores, dispensaries, hospital outpatient pharmacies, pharmacy departments and prescription laboratories but does not include a place used by a manufacturer or wholesaler.

(29) “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.

(30) “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.

(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[.]**; and**

(o) The delegation of tasks to other health care providers who are appropriately trained and authorized to perform the delegated tasks.

(32) "Practitioner" means a person licensed and operating within the scope of such license to prescribe, dispense, conduct research with respect to or administer drugs in the course of professional practice or research:

(a) In this state; or

(b) In another state or territory of the United States if the person does not reside in Oregon and is registered under the federal Controlled Substances Act.

(33) "Preceptor" means a pharmacist or a person licensed by the board to supervise the internship training of a licensed intern.

(34) "Prescription drug" or "legend drug" means a drug which is:

(a) Required by federal law, prior to being dispensed or delivered, to be labeled with either of the following statements:

(A) "Caution: Federal law prohibits dispensing without prescription"; or

(B) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; 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.

(35) "Prescription" or "prescription drug order" means a written, oral or electronically transmitted direction, given by a practitioner authorized to prescribe drugs, for the preparation and use

of a drug. When the context requires, "prescription" also means the drug prepared under such written, oral or electronically transmitted direction.

(36) "Retail drug outlet" means a place used for the conduct of the retail sale, administering or dispensing or compounding of drugs or chemicals or for the administering or dispensing of prescriptions and licensed by the board as a place where the practice of pharmacy may lawfully occur.

(37) "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. "Self-administered hormonal contraceptive" includes, but is not limited to, hormonal contraceptive patches and hormonal contraceptive pills.

(38) "Shopkeeper" means a business or other establishment, open to the general public, for the sale or nonprofit distribution of drugs.

(39) "Unit dose" means a sealed single-unit container so designed that the contents are administered to the patient as a single dose, direct from the container. Each unit dose container must bear a separate label, be labeled with the name and strength of the medication, the name of the manufacturer or distributor, an identifying lot number and, if applicable, the expiration date of the medication.

(40) "Wholesale drug outlet" means a person who imports, stores, distributes or sells for resale drugs, including legend drugs and nonprescription drugs.

SECTION 26. ORS 689.225 is amended to read:

689.225. (1) A person may not engage in the practice of pharmacy unless the person is licensed under this chapter. Nothing in this section prevents physicians, dentists, veterinarians or other practitioners of the healing arts who are licensed under the laws of this state from dispensing and administering prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law of this state.

(2) A person may not take, use or exhibit the title of pharmacist or the title of druggist or apothecary, or any other title or description of like import unless the person is licensed to practice pharmacy under this chapter.

(3) A pharmacist may not possess personally or store drugs other than in a licensed pharmacy except for those drugs legally prescribed for the personal use of the pharmacist or when the pharmacist possesses or stores the drugs in the usual course of business and within the pharmacist's scope of practice. An employee, agent or owner of any registered manufacturer, wholesaler or pharmacy may lawfully possess legend drugs if the person is acting in the usual course of the business or employment of the person.

(4) The State Board of Pharmacy shall adopt rules relating to the use of pharmacy technicians [*working under the supervision, direction and control of a pharmacist*]. For retail and institutional drug outlets, the board shall adopt rules [*which*] **that** include requirements for training, including provisions for appropriate on-the-job training, guidelines for adequate supervision, standards and appropriate ratios for the use of pharmacy technicians. Improper use of pharmacy technicians is subject to the reporting requirements of ORS 689.455.

(5) The mixing of intravenous admixtures by pharmacy technicians working under the supervision, direction and control of a pharmacist is authorized and does not constitute the practice of pharmacy by the pharmacy technicians.

(6) Any person who is found to have unlawfully engaged in the practice of pharmacy is guilty of a Class A misdemeanor.

CAPTIONS

SECTION 27. The unit captions used in this 2022 Act are provided only for the convenience of the reader and do not become part of the statutory law of this state or express any legislative intent in the enactment of this 2022 Act.

EFFECTIVE DATE

SECTION 28. This 2022 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2022 Act takes effect on its passage.

Passed by House March 2, 2022

.....
Timothy G. Sekerak, Chief Clerk of House

.....
Dan Rayfield, Speaker of House

Passed by Senate March 3, 2022

.....
Peter Courtney, President of Senate

Received by Governor:

.....M.,....., 2022

Approved:

.....M.,....., 2022

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M.,....., 2022

.....
Shemia Fagan, Secretary of State

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, 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 may 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

81st OREGON LEGISLATIVE ASSEMBLY--2022 Regular Session

Enrolled
House Bill 4096

Sponsored by Representative HAYDEN, Senator STEINER HAYWARD, Representative PRUSAK, Senator PATTERSON; Representatives ALONSO LEON, BONHAM, BYNUM, DEXTER, GRAYBER, MOORE-GREEN, NOBLE, SALINAS, SMITH DB, Senator SOLLMAN (Presession filed.)

CHAPTER .....

AN ACT

Relating to volunteer health care practitioners; creating new provisions; amending ORS 677.080, 677.135, 678.021, 679.025, 680.020, 683.020, 685.020 and 689.225; and prescribing an effective date.

Be It Enacted by the People of the State of Oregon:

SECTION 1. (1) As used in this section:

(a) "Health care practitioner" means a person authorized in another state or United States territory to practice as a physician, physician assistant, nurse, nurse practitioner, clinical nurse specialist, dentist, dental hygienist, dental therapist, pharmacist, optometrist or naturopathic physician.

(b) "Health professional regulatory board" means the:

(A) Oregon Board of Dentistry;

(B) Oregon Board of Naturopathic Medicine;

(C) Oregon Board of Optometry;

(D) Oregon Medical Board;

(E) Oregon State Board of Nursing; and

(F) State Board of Pharmacy.

(2) A health care practitioner may practice, without compensation and in connection with a coordinating organization or other entity, the health care profession that the health care practitioner is authorized to practice for 30 days each calendar year or the number of days otherwise provided pursuant to subsection (8) of this section. A health care practitioner is not required to apply for licensure or other authorization from a health professional regulatory board in order to practice under this section.

(3) To practice under this section, a health care practitioner shall submit, at least 10 days prior to commencing practice in this state, to the health professional regulatory board substantially similar to the health care practitioner's licensing agency:

(a) Proof that the health care practitioner is in good standing and is not the subject of an active disciplinary action;

(b) An acknowledgement that the health care practitioner may provide services only within the scope of practice of the health care profession that the health care practitioner is authorized to practice 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 health care practitioner 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 health care practitioner will practice; and

(e) The dates on which the health care practitioner will practice in this state.

(4) Except as otherwise provided, a health care practitioner practicing under this section is subject to the laws and rules governing the health care profession that the health care practitioner is authorized to practice and to disciplinary action by the appropriate health professional regulatory board.

(5) A health care practitioner who is authorized to practice in more than one other jurisdiction shall provide to the appropriate health professional regulatory board proof, as determined sufficient by the health professional regulatory board, that the health care practitioner is in good standing and not subject to any active disciplinary actions in any jurisdiction in which the health care practitioner is authorized to practice.

(6)(a) The coordinating organization or other entity that uses the services of a health care practitioner shall confirm with the health care practitioner's licensing agency that the health care practitioner is:

(A) Authorized to practice the health care profession claimed by the health care practitioner;

(B) In good standing; and

(C) Not subject to any active disciplinary actions.

(b) The coordinating organization or other entity shall maintain:

(A) Records of the information described in paragraph (a) of this subsection related to a health care practitioner for two years after the termination of the health care practitioner's practice in this state.

(B) Records of patients to whom a health care practitioner provided services, in compliance with all patient confidentiality requirements of this state, except as those requirements are expressly prohibited by the law of any other state where a patient's medical records are maintained.

(c) A coordinating organization or other entity may pay or reimburse a health care practitioner for actual incurred travel costs associated with the health care practitioner's practice under this section.

(7) A hospital or other health care facility may not use the services of a health care practitioner in order to meet staffing needs during a labor dispute at the hospital or facility.

(8)(a) A health professional regulatory board may adopt by rule a duration longer than 30 days each calendar year during which a health care practitioner may practice under subsection (2) of this section.

(b) A health professional regulatory board may adopt other rules necessary to carry out this section, including rules requiring a health care practitioner to receive approval of and confirmation from the health professional regulatory board that the health care practitioner is authorized to practice under this section.

(9) This section does not create a private right of action against a health professional regulatory board or limit the liability of a health professional regulatory board under any other provision of law.

SECTION 2. ORS 677.080 is amended to read:

677.080. [*No person shall*] **A person may not**:

(1) Knowingly make any false statement or representation on a matter, or willfully conceal any fact material to the right of the person to practice medicine or to obtain a license under this chapter.

(2) Sell or fraudulently obtain or furnish any medical and surgical diploma, license, record or registration, or aid or abet in the same.

(3) Impersonate anyone to whom a license has been granted by the Oregon Medical Board.

(4) Except as provided in ORS 677.060 **and section 1 of this 2022 Act**, practice medicine in this state without a license required by this chapter.

SECTION 3. ORS 677.135 is amended to read:

677.135. As used in ORS 677.135 to 677.141[*,*]**:**

(1) "The practice of medicine across state lines" means:

[*(1)*] **(a)** The rendering directly to a person of a written or otherwise documented medical opinion concerning the diagnosis or treatment of that person located within this state for the purpose of patient care by a physician or physician assistant located outside this state as a result of the transmission of individual patient data by electronic or other means from within this state to that physician, the physician's agent or a physician assistant; or

[*(2)*] **(b)** The rendering of medical treatment directly to a person located within this state by a physician or a physician assistant located outside this state as a result of the outward transmission of individual patient data by electronic or other means from within this state to that physician, the physician's agent or a physician assistant.

(2) "The practice of medicine across state lines" does not include the practice of medicine by a person practicing in this state under section 1 of this 2022 Act.

SECTION 4. ORS 678.021 is amended to read:

678.021. **Except as provided in section 1 of this 2022 Act,** it [*shall be*] **is** unlawful for any person to practice nursing or offer to practice nursing in this state or to use any title or abbreviation, sign, card or device to indicate the person is practicing either practical or registered nursing unless the person is licensed under ORS 678.010 to 678.410 at the level for which the indication of practice is made and the license is valid and in effect.

SECTION 5. ORS 679.025 is amended to read:

679.025. (1) A person may not practice dentistry or purport to be a dentist without a valid license to practice dentistry issued by the Oregon Board of Dentistry.

(2) Subsection (1) of this section does not apply to:

(a) Dentists licensed in another state or country making a clinical presentation sponsored by a bona fide dental society or association or an accredited dental educational institution approved by the board.

(b) Bona fide full-time students of dentistry who, during the period of their enrollment and as a part of the course of study in an Oregon accredited dental education program, engage in clinical studies on the premises of such institution or in a clinical setting located off the premises of the institution if the facility, the instructional staff and the course of study to be pursued at the off-premises location meet minimum requirements prescribed by the rules of the board and the clinical study is performed under the indirect supervision of a member of the faculty.

(c) Bona fide full-time students of dentistry who, during the period of their enrollment and as a part of the course of study in a dental education program located outside of Oregon that is accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency, engage in community-based or clinical studies as an elective or required rotation in a clinical setting located in Oregon if the community-based or clinical studies meet minimum requirements prescribed by the rules of the board and are performed under the indirect supervision of a member of the faculty of the Oregon Health and Science University School of Dentistry.

(d) Candidates who are preparing for a licensure examination to practice dentistry and whose application has been accepted by the board or its agent, if the clinical preparation is conducted in a clinic located on premises approved for that purpose by the board and if the procedures are limited to examination only. This exception shall exist for a period not to exceed two weeks immediately prior to a regularly scheduled licensure examination.

(e) Dentists practicing in the discharge of official duties as employees of the United States Government and any of its agencies.

(f) Instructors of dentistry, whether full- or part-time, while exclusively engaged in teaching activities and while employed in accredited dental educational institutions.

(g) Dentists **who are** employed by public health agencies **and** who are not engaged in the direct delivery of clinical dental services to patients.

(h) Persons licensed to practice medicine in the State of Oregon in the regular discharge of their duties.

(i) Persons qualified to perform services relating to general anesthesia or sedation under the direct supervision of a licensed dentist.

(j)**(A)** Dentists licensed in another [*state or*] country and in good standing, while practicing dentistry without compensation for no more than five consecutive days in any 12-month period, provided the dentist submits an application to the board at least 10 days before practicing dentistry under this [*paragraph*] **subparagraph** and the application is approved by the board.

(B) Dentists licensed in another state or United States territory and practicing in this state under section 1 of this 2022 Act.

(k) Persons practicing dentistry upon themselves as the patient.

(L) Dental hygienists, dental assistants or dental technicians performing services under the supervision of a licensed dentist in accordance with the rules adopted by the board.

(m) A person licensed as a denturist under ORS 680.500 to 680.565 engaged in the practice of denture technology.

(n) An expanded practice dental hygienist who renders services authorized by a permit issued by the board pursuant to ORS 680.200.

SECTION 6. ORS 680.020 is amended to read:

680.020. (1) It is unlawful for any person not otherwise authorized by law to practice dental hygiene or purport to be a dental hygienist without a valid license to practice dental hygiene issued by the Oregon Board of Dentistry.

(2) Subsection (1) of this section does not apply to:

(a) Dental hygienists licensed in another state making a clinical presentation sponsored by a bona fide dental or dental hygiene society or association or an accredited dental or dental hygiene education program approved by the board.

(b) Bona fide students of dental hygiene who engage in clinical studies during the period of their enrollment and as a part of the course of study in an Oregon dental hygiene education program. The program must be accredited by the Commission on Dental Accreditation of the American Dental Association, or its successor agency, and approved by the board. The clinical study may be conducted on the premises of the program or in a clinical setting located off the premises. The facility, the instructional staff and the course of study at the off-premises location must meet minimum requirements prescribed by the rules of the board, and the clinical study at the off-premises location must be performed under the indirect supervision of a member of the faculty.

(c) Bona fide students of dental hygiene who engage in community-based or clinical studies as an elective or required rotation in a clinical setting located in Oregon during the period of their enrollment and as a part of the course of study in a dental hygiene education program located outside of Oregon. The program must be accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency. The community-based or clinical studies must:

(A) Meet minimum requirements prescribed by the rules of the board; and

(B) Be performed under the indirect supervision of a member of the faculty of the Oregon Health and Science University School of Dentistry or another Oregon institution with an accredited dental hygiene education program approved by the board.

(d) Students of dental hygiene or graduates of dental hygiene programs who engage in clinical studies as part of a course of study or continuing education course offered by an institution with a dental or dental hygiene program. The program must be accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency.

(e) Candidates who are preparing for licensure examination to practice dental hygiene and whose application has been accepted by the board or its agent, if the clinical preparation is conducted in a clinic located on premises approved for that purpose by the board and if the procedures are limited to examination only.

(f) Dental hygienists practicing in the discharge of official duties as employees of the United States Government and any of its agencies.

(g) Instructors of dental hygiene, whether full- or part-time, while exclusively engaged in teaching activities and while employed in accredited dental hygiene educational programs.

(h) Dental hygienists **who are** employed by public health agencies **and** who are not engaged in direct delivery of clinical dental hygiene services to patients.

(i) Counselors and health assistants who have been trained in the application of fluoride varnishes to the teeth of children and who apply fluoride varnishes only to the teeth of children enrolled in or receiving services from the Women, Infants and Children Program, the Oregon prekindergarten program or a federal Head Start grant program.

(j) Persons acting in accordance with rules adopted by the State Board of Education under ORS 336.213 to provide dental screenings to students.

(k) Dental hygienists licensed in another state [*and in good standing, while practicing dental hygiene without compensation for no more than five consecutive days in any 12-month period, provided the dental hygienist submits an application to the Oregon Board of Dentistry at least 10 days before practicing dental hygiene under this paragraph and the application is approved by the board*] **or United States territory and practicing in this state under section 1 of this 2022 Act**.

SECTION 7. ORS 683.020 is amended to read:

683.020. [*No person shall*] **Except as provided in section 1 of this 2022 Act, a person may not** engage in the practice of optometry or purport in any way to be an optometrist or an expert in the field of optometry without having first obtained a license from the Oregon Board of Optometry as provided for in ORS 683.010 to 683.340. In any prosecution for the violation of this section, the use of test cards, test lenses or of trial frames is prima facie evidence of the practice of optometry.

SECTION 8. ORS 685.020 is amended to read:

685.020. (1) Except as provided in subsection (3) of this section, [*no person shall*] **a person may not** practice, attempt to practice, or claim to practice naturopathic medicine in this state without first complying with the provisions of this chapter.

(2) Only licensees under this chapter may use any or all of the following terms, consistent with academic degrees earned: "Doctor of Naturopathy" or its abbreviation, "N.D.," "Naturopath" or "Naturopathic Physician." However, none of these terms, or any combination of them, shall be so used as to convey the idea that the physician who uses them practices anything other than naturopathic medicine.

(3) Subsection (1) of this section does not apply to**:**

(a) A bona fide student of naturopathic medicine who, during the period of the student's enrollment and as part of a doctoral course of study in an Oregon accredited naturopathic educational institution, engages in clinical training under the supervision of institution faculty, if the clinical training facility and level of supervision meet the standards adopted by the Oregon Board of Naturopathic Medicine by rule.

(b) A person authorized to practice under section 1 of this 2022 Act.

SECTION 9. ORS 689.225 is amended to read:

689.225. (1) A person may not engage in the practice of pharmacy unless the person is licensed under this chapter **or authorized in another state or United States territory and is practicing under section 1 of this 2022 Act**. Nothing in this section prevents physicians, dentists, veterinarians or other practitioners of the healing arts who are licensed under the laws of this state from dispensing and administering prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law of this state.

(2) A person may not take, use or exhibit the title of pharmacist or the title of druggist or apothecary, or any other title or description of like import unless the person is licensed to practice pharmacy under this chapter.

(3) A pharmacist may not possess personally or store drugs other than in a licensed pharmacy except for those drugs legally prescribed for the personal use of the pharmacist or when the

pharmacist possesses or stores the drugs in the usual course of business and within the pharmacist's scope of practice. An employee, agent or owner of any registered manufacturer, wholesaler or pharmacy may lawfully possess legend drugs if the person is acting in the usual course of the business or employment of the person.

(4) The State Board of Pharmacy shall adopt rules relating to the use of pharmacy technicians working under the supervision, direction and control of a pharmacist. For retail and institutional drug outlets, the board shall adopt rules which include requirements for training, including provisions for appropriate on-the-job training, guidelines for adequate supervision, standards and appropriate ratios for the use of pharmacy technicians. Improper use of pharmacy technicians is subject to the reporting requirements of ORS 689.455.

(5) The mixing of intravenous admixtures by pharmacy technicians working under the supervision, direction and control of a pharmacist is authorized and does not constitute the practice of pharmacy by the pharmacy technicians.

(6) Any person who is found to have unlawfully engaged in the practice of pharmacy is guilty of a Class A misdemeanor.

SECTION 10. (1) Section 1 of this 2022 Act and the amendments to ORS 677.080, 677.135, 678.021, 679.025, 680.020, 683.020, 685.020 and 689.225 by sections 2 to 9 of this 2022 Act become operative on January 1, 2023.

(2) The Oregon Board of Dentistry, Oregon Board of Naturopathic Medicine, Oregon Board of Optometry, Oregon Medical Board, Oregon State Board of Nursing and State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the boards to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the boards by section 1 of this 2022 Act and the amendments to ORS 677.080, 677.135, 678.021, 679.025, 680.020, 683.020, 685.020 and 689.225 by sections 2 to 9 of this 2022 Act.

SECTION 11. This 2022 Act takes effect on the 91st day after the date on which the 2022 regular session of the Eighty-first Legislative Assembly adjourns sine die.

Passed by House February 21, 2022

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Timothy G. Sekerak, Chief Clerk of House

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Dan Rayfield, Speaker of House

Passed by Senate February 28, 2022

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Peter Courtney, President of Senate

Received by Governor:

.....M.,....., 2022

Approved:

.....M.,....., 2022

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Kate Brown, Governor

Filed in Office of Secretary of State:

.....M.,....., 2022

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Shemia Fagan, Secretary of State

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.

Documents Relied Upon per ORS 183.335(2)(b)(D): None

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): 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/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 ~~B~~**b**oard. A person must register as either:

(a) A manufacturer under **D**~~d~~ivision 60 of this chapter of rules; or

(b) A wholesaler under **D**~~d~~ivision 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 ~~B~~**b**oard and must provide information required by the ~~B~~**b**oard that shall include 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 ~~B~~**b**oard and submit it to the ~~B~~**b**oard with the appropriate fee by ~~August 31~~ **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 ~~B~~**b**oard, with the appropriate fee.

(6) The ~~B~~**b**oard 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 shall be at the applicant's expense.

(7) The ~~B~~**b**oard 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 ~~B~~**b**oard.

(9) The registrant must notify the ~~B~~**b**oard, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include 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.

(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 ~~B~~**b**oard may waive any requirement of this rule if, in the ~~B~~**b**oard'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 689.155

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, Shingles, 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)

Proposed Statewide Drug Therapy Management Protocol – Herpes Zoster (Shingles)

Proposed Statewide Drug Therapy Management Protocol – Travel Medications (Assessment & Treatment Care Pathway)

Proposed Statewide Drug Therapy Management Protocol – HIV Post-Exposure Prophylaxis (PEP) (Assessment & Treatment Care Pathway)

Proposed Statewide Drug Therapy Management Protocol – HIV Pre-Exposure Prophylaxis (PrEP)

Proposed Statewide Drug Therapy Management Protocol – Contraception – Oral, Transdermal Patch, Vaginal Ring and Injectable

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.

The risk of contracting Shingles increases with age as does the severity and long-term complications in patients over 50 years old. According to the CDC, 1 out of 3 people in the United States will develop herpes zoster during their lifetime. The need for prompt access to care is key to shortening the course of

disease and reducing risks related to Shingles. Adopting the proposed Shingles protocol will reduce patient barriers to prompt care and treatment for 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, shingles 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), Shingles 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 received a concept to add Shingles, reviewed proposed protocols with subject matter experts and drafted a statewide drug therapy management protocol for Shingles. 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 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

(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

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~~

~~(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 **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. A **P**~~p~~harmacist may 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 **P**~~p~~harmacist 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.

(4) For each drug or device the pharmacist 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 for as long as the Pharmacist participates in the prescribing activity and for 3 years after ceasing participation;

(~~a~~**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 **P**~~p~~harmacist's physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means; and

(~~b~~**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; and

(~~c~~**d**) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and

(~~d~~**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 **P**~~p~~harmacist must maintain all records associated with prescribing and other related activities performed for a minimum of ~~10~~ **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 ~~B~~**b**oard 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 may 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
Statutes/Other Implemented: ORS 689.645 & ORS 689.649

855-020-0120
Prescribing Prohibited Practices

(1) A **P**~~p~~harmacist may not prescribe a 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 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~~.~~**; and**

(b) When the Formulary and Protocol Compendia requires referral to another non-Pharmacist provider.

(c) When the patient is excluded from the protocol or does not meet the inclusion criteria for the protocol compendia.

(2) An **I**~~i~~ntern may not prescribe a drug or device.

(3) A Pharmacist may 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) 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

(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**

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~~

~~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~~

~~(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~~

~~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~~

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 or continuing education (CE) on PAXLOVID.
    - 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

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____
Preferred Pronouns (circle) She/Her, He/Him, They/Them, Ze/Hir, 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 _____
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

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
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 ____/_____/_____

4. Follow-up with patient completed within 7 days of prescription on: Date ____/_____/_____
5. FDA Form 3500 submitted because adverse event occurred: □ Yes Date ____/_____/_____ □ Not Applicable

RPH Signature_____Date ____/_____/_____

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 **<u>one</u>** 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

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.

Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

1) Immediate Physical Assessment Screen (Self-screening Patient Intake Form, REALD demographics and pharmacist physical 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 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

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.*

Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

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

11) Document follow-up with patient within 7 days, phone consultation permitted

Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

Adverse Reactions and Medication Errors Reporting Requirements:

Required reporting for serious adverse events and medication errors 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.

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:_____
_____
_____
_____

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.

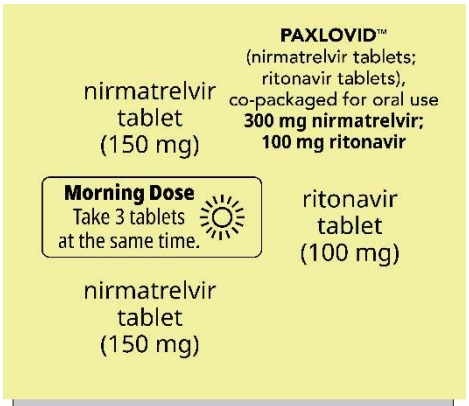
How do I take PAXLOVID?

- **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.**

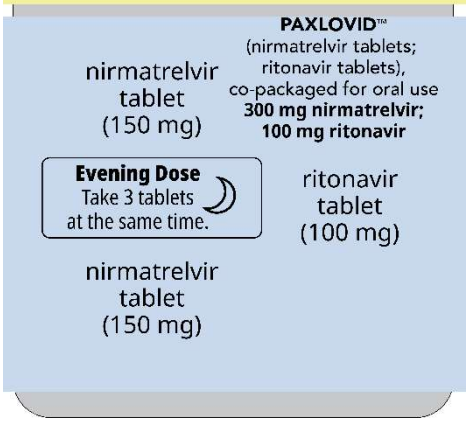
Figure A

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.

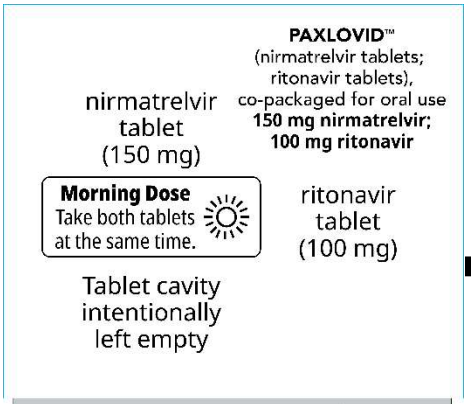


Evening Dose:
Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together at the same time each evening.

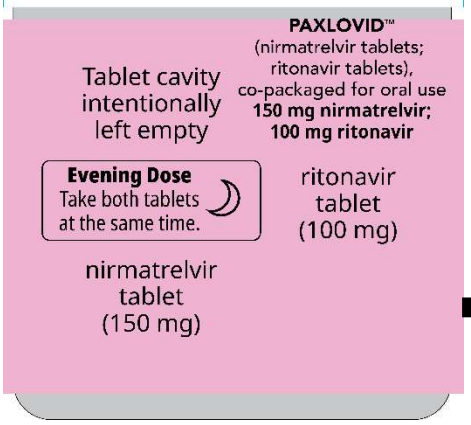
Figure B

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:_____

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

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

Herpes Zoster (Shingles)

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 herpes zoster (shingles) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized Shingles Patient Intake Form (pg. X-X)
  - Utilize the standardized Shingles Assessment and Treatment Care Pathway (pg. X-X)
  - Utilize the standardized Shingles Provider Fax (pg. X)

  PHARMACIST TRAINING/EDUCATION:
  - A minimum of 1 hour of training or continuing education (CE) on prevention and treatment of Herpes Zoster
  - Review CDC resources for healthcare providers, available at: https://www.cdc.gov/shingles/hcp/index.html

Herpes Zoster (Shingles) Self-Screening 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 _____

Background Information:

1.	Please describe your condition by selecting the following options, if they are present: A. Rash contains cluster(s) of tiny sores with a red background …… B. Did the rash start within the last 72 hours?..... - If 72 hours have passed since the rash started, have sores continued to appear?.. C. Describe location(s) of the rash or sores:_____ □ face □ neck □ scalp □ genitals □ tip of nose □ arms/legs □ buttocks □ eye/eyelid □ stomach/chest/back - Do the rash or sores appear to be in a group near the spine or middle of your body? …… - Are the rash or sores only on the left or right side of your body?..... D. Itching, burning, tingling or pain at the site of the rash……..….. - If yes, did these symptoms occur before the rash appeared?..... E. Headache: (if yes, select one: □ mild/moderate or □ severe)…….. F. Fever: >38.8°C or >100.9°F…….. G. Changes in vision or hearing, light sensitivity, or ear pain……..	 □ Yes □ No □ Not sure □ Yes □ No □ Not sure □ Yes □ No □ N/A □ Yes □ No □ Not sure □ Yes □ No □ Not sure □ Yes □ No □ Not sure □ Yes □ No □ Not sure □ Yes □ No □ Not sure □ Yes □ No □ Not sure □ Yes □ No □ Not sure
2.	Are you under 18 years old?	□ Yes □ No
3.	Are you currently pregnant or planning to become pregnant in the next 30 days?	□ Yes □ No □ Not sure
4.	Do you have any of the following? A. A weakened immune system …… B. On kidney dialysis or being considered for dialysis ……..	 □ Yes □ No □ Not sure □ Yes □ No □ Not sure
5.	Do you have any other medical conditions? If yes, list them here: _____ _____	□ Yes □ No
6.	Have you ever been vaccinated for shingles?	□ Yes □ No □ Not sure
7.	Do you have any allergies? If yes, list them here: _____ _____	□ Yes □ No □ Not sure
8.	Do you take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

Herpes Zoster (Shingles) Assessment and Treatment Care Pathway

Name: _____Date of Birth: ____/____/_____ Today's Date: ____/____/_____

<table>
<tr><td colspan="2">1A. Does the patient report that the rash appears to be cluster(s) of tiny sores with a red background?</td><td rowspan="2">Notes: Patient is describing a rash consistent with shingles</td></tr>
<tr><td>□ Yes: Go to #1B.</td><td>□ No: Do not prescribe Antiviral therapy. Advise patient to seek healthcare from a non-Pharmacist provider</td></tr>
<tr><td colspan="2">1B. Did the rash start within the last 72 hours or if 72 hours have passed since the rash started, have sores continued to appear?</td><td rowspan="2">Notes: Shingles treatment is time sensitive with evidence supporting use < 72 hours from time of visual rash. Many experts recommend treatment after 72 hours if sores are continuing to appear.</td></tr>
<tr><td>□ Yes: Go to #1C.</td><td>□ No: Do not prescribe Antiviral therapy. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, or public health clinic.</td></tr>
<tr><td colspan="2">1C. Does the rash appear in both sides of the body or in multiple dermatomes or is it located in a concerning area that includes the face, neck, scalp, genitals, tip of nose, eye/eyelid?</td><td rowspan="2">Notes: If applicable, counsel patient that a rash appearing on the face, neck, scalp, genitals, tip of nose or eye/eyelid are at high risk for permanent complications and need close monitoring. Bilateral or multiple dermatome involvement may represent disseminated herpes zoster and require more aggressive treatment.</td></tr>
<tr><td>□ Yes: Do not prescribe Antiviral therapy. Refer patient to emergency department (ED) or urgent care.</td><td>□ No: Go to #1D.</td></tr>
<tr><td colspan="2">1D. Did the patient experience itching, burning, tingling or pain at the site of the rash that was not present beforehand?</td><td rowspan="2">Notes: Shingles has a characteristic 'prodrome' period that commonly exhibits these symptoms.</td></tr>
<tr><td>□ Yes: Go to #1E.</td><td>□ No: Go to #1E.</td></tr>
<tr><td colspan="2">1E. Has the patient experienced headache? If yes, is the headache mild/moderate or severe?</td><td>Notes:</td></tr>
<tr><td>□ Yes: Go to #1F. If the headache is severe provide timely treatment as appropriate and refer patient to local primary care provider (PCP), urgent care, or public health clinic. If very severe, refer to emergency department (ED).</td><td>□ No: Go to #1F.</td><td></td></tr>
<tr><td colspan="2">1F-1G. Does the patient present with any of the following?
□ Fever >38.8°C or >100.9°F
□ Changes in vision or hearing, light sensitivity, or ear pain</td><td>Notes:</td></tr>
<tr><td>□ Yes: Do not prescribe antiviral therapy. Refer patient to emergency department (ED) or urgent care</td><td>□ No: Go to #2</td><td></td></tr>
<tr><td colspan="2">2. Is the patient less than 18 years old?</td><td rowspan="2">Notes:</td></tr>
<tr><td>□ Yes: Do not prescribe Antiviral therapy. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, or public health clinic.</td><td>□ No: Go to #3</td></tr>
</table>

Herpes Zoster (Shingles) Assessment and Treatment Care Pathway

<table>
<tr><td colspan="2">3. Is the patient currently pregnant or planning to become pregnant within 30 days?</td><td rowspan="2">Notes:</td></tr>
<tr><td>□ Yes, or Not Sure: Do not prescribe Antiviral therapy. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, or public health clinic.</td><td>□ No: Go to #4A</td></tr>
<tr><td colspan="2">4A. Does the patient have any medical condition(s) that cause them to be immunocompromised (e.g. HIV, transplant recipient on aggressive antirejection therapy, cancer, etc.)</td><td rowspan="2">Notes:</td></tr>
<tr><td>□ Yes: Caution patient on risk of disseminated zoster. Recommend follow-up with local primary care provider (PCP), emergency department (ED), urgent care, or public health clinic. Go to #4B.</td><td>□ No: Go to #4B</td></tr>
<tr><td colspan="2">4B. Is the patient on kidney dialysis or being considered for dialysis?</td><td rowspan="2"></td></tr>
<tr><td>□ Yes: Do not prescribe Antiviral therapy. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, or public health clinic.</td><td>□ No or not sure: Go to #5</td></tr>
<tr><td colspan="2">5. Does the patient have any other medical conditions that have contraindications to receiving antiviral treatment?</td><td rowspan="2">Notes:</td></tr>
<tr><td>□ Yes: Do not prescribe Antiviral therapy. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, or public health clinic.</td><td>□ No: Go to #6</td></tr>
<tr><td colspan="2">6. Is the patient fully vaccinated with the current CDC recommended shingles vaccine?</td><td rowspan="2">Notes: If the patient is eligible and not fully vaccinated with the current CDC recommendation, recommend the patient to start/complete series once symptoms are resolved and properly spaced (14 days) from antiviral therapy.</td></tr>
<tr><td>□ Yes: Go to #7</td><td>□ No: Go to #7</td></tr>
<tr><td colspan="2">7. Does the patient have hypersensitivity to acyclovir, valacyclovir, famciclovir, or any component of one of these medications?</td><td rowspan="2">Notes:</td></tr>
<tr><td>□ Yes: Do not prescribe Antiviral therapy. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, or public health clinic.</td><td>□ No: Continue to #8</td></tr>
<tr><td colspan="2">8. Does the patient take any medications, including non-prescription drugs, herbs or supplements that have known contraindications with antiviral treatment?</td><td rowspan="2">Notes:</td></tr>
<tr><td>□ Yes: Do not prescribe Antiviral therapy. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, or public health clinic.</td><td>□ No: Complete patient encounter and proceed to treatment regimen.</td></tr>
</table>

Herpes Zoster (Shingles) Assessment and Treatment Care Pathway

RECOMMENDED REGIMEN: May prescribe for up to two 7-day treatment per rolling 12-month period	
□ Valacyclovir 1000mg	Take one tablet by mouth three times a day for 7 days #21 + 0 refills
□ Famciclovir 500mg	Take one tablet by mouth three times a day for 7 days #21 + 0 refills
□ Acyclovir 800mg	Take one tablet by mouth five times a day for 7 days #35 + 0 refills

□ Recommend oral OTC analgesics for pain.

□ Recommend Zoster vaccination after the acute stage of the illness is over and symptoms abate.

□ Future Zoster vaccination not recommended.

RPH Signature_____ RPH Name (Print)_____ Date: _____

COUNSELING POINTS:

- Antiviral medications: side effects that may be seen with valacyclovir, famciclovir, and acyclovir are headache, nausea, vomiting, dizziness, and abdominal pain. Please refer to the medication guide that was provided with the medication you were prescribed for additional information.
    - **NOTE:** Drink plenty of water while taking any of these antiviral drugs.
    - Initiation within 72 hours of onset of rash may relieve symptoms, speed healing, and prevent/lessen postherpetic neuralgia (PHN).
- OTC pain management:
    - Non-Steroidal Anti-Inflammatory Drugs (NSAIDS): This drug class includes ibuprofen (Advil or Motrin) and naproxen (Aleve), among others. Their most common side effects are upset stomach, increased risk of bleeding, stomach bleeds, headache, fluid retention, worsening of chronic kidney disease, and worsening of congestive heart failure. If in severe pain or pain worsens, refer to other healthcare provider.
    - Acetaminophen: Do not take more than 3,250mg per day (from all products) and avoid alcoholic beverages while taking acetaminophen.
- Zoster vaccine: Recommend initial vaccination upon visual clearance of rash for protection against any potential future reactivation of Herpes Zoster. If patient previously fully vaccinated according to current CDC recommendations, no additional vaccination is permitted per OHA immunization protocol.
- Patients who have never had chickenpox or the chickenpox vaccine can develop chickenpox if they come in direct contact with the rash from the time it forms blisters until it crusts over.
- Patients who provide care to persons who are immunocompromised or pregnant should remain isolated from such persons.
- Rash:
    - Keep the rash clean and dry.
    - If wounds are open, cover the sores. Do not apply any topical analgesics to open sores.
    - Explain that the duration of the rash is typically 2-3 weeks, but pain may persist.
    - Warn that appearance of a disseminated rash requires immediate medical care. Lesions that cross the midline, are not unilateral, and/or have spread to more than 2 dermatomes (indicates the patient may be immunosuppressed).
    - Warn that sores in the areas of high concern □ face □ neck □ scalp □ genitals □ tip of nose □ eye/eyelid need to be urgently evaluated by a non-Pharmacist healthcare provider.
- If >1 episode of zoster per lifetime, follow-up with a healthcare provider as appropriate (i.e. could be herpes simplex, patient may be immunosuppressed).
- Postherpetic Neuralgia (PHN) may occur, especially if >50 years old, despite antiviral treatment. Patient may consider topical analgesics (capsaicin, lidocaine, etc.) if this occurs and all lesions are cleared.
- Instruct patient to contact PCP if any of the following occur
    - New vesicles appear more than 1 week after rash onset
    - An allergic reaction to the medications prescribed is seen
    - Rash worsens
    - Development of a fever
    - Rash spreads to other parts of the body

Herpes Zoster (Shingles) Assessment and Treatment Care Pathway

PHARMACIST MANDATORY FOLLOW-UP (5 days after initial visit):

1. How are you feeling? _____
2. Are your symptoms better/worse/same? _____
3. Are you having any new lesions, spreading of the rash, or new or worsening symptoms including fever or pain?

   _____
4. How have you been using your medications for shingles? _____
5. What adverse reactions have you experienced, if any? _____
6. If not fully vaccinated, a Zoster vaccine is recommended after the acute stage of the illness is over and symptoms abate.
7. What questions/concerns do you have for me? _____

Additional notes:

_____

_____

Changes/updates to regimen:

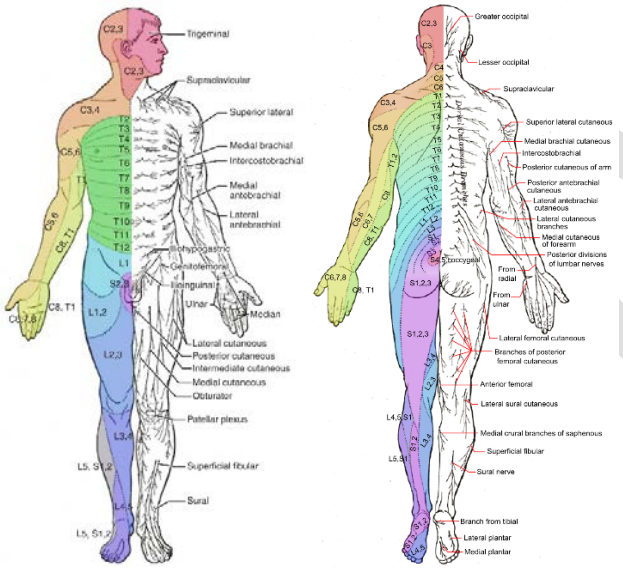
□ Referred to prescriber due to change in symptoms or other reasons:

_____

□ Unable to contact/attempts made:

_____

Pharmacist Signature_____Date____/____/_____



The shingles rash commonly presents in one or more thoracic dermatomes (labeled in green), typically on one side of the body. However, the rash can also present in multiple dermatomes, including the face, and in rare instances, appear on both sides of the midline.

Images: Häggström, Mikael (2014). "Medical gallery of Mikael Häggström 2014". *WikiJournal of Medicine* **1** (2). DOI:10.15347/wjm/2014.008. ISSN 2002-4436. Public Domain.

References:

Valacyclovir. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/7849?cesid=96ONN2zDaek&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dvalacyclovir%26t%3Dname%26va%3Dvalacyclovir Accessed July 9, 2021.

Famciclovir. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/6893?cesid=7Y0tk9FO6ns&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dfamciclovir%26t%3Dname%26va%3Dfamciclovir Accessed July 9, 2021.

Acyclovir. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/6893?cesid=7Y0tk9FO6ns&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dfamciclovir%26t%3Dname%26va%3Dfacyclovir Accessed July 9, 2021.

Herpes Zoster (Shingles) 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

☐ **Valacyclovir 1000mg**
- Take one tablet by mouth three times a day for 7 days, #21, 0 refills

-or-

☐ **Famciclovir 500mg**
- Take one tablet by mouth three times a day for 7 days, #21, 0 refills

-or-

☐ **Acyclovir 800mg**
- Take one tablet by mouth five times a day for 7 days, #35, 0 refills

Written Date: _____

Expiration Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

Provider Notification

Antiviral Therapy for Herpes Zoster (Shingles)

(CONFIDENTIAL-Protected Health Information)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Your patient _____(name) _____/_____/_____ (DOB) was:

☐ **Prescribed antiviral therapy for shingles management** at our Pharmacy on _____/_____/_____ as noted above. The prescription issued and dispensed consisted of:

- □ Valacyclovir 1000mg Take one tablet by mouth three times a day for 7 days, #21 + 0 refills
- □ Famciclovir 500mg Take one tablet by mouth three times a day for 7 days, #21 + 0 refills
- □ Acyclovir 800mg Take one tablet by mouth five times a day for 7 days, #35 + 0 refills

☐ **Referred to**:

☐ Primary care provider (PCP) ☐ Emergency department (ED) ☐ Urgent care ☐ Public health clinic and not prescribed to your patient for the following reasons:

_____
_____
_____
_____
_____

The prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-020-0300. During the visit the pharmacist integrated patient-specific information and disease-state knowledge to provide treatment and/or referral to another provider for further assessment. During this visit we carefully reviewed the patient's medical, prescription history, and lifestyle factors to ensure the safety of the patient and appropriateness of therapy.

RPH Signature_____ RPH Name (Print)_____ Date: _____

Please contact us if you have any questions about the care provided to our mutual patient or if you would like to obtain additional information. Please contact prescribing pharmacy.

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

> 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 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 tablet daily 1-2 days prior to travel
- Taken daily during trip and 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 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 tablet 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

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)

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)

4. Motion Sickness

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

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

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

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

OCTOBER 2022/B4d

Name: _____Date of Birth:____/____/_____ Today's Date:____/____/_____

1. Is the patient less than 13 years old?		Notes:
☐ 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	☐ No: Go to #2	
2. Was the patient a survivor of sexual assault?		Notes:
☐ 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.**	☐ No: Go to #3	
3. Is the patient known to be HIV-positive?		Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.
☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.	☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).	
4. What time did the exposure occur?		Notes:
☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.	☐ ≤72 hours ago: go to #5	
5. Was the exposure from a source person known to be HIV-positive?		
☐ Yes: Go to #6	☐ No: Go to #7	
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:		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.
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.	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	
7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?		Notes: This type of exposure puts the patient at a high risk for HIV acquisition
☐ Yes: Go to #9	☐ No: Go to #8	

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____/____/_____

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information) **OCTOBER 2022/B4e**

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 ~~– 2~~ 4 weeks ago ~~□ 2 – 4 week1s ago~~ □ > 4 weeks ago
4. ~~Do you see a (healthcare provider) for management of Hepatitis B?~~ Have you ever had Hepatitis B Infection?	□ yes □ no
5. Have you ever received an immunization for Hepatitis B? If yes, when:	□ yes □ no

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

• If no, would you like a Hepatitis B immunization today? □ yes □ no	Date of vaccine __/__/__
6. Have you ever been told you have a bone disease?	□ 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:

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Patient Signature: _____ **Date:** _____

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.*

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 ~~14~~ 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. ~~*If planning to monitor for Hep C, order lab at initial intake and at least annually thereafter.*~~

- 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*

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.

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 – 2 weeks ago, defer testing and PrEP until at least 2 weeks post exposure and proceed with PrEP according to the result.~~ • 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.

Provider Notification
Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy 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	____/____/_____ □ CrCl 30mL/min - 60mL/min	_____ mL/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.

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. X-X)
- Utilize the standardized Contraception Assessment and Treatment Care Pathway (pg. X-X)

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

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____

Preferred 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

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_____

Standardized Assessment and Treatment Care Pathway - Contraception

Algorithm A: Oral, Vaginal and Transdermal Contraception with Combined Hormonal Contraceptives (CHC) and Progestin Only Pills (POC). 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).

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 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 → Refer

- 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) → Refer

- 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).

Standardized Assessment and Treatment Care Pathway - Contraception

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.								

Standardized Assessment and Treatment Care Pathway - Contraception

Contraception Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

BP Reading: ____/____ mmHg

Rx

☐ **Drug:** _____

- Directions: _____
- Quantity: _____
- Refills:_____

Written Date: _____

Prescriber Name:_____Prescriber Signature: _____

Pharmacy Address:_____Pharmacy Phone: _____

Provider Notification
Contraception

Pharmacy 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

Pharmacist Referral and Visit Summary

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.

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): 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 a American Medical Association (AMA) as 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.

(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 689.255, ORS 689.285, ORS 689.486, ORS 413.450, ORS 689.490 & ORS 413.590

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) Content delivered by an instructor or a panel of instructors;

(b) The program is:

(A) A structured CPE discussion, workshop or demonstration;

(B) A structured CPE question and answer session; or

(C) An ACPE accredited program or board-approved program; or

(D) An ACCME AMA Category 1 accredited program up to the following limits per renewal cycle:

(i) 10 hours of CPE for Pharmacists;

(ii) 6 hours of CPE for Certified Oregon Pharmacy Technicians and Pharmacy Technicians.

(E) 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 may not be included in the calculation of CPE credit:

(a) Welcoming remarks;

(b) Time spent for 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 Oregon Board of Pharmacy e-Gov profile 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

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 initial course or program which has been approved for CPE credit.

(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 may only be granted credit for one presentation of the same program of CPE.

(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.

(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 Oregon Board of Pharmacy e-Gov profile.

(7) A pharmacist must retain documentation of completed CPE for six 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), and complete other renewal requirements listed in OAR 855-019.

(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 689.285, ORS 689.486, ORS 413.450, ORS 413.590

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 six 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 Oregon Board of Pharmacy e-Gov profile.

POLICY DISCUSSION: Interns and ACCME

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 413.450, ORS 689.151, ORS 689.255, ORS 689.285, ORS 676.850

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 Oregon Board of Pharmacy e-Gov profile prior to submission of the license renewal.

(6) A Certified Oregon Pharmacy Technician or Pharmacy Technician must retain documentation of completed CPE for six 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) If a license renewal is submitted after June 30th of the license renewal cycle, CPE must be completed prior to submission of the license 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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 676.850

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 Oregon Board of Pharmacy e-Gov profile 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

~~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;~~

~~(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;~~

~~(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.~~

~~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~~

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.

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 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. **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 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;

(f1) 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 notice; or

(B) ~~30~~**15** days of receiving a non-compliance notice.

(f2) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within **the time allowed by the board**~~:~~.

POLICY DISCUSSION: Specificity

(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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0005
Definitions

The following words and terms, when used in OAR 855-141, have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section has the definition set out in OAR 855-006.

(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 may not operate until a certificate of registration has been issued by the board.

(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; and

(c) The PPK Affiliated Pharmacy name, Retail Drug Outlet registration number and Pharmacist-in-Charge.

(d) 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:

(a) Failure to completely, accurately and honestly 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

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;

(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 may 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) may 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

855-141-0120
Drug: Procurement

A PPK may 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;

(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;

(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

(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;

(f) Designate in writing the Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians authorized to access the PPK;

(g) Utilize complete chain of custody tracking;

(h) Train the Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system and PPK and document the training;

(i) 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;

(j) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Pharmacist from the PPK Affiliated Pharmacy; and

(k) 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

(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.

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 may 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. When a prescription is transmitted orally, it must be transmitted to the Pharmacist from the PPK Affiliated Pharmacy and both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.

(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.

(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 may use any 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 may 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

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 kiosk 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.

POLICY DISCUSSION: Emergency Supplies

(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.

(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 kiosk 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.

(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.

(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.

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.

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;

(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.

(4) 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

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.

(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:

(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 may 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 may 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 may 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

(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

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.

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;

(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.

(g) 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.

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

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

(b) Prescribe a drug or device; or

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

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

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.025, ORS 689.151, ORS 689.155, ORS 689.645, ORS 689.682, ORS 689.689 & 2022 HB 4034

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~~**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;

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

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

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. General responsibilities, confidentiality responsibilities, duty to report responsibilities, training responsibilities and permitted and prohibited practices.

Repeals Division 025.

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.

~~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~~

(~~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;~~

~~(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

(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.~~

~~(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.~~

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.

(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;

(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

~~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**

(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.~~

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.~~

~~(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 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(5).

~~(a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.~~

~~(b) Reconstituting prescription medications. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.~~

~~(d) Entering information into the pharmacy computer. The Certified Oregon Pharmacy Technician or Pharmacy Technician shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising Pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.~~

~~(e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;~~

~~(f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The Pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.~~

~~(g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The Pharmacist must verify the accuracy of the finished task unless the requirements of OAR 855-025-0023(4) are met.~~

~~(h) Checking nursing units in a hospital or nursing home for nonjudgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a Pharmacist.~~

~~(i) Recording patient or medication information in computer systems for later verification by the Pharmacist.~~

~~(j) Bulk Compounding; Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(k) Preparation of parenteral products as follows:~~

~~(A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(l) Performing related activities approved in writing by the board.~~

~~(3) In order to protect the public, safety, health and welfare, Certified Oregon Pharmacy Technicians or Pharmacy Technicians shall not:~~

~~(a) Communicate or accept by oral communication a new or transferred prescription of any nature;~~

~~(b) Receive or transfer a prescription to another pharmacy without the prior verification of a Pharmacist.~~

~~(c) Provide a prescription or medication to a patient without a Pharmacist's verification of the accuracy of the dispensed prescription;~~

~~(d) Counsel a patient on medications or perform a drug utilization review;~~

~~(e) Perform any task that requires the 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.

(3) Perform any task while assisting in the practice or 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;~~

~~(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~~

Divisions 019/020/031/041/115: 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): Creates new Division 115 for Pharmacists. Proposes relocating and reorganizing existing Pharmacists rules from Division 019, Division 020, Division 031 and Division 041. 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): 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 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.

---------- LICENSING (3rd 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.

(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:~~

~~(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: 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

~~(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 may 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 state or United States jurisdiction with a minimum of 1440 hours in pharmacy practice in a state or United States 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 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.~~

~~(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

(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:

(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 855-021; 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 Pharmacist 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~~

~~(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~~ **Must apply per OAR 855-115-0020;**

(b) ~~By~~ **Must** provid~~e~~**e**~~ing~~ certification of completion of the continuing pharmacy education requirement in OAR 855-021 for all years in which the license was lapsed ~~and for the current year; and~~;

(c) If the~~ir~~ **Pharmacist** license has been lapsed for more than ~~one~~ **three** year**s**, pass the **Oregon** 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) ~~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 maintained an active Pharmacist license in another US state or jurisdiction, the person is eligible for licensure via reciprocity;**

(e) 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, the person must 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.

(2**4**) ~~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~~

(5) 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
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 may 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 ~~person~~ Pharmacist requests to lapse their license 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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0043
Licensure: Retire~~ment~~

(1) A Pharmacist may request that the board ~~to~~ retire ~~accept the retirement of~~ their license if the Pharmacist is in good standing, has been licensed as a Pharmacist for at least 20 years and is no longer ~~retired from the~~ practiceing ~~of~~ pharmacy.

(a) A retired~~ment of a~~ license is not considered discipline;

(b) The board has continuing authority ~~jurisdiction to proceed with any investigation or any action~~ under ORS 689.153 ~~or disciplinary against the licensee~~.
(c) A person may 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~~ment~~ the license.

(b) If the board accepts the request to retire~~ment~~ the license, the board will notify the licensee of the date the license is no longer active ~~terminates~~.

(c) The board will not accept the request to retire~~ment~~ 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 may not 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.

(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).

(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

NOTE: In rulemaking

(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, 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 may provide services only within the scope of practice of pharmacy and will provide services pursuant to the scope of practice of this state or the health care practitioner's licensing agency, whichever is more restrictive;

(c) An attestation that the Pharmacist will not receive compensation for practice in this state;

(d) The name and contact information of the coordinating organization or other entity through which the Pharmacist will practice; and

(e) The dates on which the Pharmacist will practice in this state.

(3) Except as otherwise provided, a Pharmacist practicing under this section is subject to the laws and rules governing the pharmacy profession that the Pharmacist is authorized to practice and to disciplinary action by the appropriate health professional regulatory board.

Statutory/Other Authority: ORS 689.205, ORS 689.315, 2022 HB 4096
Statutes/Other Implemented: ORS 689.151, 2022 HB 4096

~~855-019-0125~~
~~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

~~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 (2nd REVIEW)----------
~~855-019-0200~~**855-115-0070**
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 **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;

(~~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 may 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.

POLICY DISCUSSION: 1st academic year, Exceptions

(5) A Pharmacist may 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.

(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 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.

(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.

(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;

(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 may 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 may 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; or

(c) To a third-party when disclosure is authorized or required by law; or

(d) As permitted pursuant to federal and state patient confidentiality laws or;

(e) To the patient or to persons as authorized by the patient.

(3) A licensee or registrant of the board may not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

~~855-019-0205~~ **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 ~~c~~**C**onvicted 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;

(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.~~

~~(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:~~

~~(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:

(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.~~

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 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.

(g6) 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.

~~(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 state or United States 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.

(~~3~~**2**) 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.~~ **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.~~

(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) ~~Establish and~~ 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 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;~~

(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;~~

~~(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

(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.

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.~~

~~(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 ~~**for injection site and the route of administration**~~**;**

(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.

(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~~;~~

(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 may 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;~~

~~(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.~~

~~(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.~~

~~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 may 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~~

~~(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;

(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 & 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;

(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 & 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~~

~~(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 may 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.

(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 a~~n individualized patient-centered~~ 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 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 may not prescribe a **vaccine,** drug or device.

(3) A Pharmacist may 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 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;

(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 855-115-0135**, ~~via statewide drug therapy management protocol and according to rules outlined in this Division~~, a~~n~~ 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

(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**2**~~1~~);

(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 12/202**2**~~1~~);~~ 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.~~

~~(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~~

~~(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:~~

~~(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.

(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~~

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.

(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 provision of pharmaceutical care that is conducted within the physical confines or location of a licensed pharmacy registered with the Board.~~

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

~~855-041-3310~~
~~Consulting/Drugless Pharmacy - Registration~~

~~(1) The Consulting Pharmacy shall be registered as a retail or institutional drug outlet and comply with all the requirements of licensure as defined in OAR 855-041-1080 through 855-041-1100.~~

~~(2) The location must be available for inspection by the Board.~~

~~(3) A consulting pharmacist for an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure, as well as any applicable federal and state laws and rules.~~

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

~~855-041-3315~~
~~Consulting/Drugless Pharmacy - Personnel~~

~~(1) Each pharmacy must have a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the state in which the pharmacy is located if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;~~

~~(2) The pharmacy must comply with all applicable state and federal laws and rules governing the practice of pharmacy and maintain records in compliance with requirements of federal law and Board rules;~~

~~(3) A consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon; and~~

~~(4) Prospective drug utilization reviews, refill authorizations, interventions and patient counseling not associated with the dispensing of a drug for an Oregon patient must be performed by an Oregon licensed pharmacist.~~

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

~~855-041-3320~~
~~Consulting/Drugless Pharmacy - Confidentiality~~

~~(1) Each consulting pharmacy must comply with all applicable federal and state laws and rules regarding confidentiality, integrity and privacy of patient information.~~

~~(2) Each consulting pharmacy must ensure that electronic data systems are secure and comply with applicable federal and state laws and rules.~~

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

~~855-041-3325~~
~~Consulting/Drugless Pharmacy - General Provisions and Minimum Standards~~

~~(1) A consulting pharmacy shall:~~

~~(a) Maintain appropriate reference materials for drug information according to the scope of consulting services.~~

~~(b) Be located in a secure room with a door and suitable lock, and accessible only to persons authorized by the pharmacist-in-charge.~~

~~(c) Provide storage sufficient to secure confidential documents and any hardware necessary to access information.~~

~~(d) Be constructed in a manner of materials that make the space separate and distinct from the rest of the home or office building, and that protects the records from unauthorized access.~~

~~(2) A consulting pharmacy located in a residence must be approved by the Board.~~

~~(3) The consulting pharmacist must be able to provide the Board, upon request, with documentation of their pharmaceutical care activities.~~

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

~~855-041-3330~~
~~Consulting/Drugless Pharmacy - Security Requirements~~

~~(1) All consulting services must occur in a secure environment that includes but is not limited to:~~

~~(a) A closed system or other electronic storage device that is password protected;~~

~~(b) A secure room or safe that is locked to store records when the pharmacist is not directly monitoring them;~~

~~(c) Sufficient encryption for securing confidential documents and any hardware used in accessing authorized patient health information by electronic connection; and~~

~~(d) A data processing system that complies with all federal and state laws and rules to ensure compliant security software.~~

~~(2) Records stored at a practitioner's office must be kept secure either with other records at the facility or independently in a locked room where only the pharmacist, and physician and their agents have access;~~

~~(3) All records must be stored at the approved consulting or drugless pharmacy; and~~

~~(4) Any breach in the security of the system or breach of confidentiality must be documented and reported to the Board within seven days.~~

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

~~855-041-3335~~
~~Consulting/Drugless Pharmacy - Policies and Procedures~~

~~The consulting pharmacy must maintain a current policy and procedures manual that includes at a minimum:~~

~~(1) A policy on protecting confidentiality and integrity of patient information;~~

~~(2) An outline of responsibilities and scope of services;~~
~~(3) A policy on compliance with federal and state laws and rules;~~

~~(4) An operational Quality Assurance Program;~~

~~(5) A policy that describes use of computer systems.~~

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

~~855-041-3340~~
~~Consulting/Drugless Pharmacy - Records~~

~~(1) The recordkeeping and storage requirements in OAR 855-041-3300 through 855-041-3340 are in addition to the requirements of other recordkeeping and storage rules of the Board. Records and documentation may be written, electronic or a combination of the two.~~

~~(2) Each recordkeeping system must include quality improvement program documentation;~~

~~(3) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety, and welfare. Records must include but need not be limited to:~~

~~(a) Patient profiles and records;~~

~~(b) A list of current employees and their license numbers;~~

~~(A) Verification of each license and registration;~~

~~(B) The name of the individual responsible for verification of licensure and registration status.~~

~~(c) Copies of all contracts for consulting services and collaborative therapy agreements;~~

~~(d) Copies of all consultation reports submitted to practitioners and facilities.~~

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

Division 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 rule amendments 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): 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: No fiscal impact is anticipated.

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 because the rules will now be located in Division 102.

Division 102
PROCEDURAL AND UNIVERSAL RULES

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

855-102-0010
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

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

855-102-0020
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

855-102-0025
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

855-102-0035
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

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 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 may 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

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

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

~~Prior to the permanent adoption, amendment, or repeal of any rule, the State Board of Pharmacy must give notice of its intended action as required in ORS 183.335:~~
~~(1) In a manner established by rule adopted by the board under ORS183.341(4), which provides a reasonable opportunity for interested persons to be notified of the agency's proposed action;~~

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

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

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

~~(5) To persons or organizations the Board's Executive Director determines, pursuant to ORS 183.335, are interested persons in the subject matter of the proposed rule, or would be likely to notify interested persons of the proposal; and~~

~~(a) Oregon State Pharmacy Association;~~

~~(b) Oregon Society of Health System Pharmacists;~~

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

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

~~855-001-0005~~
~~Model Rules of Procedure~~

~~Pursuant to the provisions of ORS 183.341, the Board of Pharmacy adopts the Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act effective 07/2019. These rules must be controlling except as otherwise required by statute or rule.~~

~~[ED. NOTE: The full text of the Attorney General's Model Rules of Procedure is available from the office of the Attorney General or Board of Pharmacy.]~~

~~Statutory/Other Authority: ORS 183.341 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 183.341~~

~~855-001-0012~~

~~Time for Requesting a Contested Case Hearing~~

~~A request for a contested case hearing must be in writing and must be received by the board within 21 days from the date the contested case notice was served. When the board has issued a denial of a license, a request for a contested case hearing must be in writing and must be received by the board within 60 days from the date the licensure denial was served.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & ORS 183.435~~

~~855-001-0016~~

~~Filing Exceptions and Argument to the Board~~

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

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

~~855-001-0017~~

~~Petition for Reconsideration or Rehearing as Condition for Judicial Review~~

~~All parties, including limited parties, must file a petition for reconsideration or rehearing with the board as a condition for obtaining judicial review of any order of the board.~~

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

~~855-001-0035~~

~~Duty to Cooperate~~

~~(1) Applicants, licensees, and registrants must comply with all board requests, including responding fully and truthfully to inquiries and providing requested materials within the time allowed by the board and complying with a subpoena.~~

~~(2) Applicants, licensees, and registrants must comply with the terms of board orders and agreements.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 676.612~~

~~855-001-0040~~

~~Inspections~~

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

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

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

~~(b) Inspecting all drugs and devices;~~

~~(c) Taking photographs, recording video and audio; and~~

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

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

~~(a) Must be stored on-site for 12 months and must be provided to the board immediately upon request at the time of inspection;~~

~~(b) May be stored in a secured off-site location after 12 months of on-site storage and must be provided to the board upon request within three business days; and~~

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

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

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

~~Statutory/Other Authority: ORS 475.125 & ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

Division 031/120: Interns (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 120 for Interns

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates a new Division 120 for Interns. Proposes relocating existing Intern rules from Division 031 as a result of the board's 2022-2026 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

Documents Relied Upon per ORS 183.335(2)(b)(D): 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 amendments include relocating and reorganizing existing rules from Division 031 to new Division 120 in alignment with the board's strategy to systematically organize all Divisions. Amendments include revising titles, clarifying requirements for applicability, definitions, general qualifications, licensure requirements, license renewal, license reinstatement, license termination, and general responsibilities.

Division 6
DEFINITIONS

855-006-0005 *See mailing #B13
Definitions

(7) "Board-approved school or college of pharmacy" means an ACPE accredited, accredited with probation, pre-candidate or candidate status (v. 6/2022) or with Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program (v. 6/2022) with a curriculum taught in English;

(29) "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.
(40) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.

(45) "Preceptor" means a Pharmacist or a person licensed by the board to supervise the internship training of a licensed Intern.

POLICY DISCUSSION: Non-RPH preceptor, training

Division ~~31~~ 120
INTERNS

855-120-0001
Applicability

(1) This Division applies to any individual who is enrolled in or has completed a Bachelor or Doctor of Pharmacy at a board-approved school or college of pharmacy or holds a certificate from the Foreign Pharmacy Graduate Equivalency Committee (FPGEC), and who acts as Intern under the supervision of an Oregon licensed Pharmacist.

(2) Persons licensed with the board as an Intern may perform the functions of a Pharmacist at the discretion and under the supervision of a Pharmacist and must act in compliance with all applicable statutes and rules.

POLICY DISCUSSION: Functions, Exclusions, Criteria, Education

Statutory/Other Authority: 689.205
Statutes/Other Implemented: 689.225

~~855-031-0005~~ **855-120-0005**
Definitions

Note: Placeholder- No definitions specific to Division 120 at this time.

~~(1) An "intern" means any person who:~~

~~(a) Is enrolled in a course of study and is in good academic standing at a school or college of pharmacy that is approved by the Oregon Board of Pharmacy; or~~

~~(b) Is a graduate of a school or college of pharmacy that is approved by the board; or~~

~~(c) Is a foreign pharmacy graduate and holds a certificate from the Foreign Pharmacy Graduate Equivalency Committee (FPGEC); and~~

~~(d) Is licensed with the board as an intern.~~

~~(2) A "preceptor" means a pharmacist or a person licensed by the board to supervise the internship training of an intern.~~

~~(3) "Internship" means a professional experiential program or work experience.~~

~~(a) "Traditional Pharmacy-practice Internship (TPI)" means experience toward achieving competency in the practice of pharmacy for which no academic credit is granted to the intern.~~

~~(b) "School-based Rotational Internship (SRI)" means experience toward achieving competency in the practice of pharmacy in programs developed and administered by a school of pharmacy.~~

~~(c) "Other Internship" means experience toward achieving competency in the practice of pharmacy, other than in an internship as defined in (a) or (b), in a program approved by a school of pharmacy or the board.~~

POLICY DISCUSSION: TPI, SRI, Other internship

~~(4) "School of pharmacy": In this division of rules, "school of pharmacy" means a school or college of pharmacy that is approved by the board.~~

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

855-120-0010
Licensure: Qualifications

(1) To qualify for licensure as an Intern, an applicant must provide proof that they:

(a) Are enrolled in a Doctor of Pharmacy program at a board-approved school or college of pharmacy; or

POLICY DISCUSSION: Enrolled (statutory), Admitted, Registered

(b) Have graduated with a Bachelor's or Doctor of Pharmacy degree from a board-approved school or college of pharmacy for the purpose of obtaining the qualifications to apply for a Pharmacist license; or

POLICY DISCUSSION: Purpose

(c) Have graduated with a Bachelor's or Doctor of Pharmacy degree from a foreign school or college of pharmacy and:

(A) Are pursuing an Intern license for the purpose of obtaining the qualifications to apply for a Pharmacist license; and

(B) Must provide a copy of the original certificate issued by the NABP Foreign Pharmacy Graduate Examination Committee (FPGEC).

POLICY DISCUSSION: Purpose

(2) Graduates from a Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program with a curriculum taught in English are exempt from (1)(c)(B).

(3) If residing in the United States, an applicant must provide proof of citizenship, legal permanent residency or qualifying visa as required by 8 USC 1621.

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

~~855-031-0050~~
~~Eligibility for Exams — Foreign Pharmacy Graduates~~

~~In addition to the other requirements of this Division, a foreign pharmacy graduate must complete 1440 internship hours before applying to take the Multistate Pharmacy Jurisprudence Examination (MPJE) and before applying for licensure as a pharmacist as specified in OAR 855-019-0150. Evidence of completing this requirement must be provided to the board by the applicant and must be authenticated by each preceptor.~~

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

~~855-031-0010~~ **855-120-0020**
Licensure: ~~Intern License~~ Application- Intern

(1) A**n a**pplication~~s~~ for licensure as an ~~i~~**I**ntern may be ~~obtained from~~ **accessed on** the board website.

~~(a) Failure to completely, accurately and honestly answer all questions on the application form for licensure or renewal of licensure is grounds for discipline;~~

~~(b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

(2) The board may issue a license to a qualified ~~intern~~ **applicant** after the receipt of:

(a) Documentation required in OAR 855-120-0010; and

(~~a~~**b**) 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);

(C) Personal identification or proof of identity;

(~~d~~**D**) ~~Furnish documentation required to conduct a~~**A completed** national fingerprint-based background check; and

(E) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405.

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

(5) The license of an Intern expires November 30 following the second anniversary of issue and may be renewed twice.

POLICY DISCUSSION: Length, Maximum

(6) The license of a Graduate Intern expires two years following the anniversary of issue and may not be renewed.

POLICY DISCUSSION: Graduates, Length, Maximum

~~(c) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study, except for foreign pharmacy graduates who must:~~

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

~~(B) Provide a copy of the original certificate issued by the Foreign Pharmacy Graduate Equivalency Examination Committee; and~~

~~(C) Provide evidence that they have passed the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT).~~

~~(3) The board may issue an intern license after processing the application, however unless the applicant is a foreign graduate or an applicant for licensure by reciprocity, it is not valid until the intern has started a course of study. The initial license is valid until the last day of November following the second anniversary of issue unless terminated automatically by any one of the following events. Renewed licenses are valid for two years unless terminated automatically by any one of the following events:~~

~~(a) Licensure to practice pharmacy is granted in any state; or~~

~~(b) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, fails to maintain enrollment or active registration in a pharmacy degree program for a period greater than one year; or~~

~~(c) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, has been graduated from a school of pharmacy for 12 months;~~

~~(d) The intern is dismissed, terminated or expelled by the school of pharmacy, or withdraws from the program.~~

~~(4) An intern must surrender their license to the board within 30 days of one of the above events.~~

~~(5) Notwithstanding the requirements of section (3) above, upon written request the board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section must only be effective when it is issued in writing.~~

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

~~855-031-0016~~ **855-120-0030**
Licensure: Renewal or Reinstatement Applications ~~of Licensure as an~~ **Intern**

(1) **When** ~~An~~ apply**ing**~~ication~~ for renewal of an ~~i~~**I**ntern license, **an applicant** must ~~include documentation of~~:

~~(a) Completion of continuing pharmacy education requirements as directed 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 directed in OAR 855-021;

(~~2~~**c**) ~~An intern 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) An Intern who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license.

(3) An Intern or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-120-0020; and

(b) Provide certification of completion of the continuing pharmacy education requirement in OAR 855-021 for all years in which the license was lapsed.

(4) A Graduate Intern license may not be renewed or reinstated.

(5) A person whose Intern license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition to the Board in writing for reinstatement of such license pursuant to ORS 689.445 and in conjunction with the application process identified in OAR 855-120-0020.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.275, ORS 689.445

855-120-0040
Licensure: Lapse

(1) An Intern may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not practice as an Intern if the license is lapsed.

(d) A person may apply for renewal or reinstatement according to OAR 855-120-0030.

(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.

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-0046
Licensure: Voluntary Surrender

An Intern may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date 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 may not be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-120-0030 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-00XX
Grounds for Discipline

The State Board of Pharmacy may suspend, revoke, or restrict the license of an Intern or may impose a civil penalty upon the Intern upon the following grounds:

(1) Continuing to practice as an Intern when one of the following has occurred:

(a) Prior to graduation, failing to maintain enrollment in a Doctor of Pharmacy degree program for a period greater than 12 months; or

POLICY DISCUSSION: Length

(b) Prior to graduation, failing to maintain good academic standing in a Doctor of Pharmacy degree program for a period greater than 12 months; or

POLICY DISCUSSION: Good academic standing, length

(c) Failing to meet the qualifications for licensure in OAR 855-120-0010; or

(d) Any other grounds found in ORS 689.405.

(2) Failure to notify the board within 15 days of any change in their enrollment or pursuit of a Pharmacist license that might affect their eligibility to work as an Intern.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.405

~~855-031-0010~~

~~Intern License Application~~

~~(1) Applications for licensure as an intern may be obtained from the board website.~~

~~(a) Failure to completely, accurately and honestly answer all questions on the application form for licensure or renewal of licensure is grounds for discipline;~~

~~(b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(2) The board may issue a license to a qualified intern after the receipt of:~~

~~(a) A completed application;~~

~~(b) Payment of the fee prescribed in OAR 855-110;~~

~~(c) A current, passport regulation size photograph (full front, head to shoulders);~~

~~(d) Furnish documentation required to conduct a national fingerprint-based background check; and~~

~~(e) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study, except for foreign pharmacy graduates who must:~~

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

~~(B) Provide a copy of the original certificate issued by the Foreign Pharmacy Graduate Equivalency Examination Committee; and~~

~~(C) Provide evidence that they have passed the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT).~~

~~(3) The board may issue an intern license after processing the application, however unless the applicant is a foreign graduate or an applicant for licensure by reciprocity, it is not valid until the intern has started a course of study. The initial license is valid until the last day of November following the second anniversary of issue unless terminated automatically by any one of the following events. Renewed licenses are valid for two years unless terminated automatically by any one of the following events:~~

~~(a) Licensure to practice pharmacy is granted in any state; or~~

~~(b) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, fails to maintain enrollment or active registration in a pharmacy degree program for a period greater than one year; or~~

~~(c) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, has been graduated from a school of pharmacy for 12 months;~~

~~(d) The intern is dismissed, terminated or expelled by the school of pharmacy, or withdraws from the program.~~

~~(4) An intern must surrender their license to the board within 30 days of one of the above events.~~

~~(5) Notwithstanding the requirements of section (3) above, upon written request the board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section must only be effective when it is issued in writing.~~

~~[Publications: Publications referenced are available from the agency.]~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.207, ORS 689.255 & ORS 689.455~~

~~855-031-0055~~
~~Eligibility for Exams and Pharmacist Licensure~~

~~(1) An intern is eligible to take the North American Pharmacist Licensure Examination (NAPLEX) and the MPJE, upon graduation and notification to the board by the school of pharmacy that their degree, with not less than 1440 hours of SRI, has been conferred.~~

~~(2) Upon meeting all requirements for pharmacist licensure, and before practicing pharmacy in the State of Oregon, a person must:~~

~~(a) Complete an application for licensure including providing any fingerprint card or other documentation required by the board to conduct a criminal background check;~~

~~(b) Pay the license fee as prescribed in OAR 855-110; and~~

~~(c) Obtain a license, which will expire on June 30 in odd numbered years.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.135, ORS 689.207, ORS 689.225 & ORS 689.275~~

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): Modifies patient records requirements to include 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)

Resources

- 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.

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 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 **P**~~p~~harmacist or intern shall perform a DUR prior to dispensing or preparing for administration any prescription or refill.

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

855-019-0290
Immunization Record Keeping and Reporting

(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

(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

(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

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

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.

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;

NOTE: In rulemaking: Div 115

(~~7~~**8**) “Certified health care interpreter” has the meaning given that term in ORS 413.550.

(~~8~~**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.

(~~9~~**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**.

NOTE: In rulemaking: Div 115

(1~~0~~**1**) "Collaborative Drug Therapy Management" means the participation by a Pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration, and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one Pharmacist and one practitioner; or

(b) Is agreed to by one or more Pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic, or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.

NOTE: In rulemaking: Div 115

(1~~1~~**2**) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(a) As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the Pharmacist and the patient, in the course of professional practice; or

(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or

(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(1~~2~~**3**) "Confidential Information" means any patient information obtained by a Pharmacist or pharmacy.

(1~~3~~**4**) "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**5**) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(16) "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.

NOTE: In rulemaking: Div 115

(1~~5~~**7**) "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.

(1~~6~~**8**) "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.

(19) "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.

(20) "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.

NOTE: In rulemaking: Div 115

(~~17~~**21**) "Entry system" enables control of access to a secured area.

(~~18~~**22**) "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.

(23) "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.

NOTE: In rulemaking: Div 115

(~~19~~**24**) "Health care interpreter" has the meaning given that term in ORS 413.550.

(2~~0~~**5**) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.

(26) "Independent Practice of Pharmacy" means the provision of clinical pharmacy services not related to the dispensing, distribution and delivery of drugs or devices.

(2~~1~~**7**) "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.

(2~~2~~**8**) "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).

(29) "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.

NOTE: In rulemaking: Div 115

(~~23~~**30**) "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.

(~~24~~**31**) "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.

(~~25~~**32**) “Misbranded” has the same definition as set forth in 21 USC 352 (v. 03/15/2022).

(~~26~~**33**) "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.

(~~27~~**34**) "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.

(~~28~~**35**) "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.

(~~29~~**36**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(3~~0~~**7**) "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.

(3~~1~~**8**) “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.

~~(32) "Oral Counseling" means an oral communication process between a Pharmacist and a patient or a patient’s agent in which the Pharmacist obtains information from the patient (or agent) and the patient's pharmacy records, assesses that information, and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.~~

NOTE: In rulemaking: Div 115

~~(33) Participation in Drug Selection and Drug Utilization Review:~~

~~(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.~~

~~(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the Pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review include, but are not limited to:~~

~~(A) Over-utilization or under-utilization;~~

~~(B) Therapeutic duplication;~~

~~(C) Drug-disease contraindications;~~

~~(D) Drug-drug interactions;~~

~~(E) Incorrect drug dosage;~~

~~(F) Incorrect duration of treatment;~~

~~(G) Drug-allergy interactions; and~~

~~(H) Clinical drug abuse or misuse.~~

NOTE: In rulemaking: Div 115

(3~~4~~**9**) "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.

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

NOTE: In rulemaking: Div 115

(41) "Pharmacy Area" means each area where prescription drugs or devices, records, and equipment used to access pharmacy records are located.

NOTE: In rulemaking: Div 115

(~~35~~**42**) "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.

(~~36~~**43**) “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.

(~~37~~**44**) “Practice of pharmacy” is as defined in ORS 689.005.

(45) “Preceptor” means a Pharmacist or a person licensed by the board to supervise the internship training of a licensed Intern.

NOTE: In rulemaking: Div 115

(~~38~~**46**) “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.

(~~39~~**47**) "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.

(4~~0~~**8**) “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.

(4~~1~~**9**) "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.

(~~42~~**50**) “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.

(~~43~~**51**) “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.

(~~44~~**52**) “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.

(~~45~~**53**) “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.

~~(46) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication, the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.~~

NOTE: In rulemaking: Div 115

(~~47~~**54**) "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.

(~~48~~**55**) “Still image capture” means a specific image captured electronically from a video or other image capture device.

(~~49~~**56**) “Store and forward” means a video or still image record which is saved electronically for future review.

(5~~0~~**7**) "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.

(5~~1~~**8**) “Surveillance system” means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

(5~~2~~**9**) "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.

(~~53~~**60**) "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.

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) An "intern" means any person who:~~

~~(a) Is enrolled in a course of study and is in good academic standing at a school or college of pharmacy that is approved by the Oregon Board of Pharmacy; or~~

~~(b) Is a graduate of a school or college of pharmacy that is approved by the board; or~~

~~(c) Is a foreign pharmacy graduate and holds a certificate from the Foreign Pharmacy Graduate Equivalency Committee (FPGEC); and~~

~~(d) Is licensed with the board as an intern.~~

~~(2) A "preceptor" means a pharmacist or a person licensed by the board to supervise the internship training of an intern.~~

(**1**~~3~~) "Internship" means a professional experiential program or work experience.

(a) "Traditional Pharmacy-practice Internship (TPI)" means experience toward achieving competency in the practice of pharmacy for which no academic credit is granted to the intern.

(b) "School-based Rotational Internship (SRI)" means experience toward achieving competency in the practice of pharmacy in programs developed and administered by a school of pharmacy.

(c) "Other Internship" means experience toward achieving competency in the practice of pharmacy, other than in an internship as defined in (a) or (b), in a program approved by a school of pharmacy or the board.

(**2**4) "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** ~~that is approved by the board~~.

Statutory/Other Authority: ORS 689.151 & ORS 689.205

Statutes/Other Implemented: ORS 689.255

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 ~~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~~ **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.

(1~~1~~**2**) 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

SBAR: Deschutes County Health Services

S	**Situation:** • Deschutes County Health Services (Downtown Health Services) in Bend (CHC# 0000095) and in Redmond (CHC# 0000097) requests to modify and renew their security waiver for 5 years per OAR 855-043-0720(3) to permit Certified Medical Assistant Alison Medina and Certified Medical Assistant Kayley Houle to have access to the drug storage area at both the Bend and Redmond locations.
B	**Background:** • **OAR 855-043-0720 Community Health Clinic (CHC) - Security** (1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use. (2) Only a Physician, Clinical Nurse Specialist, Nurse Practitioner, or Registered Nurse shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room must remain locked. **(3) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.** Past Board Meeting: • February 2019 Board Meeting o Board approved request to permit the following individuals access to the drug storage area: ▪ Clinic Operations Supervisor Matt Palmer ▪ MA Ana Silveira ▪ MA Lucia Tapia o The approval was good for 5 years. Expires on 8/7/2024
A	**Assessment:** • Per OAR 855-043-0720(3) Will this further public health or safety or the health and safety of a patient? • NP Anne Kilty who is Clinical Services Manager at Deschutes County Health Services states that she runs the two Family Planning /STD clinics in Bend and Redmond and that they have a very small staff. • NP Kilty, a half-time MD, and another part-time NP split their time between both clinics with the assistance of the two Certified Medical Assistants (CMAs) who manage the day-to-day operations. • It is imperative that the CMAs have access to the locked pharmacy area given their small staff size and their limited public health budget for operations. • It would not be feasible for their operations to function without CMAs having access to the secure drug area. • NP Kilty states that both requested CMAs are trustworthy and experienced and that she maintains close oversight. • The CMAs provide the following assistance in the drug storage area:

	○ Adding stock to the shelves, confirming lot numbers, adding inventory to their tracking system, completing bi-weekly inventory of all medications and reconciling counts, and notifying NP Kilty of any discrepancies or concerns. • NP Kilty stated the CMAs do not package or dispense medications. • The 2019 security waiver granted access to 2 Medical Assistance that no longer work at these locations. Deschutes County Health Services is requesting to update this to staff that is currently working at these locations to ensure there is no disruption to patient care and are also requesting a 5 year waiver from today's review.
R	**Recommendation:** • Motion to Grant Waiver • Note: ○ To permit Certified Medical Assistant Alison Medina and Certified Medical Assistant Kayley Houle to have access at both the Bend and Redmond locations. (CHC# 0000095 and CHC# 0000097). ○ To permit for 5 years from approval date, expires 10/16/2027.

Date: 10/2022

DESCHUTES COUNTY

HEALTH SERVICES

1340 NW Wall Street • Bend, Oregon 97703
Behavioral Health (541) 322-7500 • FAX (541) 617-4793
Intensive Youth Services Screening Line (541) 213-6851
Public Health (541) 322-7400 • FAX (541) 322-7465
www.deschutes.org

August 19, 2022

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

Security Waiver modification request (OAR 855-043-0720)

Dear Board Members,

On February 7, 2019 we were granted a security waiver allowing for our Medical Assistants to access our locked pharmacy area. It has recently come to my attention that the waiver was specific to the staff identified in the waiver. Those staff are no longer with us and have been replaced by two highly responsible Certified Medical Assistants (Allison Medina and Kayley Houle).

I am writing to you requesting modification of our current waiver to include these two individuals and if possible at the same time to request extension of the waiver period.

I run the two Family Planning/STD clinics for Deschutes County Public Health, one in Bend and one in Redmond. We have a very small staff. I run the clinical services program and see patients 2 days/week. I have another half-time MD who splits time between the two clinics and a part-time NP who also splits time between the clinics, and the two Certified Medical Assistants (CMAs) named above who manage the day-to-day operations at each site. We do not have any RNs on our team.

Given our small team, two locations and limited licensed staff who mostly work part-time, it is imperative that our CMAs continue to have access to the locked pharmacy areas. They are both trustworthy and experienced. I maintain close oversight on both of them. Their duties in the pharmacy include adding new stock to the shelves by confirming lot numbers and making log sheets for our inventory binder, bi-weekly inventory of all medications and cross referencing with the log book, notifying me of any discrepancies and working with providers to determine source of the discrepancies so that they can be corrected. They do not package or dispense any medications ever.

It is not feasible for our operations to function without the CMAs having access to the secure pharmacy. We operate on a very limited Public Health budget and hiring a Registered Nurse to perform these functions is not possible at this time.

If further information is required, please let me know. I will be on leave for a few weeks, which may overlap with the Board's timing. If it does, in my absence please contact my colleague Pamela Ferguson RN, manager for our Healthy People & Families programs. I have updated her on my request for this modification. Her email is Pamela.Ferguson@deschutes.org.

I thank you for your time and attention to this matter.

Sincerely,

Anne Kilty NP
Clinical Services Manager
Deschutes County Health Services
Office: 541-322-7445
Anne.Kilty@deschutes.org

SBAR: Murray's Drug Waiver Request

S	**Situation:** • Murray's Drug (RP# 0000167) in Condon requests to renew their waiver per OAR 855-041-01050(2) to permit the storage and prescription pickup by patients at 2 Asher Federally Qualified Health Center (FQHCs).
B	**Background:** **• OAR 855-041-1050 Pharmacy Depots** (1) Except when delivering directly to a patient, licensed pharmacists may not participate in the transfer of completed prescription medication containers to or from any location that is not a licensed pharmacy, unless the transfer occurs to: (a) The office of the patient's health care practitioner; or (b) The location of the patient; or (A) Patient's primary residence; or (B) Alternate residence designated by the patient; or (C) Patient's workplace; or (c) The hospital or medical care facility in which a patient is receiving care. **(2) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.** • First approval in 2015: • No changes in the process have occurred in the past 7 years. • August 2021 Waiver Request: Approved
A	**Assessment:** • Per OAR 855-041-1050(2) Will this further public health or safety or the health and safety of a patient? • Per Murry's Drug submission: o The Need: ▪ They are the sole pharmacy service for several remote counties, that have a FQHC in the town of Fossil and Spray. ▪ Their patient base is disproportionally elderly and low income. It is difficult for patient to economically and logistically to drive to the pharmacy to pick up their prescriptions. ▪ Delivering prescriptions to patient home or employment does not work for many of their patients and delivering directly to patients' home is not feasible and during winter is dangerous. ▪ This waiver has helped to improve access to pharmacy services in their rural underserved area. o Safety Parameters: ▪ Prescription drugs are stored in secure storage cabinets at the Asher's clinics.

	▪ Cabinets are only accessed by HIPAA trained staff in response to a customer picking up a prescription, as arranged with Murray's pharmacy. ▪ The Clinic will have a list of patient names on the exterior of the cabinet to be referenced prior to opening the cabinet. ▪ There is a video camera for monitoring of the area. ▪ The cabinet is reviewed and prescriptions older than 14 days are returned to Murray's on a weekly basis. ▪ The clinic has phone accessible at all times for patient prescription questions. ▪ The clinic and prescription list will be available for inspection by BOP at any time. o Murray's Drug stated they will continue to deliver directly to patient residences whenever possible. • There are no substantive changes in this request from last year's request.
R	**Recommendation:** • Motion to Grant waiver • Note: o To permit 2 FQHC clinics to securely store prescriptions for patient pickup, per OAR 855-041-1050(2) for 2 years. o This approval ends after one year or if the rule allowing the waiver is repealed, whichever comes first. ▪ If these rules are repealed, staff will work with outlet through the transition process.

Date: 10/2022

August 16, 2022

To: Brianne Efremoff

Compliance Director

Oregon Board of Pharmacy

800 NE Oregon Street, Suite 150

Portland, OR 97232

Re: Waiver Request

Dear Ms. Efremoff,

Murray's Condon Pharmacy is applying to renew our waiver to OAR 855-041-1050 (Pharmacy Depots).

Since 1963, Murray's Pharmacy in Condon (Gilliam County) has served as the "local" or closest pharmacy for Wheeler County towns of Fossil and Spray. The distance from Condon to Fossil is 20 miles and the distance from Condon to Spray is 51 miles. Each of these towns has an Asher Community Health Services FQHC.

For decades, our mutual patients in Fossil and Spray have seen their primary care prover and then driven to our pharmacy for their medications. Our patient base is disproportionately elderly and low income, so this trip has historically been difficult economically and logistically. In addition, our counties experience hazardous driving conditions for months in the wintertime.

Delivery to Board-approved locations (e.g. patients' homes or places of employment) does work for some townspeople, but patients living on farms and ranches may already drive an hour just to get to Fossil and Spray, let alone to the pharmacy. Delivering directly to patients who live out of town is not feasible because of remote access, long distances and dangerous winter driving conditions.

We received a waiver from the Board in 2015 to deliver to secure cabinets in Fossil and Spray FQHC clinic. In the 7 years since that approval, this service has become an integral part of our community's healthcare system. Our clinics and patients have reported improved access and adherence to prescribed therapies and we have spared our patients immeasurable time, money and difficulty.

The system we outlined in our 2015 waiver application to the Board has been working smoothly and we hope to continue the following practices:

- We will continue to deliver directly to patients' residences whenever possible.
- Secure storage cabinets onsite at Asher Clinic Fossil and Asher Clinic Spray will be managed according to the following standards:
    - Each Cabinet will be in a secure, staff-only area of the clinic.

- Cabinets will only be accessed by HIPAA-trained staff in response to a customer picking up a prescription, as arranged with Murray's Pharmacy.

- There will be a list of patient names on the exterior of the cabinet to be referenced prior to opening cabinet.

- There will be a video camera for security purposes monitoring the area of the cabinet.

- Cabinet will be reviewed and prescriptions returned to Murrays' weekly, all prescriptions older than 14 days will be returned.

- The clinic will have a phone accessible at all times for questions patients may have for the Pharmacist when picking up prescriptions.

- Cabinet and prescription list will be available for inspection by the Board of Pharmacy at any time.

This waiver has truly helped to deliver pharmacy services in our rural, underserved area. Accessibility and equity of services is improved through access to "local" service.

Murrays appreciates the Board's consideration of our renewed request, may we ask however that the waiver be granted for longer than one year please? The original was for 5 years, this last one, only 1 year. Thank you.

Best Regards,

John Murray RPH, Pres.

SBAR: 9/26/2022 – NAPLEX Score Extension Request

S	**Situation**: Received request from pharmacist candidate R.T. for a 3rd extension of NAPLEX score which would allow additional time to retake and pass the Oregon MPJE and obtain licensure without requirement to retake the NAPLEX exam.
B	**Background:** • Foreign Pharmacy Graduate • Passed NAPLEX on 1st attempt on 3/23/2021 – Score valid through 3/23/2022 per OAR 855-019-0150(1)(c). o MPJE 1st attempt - 11/22/2021 o MPJE 2nd attempt – 2/4/2022 • **2/16/2022** – 1st extension request of NAPLEX score –E.D. Schnabel approved 60 day extension through 5/22/2022 o MPJE 3rd attempt – 4/12/2022 • **4/26/2022** - Requested 2nd extension of NAPLEX score – E.D. Schnabel approved through 12/31/2022. o Not eligible for MPJE 4th attempt until 11/22/2022 or later • **9/21/2022** - Requested 3rd extension of NAPLEX Score
A	**Assessment:** • Individual has requested an additional extension beyond 12/31/2022 due to concerns of testing availability in local area. • Will not know if availability exists at additional locations until they receive the Authorization to Test to schedule an exam.
R	**Recommendation:** • *Board Discussion*

855-019-0120 Licensure

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

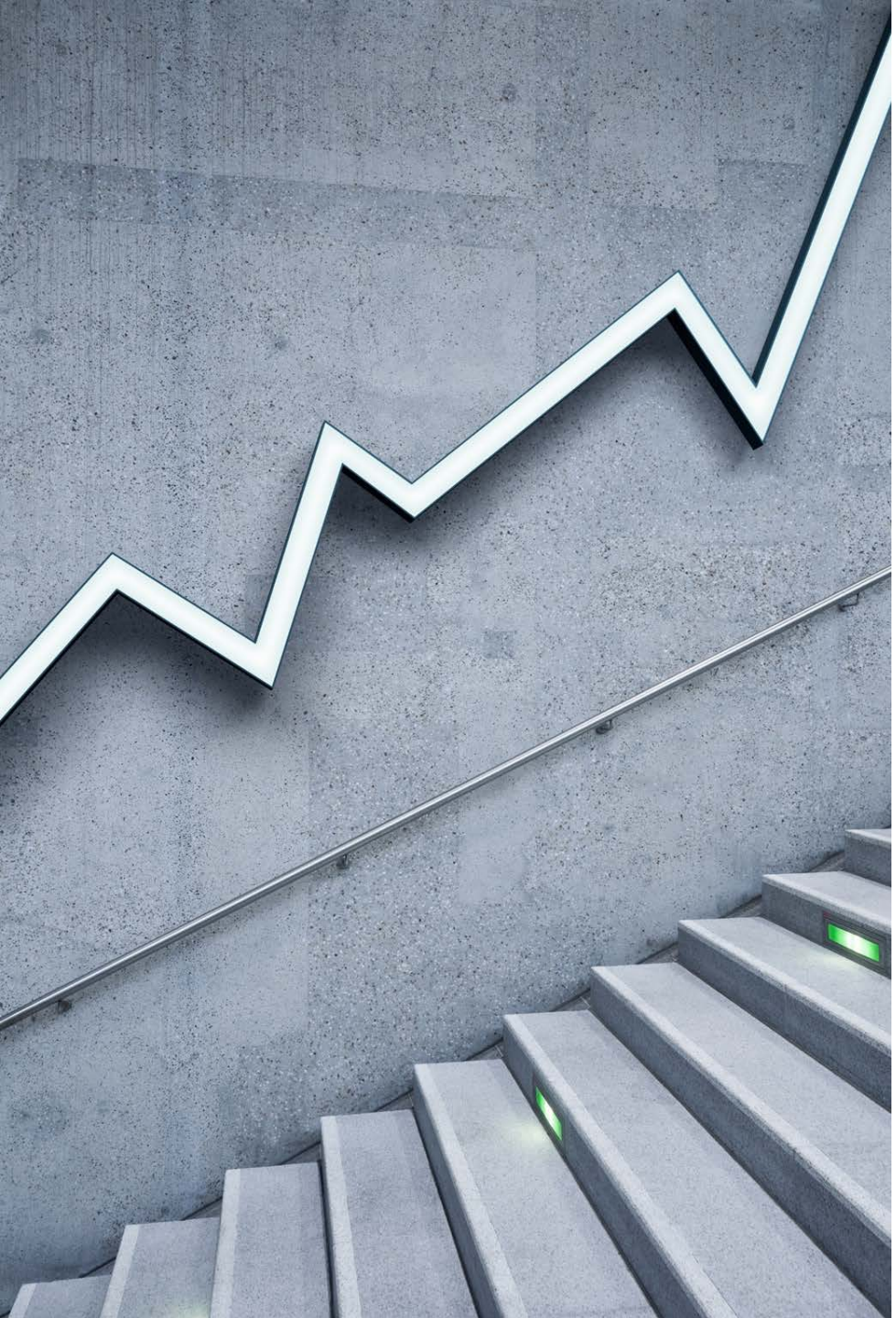
(a) Provide evidence from a school or college of pharmacy approved by the board that they have successfully completed all the requirements for graduation and, starting with the graduating class of 2011, including not less than 1440 hours of School-based Rotational Internships as that term is defined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

(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. This score is valid for only one year unless the board grants an extension. A candidate who does not attain this score may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times;

(c) Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) exam with a score of not less than 75. The applicant may not take the MPJE until they have graduated from a school or college of pharmacy approved by the board. A candidate who does not attain this score may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times. The MPJE score is valid for 6 months unless extended by the board;

Staff Delegated Authority – Licensing -

6. Approve extensions of MPJE / NAPLEX score expiration dates (OAR 855-019-0120(1)(b) & (c))



OCTOBER 2022/D

Pharmacy Workforce 2022

OREGON BOARD OF PHARMACY
September 21, 2022

Board of Pharmacy Mission

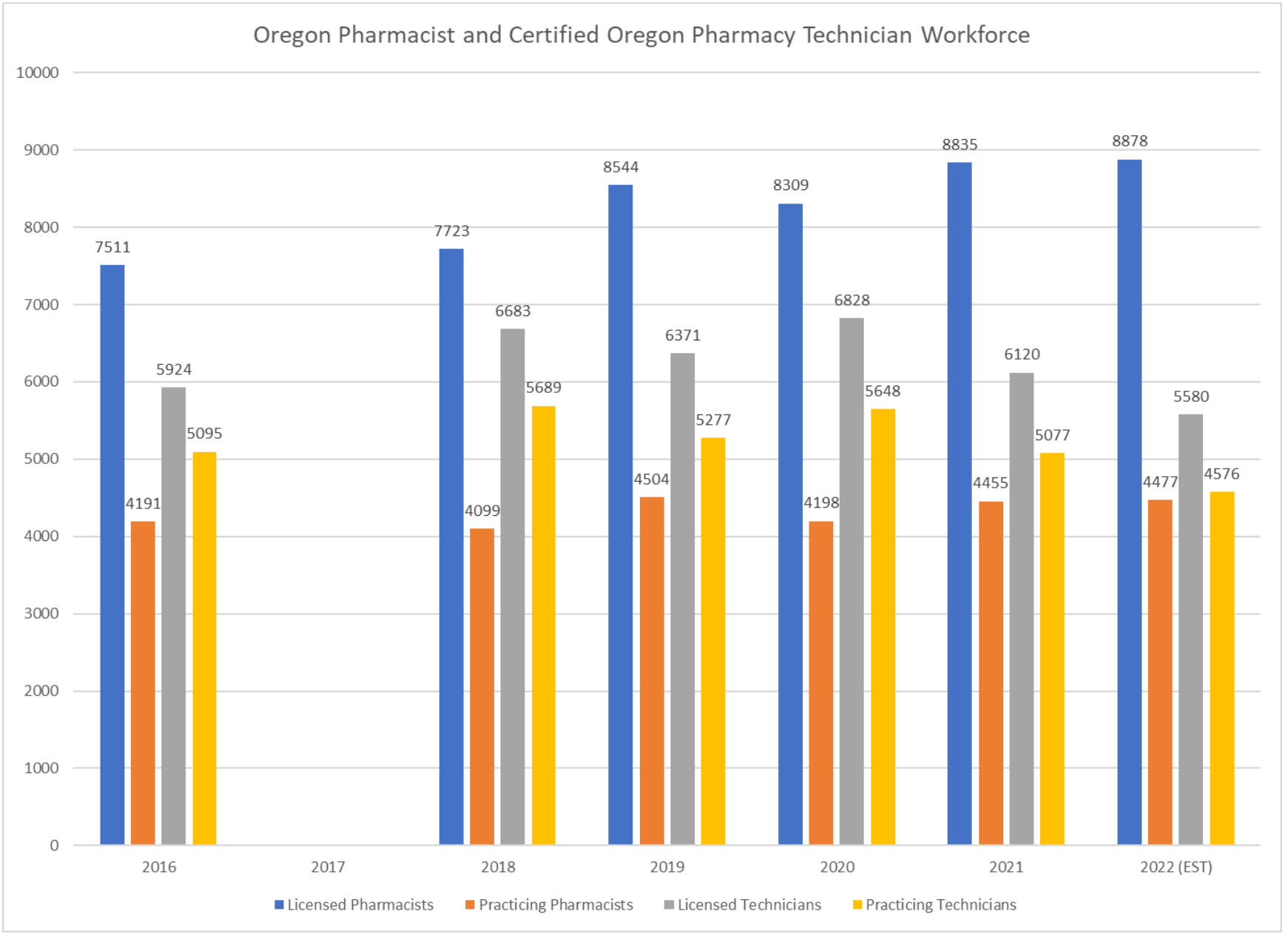
The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

Licenses Issued by OBOP

- Pharmacist (8,878)
- Intern (805)
- Certified Oregon Pharmacy Technician (5,580)
- Pharmacy Technician (1,743)

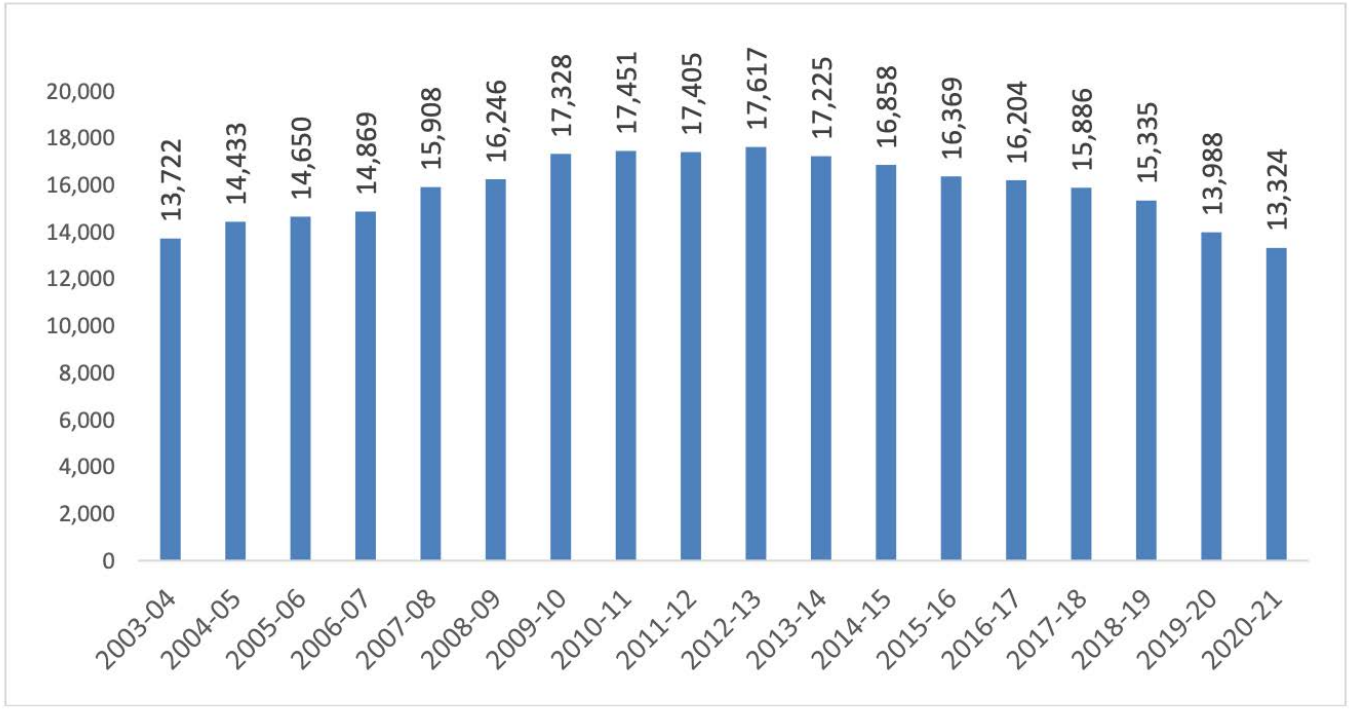
Requirements for Licensure

- **Pharmacist**
  - 2-4 years pre-pharmacy, bachelor's degree, 3- to 4-year pharmacy program
  - Board exams (Pharmacy Practice (NAPLEX), Jurisprudence (MPJE))
- **Intern**
  - Enrolled in approved college/school of pharmacy
- **Certified Oregon Pharmacy Technician**
  - 18 years old, high school/equivalent, national certification (one-time)
- **Pharmacy Technician**
  - 18 years old, high school/equivalent


Oregon Pharmacist and Certified Oregon Pharmacy Technician Workforce
10000
9000
8000
7000
6000
5000
4000
3000
2000
1000
0
7511
4191
5924
5095
7723
4099
6683
5689
8544
4504
6371
5277
8309
4198
6828
5648
8835
4455
6120
5077
8878
4477
5580
4576
2016
2017
2018
2019
2020
2021
2022 (EST)
Licensed Pharmacists
Practicing Pharmacists
Licensed Technicians
Practicing Technicians

Applications for pharmacy education decreasing

Figure 5: Total Number of PharmCAS Applicants (2004-2021)



94% of 142 SOP/COP participate in PharmCAS

2020-2021 PharmCAS Applicant Data Report, American Association of Colleges of Pharmacy (AACP).
AACP bears no responsibility for interpretations presented or conclusions reached based on analysis of the data.

Not all graduates pass NAPLEX & MJPE licensing exams

NAPLEX – 1ST TIME PASS RATES

	2017	2018	2019	2020	2021
State* (%)	90.1	88.4	80.9	94.3	80.9
Nat'l (%)	86.9	88.2	87	86.5	83.6

State and national first attempt pass rates of students who graduated from any program for up to the past five years, based on the calendar year of their graduation.
*Two Oregon institutions

MPJE – 1ST TIME PASS RATES

	2017	2018	2019	2020	2021
In-state (%)	81.2	83.7	75.8	85.8	83.3
Out-of-state (%)	76.9	72.3	69.6	76.1	80.4

Pass rates of students in [OR] for most recent five years for their first attempt on any specific exam jurisdiction.
"In-State": students took the MPJE® for the state in which their university is located.
"Out-of-State": students took the MPJE® for states other than the state in which their university is located.

NAPLEX® 2021 Calendar Year Report; MPJE® 2021 Calendar Year Report

Pharmacy Demand Report (PDR) 2021 Yearly Summary

Pharmacists

	Q1 2020	Q1 2021	Q1 % Change	Q2 2020	Q2 2021	Q2 % Change	Q3 2020	Q3 2021	Q3 % Change	Q4 2020	Q4 2021	Q4 % Change	Total 2020	Total 2021	Total % Change
Northeast	842	724	-14%	440	530	**20%**	372	514	38%	424	532	25%	2,078	2,300	11%
South	1,511	1,667	10%	565	1,101	**95%**	969	1,008	4%	909	1,080	19%	3,954	4,856	23%
Midwest	1,214	992	-18%	401	776	**94%**	440	616	40%	614	791	29%	2,669	3,175	19%
West	1,693	1,255	-26%	709	1,162	**64%**	740	1,011	37%	796	1,156	45%	3,938	4,584	16%
Total:	5,260	4,638	-12%	2115	3,569	**69%**	2,521	3,149	25%	2,743	3,559	30%	12,639	14,915	18%

https://www.aacp.org/article/pharmacy-demand-report-pdr

Pharmacy Demand Report (PDR) 2021 Yearly Summary

Occupation with Largest Growth:
Retail Pharmacists

State	2020 Postings	2020 Postings Quotient	2021 Postings	2021 Postings Quotient	Postings Quotient Change*
Iowa	10	1.58	39	5.93	**276%**
South Dakota	6	2.93	21	10.07	**243%**
Minnesota	27	2.99	94	10.24	**243%**
Utah	13	3.18	36	8.46	**166%**
Connecticut	23	4.15	60	10.82	**161%**
Mississippi	8	1.26	21	3.21	**155%**
Idaho	28	6.86	63	17.38	**153%**
Delaware	6	2.48	15	6.21	**150%**
Oregon	63	7.42	160	17.77	**139%**
Arkansas	14	2.14	31	4.74	**121%**

https://www.aacp.org/article/pharmacy-demand-report-pdr

Pharmacy Demand Report (PDR) 2021 Yearly Summary

Pharmacist Profession Postings: **Largest Growth**

State	2020 Postings	2020 Postings Quotient	2021 Postings	2021 Postings Quotient	Postings Quotient Change*
South Dakota	11	5.38	37	17.75	**230%**
Vermont	6	4.87	19	15.48	**218%**
Alabama	47	4.55	108	11.24	**147%**
Mississippi	19	2.99	47	7.19	**140%**
Montana	35	16.58	79	35.91	**117%**
Oregon	118	13.90	271	30.09	**116%**
Idaho	84	20.58	145	40.01	**94%**
Wyoming	10	6.94	19	13.22	**91%**
Alaska	40	39.92	73	72.85	**83%**
Arkansas	58	8.87	101	15.44	**74%**

2021 job postings: 1014
Jan-Jun 2022 job postings: 552

https://www.aacp.org/article/pharmacy-demand-report-pdr

Pharmacy Demand Report (PDR) 2021 Yearly Summary

Pharmacist Technicians

2020… 140,623 Pharmacy Technician postings

2021…. 166,479 Pharmacy Technician postings (18% growth)

Pharmacy Technicians saw growth in 44 states and a loss in 8 states

Oregon

2021… 1819 postings

First half of 2022… 1006 postings

https://www.aacp.org/article/pharmacy-demand-report-pdr

Stressors leading to burnout, vacancy

Stressors:

Long professional hours, harassment and demands from patients, insurance issues like prior authorizations, and staffing shortages.

Stressors that may have been exacerbated by the COVID-19 pandemic:

Reimbursement and public perception of pharmacy (staff shortages can cause delays in prescription filling, testing, and vaccinations, which can lead to strained encounters between pharmacy and patient)

The **decline in reimbursement** is one of the leading factors that led pharmacies to include clinical services to make up revenue, which has led to increased burnout among pharmacists.

Addressing Burnout in Pharmacy
September 12, 2022. Drug Topics, https://www.drugtopics.com/view/addressing-burnout-in-pharmacy. Accessed 9/17/2022

Modernizing interstate portability and removal of state law exam

American Association of Colleges of Pharmacy (AACP), July 2022 resolutions:

- *AACP supports the development of an interstate portability multistate licensure compact for pharmacists and student pharmacists.*

  NABP has adopted a resolution to examine the feasibility of creating a system to allow efficient interstate portability through a multistate licensure compact

  Modernization of interstate reciprocity could allow for flexibility in providing pharmacist-provided patient care in areas with pharmacist shortages without compromising patient safety.

- *AACP recommends the removal of a stand-alone examination of federal and/or state pharmacy law as a requirement for licensure.*

  Several states are already moving to a simple attestation that declares that as practicing pharmacists they will abide by the laws of the state. This is similar to how most other health professions approach state-related practice laws.

  Failure to pass the MPJE has resulted in graduates losing their highly coveted residency positions and job offers.

  NABP has adopted a resolution to examine the development of a national standardized pharmacy jurisprudence examination on behalf of the state boards of pharmacy to assess competence for licensure.

Ideas:

Legislation to improve reimbursement for filling prescriptions and providing clinical services, such as immunizations and prescribing services

Legislation (or OBOP rulemaking) to improve pharmacy workplace conditions following completion of workgroup activities on this topic

Legislative action to aid students with funding for education (loan forgiveness)

Oregon Board of Pharmacy

Budget Report: June 2022 (Month 12)

Revenue:

Through June, revenue is $3,816,973 (-16.0%) **under** budget

Expenditures:

Through June, **total expenditures** are $4,309,000 (11.1%) **under** budget

Personal services are $3,131,232 (6.7%) **under** budget

Services and Supplies are $1,177,768 (26.0%) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: ($492,027)

Cash Balance:

Cash balance through June is $4,049,283 which represents (10.03) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through June 2022. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,919,562, which represents (13.11) months of operating expense*)

Cash balance target is $2,252,026, (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 JUNE 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	8,877,111.50	(160,611.50)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	285,264.00	(92,269.00)
505	FINES AND FORFEITS	410,000.00	376,655.18	33,344.82
605	INTEREST AND INVESTMENTS	131,250.00	58,827.23	72,422.77
975	OTHER REVENUE	84,335.00	58,781.31	25,553.69
	TOTAL REVENUE	**9,535,080.00**	**9,656,639.22**	**(121,559.22)**
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	443,120.00	-
	TOTAL TRANSFER OUT	**443,120.00**	**443,120.00**	**0.00**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,283,003.00	4,192,799.81	90,203.19
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	5,929.34	(5,929.34)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	198,616.00	171,714.76	26,901.24
3210	ERB ASSESSMENT	1,276.00	1,240.80	35.20
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	770,781.56	(10,044.56)
3221	PENSION BOND CONTRIBUTION	236,241.00	237,407.34	(1,166.34)
3230	SOCIAL SECURITY TAX	334,236.00	324,791.25	9,444.75
3240	UNEMPLOYMENT ASSESSMENT	-	86.40	(86.40)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	935.11	76.89
3260	MASS TRANSIT	27,053.00	25,948.14	1,104.86
3270	FLEXIBLE BENEFITS	841,104.00	763,861.95	77,242.05
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,497,696.01**	**212,887.99**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	20,343.07	95,550.93
4125	OUT-OF-STATE TRAVEL	17,024.00	1,316.67	15,707.33
4150	EMPLOYEE TRAINING	22,320.00	14,935.85	7,384.15
4175	OFFICE EXPENSES	134,566.00	78,935.92	55,630.08
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	54,722.09	(3,792.09)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	202,566.04	(25.04)
4250	DATA PROCESSING	318,678.00	351,005.33	(32,327.33)
4275	PUBLICITY & PUBLICATIONS	43,329.00	14,902.30	28,426.70
4300	PROFESSIONAL SERVICES	339,713.00	248,287.12	91,425.88
4315	IT PROFESSIONAL SERVICES	134,467.00	48,850.00	85,617.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	555,918.28	65,916.72
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,115.00	2,303.00
4425	FACILITIES RENT & TAXES	229,042.00	273,222.75	(44,180.75)
4475	FACILITIES MAINTENANCE	55.00	1,851.13	(1,796.13)
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	1,000.00	202.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	207,087.82	43,391.18
4650	OTHER SERVICES AND SUPPLIES	411,285.00	406,774.12	4,510.88
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	10,000.00	4,108.00
4715	IT EXPENDABLE PROPERTY	45,228.00	15,573.24	29,654.76
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,510,406.73**	**448,388.27**
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**	**9,008,102.74**	**683,239.26**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**4,919,562**	
	End of biennium projected cash balance in months		13.11	
	Cash balance target of 6.0 months (working capital)		2,252,026	

Oregon Board of Pharmacy

Budget Report: July 2022 (Month 13)

Revenue:

Through July, revenue is $4,356,170 (-11.5%) **under** budget

Expenditures:

Through July, **total expenditures** are $4,641,026 (11.6%) **under** budget

Personal services are $3,401,314 (6.4%) **under** budget

Services and Supplies are $1,239,712 (29.7%) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: ($284,855)

Cash Balance:

Cash balance through July 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 July 2022. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,908,867 which represents (13.09) months of operating expense*)

Cash balance target is $2,249,510, (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 July 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	8,847,638.24	(131,138.24)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	289,401.00	(96,406.00)
505	FINES AND FORFEITS	410,000.00	384,922.08	25,077.92
605	INTEREST AND INVESTMENTS	131,250.00	59,676.26	71,573.74
975	OTHER REVENUE	84,335.00	60,956.83	23,378.17
	TOTAL REVENUE	**9,535,080.00**	**9,642,594.41**	**(107,514.41)**
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	4,201,557.06	81,445.94
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	7,639.30	(7,639.30)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	198,616.00	172,448.63	26,167.37
3210	ERB ASSESSMENT	1,276.00	1,243.80	32.20
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	767,343.44	(6,606.44)
3221	PENSION BOND CONTRIBUTION	236,241.00	236,237.23	3.77
3230	SOCIAL SECURITY TAX	334,236.00	324,774.22	9,461.78
3240	UNEMPLOYMENT ASSESSMENT	-	86.40	(86.40)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	923.95	88.05
3260	MASS TRANSIT	27,053.00	26,015.28	1,037.72
3270	FLEXIBLE BENEFITS	841,104.00	755,526.78	85,577.22
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,495,995.64**	**214,588.36**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	34,432.57	81,461.43
4125	OUT-OF-STATE TRAVEL	17,024.00	3,639.54	13,384.46
4150	EMPLOYEE TRAINING	22,320.00	19,442.85	2,877.15
4175	OFFICE EXPENSES	134,566.00	64,503.86	70,062.14
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	58,769.40	(7,839.40)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	203,802.90	(1,261.90)
4250	DATA PROCESSING	318,678.00	360,009.66	(41,331.66)
4275	PUBLICITY & PUBLICATIONS	43,329.00	14,464.03	28,864.97
4300	PROFESSIONAL SERVICES	339,713.00	256,489.58	83,223.42
4315	IT PROFESSIONAL SERVICES	134,467.00	44,850.00	89,617.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	530,918.28	90,916.72
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,909.00	1,509.00
4425	FACILITIES RENT & TAXES	229,042.00	273,222.75	(44,180.75)
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	205,128.10	45,350.90
4650	OTHER SERVICES AND SUPPLIES	411,285.00	406,283.51	5,001.49
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	5,423.49	8,684.51
4715	IT EXPENDABLE PROPERTY	45,228.00	14,402.28	30,825.72
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,502,042.93**	**456,752.07**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,691,342.00**	**8,998,038.57**	**693,303.43**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**4,908,867**	
	End of biennium projected cash balance in months		13.09	
	Cash balance target of 6.0 months (working capital)		2,249,510	

Oregon Board of Pharmacy

Budget Report: August 2022 (Month 14)

Revenue:

Through August, revenue is $5,067,711 (-4.4%) **under** budget

Expenditures:

Through August, **total expenditures** are $5,047,023 (10.7%) **under** budget

Personal services are $3,687,681 (5.8%) **under** budget

Services and Supplies are $1,359,342 (27.4%) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: ($20,688)

Cash Balance:

Cash balance through August 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 August 2022. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,860,756 which represents (12.88) months of operating expense*)

Cash balance target is $2,265,071, (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 August 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	8,867,213.99	(150,713.99)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	292,763.75	(99,768.75)
505	FINES AND FORFEITS	410,000.00	372,359.01	37,640.99
605	INTEREST AND INVESTMENTS	131,250.00	62,731.76	68,518.24
975	OTHER REVENUE	84,335.00	61,659.33	22,675.67
	TOTAL REVENUE	**9,535,080.00**	**9,656,727.84**	**(121,647.84)**
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	4,194,916.24	88,086.76
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	8,967.94	(8,967.94)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	198,616.00	173,647.47	24,968.53
3210	ERB ASSESSMENT	1,276.00	1,242.80	33.20
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	766,709.50	(5,972.50)
3221	PENSION BOND CONTRIBUTION	236,241.00	235,991.42	249.58
3230	SOCIAL SECURITY TAX	334,236.00	323,944.92	10,291.08
3240	UNEMPLOYMENT ASSESSMENT	-	86.40	(86.40)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	929.81	82.19
3260	MASS TRANSIT	27,053.00	25,995.18	1,057.82
3270	FLEXIBLE BENEFITS	841,104.00	780,613.82	60,490.18
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,515,245.06**	**195,338.94**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	37,749.94	78,144.06
4125	OUT-OF-STATE TRAVEL	17,024.00	3,625.77	13,398.23
4150	EMPLOYEE TRAINING	22,320.00	18,792.85	3,527.15
4175	OFFICE EXPENSES	134,566.00	63,789.80	70,776.20
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	59,911.24	(8,981.24)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	202,541.00	-
4250	DATA PROCESSING	318,678.00	360,467.57	(41,789.57)
4275	PUBLICITY & PUBLICATIONS	43,329.00	14,464.03	28,864.97
4300	PROFESSIONAL SERVICES	339,713.00	249,721.08	89,991.92
4315	IT PROFESSIONAL SERVICES	134,467.00	40,850.00	93,617.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	557,199.58	64,635.42
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,839.00	1,579.00
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	215,130.00	35,349.00
4650	OTHER SERVICES AND SUPPLIES	411,285.00	411,035.59	249.41
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	5,423.49	8,684.51
4715	IT EXPENDABLE PROPERTY	45,228.00	13,199.92	32,028.08
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,545,037.82**	**413,757.18**
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**	**9,060,282.88**	**631,059.12**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**4,860,756**	
	End of biennium projected cash balance in months		12.88	
	Cash balance target of 6.0 months (working capital)		2,265,071	

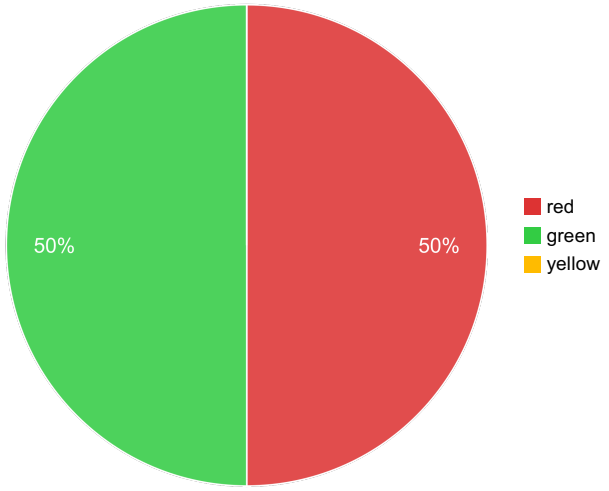
Pharmacy, Board of

Annual Performance Progress Report

Reporting Year 2022

Published: 10/3/2022 9:41:39 PM

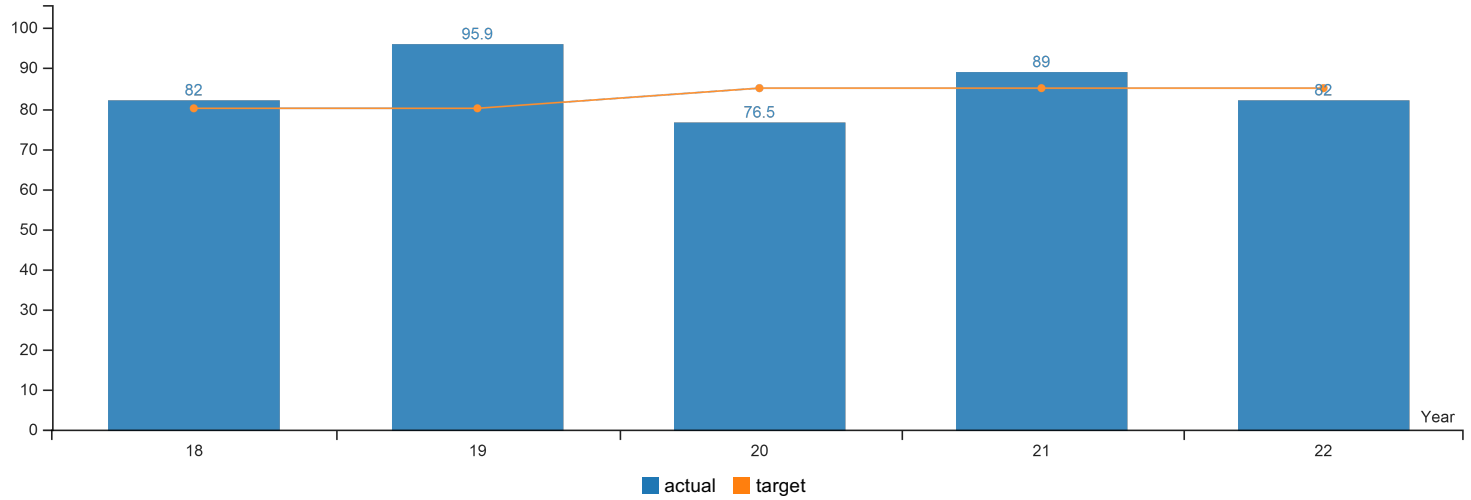
KPM #	Approved Key Performance Measures (KPMs)
1	Percent of inspected pharmacies that are in compliance annually. -
2	Percentage of individual and facility licenses that are issued within 30 days. -
3	Percent of pharmacies inspected every two years. -
4	Average number of days to complete an investigation from complaint to board presentation. -
5	CUSTOMER SERVICE - Percent of Customers Rating Their Satisfaction With the Agency's Customer Service as "Good" or "Excellent" : Overall Customer Service, Timeliness, Accuracy, Helpfulness, Expertise, and Availability of Information.
6	Board Best Practices - Percent of total best practices met by the Board.



Performance Summary	Green	Yellow	Red
	= Target to -5%	= Target -5% to -15%	= Target > -15%
Summary Stats:	50%	0%	50%

KPM #1	Percent of inspected pharmacies that are in compliance annually. -
	Data Collection Period: Feb 01 - Jan 31

** Upward Trend = positive result*



Report Year	2018	2019	2020	2021	2022
Percentage of Pharmacies that are in compliance annually.					
Actual	82%	95.90%	76.50%	89%	82%
Target	80%	80%	85%	85%	85%

How Are We Doing

From February 1, 2021 - January 31, 2022, board Compliance Officers completed 173 Retail and Institutional pharmacy inspections of which 141 were in compliance. Of the 173 completed inspections, 47 passed inspection, 94 passed with notes for improvement, 6 received deficiency notifications and 27 notifications of non compliance were issued; note all notifications are reviewed by the board to determine if disciplinary action is warranted.

1 additional non-pharmacy inspection, a wholesaler was also completed and in compliance.

82% of outlets inspected in 2021 were in compliance.

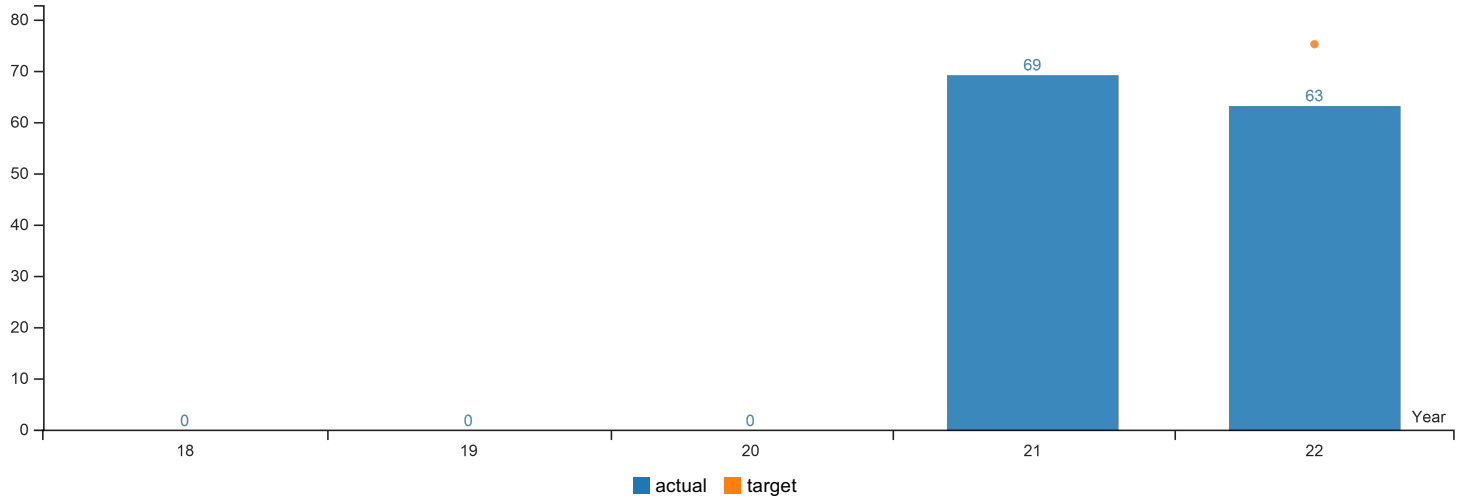
Factors Affecting Results

The COVID-19 public health emergency continued in 2021, virtual inspections were implemented late spring 2021 with a focus on locations assessed to be places of concern related to patient safety. Virtual inspections take more time than in person inspections due to the time to get information from outlets and review off-site while pharmacies and staffing shortages have been stretched to provide increased COVID-19 services.

Compliance staff' focus was on responding to COVID-19 questions and the many rule or guidance changes that impacted licensees/registrants throughout the year. COVID-19 had a significant impact on pharmacies due to staff shortages and changing rules due to the public health emergency.

KPM #2	Percentage of individual and facility licenses that are issued within 30 days. -
	Data Collection Period: Jan 01 - Dec 31

** Upward Trend = positive result*



Report Year	2018	2019	2020	2021	2022
Percentage of individual and facility licenses that are issued within 30 days.					
Actual				69%	63%
Target					75%

How Are We Doing

In 2021, the percentage of licenses that were issued within 30 days was 63%. There was a total of 3103 licenses issued in 2021. The average number of days to issue a license was 48 days for facilities and 54 days for individuals.

This number issued within 30 days is down from 2020. The COVID 19 public health emergency continues to impact licensure times. Daily mail and application review timeframes were extended due to limited staffing physically in the office. There was also a timeframe of high-volume applications where we experienced significant delays in receiving fingerprint results which had a major impact on the timeliness of licenses issued.

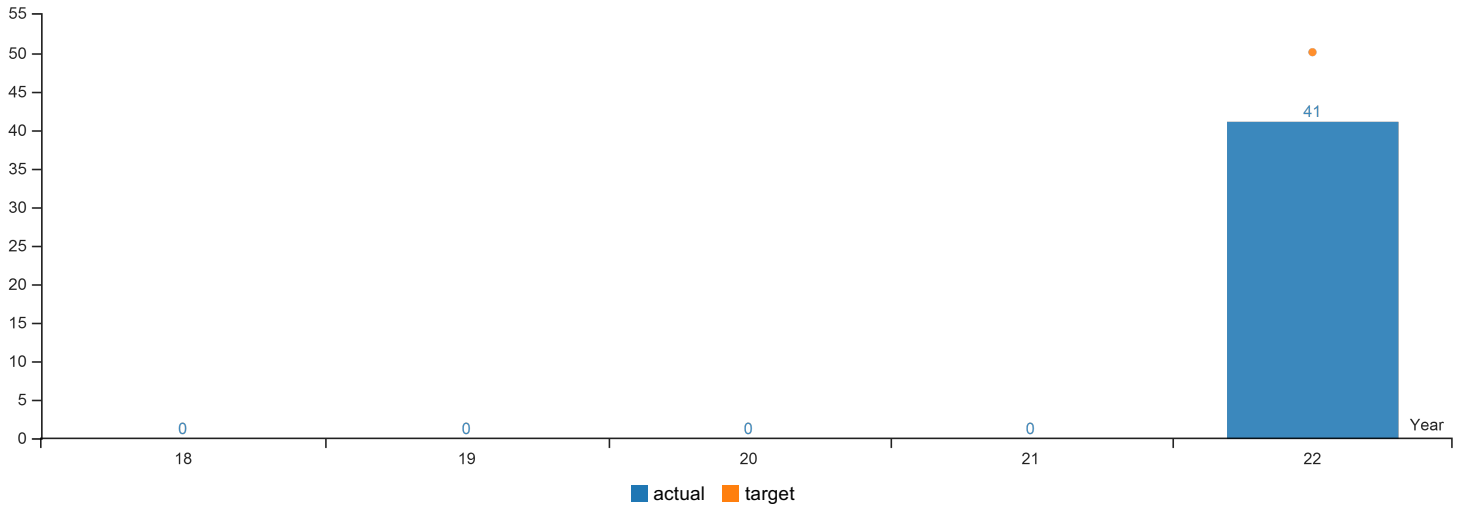
Factors Affecting Results

Applications that required compliance department and board review were also impacted by the COVID-19 public health emergency. The board staff is seeing increasing numbers of cases that need to go before the board for review. This delayed the review and approval of applications when required. Additionally, the compliance staff is seeing that case complexity is changing, which causes increased time for investigations and board review, which has contributed to the increase in days to issuance/ or denial depending on the board decision.

Board staff is focusing on improving communication with applicants and updating processes within the agency to streamline the licensure process to meet the key performance measure targets.

KPM #3	Percent of pharmacies inspected every two years. -
	Data Collection Period: Feb 01 - Jan 31

** Upward Trend = positive result*



Report Year	2018	2019	2020	2021	2022
Percent of pharmacies inspected every 2 years.					
Actual					41%
Target					50%

How Are We Doing

In 2021, this measure was changed to reflect a two year inspection cycle where a focused priority to complete inspections at places of concern related to patient safety. 2022 is the first year reporting with 2021 data. Due to the COVID-19 public health emergency, staff were not able to get out to travel around the state, however, virtual inspections were implemented in late spring 2021. 174 inspections were completed in calendar year 2021 equaling 41% of half the pharmacies.

At present, in a two year cycle, there are 847 retail and institutional pharmacies located in Oregon. The board seeks to also complete inspections of other drug outlet registration on a rotating basis.

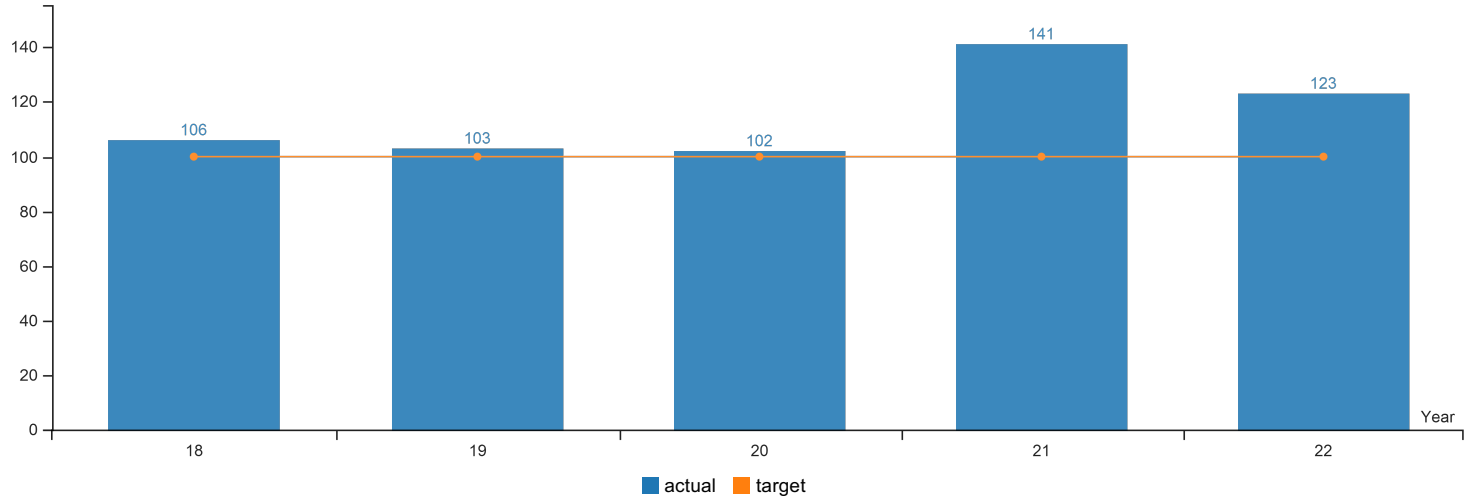
Factors Affecting Results

The COVID-19 public health emergency continued in 2021. Virtual inspections take more time than in person inspections due to the time to get information from outlets and review off-site while pharmacies and staffing shortages have been stretched to provide increased COVID-19 services. Compliance staff' focus was on responding to COVID-19 questions and the many rule or guidance changes that impacted licensees/registrants throughout the year. COVID-19 had and continues to have a significant impact on pharmacies due to staff shortages and changing rules due to the public health emergency.

Compliance Officers have resumed in person inspections in 2022 and anticipate successfully achieving a 100% of in-state retail and institutional pharmacy inspections by the end of the inspection year 1/30/2022.

KPM #4	Average number of days to complete an investigation from complaint to board presentation. -
	Data Collection Period: Jan 01 - Dec 31

** Upward Trend = negative result*



Report Year	2018	2019	2020	2021	2022
Number of days to process complete investigation from complaint to Board presentation.					
Actual	106	103	102	141	123
Target	100	100	100	100	100

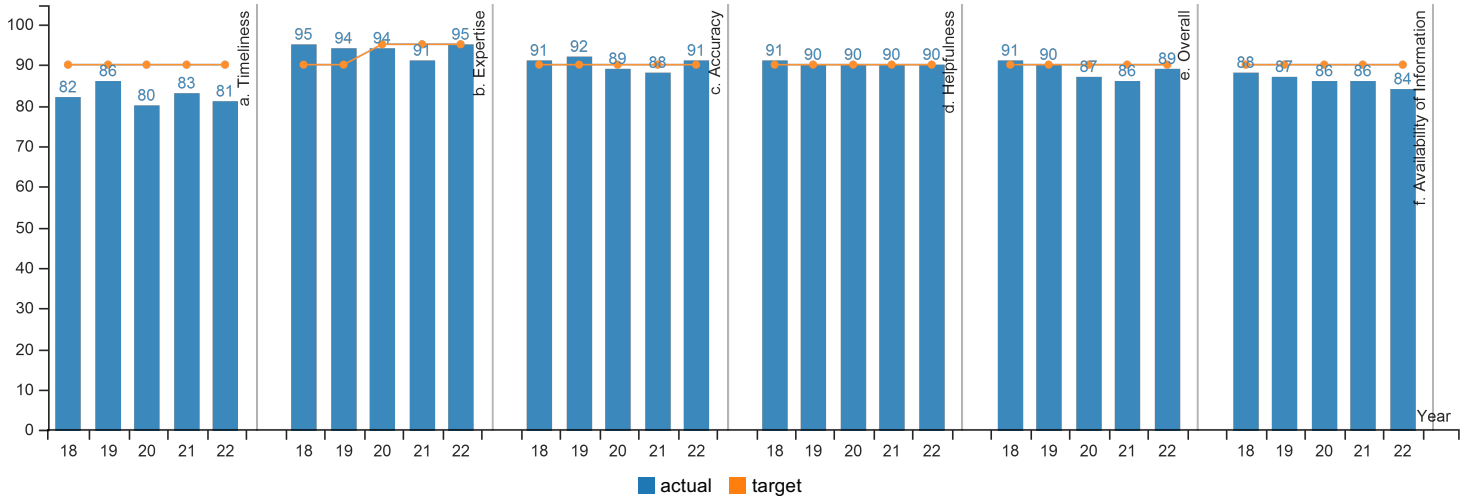
How Are We Doing

The total number of investigatory cases from January 1, 2021 - December 31, 2021 was 841, which is a increase of 145 from 2020. This number is inclusive of all cases, which include those initiated from inspection results, licensee and registrant application cases, drug diversion and theft cases, impairment cases, unprofessional conduct cases and all consumer complaints. Cases are triaged to ensure that the public's safety is maintained which may cause delays in processing of other types of cases. On average, cases were reported and presented to the Board within 123 days. This is a decrease of 18 days from 2020 and 3 days from the statutory requirement of 120 days unless an exception is allowed.

Factors Affecting Results

Continuous quality process improvements and redirected resources allowed for greater focus on investigations during 2021, which helped see improvement for this measure. An additional Compliance Officer position is being requested in the 2023-25 Agency Request Budget to address increased case workload.

KPM #5	CUSTOMER SERVICE - Percent of Customers Rating Their Satisfaction With the Agency's Customer Service as "Good" or "Excellent" : Overall Customer Service, Timeliness, Accuracy, Helpfulness, Expertise, and Availability of Information.
	Data Collection Period: Jan 01 - Dec 31



Report Year	2018	2019	2020	2021	2022
a. Timeliness					
Actual	82%	86%	80%	83%	81%
Target	90%	90%	90%	90%	90%
b. Expertise					
Actual	95%	94%	94%	91%	95%
Target	90%	90%	95%	95%	95%
c. Accuracy					
Actual	91%	92%	89%	88%	91%
Target	90%	90%	90%	90%	90%
d. Helpfulness					
Actual	91%	90%	90%	90%	90%
Target	90%	90%	90%	90%	90%
e. Overall					
Actual	91%	90%	87%	86%	89%
Target	90%	90%	90%	90%	90%
f. Availability of Information					
Actual	88%	87%	86%	86%	84%
Target	90%	90%	90%	90%	90%

How Are We Doing

We emailed a link to the SurveyMonkey Customer Service Survey to board customers that obtained a new license between the dates of January 1, 2021 and December 31, 2021. We utilized the tools in Survey Monkey to directly email the survey link to 3060 new licensees. 329 individuals either fully completed or partially completed the survey. This represents an overall response rate of 10.8%. This is a .3% decrease from the 2020 overall response rate of 11.1%.

2222 of the 3060 licensees opened the email and of those 14.8% responded to the survey.

Factors Affecting Results

The percentage results provided represent the respondents who responded with a rating of either Excellent or Good. Those that responded “Don’t Know” or “N/A” were not factored into these ratings.

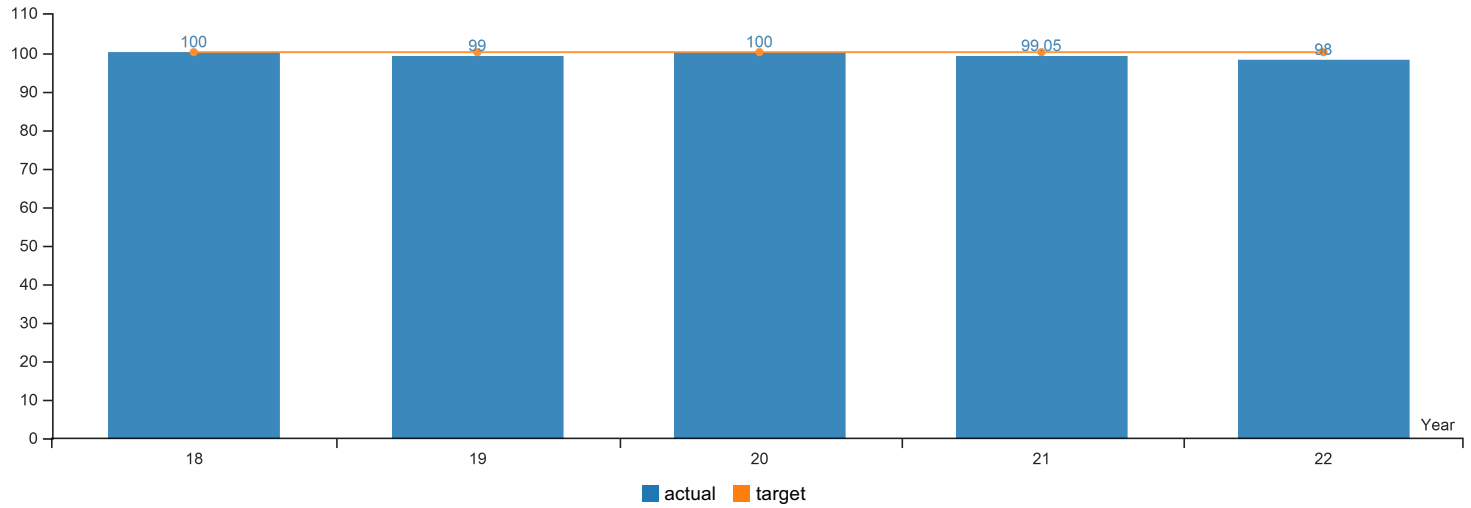
Our overall average of 88.3% is an increase of .8% from 2020. The overall service questions indicate an increased satisfaction of applicants. Timeliness and availability of information both decreased. Based on the comments received in the survey, this was largely due to the delays the agency experienced in receiving fingerprint results during the time of the year that we see the largest influx of application from individuals. This occurred during the timeframe where individuals were graduating from pharmacy schools as well as the deadline for pharmacy technicians to obtain additional licensure due to the expiration of the license.

Factors that contributed to the results:

- Fully staffed / experienced licensing staff for more than 50% of the year
- Additional online services available
- Delays in receiving fingerprinting results
- Decrease in the number of days from case opening to board presentation for applications that required board deliberation.
- Increased number of applicants

KPM #6	Board Best Practices - Percent of total best practices met by the Board.
	Data Collection Period: Jan 01 - Dec 31

** Upward Trend = positive result*



Report Year	2018	2019	2020	2021	2022
Is the Board following Best Practices?					
Actual	100%	99%	100%	99.05%	98%
Target	100%	100%	100%	100%	100%

How Are We Doing

The Board regularly works to follow best practices. The Executive Director provides weekly communication to the Board and meets with the President and Vice President as needed.

Factors Affecting Results

This year, six out of nine members participated in providing feedback for this measure, two positions were vacant at the time of the survey. There was a dissenting response on two questions making it impossible to achieve the 100% target. The opportunity to regularly orient the Board to best practices and answer questions is very useful.