Oregon Board of Pharmacy
*REVISED BOARD MEETING AGENDA
June 12-14, 2024

Public Attendance Options:

1. **In-person: 800 NE Oregon St. Conference Room 1A, Portland, OR**
2. **Virtually via Teams: Link**
3. **Audio only: (503) 446-4951 Phone Conference ID: 337 712 916#**

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.

Vision

All Oregonians have equitable access to medication and pharmacy services, provided safely and conveniently, through a network of highly skilled and dedicated Pharmacists, Interns and Pharmacy Technicians along with a well-regulated manufacturing and distribution network.

Equity Statement

The Oregon Board of Pharmacy is committed to Diversity, Equity, Inclusion, and Belonging (DEIB) within its organization and for the public it serves. This commitment is reflected in board membership, agency staffing, the services provided, and its efforts to promote patient safety and ensure access to quality pharmacy care. Our actions, outlined in our DEIB and Affirmative Action Plans, demonstrate this commitment.

The following principles guide our approach:

- *Promote a welcoming, safe, and inclusive culture for people of all backgrounds*
- *Foster an inclusive environment where all current and prospective licensees and registrants receive fair and unbiased service from the agency staff and board*
- *Advance Diversity and Equity in access through culturally responsive service delivery that addresses the changing climate within the pharmacy profession*
- *Ensure all patients needing pharmacy services are able to receive safe and timely access to medications, regardless of place of residence, economic or social status, physical ability, ethnicity, or gender identity*

Values

These values reflect both how our Board and staff strive to conduct ourselves, and the behaviors we seek to instill across the practice of pharmacy in Oregon.

Equity - *Each individual and group are valued, respected, and treated fairly ensuring equal access to medications and support for their unique and diverse requirements.*

Service - *We deliver a consistent standard of excellence in all work and respond promptly to the needs of patients, Licensees, Registrants, providers and partners.*

Safety - *We are committed to protecting the health, safety and welfare of the public. Safety is the foundation of the board's Mission.*

Adaptability - *We are open to new ideas and to responding to the changing needs and challenges in the field of healthcare and pharmacy.*

Integrity & Accountability - *Transparency and honesty govern the board's work. We accept responsibility for our actions, products, decisions, and policies.*

Professionalism - *We are committed to promoting excellence in pharmacy practice through expertise, commitment, and competence.*

Oregon Board of Pharmacy
*REVISED BOARD MEETING AGENDA
June 12-14, 2024

Wednesday, June 12, 2024 @ 8:30AM
Thursday, June 13, 2024 @ 8:30AM
Friday, June 14, 2024 @ 8:30AM

- All OBOP meetings, except Executive Sessions, are open to the public. Pursuant to ORS 192.660(1)(2)(f)(L), Executive Sessions are closed to the public, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the board will return to Open Session
- To sign up for Public Comment, email your request to pharmacy.board@bop.oregon.gov by **12:00PM on 6/14/2024**

If you need accommodations under the Americans with Disabilities Act (ADA), complete and submit the online OBOP Request for ADA Accommodations for Public Meetings form located on our website.

Board Members

- Ian Doyle, Pharm.D., R.Ph., FOSHP, President
- Kathleen Chinn, APRN, FNP-BC, Vice President
- Shannon Beaman, Pharm.D., R.Ph.
- Rachael DeBarmore, R.Ph.
- Jennifer Hall, Pharm.D., R.Ph.
- Rosemarie Hemmings, Ph.D., LCSW, CCTP-II
- Rich Joyce, CPT
- Priyal Patel, Pharm.D., R.Ph.

Agency Staff

- Joe Ball, R.Ph., Chief Compliance Officer
- Chelsea Dascher, Strategic Initiatives Manager
- Jennifer Davis, Pharm.D., MS, BCACP, R.Ph., Pharmacy Consultant
- Brianne Efremoff, Pharm.D., R.Ph., Compliance Director
- Cheryl Fox, R.Ph., Compliance Officer
- Jamal T. Fox, MPA, Executive Director
- Chrisy Hennigan, Licensing Director
- Jane Lee, Pharm.D., R.Ph., Compliance Officer
- Rachel Melvin, Operations Manager
- Brian Murch, Pharm.D., R.Ph., Compliance Officer
- Erin Richmond, Pharm.D., M.S., R.Ph., Compliance Officer
- Gary Runyon, Pharm.D., R.Ph., Compliance Officer
- Rachel Bertoni, Board Counsel

WEDNESDAY, JUNE 12, 2024

I. OPEN SESSION, Ian Doyle RPh, Presiding

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

a. Roll Call
b. Public Comment Information
   i. The board will not deliberate any issues or requests during public comment such as formal requests, issues currently under investigation, requests pending before the board or currently proposed rules
   ii. Public comment is limited to matters that were noticed on the board meeting agenda
   iii. Comments will not be allowed that are longer that the time allotted by the chair
   iv. To sign up to provide public comment, email your request to pharmacy.board@bop.oregon.gov by 12PM on Friday 6/14/2024
c. Housekeeping & Meeting Etiquette
d. Agenda Review and Approval *Action Necessary*

e. Recusal Announcements
f. Introduction of new staff

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, JUNE 13, 2024

I. OPEN SESSION, Ian Doyle RPh, Presiding

a. Roll Call
b. Public Comment Information
   i. The board will not deliberate any issues or requests during public comment such as formal requests, issues currently under investigation, requests pending before the board or currently proposed rules
   ii. Public comment is limited to matters that were noticed on the board meeting agenda
   iii. Comments will not be allowed that are longer that the time allotted by the chair
   iv. To sign up to provide public comment, email your request to pharmacy.board@bop.oregon.gov by 12PM on Friday 6/14/2024
c. Housekeeping & Meeting Etiquette

II. GENERAL ADMINISTRATION

a. Discussion Items
   i. Rules
      1. Review Rulemaking Hearing Report & Comments **#A** *Action Necessary*
   ii. Consider Adoption of Temporary Rules – *None*
   iii. Consider Adoption of Rules
      1. Div 115 – Pharmacists - PIC Qualifications & Limitations (OAR 855-115-0200) *REPEAL **#B** *Action Necessary*

      2. Div 115 - Pharmacists – Services: Prescribing – Formulary & Protocol Compendium (OAR 855-115-0340, OAR 855-115-0345) **#B1** *Action Necessary*
         a. Formulary Devices and Supplies **#B1a**
         b. Continuation of Therapy (v. 06/2024) **#B1b**
         c. Pseudoephedrine (v. 06/2021) *REPEAL **#B1c**
         d. Tobacco Cessation (v. 06/2024) **#B1d**
         e. Travel Medications (v. 06/2024) **#B1e**

f. Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) (v. 06/2024) **#B1f**
g. Short-acting Opioid Antagonists (v. 06/2024) **#B1g**
h. Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 06/2024) **#B1h**
i. Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 06/2024) **#B1i**
j. Coronavirus 19 (v. 06/2024) **#B1j**
k. Haemophilus Influenzae type b (v. 06/2024) **#B1k**
l. Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024 (v. 06/2024) **#B1l**
m. Japanese Encephalitis (v. 06/2024) **#B1m**
n. Meningococcal containing vaccines (v. 06/2024) **#B1n**
o. Pneumococcal (v. 06/2024) **#B1o**
p. Polio (v. 06/2024) **#B1p**
q. Respiratory Syncytial Virus (v. 06/2024) **#B1q**
r. Tetanus, Diphtheria containing vaccines (v. 06/2024) **#B1r**
s. Yellow Fever (v. 06/2024) **#B1s**

3. Div 115 – Pharmacists – Services: Prescribing Practices – Short-acting Opioid Antagonists (OAR 855-115-0350) **#B2** *Action Necessary*

4. Div 120 – Interns & Preceptors – Prohibited Practices (OAR 855-120-0150) **#B3** *Action Necessary*

5. Div 020 – Pharmacist Prescriptive Authority – Protocol Compendium *REPEAL (OAR 855-020-0300) **#B4** *Action Necessary*

6. Div 006/041/043/045/080/115/120/135/139/141 – Standards Adopted by Reference (OAR 855-006-0005, OAR 855-041-1046, OAR 855-041-1092, OAR 855-041-1145, OAR 855-041-7050, OAR 855-043-0545, OAR 855-043-0740, OAR 855-045-0200, OAR 855-045-0205, OAR 855-080-0020, OAR 855-080-0021, OAR 855-080-0022, OAR 855-080-0023, OAR 855-080-0024, OAR 855-080-0026, OAR 855-080-0028, OAR 855-080-0031, OAR 855-080-0065, OAR 855-080-0070, OAR 855-080-0075, OAR 855-0085, OAR 855-115-0125, OAR 855-120-0005, OAR 855-135-0001, OAR 855-139-0145, OAR 855-139-0350, OAR 855-139-0460, OAR 855-141-0350) **#B5** *Action Necessary*

7. Div 115 – Pharmacists – Responsibilities: Outlet – Delegation of Final Verification (OAR 855-115-0130) **#B6** *Action Necessary*

iv. Proposed July 23, 2024 Rulemaking Hearing
v. Rulemaking Policy Discussion Items

1. Div 139 - RDSP- Mileage (OAR 855-139-0200) **#C** *Action Necessary*
2. Div 115 – Pharmacists – Services: Protocol Compendium (OAR 855-115-0345) **#C1** *Action Necessary*
    a. Continuation of Therapy **#C1a**
    b. Vulvovaginal Candidiasis (VVC) Vaginal Itching **#C1b**
    c. SARS-CoV-2 Antiviral **#C1c**
    d. Coronavirus 19 - **#C1d**
3. Div 135 – Continuing Pharmacy Education – Veterinary (OAR 855-135-0001, OAR 855-135-0010) **#C2** *Action Necessary*
4. Div 006/041/043/045/183 – Drug Compounding (OAR 855-006-0005, OAR 855-041-1018, OAR 855-043-0545, OAR 855-043-0630, OAR 855-043-0740, OAR 855-183-0001, OAR 855-183-0005, OAR 855-183-0010, OAR 855-183-0050, OAR 855-183-0200, OAR 855-183-0205, OAR 855-183-0370, OAR 855-183-0400, OAR 855-183-0410, OAR 855-183-0420, OAR 855-183-0450, OAR 855-183-0500, OAR 855-183-0520, OAR 855-183-0550, OAR 855-183-0560, OAR 855-183-0565, OAR 855-183-0570, OAR 855-183-0575, OAR 855-183-0600, OAR 855-183-0700, OAR 183-0710, OAR 855-183-0730, OAR 855-045-0200, OAR 855-045-0210, OAR 855-045-0220, OAR 855-045-0240, OAR 855-045-0270) **#C3** **The board will focus discussion on OAR 855-183-0710 and OAR 855-183-0730*

vi. Oregon Board of Pharmacy Board Member Policy Topics Ranking Survey Results **#D** *Action Necessary*

vii. Petition to Amend – Oregon State Pharmacy Association -SBAR **#E, #E1** *Action Necessary*

Adjourn *Action Necessary*

FRIDAY, JUNE 14, 2024

I. OPEN SESSION, Ian Doyle RPh, Presiding

a. Roll Call
b. Public Comment
    v. The board will not deliberate any issues or requests during public comment such as formal requests, issues currently under investigation, requests pending before the board or currently proposed rules
    vi. Public comment is limited to matters that were noticed on the board meeting agenda
    vii. Comments will not be allowed that are longer that the time allotted by the chair
    viii. To sign up to provide public comment, email your request to pharmacy.board@bop.oregon.gov by 12PM on Friday 6/14/2024
c. Housekeeping & Meeting Etiquette

II. MOTIONS RELATED TO DISCIPLINARY ACTIONS *Action Necessary*

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

III. ANNUAL BOARD BUSINESS MEETING

a. Update on Board & PHPFAC appointments

b. Board Election Process Discussion
c. Election of New Officers *Action Necessary*
d. Recognition of outgoing Board Members Doyle and DeBarmore
e. Roberts Rule of Order – Newly Revised 12 Edition *Action Necessary*

IV. GENERAL ADMINISTRATION

a. Rules Policy Discussion Continued
b. Discussion Items
   i. Annual Board Best Practices Survey results & Annual Performance Progress Report (KPMS) - **#F, F1**
   ii. Requests –
      1. Lincoln County Public Health & Human Services CHC-000087 **#G** *Action Necessary*
      2. Monroe Health Center CHC-000080 **#G1** *Action Necessary*
      3. Prairie City School-Based Community Clinic CHC-0000162 **#G2** *Action Necessary*
      4. Oregon Veterinary Medical Examining Board *Action Necessary*
   iii. Financial/Budget Update

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

2024 Board Meeting Dates

- August 7-9, 2024 Portland
- October 9-11, 2024 Portland
- November 7, 2024 Portland (*TBD – Board Planning Retreat)
- December 11-13, 2024 Portland

2025 Board Meeting Dates

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

- July 23, 2024
- November 26, 2024

Conferences/Meetings

- NABP District 6, 7, 8 Meeting October 20-24, 2024 Alburquerque, NM

VI. APPROVE CONSENT AGENDA* *Action Necessary*

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

a. License/Registration Ratification 3.19.2024 – 5.20.2024 - **# CONSENT-1**
b. Board Meeting Summary April 2024 - **# CONSENT-2**

VII. PUBLIC COMMENT

VIII. MATTERS TO BE DICUSSED BY THE BOARD

IX. MATTERS TO BE DICUSSED BY THE EXECUTIVE DIRECTOR AND/OR AGENCY STAFF

Adjourn *Action Necessary*

Oregon
Tina Kotek, Governor

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

Date: May 23, 2024

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

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: May 22, 2024

Hearing Location: Virtual Hearing

Proposed Rules:

- Division 115 – Pharmacists - PIC Qualifications & Limitations *REPEAL
- Division 115 – Pharmacists – Services: Prescribing – Formulary & Protocol Compendium
  - Formulary Devices and Supplies
  - Continuation of Therapy (v. 06/2024)
  - Pseudoephedrine (v. 06/2021) *REPEAL
  - Tobacco Cessation (v. 06/2024)
  - Travel Medications (v. 06/2024)
  - Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) (v.06/2024)
  - Short-acting Opioid Antagonists (v.06/2024)
  - Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 06/2024)
  - Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 06/2024)
  - Coronavirus 19 (v. 06/2024)
  - Haemophilus Influenzae type b (v. 06/2024)
  - Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024 (v. 06/2024)
  - Japanese Encephalitis (v. 06/2024)
  - Meningococcal containing vaccines (v. 06/2024)
  - Pneumococcal (v. 06/2024)
  - Polio (v. 06/2024)
  - Respiratory Syncytial Virus (v. 06/2024)
  - Tetanus, Diphtheria containing vaccines (v. 06/2024)
  - Yellow Fever (v. 06/2024)
- Div 115 – Pharmacists – Services: Prescribing Practices – Short-acting Opioid Antagonists
- Div 120 – Interns & Preceptors – Prohibited Practices
- Div 020 – Pharmacist Prescriptive Authority – Protocol Compendium *REPEAL
- Div 006/041/043/045/080/115/120/135/139/141 – Standards Adopted by Reference
- Div 115 – Pharmacists – Responsibilities: Outlet – Delegation of Final Verification

Oregon
Tina Kotek, Governor

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

On April 17, 2024, the May 22, 2024 Rulemaking Hearing public notice was sent out via GovDelivery to 4,727 rulemaking/adopted rules subscribers.

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

The rulemaking hearing convened at 9:31AM and adjourned at 9:38AM. #4 people joined the public call to listen to the hearing. No participants signed up or provided oral testimony during the hearing. #2 written comments were received during the open comment period from 4/17/2024 through 4:30PM on 5/22/2024. The hearing was recorded, and the notice of proposed rulemaking filings were available on our website.

The following board and staff members participated:

Board President Doyle
Board Member Joyce
Staff Member Davis
Staff Member Melvin

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Division 115 – Pharmacists – PIC Qualifications & Limitations
REPEAL: OAR 855-115-0200

- No oral testimony was provided.

RULES PROPOSED: Division 115 – Pharmacists – Services: Prescribing – Formulary & Protocol Compendium
AMEND: OAR 855-115-0340 and OAR 855-115-0345

- No oral testimony was provided.

RULES PROPOSED: Division 115 – Pharmacists – Services: Prescribing Practices – Short-acting Opioid Antagonists
AMEND: OAR 855-115-0350

- No oral testimony was provided.

Oregon
Tina Kotek, Governor

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RULES PROPOSED: Division 120 – Interns & Preceptors – Prohibited Practices
AMEND: OAR 855-120-0150

- No oral testimony was provided.

RULES PROPOSED: Division 020 – Pharmacist Prescriptive Authority – Protocol Compendium
REPEAL: OAR 855-020-0300

- No oral testimony was provided.

RULES PROPOSED: Divisions 006/041/043/045/080/115/120/135/139/141 – Standards Adopted by Reference
AMEND: OAR 855-006-0005, OAR 855-041-1046, OAR 855-041-1092, OAR 855-041-1145, OAR 855-041-7050, OAR 855-043-0545, OAR 855-043-0740, OAR 855-045-0200, OAR 855-045-0205, OAR 855-080-0020, OAR 855-080-0021, OAR 855-080-0022, OAR 855-080-0023, OAR 855-080-0024, OAR 855-080-0026, OAR 855-080-0028, OAR 855-080-0031, OAR 855-080-0065, OAR 855-080-0070, OAR 855-080-0075, OAR 855-0085, OAR 855-115-0125, OAR 855-120-0005, OAR 855-135-0001, OAR 855-139-0145, OAR 855-139-0350, OAR 855-139-0460, and OAR 855-141-0350

- No oral testimony was provided.

RULES PROPOSED: Division 115 – Pharmacists – Responsibilities: Outlet – Delegation of Final Verification
AMEND: OAR 855-115-0130

- No oral testimony was provided.

All written comments received by the public comment deadline date of 5/22/2024 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 4/17/2024 Notice of Proposed Rulemaking.

Lauren Paul, RPh, PharmD, MS
Executive Director, Pharmacy Regulatory Affairs
CVS Pharmacy

One CVS Drive
Woonsocket, RI 02895

c 540-604-3661

lauren.paul@cvshealth.com

May 20, 2024

Jamal Fox, MPA
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Amendments to Division 115 and Vaccine Protocols

Dear Executive Director Fox and Members of the Oregon State Board of Pharmacy,

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

OAR 855-115-0345 Service: Prescribing – Protocol Compendium

CVS Health is supportive of pharmacist's prescribing of vaccine. To provide clarity and streamline practice in Oregon, we request the Board consider not adopting individual vaccine protocols as standards adopted by reference, but instead adopt one protocol to cover all vaccines. Most recently, the Virginia Board of Pharmacy was granted statutory authority to develop statewide protocols for various treatments, including vaccines.[1] The Board then adopted simple statewide protocols, one for ages 3 to 17 and one for ages 18+. We request the Oregon Board of Pharmacy review this method and consider adoption of a simplified protocol for all vaccines, which includes pharmacist's shared clinical decision making as well as recommendations by the Centers for Disease Control.

CVS Health appreciates the opportunity to provide feedback and submit comments on the proposed rules. Should the Board have any questions, please do not hesitate to contact me.

Sincerely,

Lauren Paul, PharmD, RPh, MS

Lauren Paul, PharmD, RPh, MS
Executive Director, CVS Health

References

1. Virginia Board of Pharmacy, Statewide Protocols. Available from: Virginia Board of Pharmacy - Statewide Protocols (Accessed May 13, 2024)

From:	Paul, Lauren N.
To:	PHARMACY RULEMAKING * BOP
Cc:	Johnston, Mark D; Paul, Lauren N.
Subject:	CVS Health Comments on Proposed Amendments to Division 115 and Vaccine Protocols
Date:	Monday, May 20, 2024 1:03:40 PM
Attachments:	image001.png CVS Health Comments on Proposed Amendments to Division 115 and Vaccine Protocols .pdf

Good afternoon,

Attached you will find comments on behalf of CVS Health for proposed amendments to Division 115 and vaccine protocols. Should there be any questions on these comments, please do not hesitate to contact me.

Thanks,

Lauren

Lauren Paul PharmD, MS | Executive Director, Pharmacy Advocacy & Regulatory Affairs
c 540-604-3661
1 CVS Drive, Mail Code 2325, Woonsocket, RI 02895

Planned Business Travel: May 21-23, May 29-30, June 12-14, June 19-20, June 24-25

Planned PTO: June 3-7, July 1-5

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

May 13, 2024
Oregon State Board of Pharmacy
Attention: Jamal Fox, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232
Via Email: pharmacy.rulemaking@bop.oregon.gov

RE: Divisions 120 – Interns & Preceptors – Prohibited Practices

Dear Executive Director Fox and members of the Oregon Board of Pharmacy,

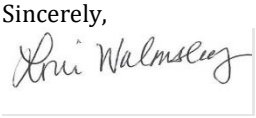
On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of Oregon, we thank the Board for the opportunity to comment on the proposed rules. The ability of licensees and registrants of the board, as well as the general public, to clearly understand the rules is paramount to ensuring public health and safety. We ask the board to review our comments, concerns, and suggested edits to the proposed rules.

Patient access to interpretation services is paramount to equitable healthcare and improved health outcomes for patients who may need these services. Walgreens requests the board to review the provisions in OAR 855-041-1133 and ensure that the prohibited practices of an intern clearly reflect the requirements and allowances for interpretation services. Pursuant to OAR 855-041-1133, if a patient declines an OHA registered interpreter, another interpreter may be utilized, which could include the patient's family member, friend, licensed tech or an intern who is proficient in the patient's preferred language. The proposed rules as well as OAR 855-115-0145(5) seem to imply that patients do not have a choice in how they receive interpretation services and may only receive interpretation from an OHA-registered interpreter or a fluent pharmacist. While formal interpretation services should be the first option for patients, limiting patient choice and access to other interpreters was not the intent of the legislature nor in the best interest of patient care. Patient choice should not be overlooked when requiring accessibility to these services and the rules should ensure clarity for all licensees.

855-120-0150 Prohibited Practices - Intern
(1) An Intern must not:
(a) Practice pharmacy as defined in ORS 689.005 except as permitted by the Pharmacist or Healthcare Preceptor who is supervising the Intern;
(b) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace;
(c) Communicate (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, unless following the provisions in OAR 855-041-1133 ~~the Intern is a health care interpreter registered by the Oregon Health Authority under ORS 413.558 or the supervising Pharmacist or Preceptor is also Page 2 of 3 fluent in the language being interpreted; or~~

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please contact me.

Sincerely,



Lorri Walmsley, RPh, FAzPA

From:	Walmsley, Lorri
To:	PHARMACY RULEMAKING * BOP
Cc:	FOX Jamal T * BOP
Subject:	RE: Walgreens Comments 855-120-150
Date:	Monday, May 13, 2024 10:42:21 AM
Attachments:	image001.png image002.png Oregon Comment Letter May Interns (1).pdf

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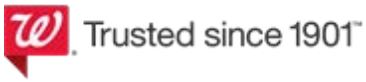
Thanks, Rachel. Updated

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs
Walgreen Co.
She/Her why this matters
Mobile 602-214-6618



From: PHARMACY RULEMAKING * BOP <PHARMACY.RULEMAKING@bop.oregon.gov>
Sent: Monday, May 13, 2024 10:39 AM
To: Walmsley, Lorri <lorri.walmsley@walgreens.com>; PHARMACY RULEMAKING * BOP <PHARMACY.RULEMAKING@bop.oregon.gov>
Cc: FOX Jamal T * BOP <Jamal.T.FOX@bop.oregon.gov>
Subject: RE: Walgreens Comments 855-120-150

Hi Lorri,

The date is incorrect on your attachment, it states “May 13, 2023”. Would you like to resubmit, or would you like to provide this version to the board?

Sincerely,

Rachel Melvin
Operations Policy Analyst

Oregon Board of Pharmacy
rachel.melvin@bop.oregon.gov
(971) 673-0001

Oregon.Gov/Pharmacy

From: Walmsley, Lorri <lorri.walmsley@walgreens.com
Sent: Monday, May 13, 2024 10:01 AM
To: PHARMACY RULEMAKING * BOP <pharmacy.rulemaking@bop.oregon.gov>
Cc: FOX Jamal T * BOP <Jamal.T.FOX@bop.oregon.gov>
Subject: Walgreens Comments 855-120-150

Hello,

Please accept these comments on behalf of Walgreens regarding 855-120-150

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs
Walgreen Co.
She/Her why this matters
Mobile 602-214-6618
Trusted since 1901
Member of Walgreens Boots Alliance

OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/17/2024 9:48 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Repeals PIC Qualifications & Limitations Rule

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@bop.oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/22/2024
TIME: 9:30 AM
OFFICER: Rachel Melvin

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 392711816
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.
If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name and email address to pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes to repeal OAR 855-115-0200 which was replaced with OAR 855-115-0205, effective 3/1/2024.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

OAR 855-115-0205 Pharmacist-in-Charge: Qualifications and Limitations *Effective 3/1/2024
https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=308902

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

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

FISCAL AND ECONOMIC IMPACT:

The proposed repeal of this rule has no anticipated fiscal and economic impact.

COST OF COMPLIANCE:

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

The proposed repeal of this rule will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

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

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

The board adopted new Division 115 Pharmacists rules effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

REPEAL: 855-115-0200

RULE SUMMARY: Proposes to repeal OAR 855-115-0200, effective upon filing. The board adopted OAR 855-115-0205 in December 2023, effective 3/1/2024 which replaces OAR 855-115-0200.

CHANGES TO RULE:

~~855-115-0200~~
~~Pharmacist-in-Charge: Qualifications and Limitations~~
~~Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:¶~~
~~(1) Complete a board-provided PIC training course as described below:¶~~
~~(a) A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90-days after appointment.¶~~
~~(b) A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to the appointment.¶~~
~~(2) Complete a board-provided PIC training course at least every five years.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, ORS 689.155~~

OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/17/2024 10:06 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Adds CGM to formulary, adds STI prevention and short-acting opioid antagonists protocols, repeals pseudoephedrine

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@bop.oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/22/2024
TIME: 9:30 AM
OFFICER: Rachel Melvin

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 392711816
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.
If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name and email address to pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes to add continuous glucose monitors and related supplies to formulary. Proposes to repeal pseudoephedrine protocol from the protocol compendium. Proposes to amend the tobacco cessation, travel medications, and vaccine protocols in the protocol compendium. Vaccine protocols amended include Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway, Standard Protocol for All Vaccines: Managing Adverse Reactions, Coronavirus 2019, Haemophilus Influenza type b, Influenza - Inactivated Influenza Vaccines and Recombinant Influenza

Vaccines 2023-24, Japanese Encephalitis, Meningococcal containing vaccines, Measles Mumps & Rubella containing vaccines, Pneumococcal, Polio, Respiratory Syncytial Virus, Tetanus Diphtheria containing vaccines, Yellow fever, and Zoster. Proposes to add Sexually Transmitted Infections Post-exposure Prophylaxis protocol and Short-acting Opioid Antagonists protocol to the protocol compendium.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Pseudoephedrine: ORS 475.005(6),(17) Definitions- “Controlled substance”, “Practitioner”; ORS 475.035 Authority to control sch
Prescriptions Required; ORS 475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phe
855-080-0026 Schedule V

Formulary Compendium:
Device and Supplies: Continuous Glucose Monitors & Associated Supplies
https://www.oregon.gov/pharmacy/Documents/Formulary_Devices_Supplies_4.2024.pdf

Protocol Compendium:
Continuation of Therapy https://www.oregon.gov/pharmacy/Documents/Continuation_Tx_General_4.2024.pdf
Pseudoephedrine *REPEAL https://www.oregon.gov/pharmacy/Documents/CoughColdSymptom_PSE.pdf
Tobacco Cessation https://www.oregon.gov/pharmacy/Documents/PrevCare_Tobacco_Cessation_4.2024.pdf
Travel Medications https://www.oregon.gov/pharmacy/Documents/PrevCare_Travel_Medications_4.2024.pdf

Vaccines:
Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway
https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Standard_Protocol_for_All_Vaccines_Cover_Page_&_Assessmen
Standard Protocol for All Vaccines: Managing Adverse Reactions https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ
Vaccines_Managing_Adverse_Reactions_4.2024.pdf
Coronavirus 19 https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Coronavirus_19_4.2024.pdf
Haemophilus Influenzae type b https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Haemophillus_Influenza_Type_B
Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024
Japanese Encephalitis https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Japanese_Encephalitis_4.2024.pdf
Meningococcal containing vaccines https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Meningococcal_Containing_
Pneumococcal https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Pneumococcal_4.2024.pdf
Polio https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Polio_4.2024.pdf
Respiratory Syncytial Virus https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Respiratory_Syncytial_Virus_4.2024
Tetanus, Diphtheria containing vaccines https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Tetanus_Diphtheria_Co
Yellow Fever https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Yellow_Fever_4.2024.pdf
Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) https://www.oregon.gov/pharmacy/Documents/PrevCare_
Short-acting Opioid Antagonists https://www.oregon.gov/pharmacy/Documents/PrevCare_SaOA_4.2024.pdf

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

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

FISCAL AND ECONOMIC IMPACT:

Repealing the pseudoephedrine protocol might lead to higher out-of-pocket costs for patients because insurance cannot be billed without a prescription. No fiscal anticipated for the remaining proposed protocol amendments.

Licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the rulemaking open comment period.

COST OF COMPLIANCE:

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

The proposed rule amendments with will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Subject Matter Experts (SME) are responsible for drafting proposed protocols and then the Public Health and Pharmacy Formulary Advisory Committee is responsible for recommending changes to the drafts or recommending the proposed protocols are sent to the board for consideration.

RULES PROPOSED:
855-115-0340, 855-115-0345

AMEND: 855-115-0340

RULE SUMMARY: Proposes to add continuous glucose monitors and related supplies to the formulary compendium.

CHANGES TO RULE:

855-115-0340
Services: Prescribing - Formulary Compendium
A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, a FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented. Devices and supplies:¶
(1) Diabetic blood sugar testing supplies;¶
(2) Injection supplies;¶
(3) Nebulizers and associated supplies;¶
(4) Inhalation spacers;¶
(5) Peak flow meters;¶
(6) International Normalized Ratio (INR) testing supplies;¶
(7) Enteral nutrition supplies; ¶
(8) Ostomy products and supplies; ~~and~~¶
(9) Non-invasive blood pressure monitors; and¶
(10) Continuous glucose monitors and associated supplies.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-115-0345

RULE SUMMARY: Proposes to repeal pseudoephedrine protocol from the protocol compendium. ORS 475.005(6),(17) and ORS 475.185 prohibit a pharmacist from prescribing a controlled substance. Controlled substances include those scheduled by the board under ORS 475.035. Pseudoephedrine is scheduled by the board as a schedule V controlled substance under ORS 475.035 in OAR 855-080-0026 in accordance with ORS 475.973.

Proposes to amend the tobacco cessation, travel medications, and vaccine protocols in the protocol compendium. Vaccine protocols amended include Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway, Standard Protocol for All Vaccines: Managing Adverse Reactions, Coronavirus 2019, Haemophilus Influenza type b, Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24, Japanese Encephalitis, Meningococcal containing vaccines, Measles Mumps & Rubella containing vaccines, Pneumococcal, Polio, Respiratory Syncytial Virus, Tetanus Diphtheria containing vaccines, Yellow fever, and Zoster.

Proposes to add Sexually Transmitted Infections Post-exposure Prophylaxis protocol and Short-acting Opioid Antagonists protocol to the protocol compendium.

CHANGES TO RULE:

855-115-0345
Services: Prescribing - Protocol Compendium
A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, FDA-approved drugs and devices listed in the following compendium, pursuant to a statewide drug therapy management protocol. ¶
(1) Continuation of therapy including emergency refills of insulin (v. 06/202~~3~~4)¶
(2) Conditions¶
(a) Cough and cold symptom management¶
(A) ~~Pseudoephedrine (v. 06/2021);¶~~
~~(B)~~ Benzonatate (v. 06/2021);¶
(~~C~~B) Short-acting beta agonists (v. 06/2021);¶
(~~D~~C) Intranasal corticosteroids (v. 06/2021);¶
(b) Vulvovaginal candidiasis (VVC) (v. 06/2021);¶
(c) COVID-19 Antigen Self-Test (v. 12/2021);¶
(3) Preventative care¶
(a) Emergency Contraception (v. 06/2021);¶
(b) Male and female condoms (v. 06/2021);¶
(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT (v. 06/202~~2~~4);¶
(d) Travel Medications (v. 06/202~~3~~4);¶
(e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);¶
(f) HIV Pre-exposure Prophylaxis (PrEP) (v.06/2023); ~~and~~¶
(g) Contraception (v. 06/2023); ¶
(h) Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) (v. 06/2024);¶
(i) Short-acting Opioid Antagonists (v. 06/2024); and¶
(j) Vaccines:¶
(A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 06/2024); ¶
(B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 06/2024); ¶
(C) Cholera (v. 2/2024); ¶
(D) Coronavirus 2019 (v. 06/2024); ¶
(E) Haemophilus Influenza type b (v. 06/2024);¶
(F) Hepatitis A containing vaccines (v. 02/2024); ¶
(G) Hepatitis B containing vaccines (v. 02/2024); ¶
(H) Human Papillomavirus (v. 02/2024); ¶
(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 06/2024); ¶
(J) Influenza - Live Attenuated Influenza Vaccine 2023-24 (v. 02/2024); ¶
(K) Japanese Encephalitis (v. 06/2024); ¶
(L) Meningococcal containing vaccines (v. 06/2024); ¶
(M) Measles Mumps & Rubella containing vaccines (v. 02/2024); ¶

(N) Pneumococcal (v. 06/2024); ¶
(O) Polio (v. 06/2024);¶
(P) Rabies (v. 02/2024); ¶
(Q) Respiratory Syncytial Virus (v. 06/2024);¶
(R) Tetanus Diphtheria containing vaccines (v. 06/2024);¶
(S) Typhoid (v. 02/2024); ¶
(T) Varicella containing vaccines (v. 02/2024);¶
(U) Yellow fever (v. 06/2024); and¶
(V) Zoster (v. 02/2024).¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689

DEVICES AND SUPPLIES

PRESCRIPTIVE AUTHORITY - OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may prescribe and dispense an FDA-approved drug or device, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis

➢ Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe the following devices and supplies:

- Diabetic blood sugar testing supplies;
- Injection supplies;
- Nebulizers and associated supplies;
- Inhalation spacers;
- Peak flow meters;
- International Normalized Ratio (INR) testing supplies;
- Enteral nutrition supplies;
- Ostomy products and supplies;
- Non-invasive blood pressure monitors; and
- Continuous glucose monitors and associated supplies.

CONTINUATION OF THERAPY

Including Emergency Refills of Insulin

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.
- Per ORS 689.696, a pharmacist may prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies to a person who has evidence of a previous prescription from a licensed health care provider.

- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe any non-controlled drug or device to a person who has evidence of a previous prescription drug or device from a licensed health care provider in order to:
  - Replace a damaged* prescription drug or device within the original duration of therapy; or
  - Extend a patient's current prescription drug or device (same drug/device, dose and directions) to avoid interruption of treatment.

*The Pharmacist must use their reasonable professional judgment as defined by OAR 855-006-0005 to determine if the drug or device is damaged. This includes physical damage like broken containers or spills, chemical changes like discoloration or unusual odors, and damage from exposure to heat or moisture, which can affect the drug or device's effectiveness and safety.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Continuation of Therapy Patient Intake Form (pg. 2)
- Utilize the standardized Continuation of Therapy Assessment and Treatment Care Pathway (pg. 3)
- Utilize the standardized Continuation of Therapy Prescription Template *optional* (pg. 4)
- Utilize the standardized Patient Informational Handout *optional* (pg. 5)
- Utilize the standardized Continuation of Therapy Provider Fax *optional* (pg. 6)

PRESCRIBING PARAMETERS

- **For Non-Insulin Medication, Medication Related Devices and Supplies:**
  - Quantity sufficient for the circumstances
  - Maximum quantity:
    - Damaged: May not exceed original duration of therapy
    - Extend: May not exceed a 60-day supply
  - Maximum frequency:
    - Damaged: No more than one replacement in a rolling 12-month period per medication
    - Extend: No more than two extensions in a rolling 12-month period per medication

- **For Insulin, Insulin Related Devices and Supplies (excluding pump devices):**
  - Quantity sufficient for the circumstances
  - Maximum quantity: Lesser of a 30-day supply or the smallest available package size
  - Maximum frequency: No more than three extensions in a calendar year (Jan 1- Dec 31)

PHARMACIST TRAINING/EDUCATION: None required.

Continuation of Therapy: Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Which medication or medication-related devices and supplies do you need an refill of today?_____ _____	
2.	Why are you unable to obtain a refill from your previous prescriber? _____	
3.	Have you previously had the medication or medication-related devices and supplies needed in #1 prescribed to you by a licensed health care provider? - If yes, what is the name and contact information for your licensed health care provider? _____ - If yes, when was the last time your provider prescribed the medication or medication-related device or supply to you? ___/___/_____	□ Yes □ No
4.	Do you have evidence of a previous prescription for the medication or medication-related device or supply needed in #1 from a licensed health care provider? - If yes, what evidence do you have? □ Prescription Vial □ Medical Record □ Other _____	□ Yes □ No
5.	Have you previously had medication or medication-related device or supplies prescribed to you by a Pharmacist? - If yes, what is the name and contact information for your pharmacist/pharmacy that prescribed to you? _____ - If yes, when was the last time a pharmacist prescribed medication or medication-related device or supply to you? ___/___/_____	□ Yes □ No

Patient Signature_____Date_____
(Parent or Legal Guardian signature needed if patient is under 18 years of age)

To Be Completed by a Pharmacist:

If medication or medication-related device or supply were prescribed/dispensed, please complete the following:

Drug or Device: _____ Directions: _____ Quantity: _____ + 0 refills Evidence: □ Prescription Vial □ Medical Record □ Other	Drug or Device: _____ Directions: _____ Quantity: _____ + 0 refills Evidence: □ Prescription Vial □ Medical Record □ Other
Drug or Device: _____ Directions: _____ Quantity: _____ + 0 refills Evidence: □ Prescription Vial □ Medical Record □ Other	Drug or Device: _____ Directions: _____ Quantity: _____ + 0 refills Evidence: □ Prescription Vial □ Medical Record □ Other

Primary Care Provider (if known) contacted/notified of therapy Date _____/_____/_____

If medication or medication related device or supplies were not prescribed/dispensed/administered, please indicate reason(s) for referral: _____
_____

RPH Signature_____Date_____

Emergency Refills of Insulin or Insulin-Related Devices
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

1. Does the patient need a medication or medication-related device/supply today?	
☐ Yes. Go to #2	☐ No. Do not prescribe.
2. If insulin-related supplies are needed, do these supplies include insulin pump devices?	
☐ Yes. Refer patient to other HCP	☐ No. Go to #3
3. Does the patient have evidence of a previous prescription for the needed medication or medication-related device or supply from a licensed health care provider?	
☐ Yes. Go to #4	☐ No. Refer patient to local primary care provider (PCP), emergency department (ED) or urgent care.
4. Has the patient received more than: a. one refill of non-insulin medication, medication-related device or supply from a pharmacist in the past rolling 12-months? b. two emergency refills of insulin or insulin-related supplies from a pharmacist in the past calendar year (1/1-12/31)	
☐ Yes. Do not prescribe. Refer patient to local primary care provider (PCP), emergency department (ED) or urgent care.	☐ No. Prescription recommended. Pharmacist must notify the provider.

Please refer to ORS 689.696 for specific laws concerning emergency refills of insulin and associated insulin-related devices and supplies.

RECOMMENDED REGIMEN:

Medication or medication-related device or supply	Notes:
	• Emergency prescribing must be for the same drug or related supply, strength, and dosage as shown by the patient evidence. • Emergency prescribing for non-insulin medications, devices or supplies is limited to a 60-day supply • Emergency prescribing for insulin or insulin-related supplies is limited to the lesser of a 30-day supply or the smallest available package size.

COUNSELING POINTS:

- To help plan, ask your health care provider for a prescription lasting more than 30 days to ensure you always have enough.
- In a case where you know you are going to need a refill while traveling, you may be able to order an additional supply in advance. Some health insurance plans allow for prescription overrides so that you can get a prescription filled early or obtain more than a 30-day supply.
- Keep an up-to-date list of all your prescription medications.

Continuation of Therapy Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Rx

☐ **Drug:** _____
- Directions: _____
- Quantity: _____ + 0 refills

☐ **Drug:** _____
- Directions: _____
- Quantity: _____ + 0 refills

☐ **Drug:** _____
- Directions: _____
- Quantity: _____ + 0 refills

☐ **Drug:** _____
- Directions: _____
- Quantity: _____ + 0 refills

Written Date: _____

Prescriber Name:_____Prescriber Signature: _____

Pharmacy Address:_____Pharmacy Phone: _____

Optional-May be used by pharmacy if desired

Patient Information
Continuation of Therapy

Pharmacy Name: _____Pharmacist Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

Your pharmacist, _____, authorized a refill of the medication, devices and/or supplies listed below to prevent an interruption in your therapy.

- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills

Follow-up and Next Steps

- Please contact your primary care provider to obtain further authorization to fill this medication.

Provider Notification
Continuation of Therapy

Pharmacy Name:_____ Pharmacist Name: _____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

On _____/_____/_____, your patient _____(name) _____/_____/_____ (DOB) was assessed for a refill of the medication, medication-related devices, and supplies listed below at _____ Pharmacy. Your patient was:

☐ **Prescribed medication or medication related devices and supplies**. The prescription(s) issued and dispensed consisted of:

- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
  - Evidence Provided: ☐ Prescription Vial ☐ Medical Record ☐ Other
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
  - Evidence Provided: ☐ Prescription Vial ☐ Medical Record ☐ Other
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
  - Evidence Provided: ☐ Prescription Vial ☐ Medical Record ☐ Other
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
  - Evidence Provided: ☐ Prescription Vial ☐ Medical Record ☐ Other

☐ **Referred to**: ☐ Primary care provider (PCP) ☐ Emergency department (ED) ☐ Urgent care for the following reasons:

_____
_____
_____
_____
_____

Medication or medication-related devices and supplies were not prescribed to your patient.

In authorizing this refill, the pharmacist used their professional judgment to meet the patient's medical needs.

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 the pharmacy. The prescription(s) was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

COUGH AND COLD SYMPTOM MANAGEMENT – PSEUDOEPHEDRINE

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 pseudoephedrine.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- INCLUSION CRITERIA: Age 18 and older, verified by positive ID
- EXCLUSION/REFERRAL CRITERIA: Age < 18

PRESCRIBING PARAMETERS:

- Pharmacist must review PDMP prior to issuing prescription, and retain documentation of review
- Maximum quantity: 3.6g or a 60 count quantity per prescription, whichever is less
- Maximum frequency: 3 prescriptions in a rolling 12-month period

PREVENTIVE CARE

TOBACCO CESSATION – NRT (Nicotine Replacement Therapy) and Non-NRT

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 855-115-0330 and OAR 855-115-0335 a pharmacist licensed and located in Oregon may prescribe individual or multiple Nicotine Replacement Therapy (NRT) OTC and Rx for tobacco cessation.

- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe non-NRT medications for tobacco cessation.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Tobacco Cessation Patient Intake Form (pg. 2-3)
- Utilize the standardized Tobacco Cessation Assessment and Treatment Care Pathway (pg. 4-7)

PHARMACIST TRAINING/EDUCATION:

- Minimum 2 hours of documented ACPE CE related to pharmacist prescribing of tobacco cessation products

Tobacco Cessation Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred 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. menthol/soy)? Yes / No If yes, please list: _____
List of medicine(s) you take:_____

_____

_____

In addition to smoking, are you also currently using non-cigarette products (e.g., chewing tobacco, vaping, e-cigarettes, juul)? If yes, what products are you using and how much do you use in a day? _____

_____

Do you have a preferred tobacco cessation product you would like to use?_____
Have you tried quitting smoking in the past? If so, please describe: _____
What best describes how you have tried to stop smoking in the past?

- ☐ "Cold turkey"
- ☐ Tapering or slowly reducing the number of cigarettes you smoke a day
- ☐ Medicine
  - o Nicotine replacement (e.g. patches, gum, inhalers, lozenges, etc.)
  - o Prescription medications (e.g. bupropion [Zyban®, Wellbutrin®], varenicline [Chantix®])
- ☐ Other_____

Health and History Screen – Background Information:

1.	Are you under 18 years old?	□ Yes □ No
2.	Are you pregnant, nursing, or planning on getting pregnant or nursing in the next 6 months?	□ Yes □ No □ Not sure

Medical History:

3.	Have you ever had a heart attack, irregular heartbeat or angina, or chest pains in the past two weeks?	□ Yes □ No □ Not sure
4.	Do you have stomach ulcers?	□ Yes □ No □ Not sure
5.	Do you wear dentures or have TMJ (temporomandibular joint disease)?	□ Yes □ No □ Not sure
6.	Do you have a chronic nasal disorder (ex. nasal polyps, sinusitis, rhinitis)?	□ Yes □ No □ Not sure

Tobacco History:

7.	Do you smoke fewer than 10 cigarettes a day?	□ Yes □ No

Blood Pressure Reading _____/_____ mmHg (**Note: Must be taken by a pharmacist*)

Stop here if patient and pharmacist are considering nicotine replacement therapy or blood pressure is ≥ 160/100 mmHg.

If patient and pharmacist are considering non-nicotine replacement therapy (e.g., varenicline or bupropion) and blood pressure is < 160/100mmHg continue to answer the questions below.

Tobacco Cessation Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Medical History Continued:

8.	Have you ever had an eating disorder such as anorexia or bulimia?	□ Yes □ No □ Not sure
9	Have you ever had a seizure, convulsion, significant head trauma, brain surgery, history of stroke, or a diagnosis of epilepsy?	□ Yes □ No □ Not sure
10.	Have you ever been diagnosed with chronic kidney disease?	□ Yes □ No □ Not sure
11.	Have you ever been diagnosed with liver disease?	□ Yes □ No □ Not sure
12.	Have you been diagnosed with or treated for a mental health illness in the past 2 years? (e.g. depression, anxiety, bipolar disorder, schizophrenia)?	□ Yes □ No □ Not sure

Medication History:

13.	Do you take a monoamine oxidase inhibitor (MAOI) antidepressant? (e.g. selegiline [Emsam®, Zelapar®], phenelzine [Nardil®], isocarboxazid [Marplan®], tranylcypromine [Parnate®], rasagiline [Azilect®])	□ Yes □ No □ Not sure
14.	Do you take linezolid?	□ Yes □ No □ Not sure
15.	Do you use alcohol or have you recently stopped taking sedatives? (e.g. benzodiazepines)	□ Yes □ No □ Not sure

The Patient Health Questionnaire 2 (PHQ 2):

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not At All	Several Days	More Than Half the Days	Nearly Every Day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3

Suicide Screening:

Over the last 2 weeks, how often have you had thoughts that you would be better off dead, or have you hurt yourself or had thoughts of hurting yourself in some way?	0	1	2	3

Patient Signature_____Date_____

Tobacco Cessation Assessment & Treatment Care Pathway

STEP 1: Health and History Screen Part 1 Review Tobacco Cessation Patient Questionnaire (Questions 1 -2)	No = No Contraindicating Conditions (Continue to step 2)	Yes/Not sure = Contraindicating Conditions → Refer	Refer to PCP and/or Oregon Quit Line 1-800-QUIT-NOW

STEP 2: Blood Pressure Screen Take and document patient's current blood pressure (note: RPh may choose to take a second reading if initial is high)	BP < 160/100 (Continue to step 4)	BP ≥ 160/100 → Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW

STEP 3: Medical History Nicotine Replacement Therapy Questions (Questions 3-4)	No to question 4 and 5 (Continue to step 5)	Yes to question 4 and/or 5 → Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW

STEP 4: Medical History Nicotine Replacement Therapy Questions (Questions 5-6) Question 5 = if Yes, avoid using nicotine gum Question 6 = if Yes, avoid using nicotine nasal spray	If patient wants NRT, prescribe NRT*	If patient wants bupropion or varenicline, continue to step 6

Prescribing NRT*(pg.6):	• Combination NRT is preferred (nicotine patch + acute NRT) • Acute NRT = nicotine gum, nicotine lozenge, nicotine nasal spray	**Tobacco History (Question 9 on questionnaire)** If Yes to smoking ≤=10 cigs/day (if patient also uses e-cigarettes and/or chewing tobacco calculate patient's total daily nicotine including nicotine from cigarettes, e-cigarettes, and chewing tobacco. If less than 20mg of nicotine per day), start with nicotine patch 14mg/day If No to smoking > 10 cigs/day (if patient also uses e-cigarettes and/or chewing tobacco calculate patient's total daily nicotine including nicotine from cigarettes, e-cigarettes, and chewing tobacco. If equal to or more than 20mg of nicotine per day) start with nicotine patch 21mg/day

STEP 6: Medical History Bupropion and varenicline screening (Questions 8-12)	Consider NRT* if yes to any question from 10-14		
	a) If yes to any question → avoid bupropion = If patient still wants bupropion, refer → Refer		Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW; NRT* can be considered
	b) If yes to any questions from 12-14→ avoid varenicline - If patient still wants varenicline, refer → Refer		
	If patient answered no to questions 10- 14, continue to step 7 If patient answered no to questions 12-14, but yes to question 10 and/or 11, AND wants varenicline (but not bupropion), skip to step 8		

STEP 7: Medication History (Questions 13-15)	If patient answered no to questions 15-17, review depression screening step 8	If patient answered yes to any question from 15-17 → avoid bupropion → Refer - Refer if patient still wants bupropion - If patient wants varenicline, continue to depression screening step 8	Refer to PCP if patient wants bupropion; NRT* can be considered

STEP 8: The Patient Health Questionnaire 2 (PHQ 2): Depression Screening	If score < 3 on PHQ2, review Suicide Screening in step 9	If score ≥ 3 on PHQ, avoid bupropion and varenicline and refer to PCP for treatment. NRT* can be offered. → Refer	Refer to PCP; NRT* can be considered

STEP 9: Suicide Screening	If score of 0 on suicide screening, may prescribe bupropion or varenicline	If score ≥ 1 on suicide screening, place **immediate** referral to PCP → Refer	Call PCP office to notify them of positive suicide screening and determine next steps. After hours, refer to suicide hotline 1-800-273-8255

Tobacco Cessation Assessment & Treatment Care Pathway

Prescribing Bupropion:	Prescribing Varenicline:
150mg SR daily for 3 days then 150mg SR twice daily for 8 weeks or longer. Quit day after day 7. Consider combining with nicotine patch or nicotine lozenge or nicotine gum for increased efficacy.* For patients who do not tolerate titration to the full dose, consider continuing 150mg once daily as the lower dose has shown efficacy.	0.5mg daily for 3 days then 0.5mg twice daily for 4 days then 1mg twice daily for 12 to 24 weeks. Quit day between days 8 and 35 after initiation of varenicline. Generally not used in combination with other tobacco cessation medications as first line therapy.

*Nicotine Replacement Dosing:

	Dose
Long Acting NRT	
Nicotine Patches	• Patients smoking >10 cigarettes/day (if patient also uses e-cigarettes and/or chewing tobacco calculate patient's total daily nicotine including nicotine from cigarettes, e-cigarettes, and chewing tobacco. If equal to or more than 20mg of nicotine per day): begin with 21mg/day for 6 weeks, followed by 14mg/day for 2 weeks, finish with 7mg/day for 2 weeks. • Patients smoking ≤ 10 cigarettes/day (if patient also uses e-cigarettes and/or chewing tobacco calculate patient's total daily nicotine including nicotine from cigarettes, e-cigarettes, and chewing tobacco. If less than 20mg of nicotine per day): begin with 14mg/day for 6 weeks, followed by 7mg/day for 2 weeks. • **Note:** Adjustment may be required during initial treatment (move to higher dose if experiencing withdrawal symptoms; lower dose if side effects are experienced).
Acute NRT	
Nicotine Gum	• Chew 1 piece of gum when urge to smoke occurs. If strong or frequent cravings are present after 1 piece of gum, may use a second piece within the hour (do not continuously use one piece after the other). • Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise, the 2 mg strength is recommended. • Use according to the following 12-week dosing schedule: o Weeks 1 to 6: Chew 1 piece of gum every 1 to 2 hours (maximum: 24 pieces/day); if using nicotine gum alone without nicotine patches, to increase chances of quitting, chew at least 9 pieces/day during the first 6 weeks o Weeks 7 to 9: Chew 1 piece of gum every 2 to 4 hours (maximum: 24 pieces/day) o Weeks 10 to 12: Chew 1 piece of gum every 4 to 8 hours (maximum: 24 pieces/day)
Nicotine Lozenges	• 1 lozenge when urge to smoke occurs; do not use more than 1 lozenge at a time • Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended. • Use according to the following 12-week dosing schedule: o Weeks 1 to 6: 1 lozenge every 1 to 2 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day); if using nicotine lozenges alone without nicotine patches, to increase chances of quitting, use at least 9 lozenges/day during the first 6 weeks o Weeks 7 to 9: 1 lozenge every 2 to 4 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day) o Weeks 10 to 12: 1 lozenge every 4 to 8 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day)
Nicotine Nasal Spray	• Initial: 1 to 2 doses/hour (each dose [2 sprays, one in each nostril] contains 1 mg of nicotine) • Adjust dose as needed based on patient response; do not exceed more than 5 doses (10 sprays) per hour [maximum: 40 mg/day (80 sprays)] or 3 months of treatment • If using nicotine nasal spray alone without nicotine patches, for best results, use at least the recommended minimum of 8 doses per day (less is likely to be effective) • Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation. • *Discontinuation of therapy:* Discontinue over 4 to 6 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.

Oregon licensed pharmacist must adhere to Prescribing Parameters, when issuing any prescription for tobacco cessation.

PRESCRIBING PARAMETERS:

- 1st prescription(s) up to 30 days

- Maximum duration = 24 weeks
- Maximum frequency = 2x in a rolling 12-month period

TREATMENT CARE PLAN:

- Documented follow-up: within 7-21 days after patient starts tobacco cessation medication(s), phone consultation permitted

Medication Counseling Points

Long Acting NRT	
Nicotine Patches	• Local skin reactions (redness, rash, itching) • Sleep disturbances (abnormal dreams, insomnia)
Acute NRT	
Nicotine Gum	• Jaw soreness • Mouth and throat irritation • Hiccups • Nausea • Heartburn • Lightheadedness/dizziness
Nicotine Lozenges	• Mouth and throat irritation • Hiccups • Nausea • Heartburn • Lightheadedness/dizziness
Nicotine Nasal Spray	• Nasal or throat irritation (hot, peppery sensation) • Runny nose • Runny, itchy eyes • Sneezing • Cough • Headache
Other Agents	
Bupropion	• Insomnia • Dry mouth • Nausea • Anxiety • Constipation • Tremor • Rash
Varenicline	• Nausea • Sleep disturbances (abnormal dreams, insomnia) • Headache • Gas • Constipation • Altered taste

Managing Withdrawal from Tobacco Products

Anxiety	• Typically occurs within two days of last cigarette and lasts around two weeks • Take a walk or a hot bath • Limit caffeine • Use relaxation techniques (deep breathing, quiet time, etc.)
Depressed mood	• Can last weeks and usually resolves after a month • Engage in activities/hobbies that you enjoy • Spend time with family and friends
Hunger/weight gain	• Drink extra water or low-calorie beverages • Have low-calorie snacks available
Insomnia	• Variable and can last weeks to months • Limit caffeine

	• Use relaxation techniques (deep breathing, quiet time, etc.)
Irritability	• Generally peaks in the first week of stopping smoking and usually resolves in the first month • Take a walk or a hot bath • Limit caffeine • Use relaxation techniques (deep breathing, quiet time, etc.)
Nicotine cravings	• Can occur frequently for the first 2-3 days and last for months to years • Wait out the urge as able, it usually only lasts a few minutes • Avoid situation and activities that may trigger a craving • Increase activity • Do something to keep mind and hands busy (word search, crossword, some sort of craft, etc.) • Use relaxation techniques (deep breathing, quiet time, etc.)

Tobacco Cessation Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Referred patient to Oregon Quit Line (1-800-QUIT-NOW or www.quitnow.net/oregon)

☐ BP Reading: ____/____ mmHg *must be taken by a RPh

Note: RPh must refer patient if blood pressure ≥ 160/100

Rx

Written Date: _____

Prescriber Name:_____Prescriber Signature: _____

Pharmacy Address:_____Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____

_____

_____

_____

_____

PREVENTIVE CARE

TRAVEL MEDICATIONS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe pre-travel medications.
  - Malaria prophylaxis
  - Traveler's diarrhea
  - Altitude illness prophylaxis
  - Motion sickness

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Travel Medications Patient Intake Form (pg. 2-4)
- Utilize the standardized Travel Medications Assessment and Treatment Care Pathway (pg. 5-11)
- Utilize the standardized Travel Medication Prescription Template *optional* (pg. 12)
- Utilize the standardized Travel Medication Provider Notification (pg. 13-14)
- Utilize the standardized Travel Medication Patient Visit Summary (pg. 15)

PHARMACIST TRAINING/EDUCATION:

- APhA Pharmacy-Based Immunization Delivery certificate (or equivalent); and
- Minimum of 4 hour comprehensive training program related to pharmacy-based travel medicine services intended for the pharmacist (one-time requirement); and
- A minimum of 1 hour of travel medication continuing education (CE), every 24 months.

RESOURCES:

- CDC Yellow Book 2024: Health Information for International Travel. Oxford University Press; 2023. https://wwwnc.cdc.gov/travel/page/yellowbook-home.

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

PATIENT INFORMATION

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____

Legal Name_____ Name _____

Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other_____

Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____

Street Address _____

Phone ( ) _____ Email Address _____

Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____

Do you have health insurance? Yes / No Insurance Provider Name _____

TRAVEL SPECIFICS

Purpose of Trip: _____

Activities: _____

Departure Date: _____ Return Date: _____

List Countries AND Cities to be Visited Chronologically (Include Layovers)	**Arrival Date**	**Departure Date**

Have you traveled outside the United States before? □ Yes □ No

If yes, where and when?

_____

_____

1.	Will you ONLY be using airplane as your mode of transportation If no, explain: _____	□ Yes □ No □ Not sure
2.	Will you ONLY be visiting major cities? If no, explain: _____	□ Yes □ No □ Not sure
3.	Will you ONLY be staying in hotels? If no, explain: _____	□ Yes □ No □ Not sure
4.	Will you be visiting friends and family?	□ Yes □ No □ Not sure
5.	Will you be ascending to high altitudes? (≥8,000 ft or 2,450 meters) in the mountains	□ Yes □ No □ Not sure
6.	Will you be working in the medical or dental field with exposure to blood or bodily fluids?	□ Yes □ No □ Not sure

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

ALLERGIES

□ No known drug or vaccine allergies □ No known food allergies

Drug/Vaccine Allergies: (describe reaction-e.g., rash, hives, anaphylaxis, etc.)

_____

Food Allergies: (describe reaction- e.g., rash, hives, anaphylaxis, etc.) -

_____

VACCINE MEDICAL INFORMATION

Please complete the table below ***(please bring your vaccination record to the pre-travel consult)***

Vaccinations	Yes – *(Enter vaccination date below)*	No	Not Sure
Chikungunya			
Cholera			
COVID-19	Dose 1: 2: Booster(s):		
Haemophilus Influenzae B (HIB)			
Hepatitis A	Dose 1: 2:		
Hepatitis B (Manufacturer):_____	Dose 1: 2: 3:		
Hepatitis A/B Combo	Dose 1: 2: 3:		
Human Papillomavirus (HPV)			
Influenza			
Japanese Encephalitis	Dose 1: 2:		
Meningococcal B	Dose 1: 2:		
Meningococcal ACWY	Dose 1: 2:		
Measles, Mumps, Rubella (MMR)	Dose 1: 2:		
Pneumonia			
PPSV23			
PCV (Select: 13/15/20)			
Polio			
Rabies	Dose 1: 2:		
Respiratory Syncytial Virus (RSV)			
Shingles	Dose 1: 2:		
Tetanus (Select: Tdap/Td/DTaP/DT)			
Tick-Borne Encephalitis	Dose 1: 2: 3: 4:		
Typhoid (Select: Oral / Injection)			
Varicella	Dose 1: 2:		
Yellow Fever			
Other:			
Other:			

MEDICAL HISTORY

List your current prescription medications and medical conditions treated (include birth control pills and anti-depressants):

Current Medical Conditions:_____

_____

Current Prescription Medications:_____

_____

Regularly used Non-Prescription Medications (over the counter, herbal, homeopathic, vitamins, and supplements including those purchased at health-food stores):_____

1.	Are you currently using steroids?	□ Yes □ No □ Not sure
2.	Are you currently receiving radiation therapy?	□ Yes □ No □ Not sure

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

3.	Are you currently receiving immunosuppressive therapy?	□ Yes □ No □ Not sure
4.	Are you pregnant or are you planning to become pregnant within the next year?	□ Yes □ No □ Not sure
5.	Are you currently breastfeeding?	□ Yes □ No □ Not sure

QUESTIONS/CONCERNS

Please list additional questions or concerns that you might have regarding your travel: _____

_____

Signature:_____Date:_____

Travel Medications - Assessment and Treatment Care Pathway

STEP 1: Assess routine and travel vaccinations.
STEP 2: Choose and issue prescription(s) for appropriate prophylaxis medication(s), in adherence to the CDC's 2024 Yellow Book: Health Information for International; https://wwwnc.cdc.gov/travel/page/yellowbook-home and this protocol. Must also 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 entering the malaria risk area-1 tablet weekly
                - Take once weekly while in the malaria risk area and for 4 weeks after leaving risk area

                Pediatric dosing:
                8.3 mg/kg (maximum is 500 mg)
                - Begin 1-2 weeks prior to entering the malaria risk area -1 dose weekly
                - Taken once weekly during trip and for 4 weeks after leaving the malaria risk area

                OR

                b. *Hydroxychloroquine (Plaquenil®)*
                Adult Dosing: Hydroxychloroquine 400 mg
                - Begin 1-2 weeks prior to entering the malaria risk area -1 tablet weekly
                - Take once weekly during trip and for 4 weeks after leaving the malaria risk area

                Pediatric Dosing:
                6.5 mg/kg (maximum is 400mg)
                - Begin 1-2 weeks prior to entering the malaria risk area -1 dose weekly
                - Take once weekly during trip and for 4 weeks after leaving the malaria risk area

            2. **Chloroquine-resistant zone**
                a. Atovaquone/Proguanil (Malarone®)
                Adult Dosing: Atovaquone/Proguanil 250mg/100mg
                - Begin 1 tablet daily 1-2 days prior to entering the malaria risk area
                - Take daily during trip and 7 days after leaving the malaria risk area

                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 dose daily 1-2 days prior to entering the malaria risk area
- Take daily during trip and 7 days after leaving the malaria risk area

OR

b. *Doxycycline monohydrate (Monodox®) or hyclate (Vibramycin®) (≥8 years)*
Adult Dosing: Doxycycline 100mg

- Begin 1 tablet or capsule daily 1-2 days prior to entering the malaria risk area
- Take daily during trip and for 4 weeks after leaving the malaria risk area

Pediatric Dosing:
≥8 years old: 2.2 mg/kg (maximum is 100 mg) daily

- Begin 1 dose daily 1-2 days prior to entering the malaria risk area
- Take daily during trip and for 4 weeks after leaving malaria risk area

OR

c. *Mefloquine (Lariam®)*
Adult Dosing: Mefloquine 250mg

- Begin ≥2 weeks prior to entering the malaria risk area -1 tablet weekly
- Take once weekly during travel in the malaria risk area and for 4 weeks after leaving the malaria risk area

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 entering the malaria risk area -1 dose weekly
- Take once weekly during and for 4 weeks after leaving the malaria risk area

3. Mefloquine-Resistant zone

a. *Doxycycline monohydrate (Monodox®) or hyclate (Vibramycin®) (≥8 years)*
Adult dosing: Doxycycline 100 mg

- Begin 1 tablet or capsule daily 1-2 days prior to entering the malaria risk area
- Take daily during trip and 4 weeks after leaving the malaria risk area

Pediatric dosing:
≥8 years old: 2.2 mg/kg (maximum is 100 mg) daily

- Begin 1 dose daily 1-2 days prior to entering the malaria risk area
- Take daily during trip and 4 weeks after leaving the malaria risk area

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 dose daily 1-2 days prior to entering the malaria risk area
- Take daily during trip and 7 days after leaving the malaria risk area

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 Yellow Book 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 the CDC 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 the CDC Yellow Book for resistance rates to antibiotics
      2. Empiric treatment for moderate TD and severe TD (age <18 requires a prescription from PCP) a
         a. *Azithromycin 500mg*
            • 1 tablet daily for 3 days
            • 1 course/14 days, Max 2 courses for trips >14 days

3. <u>Altitude Illness</u>

a. Patient assessment/Education
   i. Review detailed itinerary and identify travel areas of increased risk
   ii. Assess patients' risk of acquiring altitude illness and body weight (kg)
   iii. Review signs/symptoms of altitude illness, 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 the CDC Yellow Book 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; 250 mg if >100 kg
         - Take 1 dose twice daily starting 24 hours before ascent, continuing the first 2 days at elevation, and longer if ascent continues

         <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. <u>Motion Sickness</u>

a. Patient assessment
   i. Review detailed itinerary and identify travel areas of increased risk
   ii. Assess patients' risk of acquiring motion sickness and body weight (kg)
   iii. Review signs/symptoms of motion sickness, discuss tips for reducing motion sickness: being aware of triggers, reducing sensory input
   iv. Screen for contraindications

b. Prophylaxis
   i. Consult the CDC Yellow Book 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 Protocol 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)
    e. Cannot be used by women who are pregnant or breastfeeding a child that weighs < 5 kg
4. Doxycycline
    a. Age < 8 years old
    b. Hypersensitivity to doxycycline, other tetracyclines
    c. Pregnancy
    d. 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)
    d. Not recommended for people with cardiac conduction abnormalities

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 or 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

Altitude Illness

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
i. Hypersensitivity to acetazolamide or any excipients in the formulation. Since acetazolamide is a sulfonamide derivative, cross sensitivity between acetazolamide, sulfonamides and other sulfonamide derivatives is possible.

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 conditions (e.g., 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
5. DiphenhydrAMINE
    a. Age < 7 years old
    b. Hypersensitivity to diphenhydrAMINE or other structurally related antihistamines or any component of the formulation
    c. Breastfeeding

Travel Medications - Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:
Patient Weight (kg):	

Rx

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ____

- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ____

- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ____

- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ____

- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ____

- Directions: ____
- Quantity: _______ + 0 refills

Written Date: ____________________________________

Prescriber Name:______________________________Prescriber Signature: _________________________

Pharmacy Address:____________________________________Pharmacy Phone: _____________________

Provider Notification
Travel Medications

Pharmacy Name:_________________________ Pharmacist Name: ___________________________________
Pharmacy Address:____
Pharmacy Phone:________________________ Pharmacy Fax: ______________________________________

Patient Name:____ DOB: ____/_____/_____ Age:_____

Healthcare Provider:___________________________________ Phone: (____)_____-________ Fax: (____)_____-________

Your patient was seen at our pharmacy on ____/____/____ for a professional travel consultation. During this visit, we carefully reviewed the patient's medical history, prescription history, and lifestyle factors to ensure the safety of all medications prescribed and vaccines administered. Upon review it was determined that the patient could benefit from prescription/vaccine therapy. The following prescription(s) and/or vaccines were provided to your patient:

☐ **Medications Prescribed**

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ____
- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ____
- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ____
- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ____
- Directions: ____
- Quantity: _______ + 0 refills

☐ **Vaccines Administered**

Vaccines							
Recommended	Given	Declined	Dose #	Recommended	Given	Declined	Dose#
☐ Cholera	☐	☐		☐ Polio	☐	☐	
☐ COVID-19	☐	☐		☐ PPSV23	☐	☐	
☐ Hepatitis A/B	☐	☐		☐ Rabies	☐	☐	
☐ Hepatitis A	☐	☐		☐ RSV	☐	☐	
☐ Hepatitis B	☐	☐		☐ Shingles	☐	☐	
☐ Hib	☐	☐		☐ Td/Tdap	☐	☐	
☐ HPV	☐	☐		☐ Typhoid IM	☐	☐	
☐ Influenza	☐	☐		☐ Typhoid PO	☐	☐	
☐ Japanese Encephalitis	☐	☐		☐ Varicella	☐	☐	
☐ Meningococcal	☐	☐		☐ Yellow Fever	☐	☐	
☐ PCV 15/20	☐	☐		☐ Other: ______________	☐	☐	

☐ **Medications and/or Vaccines NOT provided at our pharmacy, because:**

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine.

- ☐ **Drug/Vaccine:** ____
- ☐ **Reason for Referral:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine.

- ☐ **Drug/Vaccine:** ____
- ☐ **Reason for Referral:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine.

- ☐ **Drug/Vaccine:** ____
- ☐ **Reason for Referral:** ____

Please contact us if you have any questions about the care provided to your patient or if you would like to obtain additional information about our pharmacy's patient care services.

Pharmacist Signature:______________________________________ Date:_____________________________
Pharmacist Name (Print):______________________________________

The prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

- **CDC Yellow Book 2024: Health Information for International Travel.** New York: Oxford University Press; 2023.Retrieved from https://wwwnc.cdc.gov/travel/page/yellowbook-home.

Patient Visit Summary
Travel Medications

Pharmacy Name:________________________________ Pharmacist Name:______________________________________

Pharmacy Address:____

Pharmacy Phone: _____________________________ Pharmacy Fax: _____________________________

Today, on ____/____/____ , you were seen by Pharmacist, ________________________________ for a professional travel consultation.

☐ **<u>You were provided</u>** the following travel medications and/or vaccines:

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine
☐ **Drug/Vaccine:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine
☐ **Drug/Vaccine:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine
☐ **Drug/Vaccine:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine
☐ **Drug/Vaccine:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine
☐ **Drug/Vaccine:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine
☐ **Drug/Vaccine:** ____

-- and/or --

☐ You were **<u>not able to receive</u>** the following travel medications and/or vaccines today, and *must consult with a primary care provider for additional evaluation* prior to receiving services, because:

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine.
☐ **Drug/Vaccine:** ____
☐ **Reason for Referral:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine
☐ **Drug/Vaccine:** ____
☐ **Reason for Referral:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine
☐ **Drug/Vaccine:** ____
☐ **Reason for Referral:** ____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ Vaccine
☐ **Drug/Vaccine:** ____
☐ **Reason for Referral:** ____

PREVENTATIVE CARE

POST-EXPOSURE PROPHYLAXIS FOR BACTERIAL SEXUALLY TRANSMITTED INFECTIONS (STI PEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335 a pharmacist licensed and located in Oregon may prescribe post-exposure preventative treatment for chlamydia, gonorrhea, and syphilis (STI PEP).

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized STI PEP Patient Intake Form (pg. 2)
- Utilize the standardized STI PEP Assessment and Treatment Care Pathway (pg. 3-6)
- Utilize the standardized STI PEP Prescription Template *optional* (pg. 7)
- Utilize the standardized STI PEP Provider Fax (pg. 8)
- Utilize the standardized STI PEP Patient Informational Handout (pg. 9-10)

PHARMACIST TRAINING/EDUCATION:

- No required training/education
- *Recommended*: Completion of an educational training program of at least 1 hour related to the prescribing of STI PEP or STI curriculum, to include related trauma-informed care*.
    - DoxyPEP: Who, When, and How. https://www.iasusa.org/events/webinar-2023-luetkemeyer/ International Antiviral Society–USA (IAS–USA); Program is Accreditation Council for Pharmacy Education (ACPE) accredited
    - National STD Curriculum (A free educational website from the University of Washington STD Prevention Training Center). https://www.std.uw.edu/

    *The programs listed above do not include specific training on trauma-informed care.

RESOURCES:

- Doxycycline for STI PEP Implementation Toolkit. National Coalition of STD Directors. https://www.ncsddc.org/wp-content/uploads/2023/07/Doxycycline-as-STI-PEP-Toolkit-July-2023.pdf (accessed 1/5/2024)

Post-Exposure Prophylaxis for Bacterial STIs (STI PEP)
Self-Screening Intake Form (CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred 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 _____

1.	Are you UNDER 13 years old?	□ Yes □ No
2.	Do you identify as gay, bisexual, or a man who has sex with men? Do you identify as a transgender woman?	□ Yes □ No □ Yes □ No
3.	a) Has a healthcare provider EVER tested or diagnosed you with a chlamydia OR gonorrhea OR syphilis infection? b) If yes, how recently? _____ What were the results? _____ _____ c) How many infections have you experienced within the last 12 months? _____	□ Yes □ No □ Not sure
4.	a) Have you ever failed to complete treatment for chlamydia OR gonorrhea OR syphilis infection, or had the treatment not work? b) What treatments (if any) have you tried for past and/or current chlamydia OR gonorrhea OR syphilis infections? Please list them here: _____ _____	□ Yes □ No □ Not sure
5.	Symptom review: Do you currently have: - Abnormal discharge (color, smell, consistency, etc.) from penis - Burning sensation when peeing (urination) - Anal itching, discharge, or bleeding - One or multiple sores in, on, or around penis, anus, or rectum; or rash anywhere - Soreness in rectum, or painful bowel movements - Pain and swelling in one or both testicles - Other symptoms (describe): _____	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
6.	Have you used antibiotics in the last month?	□ Yes □ No □ Not sure
7.	a) Do you have oral, anal, or vaginal sexual contact WITHOUT a condom? If yes, how recently (date)? Did this activity happen more than once in the past 12 months? b) In the future, will you have oral, anal, or vaginal sexual contact WITHOUT a condom? c) Have you had multiple sex partners in the past 12 months? d) Do you (will you) engage in group sex or chem-sex? e) Do you (will you) participate in sexual activities during weekend events, cruises, festivals, or similar?	□ Yes □ No ___/___/___ □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
8.	Have you had an exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
9.	a) Are you currently taking HIV Pre-Exposure Prophylaxis (HIV PrEP) medications? b) Do you use HIV Post-Exposure (HIV PEP) medications?	□ Yes □ No □ Not sure □ Yes □ No □ Not sure
10.	Do you have a health condition involving your esophagus, intestines, or liver?	□ Yes □ No □ Not sure
11.	Do you have any other medical problems? If yes, list them here: _____ _____	□ Yes □ No □ Not sure
12.	Are you currently taking any medications, supplements, and/or vitamins? If yes, list them here: _____ _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

Standardized Assessment and Treatment Care Pathway
Post-Exposure Prophylaxis for Bacterial STIs (STI PEP)

1) STI PEP patient population eligibility for enrollment in protocol (Form Q: #1-2)

a. Q1: If patient less than 13 years of age -> **REFER** to medical provider (doxycycline contraindicated if <8 years old)

b. Q2: If patient identifies as gay, bisexual, a man who has sex with men (GBMSM), or transgender woman (TGW) who has sex with men -> Continue algorithm (Step 2)

- If not -> **DEFER** prescribing STI PEP; advise to continue condom use. Refer to medical provider if non-protocol-eligible patient wants STI PEP. Studies do not support the use of STI PEP in other patient populations.

2) Bacterial Sexually Transmitted Infection (STI) Screen and Risk Assessment: chlamydia OR gonorrhea OR syphilis infection (Form Q: #3-7)

		Sexual Behavior or Activity	
		Q7a: Reports ***condomless*** anal, oral, or vaginal sexual contact with ≥ 1 cis-male or trans-female partner in the past 12 months	Q7a: **DOES NOT** report ***condomless*** anal, oral, or vaginal sexual contact with ≥ 1 cis-male or trans-female partner in the past 12 months
Infection History	Q3a-c: Has had one (1) or more chlamydia OR gonorrhea OR syphilis infections within 12 months	**Prescribe STI PEP**	Consider STI PEP Q7b: If expects to have ***condomless*** sex in future: -> prescribe STI PEP.
	Q3a-c: Has ***NOT*** had one (1) or more chlamydia OR gonorrhea OR syphilis infections within 12 months	Consider STI PEP If history of, or expectation for: Q7c: multiple sex partners, OR Q7d: group sex/ chem-sex, OR Q7e: participating in sexual activities that are known to increase likelihood of exposure to STIs, e.g., during weekend events, cruises, and festivals: -> prescribe STI PEP.	Consider STI PEP If history of, or expectation for: Q7c: multiple sex partners, OR Q7d: group sex/ chem-sex, OR Q7e: participating in sexual activities that are known to increase likelihood of exposure to STIs, e.g., during weekend events, cruises, and festivals: -> prescribe STI PEP.

a. **<u>EXCEPTIONS</u>**:

- Q4: If history of failing to complete treatment for chlamydia OR gonorrhea OR syphilis infection-> **NOTIFY** medical provider.
- Q4: If patient completed treatment for chlamydia OR gonorrhea OR syphilis and infection did not resolve -> **REFER to medical provider**
- Q5: If experiencing symptoms consistent with current STI: Abnormal discharge (color, smell, consistency, etc.) from penis; Burning sensation when peeing (urination); Anal itching, discharge, or bleeding; One or multiple sores in, on, or around penis, anus, or rectum; or rash anywhere; Soreness in rectum, or painful bowel movements; Pain and swelling in one or both testicles.
  - If YES to any of these symptoms -> **REFER for diagnosis and active treatment of possible STI.**
- Q7: If condomless sexual contact reported:
  - < 72 hours ago: direct patient to take doxycycline immediately after receipt of prescription
  - > 72 hours ago: direct patient not to use doxycycline; **REFER to medical provider for assessment**. May continue to provide STI PEP for future sexual activity.

b. SCREENING: IF PATIENT MEETS CRITERIA FOR PRESCRIBING STI PEP:

- Q3a-b: Recommend to patient they undergo bacterial STI testing at anatomic sites of exposure at baseline before initiation of STI PEP
    - If patient had STI testing AND has not had sexual contact since test:
        - History of negative testing may serve as baseline (patient to provide records)
    - Provide lab order for BASELINE screen: nucleic acid amplification test for gonorrhea and chlamydia at anatomic sites of exposure, and serologic testing for syphilis.
    - Pharmacy may prescribe STI PEP without baseline results.
    - If STI testing is positive for chlamydia OR gonorrhea OR syphilis -> **REFER for diagnosis and active treatment of possible STI.**

3) Comprehensive therapy assessment (Form Q: #7-9)

a. Q8: SEXUAL ASSAULT VICTIM/SURVIVOR? If the patient experienced a sexual assault, continue with the algorithm to prescribe STI PEP and then refer the patient to the emergency department for a sexual assault workup.
    - Oregon licensed pharmacists are mandatory reporters of child abuse (ORS Chapter 419B). Pharmacists must report any instance where they become aware of or have reason to believe child abuse has occurred. Pharmacists should also report elder abuse and vulnerable adult abuse. Reports must be made to the Oregon Department of Human Services @ 1-855-503-SAFE (7233).

b. Q9: Assess for the need for HIV PEP and encourage the use of HIV PrEP
    - If not currently utilizing HIV PrEP or HIV PEP, offer patient to complete respective Patient Intake Forms for these statewide protocols.

c. Q7a-e: Counsel on risk reduction strategies including:
    - Condom use for every instance of sexual contact
    - Consideration of reducing the number of partners

4) Medication and Disease State Screen (Form Q: #10-12)

a. Q10: History of gastrointestinal (GI) conditions (e.g., esophagitis, diarrhea, Crohn's, etc.) -> Use caution. Have the patient contact pharmacy or medical provider if experiencing exacerbation of condition.

b. Q11-12: Review medication history for duplicative therapy and/or drug-drug, drug-disease state interactions

5) Assess and Initiate Therapy:

All therapies are equally effective for STI PEP. Choice of therapy should be based on patient safety, preference, availability, and cost.

- Doxycycline hyclate delayed release 200 mg (1 tab) - OR - Doxycycline hyclate or monohydrate immediate release 100 mg (2 tabs/caps taken simultaneously)
    - Doxycycline 200 mg should be taken ideally within 24 hours but no later than 72 hours after condomless oral, anal or vaginal sexual contact
    - Doxycycline can be taken as often as every day, depending on frequency of sexual activity, but individuals should not take more than 200 mg within a 24 hour period
    - Suggested maximum initial quantity: #14 doses of 200 mg; NO Refills
        - Adjust quantity on individual assessment through shared decision making (sexual contact frequency)

6) Complete Patient Encounter

Advise:

- Take doxycycline exactly and prescribed and only for its intended purpose.
- Seek advice from a medical care provider if STI symptoms develop despite use of STI PEP.
    - If diagnosed with an STI while using STI PEP, patient should be treated according to standard CDC STI Treatment Guidelines
- Potential side effects (phototoxicity, esophagitis and esophageal discomfort, gastrointestinal intolerance) and methods to mitigate side effects.

- Potential for development of antimicrobial resistance in other pathogens and commensals.
- Importance of separating the doxycycline dose by at least 2 hours from antacids and supplements that contain calcium, iron, magnesium or sodium bicarbonate.
- Counsel on risk reduction strategies including:
    - Condom use for every instance of sexual contact
    - Consideration of reducing the number of partners

Encourage:

- Vaccines which protect against sexually transmitted or sexually associated infections according to current local eligibility and ACIP Guidance
    - MPX Vaccine (Jynneos)
    - Meningococcal Vaccine (MenACWY)
    - Hepatitis A/ Hepatitis B
    - HPV

Document: All required elements

7) Monitoring and Continuation of Therapy

a. Continuing therapy with STI PEP may be provided upon evidence of negative STI testing at every 3-month intervals (maximum 6-month interval)
    - Provide patient lab order for routine STI screening at 3-month intervals: nucleic acid amplification test for gonorrhea and chlamydia at anatomic sites of exposure, and serologic testing for syphilis.
    - Patient may instead receive STI screening labs via another medical provider and submit results to pharmacy
        i. It is recommended to screen for HIV in HIV-negative patients. See Step 3 above. It is possible that patients are having labs collectively completed under order of another provider.

b. If no STI is currently present, prescribe continuing therapy for STI PEP.

Standardized Assessment and Treatment Care Pathway
Post-Exposure Prophylaxis for Bacterial STIs (STI PEP)

Medication considerations:

- ***Doxycycline:***
    - *Warnings/Precautions*: Potential patient harm is associated with known side effects of taking doxycycline. It is well tolerated but may cause symptoms such as diarrhea and yeast infections. More rare side effects may include:
        - Intracranial hypertension (monitor for vision changes)
        - Skin reactions: Monitor for rash development
    - *Contraindications for doxycycline use: (consider other therapy)*
        - Hypersensitivity reactions: Use with caution in patients with hypersensitivity to other tetracyclines

References:

- Doxycycline. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Accessed January 5, 2024. http://www.micromedexsolutions.com
- Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial STI Prevention. https://www.cdc.gov/std/treatment/guidelines-for-doxycycline.htm Division of STD Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (accessed 1/5/2024)
    - Molina JM, Charreau I, Chidiac C, et al. Post-exposure prophylaxis with doxycycline to prevent sexually transmitted infections in men who have sex with men: an open-label randomised substudy of the ANRS IPERGAY trial. Lancet Infect Dis. 2018 Mar;18(3):308-317.
    - Luetkemeyer AF, Donnell D, Dombrowski JC, et al. Postexposure doxycycline to prevent bacterial sexually transmitted infections. N Engl J Med. 2023 Apr 6;388(14):1296-1306. DoxyPEP Reference (Conference Data- needs to be updated when paper available)
    - Jean-Michel Molina, Beatrice Bercot, Lambert Assoumou, Algarte-Genin Michele, Emma Rubenstein, Gilles Pialoux, et al. ANRS 174 DOXYVAC: An Open-Label Randomized Trial to Prevent STIs in MSM on PrEP. CROI [Internet]. 2023 Feb 19;Seattle, Washington. Available from: https://www.croiconference.org/abstract/anrs-174-doxyvac-an-open-label-randomized-trial-to-prevent-stis-in-msm-on-prep/
    - Stewart J, Oware K, Donnell D, Violette L, Odoyo J, Simoni J, et al. Self-reported adherence to event-driven doxycycline postexposure prophylaxis for sexually transmitted infection prevention among cisgender women. STI and HIV 2023 World Congress, Chicago, IL. 2023 Jul 24; Seattle, Washington. Available from: https://www.croiconference.org/abstract/doxycycline-postexposure-prophylaxis-for-prevention-of-stis-among-cisgender-women/
- Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention. https://www.regulations.gov/document/CDC-2023-0080-0002 Centers for Disease Control and Prevention, Regulations.gov (accessed 1/5/2024)
- Guidelines for the Use of Doxycycline Post Exposure Prophylaxis for Bacterial STI Prevention. https://www.youtube.com/watch?v=2hYvrrK_W58 Centers for Disease Control and Prevention (accessed 1/5/2024)
- Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention; Request for Comment and Informational Presentation. https://www.federalregister.gov/documents/2023/10/02/2023-21725/guidelines-for-the-use-of-doxycycline-post-exposure-prophylaxis-for-bacterial-sexually-transmitted Centers for Disease Control and Prevention, FederalRegister.gov (accessed 1/5/2024)

Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Optional -May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Rx

Doxycycline (hyclate or monohydrate) 100mg tablets or capsules

Sig: Take 2 tablets/ capsules by mouth as soon as possible within 72 hours after condomless oral, anal, or vaginal sex. Max 2 tablets/capsules per 24 hours.

Quantity: 28

Refills: 0

-or-

Doxycycline hyclate **delayed release** 200 mg tablets

Sig: Take 1 tablet by mouth as soon as possible within 72 hours after condomless oral, anal, or vaginal sex. Max 1 tablet per 24 hours.

Quantity: 14

Refills: 0

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

Provider Notification
Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been prescribed STI Post-Exposure Prophylaxis (STI PEP) by _____, RPH. This regimen was filled on _____/_____/_____ (Date) for a _____ day supply and follow-up STI testing is recommended in approximately _____ months _____/_____/_____ (Date)

This regimen consists of the following (check one):

☐ Doxycycline (hyclate or monohydrate) 100mg tablets or capsules
- Take 2 tabs/caps by mouth as soon as possible within 72 hours after condomless oral, anal, or vaginal sex. Max 2 tabs/caps per 24 hours.

☐ Doxycycline hyclate delayed release 200 mg tablets
- Take 1 tab by mouth as soon as possible within 72 hours after condomless oral, anal, or vaginal sex. Max 1 tab per 24 hours.

Your patient has been provided orders for baseline testing for, and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• Syphilis/Treponemal antibody:	____/____/_____	□ *reactive* □ *indeterminate* □ 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

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about STI PEP.*

Provider Pearls for STI PEP:

- STI PEP is prescribed for up to a 30-dose or approximately 90-day supply for each prescription to align with appropriate lab monitoring guidelines.
- An NIH-funded study found that doxycycline as STI Post-Exposure Prophylaxis (PEP) reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals taking HIV PrEP (Pre-Exposure Prophylaxis). Doxycycline as STI PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57% in people living with HIV (PLWH) (Source: N Engl J Med 2023; 388:1296-1306). This current efficacy data only applies to gay and bisexual men and other men who have sex with men (GBMSM) and transgender women; studies among heterosexual cis-gender women are ongoing.
- Patients using doxycycline as STI PEP should still engage in regular sexual health testing, including being screened for gonorrhea, chlamydia, syphilis, and HIV (if not known to be living with HIV) every three (to six) months. If a person utilizing doxycycline as STI PEP is diagnosed with an STI, they should be treated according to the 2021 CDC STI treatment guidelines.

Pharmacist Monitoring of STI PEP and Transition of Care:

- The pharmacist prescribing and dispensing STI PEP conducts and/or reviews results of STI screen and testing as part of their patient assessment.
- Patients who test reactive or indeterminate for gonorrhea/chlamydia, or syphilis will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's STI PEP from the pharmacy at any time.

This prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

If you have additional questions, please contact the prescribing pharmacy. For information about STI PEP, please visit the CDC website.

Pharmacy Name: _____Pharmacist Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

This page contains important information for you; please read it carefully.

To help prevent certain sexually transmitted bacterial infections (STI) like chlamydia, gonorrhea, and syphilis, you have been prescribed doxycycline. Listed below is the medication you have been prescribed and some key points to remember about this medication.

Medications:

- Doxycycline

Key Points:

What is STI PEP?

- STI PEP means taking the antibiotic doxycycline after sex, to prevent getting an STI. It is like a morning-after pill, but for STIs.
- It has been found that using doxycycline as STI PEP reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals also taking HIV PrEP (Pre-Exposure Prophylaxis). For people living with HIV, doxycycline as STI PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57%. This current data is specific to gay and bisexual men, and other men who have sex with men, and transgender women; studies among heterosexual cis-gender women are ongoing.
- If you use doxycycline as STI PEP, it's important to continue regular sexual health testing every three to six months for gonorrhea, chlamydia, syphilis, and HIV (if not known to be living with HIV). If you are using doxycycline as STI PEP and are diagnosed with an STI, you will need to follow treatment directions for that STI, which may include different antibiotics.

When should I take STI PEP?

- Doxycycline 200 mg should be taken ideally within 24 hours but no later than 72 hours after condomless sex. Condomless sex means oral, anal or vaginal/front-hole sex where a condom isn't used for the entire time.

What about when I have sex again?

- If you have sex again within 24 hours of taking doxycycline, take another dose 24 hours after your last dose. You can take doxycycline as often as every day when you are having condomless sex but don't take more than 200 mg every 24 hours.

How should I take STI PEP?

- Take doxycycline with plenty of water or something else to drink so that it does not get stuck when you swallow. If your stomach is upset by doxycycline, taking it with food may help.
- Avoid calcium, antacids, or multivitamins 2 hours before after taking doxycycline.
- Please do not share your doxycycline with others.

Pharmacy Name: _____Pharmacist Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

What are the possible side effects of doxycycline (STI PEP)?

- Some people are more sensitive to the sun when they take doxycycline, so wear sunscreen.
- Irritation to your esophagus (swallowing tube). If it occurs, alert your pharmacist or healthcare provider.
- Diarrhea is possible (it depends on how many doses per week you take). If severe or lasting more than a couple days, consult your pharmacist or healthcare provider.
- Yeast infections: Report any of the following presentations to your healthcare provider:
    - Mouth: white-colored patches and soreness
    - Penile-inverted vagina (front hole) of transgender women: white-colored, possibly malodorous discharge, and/or itching
    - Skin (skinfolds) or in the navel: bright-red rash, sometimes with breakdown of skin and small pustules, and itching
    - Anus: raw, white or red, and itchy
- Report any vision changes... it might be a sign of high pressure inside the skull.
- Other types of skin rashes... follow up with a medical provider immediately if this appears.

Reminders

- Call us if you run out of doxycycline, if you are having any side effects, or if you think you may have an STI. We may need to refer you to a different healthcare provider.
- Please continue to get tested for STIs every 3 months AND whenever you have STI symptoms.
- STI PEP doesn't protect against other viral infections like monkeypox or HIV.

Follow-up and Next Steps

1 . Make plans with pharmacy or a different healthcare provider to get STI screening every 3 months.

Resources used to create this document:

https://www.ncsddc.org/wp-content/uploads/2023/08/Doxycycline-as-STI-PEP-Toolkit-August-2023.pdf
https://www.sfcityclinic.org/sites/default/files/2023-02/Doxy-PEP%20info%20sheet%2012.9.22.pdf
Luetkemeyer AF, Donnell D, Dombrowski JC, et al. Postexposure doxycycline to prevent bacterial sexually transmitted infections. N Engl J Med. 2023 Apr 6;388(14):1296-1306.

PREVENTIVE CARE

SHORT-ACTING OPIOID ANTAGONIST (SAOA)- NALOXONE / NALMEFENE

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.800 and ORS 689.802, a pharmacist may prescribe, distribute and administer a short-acting opioid antagonist (SAOA) and the necessary medical supplies to administer the SAOA. Per ORS 689.689, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe a SAOA and the necessary medical supplies to administer the SAOA.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized SAOA Patient Intake Form *optional* (pg. 2)
- Utilize the standardized SAOA Assessment and Treatment Care Pathway (pg. 3-4)
- Utilize the standardized SAOA Prescription Template *optional* (pg. 5)
- Utilize the standardized SAOA Provider Fax *optional* (pg. 6)
- Utilize the standardized Patient Information *optional* (pg. 7-13)

PRESCRIBING PARAMETERS

- No limitations exist for quantity or refills

RESOURCES:

Naloxone: Opioid Overdose, Prevention, Recognition & Response – Oregon State College of Pharmacy - CE. Accessed February 4, 2024. https://oregon-state-pharmacy-ce.catalog.instructure.com/courses/naloxone

Prescribe to Prevent – Prescribe naloxone, save a life. Accessed February 4, 2024. https://prescribetoprevent.org/

Oregon Health Authority. Pharmacist Prescribing of Naloxone. Accessed February 4, 2024. https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/toolkit/RPh-info-sheet.pdf

Oregon Health Authority. Naloxone Poster for Pharmacies. Accessed February 4, 2024. https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/toolkit/Naloxone-Poster.pdf

Stay Safe Oregon: Prescription Opioid Safety, Treatment & Information. Stay Safe Oregon. Accessed February 4, 2024. http://staysafeoregon.com/

SAMSHA Behavioral Health Treatment Services Locator. Accessed February 4, 2024. https://findtreatment.samhsa.gov/

Oregon Health Authority. Reducing Opioid Overdose and Misuse. Accessed February 4, 2024. https://www.oregon.gov/oha/ph/preventionwellness/substanceuse/opioids/pages/index.aspx

Oregon Health Authority. Training on Lifesaving Treatment Protocols. Accessed February 4, 2024. https://www.oregon.gov/oha/ph/ProviderPartnerResources/EMSTraumaSystems/Pages/epi-protocol-training.aspx#opioidoverdose

Self-Screening Patient Intake Form – Short-acting Opioid Antagonist (e.g., naloxone, nalfemene)

CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____
Name of Requestor: _____

Optional Demographic Information-

Legal Name_____ Date of Birth _____/_____/_____ Age_____
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 _____

1. Would you like to receive a short-acting opioid antagonist kit (e.g., naloxone, nalfemene)? □ Yes □ No
   If yes, how many doses would you like? _____

Signature_____ Date_____

Assessment and Treatment Care Pathway- Short Acting Opioid Antagonists (SAOAs)
Naloxone / Nalmefene

(CONFIDENTIAL-Protected Health Information)

Name of Requestor: _____ Today's Date:____/____/_____

1. Is the person or entity's representative requesting an opioid antagonist?		Notes:
☐ Yes. Proceed to Step 2.	☐ No. Do not prescribe, consider giving more information regarding opioid antagonists and opioid overdoses.	
2. Choose a product based on their preference or your professional discretion. Counsel and train appropriately. If appropriate, provide information on how to administer naloxone / nalmefene.		Notes:

AVAILABLE TREATMENT OPTIONS

Naloxone	• Prepackaged intranasal naloxone 4 mg (Narcan®) or 8 mg (Kloxxado™). Dispensed as 2 unit-dose nasal spray devices per box. • Intramuscular naloxone 0.4 mg/mL SDV. Inject the contents of one vial intramuscularly into outer thigh for signs of opioid overdose. Must be dispensed with a 3 mL syringe with a 21-25 G x 1-1 ½ inch needle. • Intramuscular naloxone 5 mg/0.5 mL ready to use prefilled single dose syringe (Zimhi™). Dispensed as 2 syringes per box. Inject the contents of 1 syringe intramuscularly into outer thigh for signs of opioid overdose. • Intramuscular naloxone auto-injector (Evzio®) • Intranasal naloxone 2 mg/2 mL prefilled luer-lock syringe. Instructions for use: Attach atomizer to naloxone syringe then spray one-half of the contents of syringe into each nostril. Must be dispensed with a Mucosal Atomization Device (example MAD300) compatible with the prefilled syringe.
Nalmefene	• Prepackaged intranasal nalmefene 2.7 mg (Opvee®). Dispensed as 2 unit-dose nasal spray devices per box.

PRESCRIBING CONSIDERATIONS

- **Patient Characteristics:** Consider the patient's medical history, allergies, and any contraindications to specific formulations or delivery methods. Consider the patient's ability to administer the medication. For example, some formulations may be more user-friendly for bystanders.
- **Ease of Administration:** Evaluate the ease of use for both the patient and potential bystanders. Nasal spray formulations like Narcan® and Kloxxado™ are designed for easy administration without the need for special training.
- **Training and Familiarity:** Consider the level of training required for proper administration. Some formulations, like auto-injectors (e.g., Evzio®), provide step-by-step instructions, making them suitable for individuals without extensive medical training.
- **Onset of Action:** Different formulations may have varying onset times. Intramuscular (IM) naloxone may have a faster onset compared to intranasal formulations. Consider the urgency of the situation and the desired speed of response.
- **Storage and Stability:** Assess the storage requirements for each formulation. Some naloxone products may have specific temperature or storage conditions that need to be considered.
- **Cost and Accessibility:** Evaluate the cost and accessibility of different naloxone formulations. Some formulations may be more cost-effective or more widely available, which can impact patient access.
- **Local Guidelines and Protocols:** Familiarize yourself with local and state guidelines regarding SAOA use. Some areas may have specific recommendations or requirements for the use of certain formulations.

Assessment and Treatment Care Pathway- Short Acting Opioid Antagonists (SAOAs) Naloxone / Nalmefene

(CONFIDENTIAL-Protected Health Information)

- **Patient Preference:** Consider the patient's preference and comfort level with a specific formulation. Involving the patient in the decision-making process can enhance adherence.
- **Repeat Dosing:** Some formulations may require repeat dosing if the initial response is not sufficient. Providers should be aware of the dosing requirements for each formulation.
- **Patient Education:** Ensure that patients and potential bystanders receive proper education on the chosen naloxone formulation. Provide training materials, demonstrations, and clear instructions for use.

LABELING REQUIREMENTS

- Standard labeling requirements apply per OAR 855-041-1130 except for SAOAs in the form of a nasal spray that are personally dispensed by the Pharmacist at the pharmacy per ORS 689.813.

COUNSELING POINTS

- **Addressing Stigma and Building Trust**:
  - Start with empathy and non-judgmental language. Avoid terms like "addict" or "overdose victim," and instead use phrases like "person at risk of overdose" or "someone experiencing an opioid overdose."
  - Normalize the conversation. Explain that opioid misuse and overdose can happen to anyone, regardless of background or circumstance.
  - Focus on harm reduction. Explain that SAOAs are a tool for saving lives, not a guarantee of addiction recovery.
- **Explaining SAOAs and their Use:**
  - Clearly explain how SAOAs work. Describe how it quickly reverses the effects of opioids, restoring breathing and consciousness.
  - Demonstrate administration methods. Show patients how to use the specific product they are receiving, practicing with the nasal spray or auto-injector if available.
  - Emphasize calling 911 immediately after administering a SAOA. Explain that even after SAOAs, medical attention is crucial.
- **Addressing Concerns and Answering Questions:**
  - Anticipate and address common concerns. These might include potential side effects, dependence on SAOAs, or legal issues. Offer accurate and reassuring information.
  - Be prepared to answer specific questions. Be familiar with local resources for addiction treatment and support and connect patients with relevant information.
  - Validate potential hesitation and encourage further discussion. Let patients know you are available to answer questions and provide support at any time.
- **Additional Points:**
  - Offer training materials and resources. Provide patients with written instructions, video demonstrations, and contact information for crisis hotlines or support groups.
  - Encourage SAOAs for bystanders. Explain that anyone can carry SAOAs and save a life, regardless of their relationship to the person at risk.
  - Follow up with patients. Check in with patients who receive naloxone to see if they have any questions or need additional support.

PRESCRIBING PARAMETERS

- No limitations

TREATMENT CARE PLAN

- No documented follow-up required

Pharmacist Signature_____Date____/____/_____

Prescription- Short Acting Opioid Antagonists
(e.g., naloxone, nalmefene)

Optional-May be used by pharmacy if desired (labeling not required for intranasal sprays)

Patient (or Entity) Name:	Date of birth (if applicable):
Address:	
City/State/Zip Code:	Phone number:

Rx

☐ **Prepackaged intranasal naloxone ☐ 4 mg (Narcan®) or ☐ 8 mg (Kloxxado™)**
- Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1. #___ doses, ___ refills

☐ **Intramuscular naloxone ☐ 0.4 mg/mL single dose vial (SDV) or ☐ 5 mg/0.5mL (Zimhi™) ready to use prefilled single dose syringe (SDS)**
- Inject the contents of one vial or syringe intramuscularly into outer thigh for signs of opioid overdose. Call 911. May repeat x1. #____ SDV or SDS, ____ refills
- Supplemental devices to dispense for single dose vial:
  - 3ml Syringe with a 21-25G ×1-1 1/2 inch needle
    - Use as directed for naloxone administration, #____, ____ refills

☐ **Intramuscular naloxone auto-injector (Evzio®)**
- Administer the dose from one auto-injector for signs of opioid overdose. Call 911. May repeat ×1., #____ auto-injectors, ____ refills

☐ **Intranasal naloxone** 2 mg/2 ml prefilled luer-lock syringe
- Attach atomizer to naloxone syringe then spray one-half of the contents of syringe into each nostril for signs of opioid overdose. Call 911. May repeat ×1., #____ pre-filled syringes, ____refills
- Supplemental devices to dispense:
  - Mucosal Atomization Device (example MAD300) compatible with the prefilled syringe
    - Use as directed for naloxone administration, #____, ____ refills

☐ **Prepackaged intranasal nalmefene 2.7 mg (Opvee®)**
- Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1. #__ doses, ____ refills

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____

_____

Optional- May be used by pharmacy if desired

Provider Notification
Short-acting Opioid Antagonist (SAOA)- Naloxone / Nalmefene

Pharmacy Name:_____ Pharmacist Name: _____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Patient Name:_____ DOB: ____/_____/_____ Age:_____

Healthcare Provider:_____ Phone: (____)_____-_____ Fax: (____)_____-_____

Your patient was seen at our pharmacy on ____/____/____ requesting a short-acting opioid antagonist (SAOA). During this visit, we carefully reviewed the patient's medical history, prescription history, and lifestyle factors to ensure the safety of all medications prescribed. Upon review it was determined that the patient could benefit from obtaining a SAOA. The following prescription(s) were provided to your patient:

☐ **Prepackaged intranasal naloxone ☐ 4 mg (Narcan®) or ☐ 8 mg (Kloxxado™)**
- Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1. #___ doses, ___ refills

☐ **Intramuscular naloxone ☐ 0.4 mg/mL single dose vial (SDV) or ☐ 5 mg/0.5mL (Zimhi™) ready to use prefilled single dose syringe (SDS)**
- Inject the contents of one vial or syringe intramuscularly into outer thigh for signs of opioid overdose. Call 911. May repeat x1. #____ SDV or SDS, ___ refills
- Supplemental devices to dispense:
  - 3ml Syringe with a 21-25G ×1-1 1/2 inch needle
    - Use as directed for naloxone administration, #___, ___ refills

☐ **Intramuscular naloxone auto-injector (Evzio®)**
- Administer the dose from one auto-injector for signs of opioid overdose. Call 911. May repeat ×1., #____ auto-injectors, ___ refills

☐ **Intranasal naloxone** 2 mg/2 ml prefilled luer-lock syringe
- Attach atomizer to naloxone syringe then spray one-half of the contents of syringe into each nostril for signs of opioid overdose. Call 911. May repeat ×1., #____ pre-filled syringes, ___ refills
- Supplemental devices to dispense:
  - Mucosal Atomization Device (example MAD300) compatible with the prefilled syringe
    - Use as directed for naloxone administration, #____, 0 refills

☐ **Prepackaged intranasal nalmefene 2.7 mg (Opvee®)**
- Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1, #___doses, ___ refills

Provider Pearls for SAOAs:

- SAOAs should be administered promptly in suspected opioid overdose cases, even if the exact opioid involved is unknown.
- Repeat dosing may be necessary, as the duration of action for some opioids can outlast that of a SAOA. Close monitoring is crucial, and additional doses may be administered as needed.
- SAOAs are generally safe and well-tolerated, but withdrawal symptoms, including agitation and nausea, may occur in individuals who are opioid-dependent.
- Individuals who have been administered SAOAs should seek immediate medical attention, as the effects of the SAOA are temporary, and further medical assessment is essential.

This prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

OREGON STATE PUBLIC HEALTH DIVISION
EMS & Trauma Systems
Kate Brown, Governor

800 NE Oregon Street, Suite 465
Portland, OR 97232
Phone: 971-673-0520
Fax: 971-673-0555

October 6, 2017

For more information, contact David Lehrfeld, MD,
Medical Director, EMS & Trauma Systems:
(971) 673-0520

Opiate Overdose Treatment: Naloxone Training Protocol

As of October 6, 2017, training oversight is not required, although it is recommended that a healthcare professional or pharmacist be involved as needed for basic education on naloxone and overdose. As required per rule, a pharmacist provides patient counseling prior to dispensing naloxone.

I. Signs and symptoms of opiate overdose

The signs and symptoms of opiate overdose include:

- Unresponsiveness to yelling or stimulation, like rubbing your knuckles up and down the person's sternum, or breast bone (also called a sternum rub) [This symptom effectively draws the line between overdosing and being really high but not overdosing.]
- Slow, shallow, or no breathing
- Pulse (heartbeat) is slow, erratic, or not there at all
- Turning pale, blue or gray (especially lips and fingernails)
- Snoring/gurgling/choking sounds
- Body very limp
- Vomiting

II. Opiate overdose treatment overview

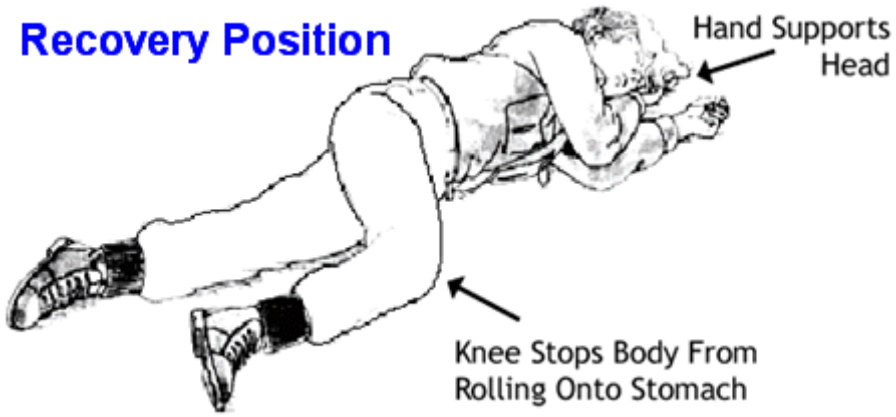
1. Check for a response.
2. Call 911.
3. Start chest compressions.
4. Administer naloxone.
5. Resume chest compressions with rescue breathing if the person has not yet started breathing.
6. Conduct follow-up – administer a second dose of naloxone if no response after 3 minutes and resume chest compressions with rescue breathing.
7. If naloxone is administered, provide details to emergency medical services.

III. Responding to an opiate overdose

1. **Check for responsiveness**.
   a. Yell.
   b. Give a sternum rub. Make a fist and rake your knuckles hard up and down the front of the person's sternum (breast bone). This is sometimes enough to wake the person up.
   c. Check for breathing. See if the person's chest rises and falls and put your ear near the person's face to listen and feel for breaths.
   d. If the person does not respond or is not breathing, proceed with the steps listed below.

2. **Call 911**. If you have to leave the person, put the person in the **recovery position.***
   a. State that someone is unconscious due to suspected overdose and indicate if the person is not breathing. (If you call police or 911 to get help for someone having a drug overdose, Oregon's Good Samaritan Law protects you from being arrested or prosecuted for drug-related charges or probation or parole violations based on information provided to emergency responders.)
   b. Give the address and location.
   c. Be aware that complications may arise in overdose cases. Naloxone only works on opiates, and the person may have overdosed on something else, e.g., alcohol or benzodiazepines. **Emergency medical services are critical.**

   ***Recovery position:**
      a. Roll the person over slightly on the person's side.
      b. Bend the top knee.
      c. Put the person's top hand under the person's head to support it.
      d. This position should keep the person from rolling onto his/her stomach or back, so the person does not choke if he/she vomits.



3. **(A) Start chest compressions with rescue breathing (CPR).**
   a. Place heel of one hand over center of person's chest.
   b. Place other hand on top of first hand, keeping elbows straight with shoulders directly above hands.
   c. Use body weight to push straight down, at least 2 inches, at rate of 100 compressions per minute.
   d. Give 2 breaths for every 30 compressions.
   e. CPR should be performed for 5 rounds (2 breaths for every 30 compressions), or for approximately 2 minutes, before reassessing.

Image courtesy of Nursing411.org

OR

(B) If overdose is witnessed, i.e., you see the person stop breathing, or you are sure it is overdose due to personal knowledge of the person or situation, you have the option to start rescue breathing. Be aware when you call 911 that they may instruct you to perform CPR as well.

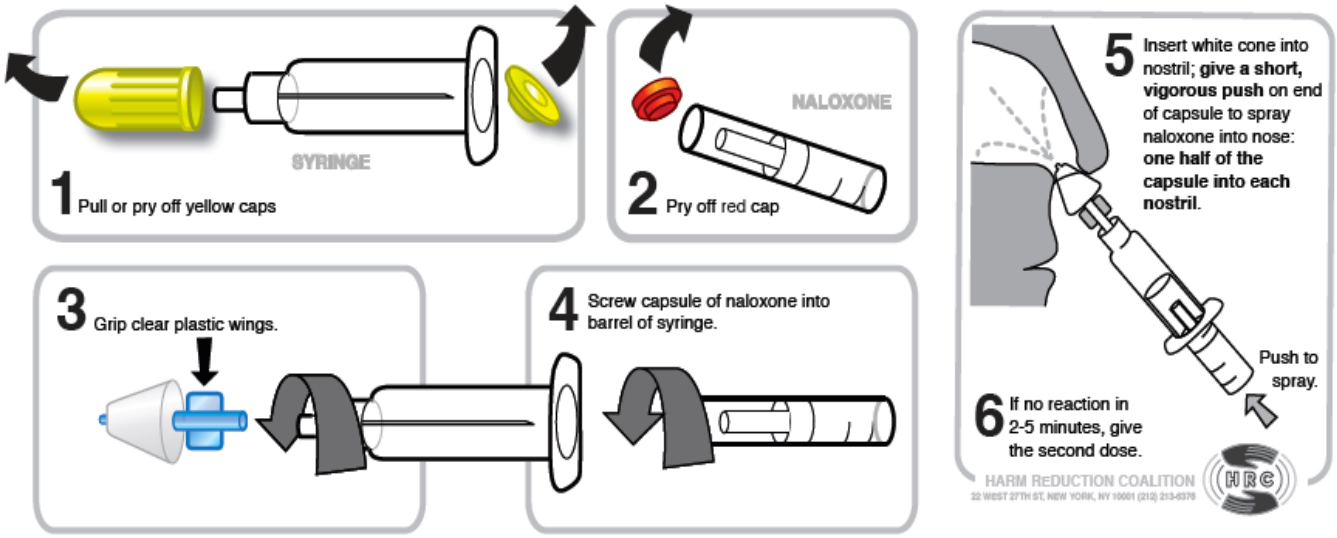
   a. Check the person's airway for obstructions and remove any obstructions that can be seen
   b. Tilt the person's forehead back and lift chin – see diagram below.
   c. Pinch the person's nose and give normal breaths – not quick and not overly powerful breaths.
   d. Give one breath every five seconds.
   e. Continue rescue breathing for approximately 30 seconds.

Image courtesy of Nursing411.org

4. **Administer naloxone**.
   If the patient has been receiving opioids, giving them naloxone may result in temporary withdrawal symptoms. This response can include abrupt waking up, vomiting, diarrhea, sweating, and agitated behavior. While these symptoms can be dramatic and unpleasant, they are not life threatening and will only last until the naloxone has worn off. See details about specific naloxone products below.

   a. **<u>If your naloxone kit is a syringe set up to be given as a nasal (nose) spray</u>**:

      1. Pull or pry off both top and bottom covers on the syringe.
      2. Pry off the cap of the naloxone capsule.
      3. Grip the clear plastic wings.
      4. Screw the naloxone cartridge into the barrel of syringe.
      5. Insert white cone into nostril; give a short vigorous push on the end of the naloxone cartridge to spray naloxone into the nose: one half of the cartridge goes into each nostril.
      6. If minimal or no response in 3 minutes, then give a second dose.



b. <u>If your naloxone kit is NARCAN® Nasal Spray</u>:

1. Peel back the package to remove the device
2. Hold the nozzle between two fingers as shown in image below.
3. Place the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.
4. Press the plunger firmly with thumb to release the dose into the patient's nose.
5. If minimal or no response in 3 minutes, then give a second dose.

NARCAN Nasal Spray: Peel back the package to remove the device

Place the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose

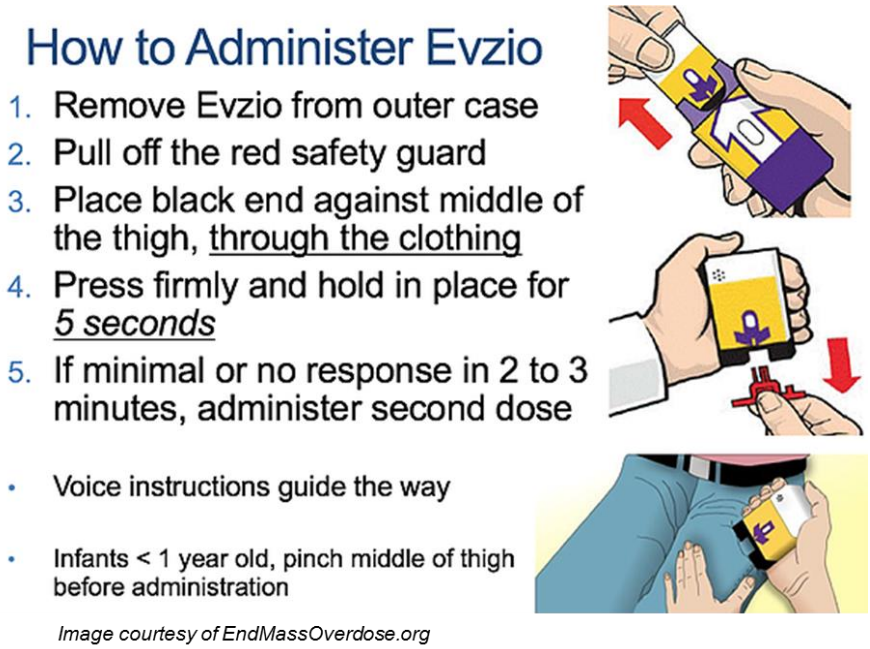
Press the plunger firmly to release the dose into the patient's nose

c. <u>If your naloxone kit is a syringe set up to be given as an injection into a muscle (intramuscular):</u>

1. Remove cap of the naloxone vial.
2. Draw up 1mL of naloxone into a syringe. (Ideally, the needle size for an injection into the muscle is 1 to 1.5-inches long and 25-gauge width)
3. If available, clean the area with an alcohol wipe before you inject.
4. Inject into muscle in the upper arm, thigh, or buttocks.
5. Insert the needle at a 90-degree angle to the skin and push in plunger.
6. If minimal or no response in 3 minutes, then give a second dose.

Image courtesy of the Chicago Recovery Alliance

d. <u>If your Naloxone kit is an Evzio® Injectable Device:</u>



5. **Resume chest compressions with rescue breathing (or chest compressions only) if the person has not yet started breathing.**
   Brain damage can occur after 3-5 minutes without oxygen. The naloxone may not kick in that quickly. You may have to perform CPR for the person until the naloxone takes effect or until emergency medical services arrive.

6. **Conduct follow-up**.
   a. Naloxone takes several minutes to kick in and wears off in 30-45 minutes. The person may go back into overdose after the naloxone wears off.
   b. It is recommended that you watch the person for at least an hour or until emergency medical services arrive, in case the person goes back into overdose.
   c. You may need to give the person more naloxone. Give a second dose if the person does not respond after 3 minutes.
   d. If an overdose victim revives, keep the person calm. Tell the person that drugs are still in his/her system and that the naloxone wears off in 30-45 minutes. Recommend that the person seek medical attention and assist him/her if necessary.
   e. Do not let the person use more opiates. The naloxone will block them and the person could overdose again after the naloxone wears off.

By signing this form, I acknowledge that I have read and understand the naloxone training protocol.

_____	_____	_____
Printed Name	Signature	Date

Name _____ Date _____
Address _____

℞

Refills _____ Pharmacist _____
Pharmacy Name / Address_____
_____

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Cover Page & Assessment and Treatment Care Pathway

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 855-115-0330 and OAR 855-115-0335 a Pharmacist licensed and located in Oregon may prescribe and administer routine and travel vaccines in adherence with current CDC ACIP recommendations, CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases and CDC Yellow Book: Health Information for International Travel information.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized All Vaccines Assessment and Treatment Care Pathway (pg. 2)
- Utilize the Protocol for each specific vaccine to be administered
- Utilize the Protocol for Managing Adverse Reactions when applicable

PHARMACIST TRAINING/EDUCATION:

- The Pharmacist has completed a course of training as outlined in OAR 855-115-0305.
- The Pharmacist maintains active CPR certification as outlined in OAR 855-115-0305.

RESOURCES:

CDC ACIP: Vaccine Recommendations and Guidelines- https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases- https://www.cdc.gov/vaccines/pubs/pinkbook/index.html

CDC Yellow Book 2024: Health Information for International Travel information- https://wwwnc.cdc.gov/travel/page/yellowbook-home

Immunization Action Coalition (IAC) Screening Checklist for Contraindications to Vaccines for Adults- http://www.immunize.org/catg.d/p4065.pdf

Immunization Action Coalition (IAC) Screening Checklist for Contraindications to Vaccines for Children and Teens- http://www.immunize.org/catg.d/p4060.pdf

CDC Adult Immunization Schedule -https://www.cdc.gov/vaccines/schedules/hcp/adult.html

CDC Child and Adolescent immunization Schedule- https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

CDC Vaccine Information Statements - https://www.cdc.gov/vaccines/hcp/vis/current-vis.html

Administering Vaccines to Adults: Dose, Route, Site, and Needle Size-https://www.immunize.org/catg.d/p3084.pdf

Vaccine Adverse Event Reporting System (VAERS) - https://vaers.hhs.gov/index

National Vaccine Errors Reporting Program (VERP)- https://www.ismp.org/form/verp-form

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Cover Page & Assessment and Treatment Care Pathway

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: COLLECT

- Gather information to screen for indications including age, health conditions, occupation, travel, and lifestyle
- Check the ALERT Immunization Information System (IIS). If ALERT is unavailable, use documentation and patient statement.
- Check patient health records and other records
- Gather information to screen for precautions and contraindications including current health status, present & past medical history, allergies, medications, immunization history, and pregnancy status

STEP 2: ASSESS

- Assess routine and travel vaccinations in adherence with current CDC ACIP recommendations, CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases and CDC Yellow Book: Health Information for International Travel information and each specific vaccine protocol
- Assess immunization needs based on age, health conditions, occupation, travel, and lifestyle indications
- Assess immunization history using IIS records, patient health records, and other sources of records to determine whether the patient needs this vaccine and any other vaccines
- Assess precautions and contraindications to needed vaccine(s) based on responses to screening questionnaire

STEP 3: PLAN

- Strongly recommend needed vaccine(s)
- Offer to administer vaccine or refer the patient to another immunizing health care provider

STEP 4: IMPLEMENT

- Provide current patient education and Vaccine Information Statements (VIS) and answer questions
- Prescribe and administer needed vaccine(s)
  - Verify needle length for injection.
  - To avoid injury related to vaccine administration, immunizer must recognize the anatomic landmarks for identifying the deltoid muscle and use proper IM administration technique.
- Provide documentation to patient and record all required data elements in the patient's permanent health record
- Report to ALERT Immunization Information System (IIS)

STEP 5: FOLLOW-UP

- Monitor patient for 15 minutes after administration of vaccine(s) for signs and symptoms of syncope, localized and/or generalized reactions
- Adverse Events Reporting
  - Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html.
  - VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html.
- Schedule follow-up for subsequent doses of multidose vaccine series
- Refer patient for other health, wellness, or follow-up services to their identified primary care provider or another provider (provide patient with documentation of referral)

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

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 855-115-0330 and OAR 855-115-0335, a Pharmacist licensed and located in Oregon may prescribe and administer medications used in the management of adverse reactions following immunization in adherence with current CDC ACIP recommendations and Epidemiology, Prevention of Vaccine-Preventable Diseases (Pink Book), and CDC Yellow Book: Health Information for International Travel information.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Managing Adverse Events Assessment and Treatment Care Pathway (pg.2)
- Utilize Managing Adverse Events Protocol (pgs. 3-9)
- Utilize Adverse Event Record Tool (Appendix A) & Emergency Kit Medications & Equipment List (Appendix B)
- Refer to Recognizing & Responding to Anaphylaxis (Appendix C)

PHARMACIST TRAINING/EDUCATION:

- The Pharmacist has completed a course of training as outlined in OAR 855-115-0305
- The Pharmacist maintains active CPR certification as outlined in OAR 855-115-0305

RESOURCES

CDC ACIP General Best Practice Guidelines: Preventing and Managing Adverse Reactions-
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.pdf

Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book): Vaccine Administration-
https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html

Medical Management of Vaccine Reactions in Adults in a Community Setting-
https://www.immunize.org/catg.d/p3082.pdf

Medical Management of Vaccine Reactions in Children and Teens in a Community Setting-
https://www.immunize.org/catg.d/p3082a.pdf

State of Oregon Trauma and EMS Systems. Treatment of severe allergic reaction; A Protocol for Training (2018).
https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EMSTRAUMASYSTEMS/Documents/Training%20Material/Epinephrine-Training-Protocol.pdf

Vaccine Adverse Event Reporting System (VAERS) - https://vaers.hhs.gov/index

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: COLLECT

- Observe patient's signs and symptoms
- Obtain prepared Emergency Kit (E-Kit)

STEP 2: ASSESS

- Assess patient's blood pressure and vital signs
- Anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than one body system is involved) or are serious or life-threatening in nature, even if they involve a single body system (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips)
- Activate emergency response (Call 911) if signs and symptoms indicate progression towards anaphylaxis

STEP 3: PLAN

- Prepare treatment medications if indicated
- Prepare for CPR

STEP 4: IMPLEMENT

- Apply treatment plan and/or administer treatment medications per protocol
- If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately and apply AED if available

STEP 5: FOLLOW-UP

- Continue assessing vitals and monitor per protocol until Emergency Medical Services arrive
- Document actions using Adverse Event Record Tool
- Report anaphylaxis and vasovagal syncope to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html.
- VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html.

Event and Interval From Vaccination
A. Anaphylaxis or anaphylactic shock (7 days) B. Vasovagal syncope (7 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Any acute complication or sequelae (including death) of above events (interval – not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert)

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

1. What's New

A. N/A

2. Anaphylaxis Protocol (Generalized Symptoms)

A. If symptoms are generalized, call 9-1-1 immediately. This should be done by a second person if available, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Do not delay transport; DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.
B. Keep patient in recumbent position (flat on back) unless patient is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
C. Take and record the patients' blood pressure and vital signs (pulse, respirations) at the initial assessment, and at minimum – every 5 minutes, and following the administration of any medication.
D. The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
E. Administer 1mg/mL epinephrine intramuscularly (IM) into the anterolateral thigh (all ages), through clothing if necessary, with the correct needle length for the patient's age and size according to the dosage chart in Table 1.
F. If no improvement in condition, repeat epinephrine dose every 5–15 minutes for up to 3 doses, depending on patient's response.
G. Complete the Adverse Event Record Tool.
H. If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately. Apply AED if available.
I. Monitor until Emergency Medical Services arrive.
J. Any patient who develops signs and symptoms of anaphylaxis MUST be transported via a fully equipped emergency vehicle to an emergency department. Any refusal of transport must be handled by EMS personnel.
K. Give report and list of medications given to emergency medical personnel upon arrival.
L. Medication Schedule: *See Table 1 on next page*

Table 1: Anaphylaxis

Inject EPINEPHRINE (1mg/mL): 0.01 mg/kg of body weight up to 0.5mg maximum dose. May be repeated every 5–15 minutes for a total of 3 doses.
Give intramuscularly (IM) in the vastus lateralis muscle of the thigh, regardless of age, either by auto injector or by syringe and needle, through the clothing if necessary. [1]

Suggested dosing of Epinephrine for children[2] and adults: consider needle length

Age Group	Weight in lb[#]	Weight in kg[#]	Epinephrine injectable (1:1000 dilution); IM =(1mg/mL) [Minimum dose: 0.05mL]	Epinephrine auto–injector 0.1mg (7.5-14.5 kg), 0.15mg (15-29.5 kg) or 0.3 mg (≥30 kg)
6 months (use only for dosing by weight)	9-16 lb	4-7 kg	0.05 mL (or mg)	Off-Label
	16.5-19 lb	7.5-8.5 kg		0.1mg/dose[*]
7-36 months (use only for dosing by weight)	20-32 lb	9-14.5 kg	0.1 mL (or mg)	0.1mg/dose[*]
37-59 months	33-39 lb	15-17.5 kg	0.15 mL (or mg)	0.15mg/dose
5-7 years	40−56 lb	18−25.5 kg	0.25 mL (or mg)	0.15mg/dose
8–10 years	57−76 lb	26−34.5 kg	0.3 mL† (or mg)	0.15 mg/dose or 0.3mg/dose
11–12 years	77−99 lb	35−45.5 kg	0.4 mL (or mg)	0.3mg/dose
≥13 years	100+ lb	46+ kg	0.5 mL‡ (or mg)	0.3mg/dose

[#]Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months. Round kg to nearest 0.5 kg.

[*] The 0.15mg epinephrine autoinjector can also be used for children 7.5 kg (16.5 lb) to 14.5 kg (32 lb) when other alternatives are not available.

†Maximum dose for children (prepubertal)[1]

‡Maximum dose for adolescents and adults[1]

3. Urticaria Protocol (Localized Symptoms)

A. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
B. Apply ice to the site where the vaccine was administered. If more than one site is involved, apply ice to the sites that appear to be red, warm, or swelling.
C. Administer diphenhydramine intramuscularly (IM) with the correct needle length for the patient's age and size according to the dosage chart in Table 2.
D. Administer hydroxyzine hydrochloride orally if diphenhydramine unavailable according to patient's age and size in the dosage chart in Table 3.
E. Complete the Adverse Event Record Tool.
F. Take and record the patient's blood pressure and vital signs at the initial assessment, and at minimum - every 10 minutes, and following the administration of any additional medication.

G. Continue to monitor for and treat signs and symptoms progressing towards anaphylaxis when indicated. If signs and symptoms present, immediately initiate anaphylaxis protocol.

H. Medication Schedule:

Table 2: Urticaria

First-Line Treatment for Urticaria: Give Diphenhydramine IM as follows:			
Suggested dosing of Diphenhydramine for children[2] and adults			
Age Group Dose	**Weight in lbs[#]**	**Weight in kg[#]**	**Injectable: 50mg/mL IM[†]**
6 months (use only for dosing by weight)	9-19 lb	4-8.5 kg	5-10 mg (0.1 - 0.2 mL)
7-36 months (use only for dosing by weight)	20-32 lbs	9-14.5 kg	10-15 mg (0.2 - 0.3 mL)
37-59 months	33-39 lbs	15-17.5 kg	15-20 mg (0.3 - 0.4 mL)
5-7 years	40–56 lbs	18–25.5 kg	20–25 mg (0.4 - 0.5 mL)
8–12 years	57–99 lbs	26–45.5 kg	25–50 mg (0.5 - 1.0 mL)
≥13 years[‡]	100+ lbs	46+ kg	50 –100 mg (1 - 2 mL)[*]

[#] Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

[†] Pediatric dose is 1-2mg/kg

[‡] Maximum single dose is 100mg for persons ≥13 years[2-3]

[*] No more than 1 mL per injection site

Table 3: Optional Treatment: Hydroxyzine Hydrochloride

Hydroxyzine Hydrochloride for urticaria when Diphenhydramine is unavailable: Give PO as follows:			
Suggested dosing of Hydroxyzine Hydrochloride for children[2] and adults			
Age Group Dose	**Weight in lbs[#]**	**Weight in Kg[#]**	**Liquid: 10mg/5mL or 25mg/5mL[†]**
6 months (use only for dosing by weight)	9-19 lb	4-8.5 kg	2.5-5 mg/dose
7-36 months (use only for dosing by weight)	20-32 lbs	9-14.5 kg	5-7.5 mg/dose
37-59 months	33-39 lbs	15-17.5 kg	7.5-10 mg/dose
5-7 years	40–56 lbs	18–25.5 kg	10-12.5 mg/dose
8–10 years	57–76 lbs	26–34.5 kg	12.5–15 mg/dose
11–12 years	77–99 lbs	35–45.5 kg	15–25 mg/dose
≥13 years	≥100 lbs	≥46 kg	25 mg/dose

[#] Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

[†] Pediatric dose is 0.5-1 mg/kg

[*] Maximum single dose is 25mg for persons ≥13 years[2-3]

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

4. Loss of Consciousness/Syncope Protocol

A. If the individual "feels faint", ammonia ampules should be used if available. Crush and wave near patient's nose.
B. Have patient lie flat with feet elevated or sit with their head down for several minutes.
C. If the patient loses consciousness, place flat on back, with feet elevated.
D. Unconsciousness from fainting should only last seconds. In a vasovagal response, the pulse should be slow. A weak, thready or rapid pulse may indicate anaphylaxis. Continue to monitor for signs and symptoms progressing towards anaphylaxis. If signs and symptoms present, immediately initiate anaphylaxis protocol.
E. Have patient rest in a quiet area for 10 minutes after regaining consciousness. Slowly have patient move to a sitting position and then standing, checking to make sure no symptoms recur.
F. Complete the Adverse Event Record Tool.

5. Contraindications

A. There are **no** contraindications for the use of epinephrine to treat anaphylaxis
B. Previous hypersensitivity is a contraindication for diphenhydramine and hydroxyzine.
C. Do not administer epinephrine auto-injector to children weighing less than 16.5 lbs.

6. Other Considerations

A. Required Documentation:
- Current Healthcare Provider CPR Card as required by OAR 855-019-0270
- Completed Adverse Event Record Tool for each event (Appendix A).

B. Required Medications & Equipment: See Emergency Kit Medications & Equipment List (Appendix B)

7. Storage and Handling

A. Store medications according to OAR 855-041-1036.

8. Adverse Events Reporting

A. Anaphylaxis and vasovagal syncope must be reported to the Vaccine Adverse Events Reporting System (VAERS) online at: https://vaers.hhs.gov/reportevent.html.
B. VAERS Table of Reportable Events Following Vaccination: https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

9. References

1. CDC. Management of Anaphylaxis at a COVID-19 Vaccination Location. Last updated 11 February 2022. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html Accessed 23 August 2022.
2. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Children and Teens in a Community Setting. July 2019. Available at: https://www.immunize.org/catg.d/p3082a.pdf. Accessed 23 August 2022.
3. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Adults in a Community Setting. July 2019. Available at: https://www.immunize.org/catg.d/p3082.pdf. Accessed 23 August 2022.

10. Appendix

A. Adverse Event Record Tool
B. Emergency Kit Medications & Equipment
C. Recognizing & Responding to Anaphylaxis Reference

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

APPENDIX A: Adverse Event Record Tool

Patient Name: _____ Allergies: _____
Date of Birth: _____ Vaccine(s) Given: _____
Date: _____ Site(s):_____
Pharmacist: _____ Route(s): _____
Patient is displaying signs of: Anaphylaxis – Urticaria – Syncope (Circle One)

VITALS							
Time	**Pulse**	**Respirations**	**Blood Pressure**	**Medication**	**Dose**	**Site–Route**	**Initials**

Notes:

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

APPENDIX B: Emergency Kit Medications & Equipment List

Required Medications & Equipment	**Quantity/Type**	**Expiration Date**	**Optional Medications & Equipment**	**Quantity/ Type**	**Expiration Date**
Epinephrine solutions	**1** multi-dose vial (MDV) of 1mg/mL Epinephrine **OR** Epinephrine auto-injectors; **3** doses each of adult and pediatric size units		Hydroxyzine Hydrochloride for use when Diphenhydramine is unavailable	Liquid: 10 mg/5 mL or 25 mg/5 mL Tablets: 10 mg or 25 mg Capsules: 25 mg	
Diphenhydramine 50 mg/mL injectable	**1** multi-dose vial (MDV) **OR 2** single-dose vials (SDV) vials		Bottle of water for swallowing oral antihistamines		
Blood Pressure Monitor (regular adult and large adult cuff size required; pediatric cuff if applicable)	Automated devices must show current calibration and replace batteries as needed		Sphygmomanometer and Stethoscope (regular adult and large adult cuff size required; pediatric cuff if applicable)		
Syringes/Needles	For Epinephrine injection only: 1-cc syringes with 22–25g, 1-1½" needles For Diphenhydramine injection only: 1-3-cc syringes with 22-25g, 1–1½" needles		Ammonia Ampules	**1** Box	
Standard injection supplies	N/A				

APPENDIX C:

Recognizing and Responding to Anaphylaxis

How to recognize anaphylaxis

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as **hives, serious or life-threatening symptoms** (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips), or **symptoms that involve more than one body system.**

Respiratory:
- sensation of throat closing
- stridor (high-pitched sound while breathing)
- shortness of breath
- wheeze, cough

Gastrointestinal:
- nausea
- vomiting
- diarrhea
- abdominal pain

Cardiovascular:
- dizziness
- fainting
- tachycardia (abnormally fast heart rate)
- hypotension (abnormally low blood pressure)

Skin/mucosal:
- generalized hives
- itching
- swelling of lips, face, or throat

Neurological:
- agitation
- convulsions
- acute change in mental status
- sense of impending doom (a feeling that something bad is about to happen)

What to do if you suspect anaphylaxis

Assess airway, breathing, and circulation

Administer epinephrine

Call Emergency Medical Services (EMS)

Place in supine position

Detailed information can be found in the Interim Considerations:
Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination

www.cdc.gov/COVID19

CS322867-A | 05/1/21

Protocol for Coronavirus 19 Vaccines
(Pfizer-BioNTech, Moderna, Novavax)

1. What's New

A. There is a new formulation of COVID-19 Vaccine (Comirnaty by Pfizer) that comes in a pre-filled single dose glass syringe. The glass syringe is stored in the refrigerator and cannot be frozen.

B. ACIP no longer categorizes Pfizer and Moderna as preferred Coronavirus 19 (COVID-19) vaccines for the 2023-2024 season. Individuals ages 12 years and older may receive either the 2023-2024 mRNA (Moderna of Pfizer) or the 2023-2024 adjuvanted (Novavax) vaccine, as appropriate.

2. Immunization Protocol

A. Administer a dose of updated 2023–2024 Pfizer, Moderna, or Novavax COVID-19 vaccine according to ACIP recommendations and the vaccine package insert. See section 3 for vaccine volume and spacing based on age and vaccine formulation.[1-5]

B. COVID-19 vaccine may be administered concomitantly with other vaccines. There is no need to separate COVID-19 vaccine from other vaccinations by 2 weeks.

3. Vaccine Schedule[1-3]

A. Any immunocompetent person 7-11 years of age who has received at least 1 dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine is currently up-to-date.[6]

B. Any immunocompetent person ≥12 years of age who has received at least 1 dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine OR who is previously vaccinated* and has received at least 1 dose of adjuvanted (Novavax) 2023-2024 COVID-19 vaccine is currently up-to-date.[5]

C. Any immunocompetent unvaccinated person 7-11 years of age may be brought up-to-date with a single dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine.[6]

D. Any Immunocompetent unvaccinated persons ≥12 years of age may be brought up-to-date with a single dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine OR a two dose series of updated adjuvanted (Novavax) 2023-2024 COVID-19 vaccine.[5,6]

E. The PREP Act currently allows pharmacists to administer COVID-19 vaccines to persons aged 3-18 years old through 12/31/24.[2] Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.

*Previously vaccinated indicates the individual has received 1 or more doses of any mRNA vaccine; 1 or more doses of Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses.

PFIZER[1,3]

Pfizer[1] 2023-2024 pediatric mRNA vaccine Dose and Route – 0.3-mL, 3 mcg, IM (yellow cap and border). ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Unvaccinated children 3-4 years of age*		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	3-4 years of age (<5 years)	
2		3 weeks
3		8 weeks

*Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive all doses with Pfizer-BioNTech COVID-19 vaccine, supplied in vials with yellow caps and borders.[1]

Children 3-4 years of age previously vaccinated with Pfizer vaccine, any formulation ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Received	**Needs Now**	**Minimum Acceptable Spacing**
1 dose	2 doses 2023-2024 Pfizer	3 weeks after last dose
2 or more doses	1 dose 2023-2024 Pfizer	8 weeks after last dose

Pfizer[1] 2023-2024 pediatric mRNA vaccine Dose and Route – 0.3-mL, 10 mcg, IM (blue cap and border) ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Children 5-11 years of age		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1*	5-11 years of age	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Pfizer 2023-2024 mRNA vaccine (COMIRNATY®) Dose and Route – 0.3-mL, 30 mcg, IM (gray cap and border or pre-filled syringe)[3]		
Unvaccinated persons ≥ 12 years of age		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1*	≥ 12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

*Immunocompromised persons may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

MODERNA[2,4]

Moderna 2023-2024 pediatric mRNA vaccine Dose and Route – 0.25-mL, 25 mcg, IM (dark blue cap and green border)[2]		
Unvaccinated children 3-4 years of age ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	6 months-4 years (<5 years)	
2*		28 days

* Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Immunocompromised children may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

Protocol for Coronavirus 19 Vaccines
(Pfizer-BioNTech, Moderna, Novavax)

Children 3-4 years previously vaccinated with Moderna COVID-19 vaccine, any formulation[2] ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Received	**Needs Now**	**Minimum Spacing**
1 dose	1 dose 2023-2024 Moderna (0.25mL, dark blue cap and green border)	4 weeks after last dose*
2 or more doses	1 dose 2023-2024 Moderna (0.25 mL, dark blue cap, green border)	8 weeks after last dose*

* Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Moderna 2023-2024 pediatric mRNA vaccine Dose and Route – 0.25-mL, 25 mcg, IM (dark blue cap and green border) ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Unvaccinated children 5-11 years of age		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1*	5-11 years (<12 years)	

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Children 5-11 years of age previously vaccinated with Moderna COVID-19 vaccine, any formulation ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Received	**Needs Now**	**Minimum Spacing**
1 or more doses	1 dose 2023-2024 Moderna* (0.25mL, dark blue cap and green border)	8 weeks after last dose

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Moderna 2023-2024 mRNA vaccine (SPIKEVAX®) Dose and Route – 0.5-mL, 50 mcg, IM (dark blue cap and border)[4]		
Unvaccinated persons ≥ 12 years of age		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1*	≥ 12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

* Immunocompromised persons may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

NOVAVAX[5]

Novavax 2023-2024 adjuvanted vaccine Dose and Route –0.5-mL, 5 mcg, IM (dark blue cap, light blue on label)		
Unvaccinated children ≥ 12 and adults		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥12 years	
2		21 days

Children ≥ 12 and adults previously vaccinated with COVID-19 vaccine		
Received	**Needs Now**	**Minimum Acceptable Spacing**
1 or more doses (any original monovalent or bivalent COVID-19 vaccine)	1 dose 2023–24 Novavax*	8 weeks after last dose

*Immunocompromised persons may receive an additional dose of Novavax COVID-19 vaccine at least two months following the last dose of 2023-2024 COVID-19 vaccine. Additional doses of 2023-2024 Novavax COVID-19 vaccine may be administered sat the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on the individual's clinical circumstances.

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Cap/Label Color**
Pfizer 2023-2024 formulation[1]	mRNA	0.9 mL, 3 dose vial 0.3 mL, single dose vial	3-4 years 5-11 years	Yellow Cap Blue Cap
Pfizer COMIRNATY®[3] 2023-2024 formulation	mRNA	0.3 mL, single dose vial 0.3 mL, prefilled syringe	≥ 12 years	Gray Cap
Moderna 2023-2024 formulation[2]	mRNA	0.25 mL, single dose vial	3-11 years	Blue Cap/Green Label
Moderna SPIKEVAX® 2023-2024 formulation[4]	mRNA	2.5 mL, 5 dose vial 0.5 mL, single dose vial 0.5 mL, prefilled syringe	≥ 12 years	Blue Cap/Blue Label
NVX-CoV2373[3] (NOVAVAX® 2023-2024 formulation)[5]	Protein subunit	2.5 mL, 5-dose vial	≥ 12 years	Royal Blue Cap

5. Recommendations for Use[1-7]

A. An updated, 2023–2024 mRNA COVID-19 vaccine dose should be offered to all persons aged ≥ 7 years. For adults and children ≥12 years of age, a 2023-2024 protein subunit (Novavax) vaccine may be used.
B. For a primary series, COVID-19 vaccines are not routinely interchangeable. When multiple doses are indicated (i.e. in unvaccinated children), the same vaccine brand should be used. In exceptional situations in which an mRNA vaccine series was begun, but the particular product administered for previous doses is not available, the other mRNA COVID-19 vaccine may be administered to complete the primary vaccine series.
C. Doses for adults and immunocompromised persons ≥7 years of age may be any authorized product.
D. Children ≤11 years of age with immune compromise require a 3-dose primary series. All three doses should be the same vaccine brand. At least one dose should be of the 2023–24 COVID-19 vaccine.[1,2]
E. For all persons with immune compromise, additional doses of vaccine may be administered at the discretion of the healthcare provider, based on the individual's clinical circumstances.[7]
F. Persons with immune compromise may self-attest to the need for additional doses. No other documentation is necessary.
G. Conditions causing moderate to severe immunodeficiency include:
    - Active treatment for solid tumor and hematologic malignancies
    - Receipt of solid-organ transplant and taking immunosuppressive therapy
    - Receipt of Chimeric antigen receptor (CAR)-T-cell or hematopoietic cell transplant (HCT) within 2 years of transplantation or taking immunosuppression therapy
    - Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
    - Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
    - Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day)
    - Alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1-5]

Vaccine	Contains
Pfizer 2023-2024 formulation[1] (yellow cap and border)[1]	Lipids (0.04 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]-N,N itetradecylacetamide, 0.01 mg 1,2-distearoyl-snglycero-3-phosphocholine, and 0.02 mg cholesterol), 9.4 mg sucrose, 0.02 mg tromethamine, and 0.12 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 1.88 mg sodium chloride per dose.
Pfizer 2023-2024 formulation[1] (blue cap and border)	Lipids (0.14 mg ((4- hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2[(polyethylene glycol)-

	2000]-N,N-ditetradecylacetamide, 0.03 mg 1,2- distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 31 mg sucrose, 0.06 mg tromethamine, and 0.4 mg tromethamine hydrochloride.
Pfizer COMIRNATY® 2023-2024 formulation[3] (gray cap and border)	Lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate),0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose
Moderna 2023-2024 formulation[2] (dark blue cap and green border)	Total lipid content of 0.5 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC]), 0.13 mg tromethamine, 0.62 mg tromethamine hydrochloride, 0.011 mg acetic acid, 0.049 mg sodium acetate trihydrate, and 21.8 mg sucrose.
Moderna SPIKEVAX® 2023-2024 formulation[4] (dark blue cap and border)	Total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose.
NVA-CoV2373 (NOVAVAX® 2023-2024 formulation)[5]	Cholesterol, phosphatidylcholine, potassium dihydrogen phosphate (3.85 µg), potassium chloride (2.25 µg), disodium hydrogen phosphate dihydrate (14.7 µg), disodium hydrogen phosphate heptahydrate (2.465 mg), sodium dihydrogen phosphate monohydrate (0.445 mg), sodium chloride (8.766 mg) and polysorbate 80 (0.050 mg). The vaccine contains a recombinant form of the SARS-CoV-2 spike protein produced from baculovirus infected Sf9 (fall armyworm) insect cells and Matrix-M™ adjuvant is composed of Fraction-A (42.5 µg) and Fraction-C (7.5 µg) of saponin extracts from the soapbark tree, Quillaja saponaria Molina. The pH is adjusted with sodium hydroxide or hydrochloric acid.

7. Warnings and Precautions[7]

A. History of severe allergic reaction (e.g. anaphylaxis) to any other vaccine or injectable therapy (e.g. intravenous, intramuscular or subcutaneous).

B. Persons who have a contraindication to additional doses of mRNA COVID-19 vaccines are considered to have a precaution to the Novavax vaccine. A single dose may be given in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist. This additional dose could be considered after a minimum interval of 28 days after the mRNA COVID-19 vaccine dose. See Appendix A for additional information.

C. Moderate or severe acute illness.

8. Other Considerations[7]

A. Patients with known COVID-19 infection should wait until their symptoms have resolved and criteria have been met to discontinue isolation. Persons who have a history of COVID-19

disease should be vaccinated if otherwise indicated. If desired, persons with acute COVID-19 may wait up to 90 days to receive vaccination, as reinfection within 90 days is uncommon. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

B. Patients who received monoclonal antibodies or convalescent plasma during COVID-19 treatment may be vaccinated as soon as their symptoms have resolved.
C. Patients with a known community or outpatient setting COVID-19 exposure should wait until the end of their quarantine period before seeking vaccination to avoid potentially exposing healthcare personnel.
D. Patients who have been exposed to COVID-19 living in congregate settings, including long-term care, homeless shelters, or correctional institutions, where exposure or transmission can occur repeatedly over a long period of time may be vaccinated without completing a quarantine period.
E. Ask patient to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint. Patients with a history of severe allergic reactions should be asked to remain for 30 minutes.
F. CDC recommends that vaccine for children aged 5–17 years of age with history of Multisystem Inflammatory Syndrome of Children (MIS-C) be delayed for 90 days after their diagnosis of MIS-C. Providers should inform patients that the risk of reinfection, and therefore the potential benefit from vaccination, may increase with time following initial infection.
G. COVID-19 vaccination is recommended for all people of childbearing age, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.
H. Persons who are trying to become pregnant do not need to avoid pregnancy after receiving COVID-19 vaccine. There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine.
I. Persons with underlying medical conditions who have no contraindications may receive COVID-19 vaccine.
J. Children 3 years through 4 years of age should complete a multi-dose initial series (2 doses of Moderna vaccine or 3 doses of Pfizer vaccine) with at least one dose of the 2023–2024 COVID-19 mRNA vaccines. Doses for adults and immunocompromised persons ≥5 years of age may receive any age-appropriate authorized product.

9. Side Effects and Adverse Reactions

A. COVID-19 vaccines appear to be more reactogenic than most. Inform patient that symptoms of immune system activation are normal (see Table) and should improve without intervention in 12-24 hours.

Pfizer[1,3] and Moderna[2,4] Adverse Events	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 93%
Systemic events (fatigue, headache, muscle ache, joint pain)	Very common, up to 77%
Fever	Up to 16%
Lymphadenopathy	Up to 20%

Serious adverse events	Uncommon, up to 1% (similar to placebo group)

Novavax[5] Adverse Events	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 82%
Systemic events (fatigue, muscle pain, headache, nausea)	Very common, up to 62%
Fever	Uncommon, up to 6%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. For Pfizer vaccine only: thaw, if needed. The single dose pre-filled glass syringe (COMIRNATY) CANNOT be frozen and stored in the refrigerator. The yellow cap formulation requires reconstitution; the blue and gray cap formulations are ready to administer.[1,3]

C. For Moderna vaccine only: thaw vaccine prior to administration.[2,4]

Vaccine	**Temp**	**Storage Issues**	**Notes**
Pfizer[1,3]	-90° to -60° C (-130° to -76° F)	Vaccine may be stored until the expiration date.	Do not freeze the single dose pre-filled glass syringe (discard if frozen)
	2° to 8° C (36° to 46° F)	**Adolescent/adult 2023-2024formulation (blue or gray cap vial OR single dose pre-filled plastic pre-filled syringe):** store in the refrigerator for up to 10 weeks	
		Pediatric 2023-2024 formulation (yellow cap): before mixing, the vaccine may be stored in the refrigerator for up to 10 weeks.	
		Adolescent/adult 2023-2024formulation (single dose pre-filled glass syringe): Store in the refrigerator for up to 6 months	
	Ambient temperatures	**Adolescent/adult 2023-2024 formulation (blue or gray cap vial OR single dose pre-filled glass syringe OR single dose pre-filled plastic syringe):** vaccine may be held at room temperature for up to 12 hours	
		Pediatric 2023-2024 formulation (yellow cap): once mixed, vaccine may be held at	

		room temperature for up to 12 hours	
Moderna[2,4]	-50° to -15° C (-58° to 5° F)	Vaccine is viable until the expiration date.	For multi-dose vials, once stopper has been punctured, all doses must be used within 12 hours. Do not refreeze once thawed. Protect vaccine from light.
	2° to 8° C (36° to 46° F)	Vaccine is viable under refrigeration for up to 30 days.	
	Ambient temperatures	Unpunctured vials of vaccine is viable for up to 24 hours at room temperature	
Novavax[5]	2°– 8°C (36° to 46° F)	No expiration date is printed on vial or carton. Lookup the expiration date of the batch/Lot number at www.novavaxcovidvaccine.com enter "United States" as the "country/region."	Once vial stopper has been punctured, store vial at 2° to 25° C (36° to 77° F) for use within 12 hours. Discard the vial 12 hours after first puncture. Do not freeze. Protect vaccine from light.

11. References

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7. Interim clinical considerations for use of COVID-19 vaccines in the United States, May 12, 2023. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html. Accessed 14 Sep 2023.

12. Appendix

A. COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, September 2023: https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-immunization-schedule-ages-6months-older.pdf

Protocol for Haemophilus influenzae type b Vaccines (ActHIB®, HIBERIX®, PedvaxHIB®)

1. What's New

A. Contraindications- Latex (Removed for ActHib® and PedvaxHIB®)[1,3]

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of Hib vaccine to persons ≥7 years of age according to high-risk group indication.

B. Hib vaccines can be given with all other routinely recommended vaccines.

3. Vaccine Schedule

A. Not routinely recommended. See recommendations for use for guidance for high-risk groups.

Hib Vaccine (ActHIB®, HIBERIX®, PedvaxHIB®)[1-3] Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
2		28 days
3		28 days

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
ActHIB®[1] (PRP-T)	Hib (tetanus toxoid conjugate)	0.5-mL lyophilized single-dose vials packaged with single-dose diluent	6 weeks through 5 years*	None
HIBERIX®[2] (PRP-T)	Hib (tetanus toxoid conjugate)		6 weeks through 4 years*	
PedvaxHIB®[3] (PRP-OMP)	Hib (meningococcal protein conjugate)	0.5-mL single-dose suspension	6 weeks through 5 years*	

*Any licensed product presentation may be used for Catch-Up for Persons at High Risk

5. Recommendations for Use

A. **Routinely Recommended Use**- N/A

B. **Catch-Up for Healthy Children**- N/A

C. **Catch-Up for Persons at High-Risk**[4]

High-Risk Group	Vaccine Guidance
Patients aged ≥7 years undergoing elective splenectomy	If unimmunized, 1 dose at least 14 days prior to procedure
Asplenic patients ≥7 years	If unimmunized, 1 dose
HIV-infected children 7-18 years	If unimmunized, 1 dose
HIV-infected persons ≥19 years	Hib immunization is not recommended
Hematopoietic stem cell transplantation (HSCT) ≥7 years	3 doses (4-week intervals) beginning 6–12 months after HSCT regardless of prior Hib vaccine history

Protocol for Haemophilus influenzae type b Vaccines (ActHIB®, HIBERIX®, PedvaxHIB®)

6. Contraindications

A. N/A

Vaccine	Contains
Hib (ActHIB®[1])	Sodium chloride, formaldehyde, sucrose
Hib (HIBERIX®[2])	Formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB®[3])	Amorphous aluminum hydroxyphosphate sulfate, sodium chloride

7. Warnings and Precautions

A. N/A

8. Other Considerations [1-3]

A. In immunosuppressed persons, including those receiving immunosuppressive therapy, the expected antibody responses may not be obtained.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Any systemic reaction—Irritability, drowsiness, loss of appetite, fever	Very common, up to 70%
Any local reaction—pain, redness, induration or swelling at injection site	Very common, up to 49%
Severe (grade 3) systemic reactions—irritability, drowsiness	Uncommon, up to 6%
Severe pain, induration or swelling at injection site	Uncommon, up to 4%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
ActHIB®[1]	2°to 8°C (36° to 46°F) vaccine & diluent	Do not freeze.	
HIBERIX®[2]	2°to 8°C (36° to 46°F) vaccine 2°to 25°C (36° to 77°F) diluent	Protect from light. Do not freeze.	Discard if the diluent has been frozen.
PedvaxHIB®[3]	2°to 8°C (36° to 46°F) vaccine	Do not freeze.	

11. References

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12. Appendix

A. N/A

Protocol for Inactivated Influenza Vaccines and Recombinant Influenza Vaccines
Inactivated Influenza Vaccine (Afluria®, Fluarix®, FluLaval®, Fluzone®), Recombinant Influenza Vaccine (Flublok®), Cell Cultured Influenza Vaccine (Flucelvax®), Adjuvanted Inactivated Influenza Vaccine (Fluad®)

1. What's New

A. ACIP Recommended that all egg-based inactivated influenza vaccines for use in the 2023-2024 influenza season Northern Hemisphere[9] contain the following:
   a. A/Victoria/4897/2022 (H1N1) pdm09-like virus
   b. A/Darwin/9/2021 (H3N2)-like virus
   c. B/Austria/1359417/2021-like virus (B/Victoria lineage)
   d. B/Phuket/3073/2013-like virus (B/Yamagata lineage)

B. ACIP Recommended that all cell-culture-based inactivated or recombinant-based influenza vaccines for the 2023-2024 influenza season Northern Hemisphere[9] contain the following:
   a. A/Wisconsin/67/2022 (H1N1) pdm09-like virus
   b. A/Darwin/6/2021 (H3N2)-like virus
   c. B/Austria/1359417/2021-like virus (B/Victoria lineage)
   d. B/Phuket/3073/2013-like virus (B/Yamagata lineage)

C. ACIP recommends that adults aged ≥65 years preferentially receive any one of the following higher dose or adjuvanted influenza vaccines: quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4).[10]

D. All persons ages ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.[11]

2. Immunization Protocol

A. Administer a 0.25-mL, 0.5-mL, or 0.7-mL dose, IM, of an appropriate influenza vaccine, to persons ≥ 6 months of age based on the patient's age and the formulation being used.

B. May be given with all ACIP-recommended child and adult vaccinations, including COVID-19 vaccines.

C. When co-administering COVID-19 vaccines and adjuvanted or high-dose influenza vaccines that might be more likely to cause a local reaction, different limbs should be used, if possible.[10]

3. Vaccine Schedule

Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV) Schedule for the 2023–2024 Flu Season[1-8] Dose and Route – 0.25-mL or 0.5-mL (dose based on age and formulation), IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥ 6 months	
2*	≥ 6 months through <9 years of age	28 days, *see flowchart in recommendations for use for determining 1 or 2 doses

Protocol for Inactivated Influenza Vaccines and Recombinant Influenza Vaccines
Inactivated Influenza Vaccine (Afluria®, Fluarix®, FluLaval®, Fluzone®),
Recombinant Influenza Vaccine (Flublok®),
Cell Cultured Influenza Vaccine (Flucelvax®),
Adjuvanted Inactivated Influenza Vaccine (Fluad®)

4. Licensed Vaccines

Product Name	Presentation	Hemagglutinin (IIV and RIV) for each vaccine virus (mcg/per dose)	FDA Age Range	Thimerosal (mcg Hg)
Afluria® Quadrivalent[1]	0.5 mL prefilled syringes	15 mcg/0.5 mL	≥ 3 years	None
	5-mL multi-dose vial†	7.5 mcg/0.25 mL 15 mcg/0.5 mL	≥ 6 through 35 months ≥ 3 years	24.5
Fluad® Quadrivalent[8]	0.5 mL prefilled syringes	15 mcg/0.5 mL	≥ 65 years	None
Fluarix® Quadrivalent[2]	0.5 mL prefilled syringes	15 mcg/0.5 mL	≥ 6 months	None
Flublok® Quadrivalent[6]	0.5 mL prefilled syringes	45 mcg/0.5 mL	≥ 18 years	None
Flucelvax® Quadrivalent[7]	0.5 mL prefilled syringes	15 mcg/0.5 mL	≥ 6 months	None
	5-mL multi-dose vial	15 mcg/0.5 mL		25
FluLaval® Quadrivalent[3]	0.5 mL prefilled syringes	15 mcg/0.5 mL	≥ 6 months	None
Fluzone High Dose® Quadrivalent[4]	0.7 mL prefilled syringes	60 mcg/0.7 mL	≥ 65 years	None
Fluzone® Quadrivalent[5]	0.5 mL prefilled syringes‡	15 mcg/0.5 mL	≥ 6 months	None
	0.5 mL single dose vial‡	15 mcg/0.5 mL		None
	5 mL multi-dose vial‡	7.5 mcg/0.25 mL 15 mcg/0.5 mL		25

IIV4= inactivated influenza vaccine, RIV4= recombinant influenza vaccine

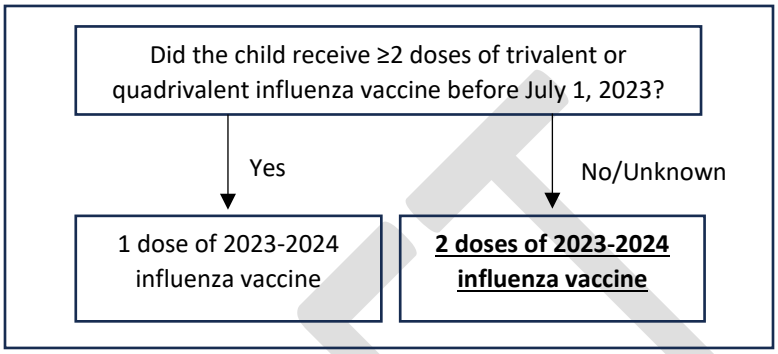
† The approved dose volume for Afluria® Quadrivalent is 0.25 mL for ages 6 through 35 months and 0.5 mL for ages ≥3 years. However, 0.25-mL prefilled syringes are no longer available. For ages 6 through 35 months, a 0.25-mL dose must be obtained from a multidose vial.

‡Fluzone® Quadrivalent is approved for children aged 6 through 35 months at either 0.25 mL or 0.5 mL per dose; however, 0.25-mL prefilled syringes are no longer available. If a prefilled syringe of Fluzone® Quadrivalent is used for a child in this age group, the dose volume will be 0.5 mL per dose.

Protocol for Inactivated Influenza Vaccines and Recombinant Influenza Vaccines
Inactivated Influenza Vaccine (Afluria®, Fluarix®, FluLaval®, Fluzone®),
Recombinant Influenza Vaccine (Flublok®),
Cell Cultured Influenza Vaccine (Flucelvax®),
Adjuvanted Inactivated Influenza Vaccine (Fluad®)

5. Recommendations for Use

A. All persons ≥ 6 months of age that do not have contraindications. Children < 9 years of age receiving flu vaccine for the first time need 2 doses, separated by at least 28 days. Children who receive the first dose at age 8 years and turn 9 during flu season should receive the 2nd dose in the same season.[10]



B. Persons who are pregnant may be vaccinated with inactivated influenza vaccine during any trimester.[10]

C. Persons with history of egg allergy may receive any vaccine (egg-based or non-egg-based) that is otherwise appropriate for their age and health status. Beginning with the 2023-2024 season, additional safety measures are no longer recommended for flu vaccination of people who are allergic to eggs beyond those recommended for receipt of any vaccine, regardless of the severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of allergic reactions are available, such as a pharmacy.[11]

D. For non-pregnant adults, vaccination in July or August should be avoided, even if vaccine is available, unless there is serious concern that later vaccination might not be possible.[10]

E. Providers should offer flu vaccination to unvaccinated persons by the end of October, if possible. Vaccination should continue to be offered as long as unexpired vaccine is available.[10]

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component. However, ACIP makes an exception for allergy to egg (see Persons with a History of Egg Allergy above).

   a. Most flu shots and the nasal spray flu vaccine are manufactured using egg-based technology. Because of this, they contain a small amount of egg proteins, such as ovalbumin. However, studies that have examined the use of both the nasal spray vaccine and flu shots in egg-allergic and non-egg-allergic patients indicate that severe allergic reactions in people with egg allergies are unlikely.[11]

Vaccine	Contains[14]
Afluria® Quadrivalent	Sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multidose vials)
Fluad® Quadrivalent	Squalene, polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, neomycin, kanamycin, barium, hydrocortisone, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde
Fluarix® Quadrivalent	Octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Flublok® Quadrivalent	Sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and Spodoptera frugiperda cell proteins, baculovirus and cellular DNA, Triton X-100
Flucelvax® Quadrivalent	Madin-Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and βpropiolactone, Thimerosal (multi-dose vials)
FluLaval® Quadrivalent	Ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution.
Fluzone High Dose® and Fluzone® Quadrivalent	formaldehyde, egg protein, octylphenol ethoxylate (Triton X100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)

7. Warnings and Precautions

A. **Persons with a history of Guillain-Barré Syndrome (GBS)** within 6 weeks following influenza vaccination have a substantially greater likelihood of subsequently developing GBS than persons without such a history. Whether influenza vaccination might be causally associated with this risk for recurrence is not known. Consult with an individual's health care provider and consider avoiding a subsequent influenza vaccination in persons known to have developed GBS within **6 weeks** of a previous influenza vaccination. Experts believe that the benefits of influenza vaccination justify yearly vaccination for most persons who have a history of GBS and who are at risk for severe complications from influenza.[10]

B. **History of severe allergic reaction to a previous dose of an egg-based influenza vaccine** is a precaution to both Flublok® and Flucelvax. ®[10]

8. Other Considerations

A. **Foreign travelers:** Travelers who want to reduce the risk for influenza infection should consider influenza vaccination, preferably at least 2 weeks before departure. In particular, persons who live in the United States and are at higher risk for complications of influenza and who were not vaccinated with influenza vaccine during the previous Northern Hemisphere fall or winter should consider receiving influenza vaccine before departure if they plan to travel to the tropics, with organized tourist groups or on cruise ships, or to the Southern Hemisphere during the Southern Hemisphere influenza season (April–September).[10]

B. **Lactation:** Inactivated and recombinant influenza vaccines are safe for breastfeeding mothers and their infants.[12]

C. **Immunocompromised:** Persons with immunocompromising conditions should receive an age appropriate IIV or RIV4. Immune response to influenza vaccines might be blunted in persons with some conditions, such as persons with congenital immune deficiencies, persons receiving cancer chemotherapy, and persons receiving immunosuppressive medications.[13]

D. **Novel adjuvants:** Because of the limited data on the safety of simultaneous administration of two or more vaccines containing novel adjuvants and the availability of nonadjuvanted influenza vaccine options, selection of a nonadjuvanted influenza vaccine may be considered in situations in which influenza vaccine and another vaccine containing a novel adjuvant are to be administered concomitantly. However, vaccination should not be delayed if a specific product is not available.

E. **Antiviral agents for influenza:** consult CDC's most recent recommendations for guidance on clinical management of influenza using antiviral agents. Available at: www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm

F. **Hematopoietic Stem Cell Transplant (HSCT) recipients:** Influenza vaccine should be administered beginning at least 6 months after HSCT and annually thereafter for the life of the patient. A dose of vaccine can be given as soon as 4 months after the transplant, but a second dose should be considered in this situation. Do not use live influenza vaccine in this population.[13]

G. **Ocular and Respiratory Symptoms after Vaccination: Oculo-respiratory syndrome** (ORS) The cause of ORS has not been established; however, studies suggest that the reaction is not IgE-mediated. When assessing whether a patient who experienced ocular and respiratory symptoms should be revaccinated, providers should determine whether signs and symptoms concerning for IgE-mediated immediate hypersensitivity are present. Health care providers who are unsure whether symptoms reported represent an IgE-mediated hypersensitivity immune response should seek advice from an allergist/immunologist. See https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html

9. Side Effects and Adverse Reactions [1-8]

Adverse Event	Frequency
Local reactions: soreness, erythema, induration at injection site	Up to 60%
Fever, malaise, chills	10% -15%
Severe allergic reactions	1 per 3 million doses

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.
B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Latex	Storage Issues	Notes
Afluria® Quadrivalent [1]	Store at 2° to 8°C (36° to 46°F)	No	Store in original package to protect from light. Store multi-dose vials in recommended conditions.	Discard opened multi-dose vials 28 days after opening.
Fluad® Quadrivalent[8]				Use opened multi-dose vials through the expiration date
Fluarix® Quadrivalent[2]				
Flublok® Quadrivalent[6]				
Flucelvax® Quadrivalent[7]				
FluLaval® Quadrivalent[3]				
Fluzone High Dose® and Fluzone® Quadrivalent[4,5]				

11. References

1. Afluria® 2023–2024. [Package insert]. Available at: www.fda.gov/media/117022/download. Accessed 14 Jul 2023
2. Fluarix® Quadrivalent 2023–2024. [Package insert]. Available at: www.fda.gov/media/79278/download. Accessed 14 Jul 2023.
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12. Appendix

A. N/A

Protocol for Japanese Encephalitis Vaccine (IXIARO®)

1. What's New

A. Updated references to reflect the updated 2024 CDC Yellow Book.

2. Immunization Protocol

A. Administer a 0.5- mL dose, IM, of Japanese Encephalitis (JE) vaccine to persons ≥7 years of age according to age and schedule if indicated.

B. IXIARO® can be given with all other ACIP-recommended vaccines.

3. Vaccine Schedule

JE Vaccine (IXIARO®) [1] Dose and Route – 0.5-mL IM				
Age	**Dose in Series**	**Acceptable Age Range**	**Dose Volume**	**Booster**
7-17 years	2 doses at 0 and 28 days	≥ 7 years	0.5 mL	≥ 1 year after primary series†
18-64 years	2 doses at 0 and 7-28 days*			
≥ 65 years	2 doses at 0 and 28 days			

* This is the only age group for which an accelerated schedule is approved.

† If ongoing exposure or re-exposure to JE virus is expected.[2]

4. Licensed Vaccine[3]

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
IXIARO®[1] (JE-VC)‡	6 antigen units purified, inactivated JEV proteins and 250 µg of aluminum hydroxide per 0.5-mL dose	0.5 mL suspension in a pre-filled single dose syringe	2 months – 65 years	None

‡JE-MB (JE-VAX) is no longer manufactured in the United States.

5. Recommendations for Use[2]

A. JE vaccination is <u>recommended</u> for the following:
   a. Persons moving to JE-endemic countries.
   b. Travelers who plan to spend a month or longer in endemic areas.
   c. Laboratory personnel who work with live, wild-type JE virus strains.[3]

B. Vaccine should also be <u>considered</u> for the following:
   a. Shorter-term travelers (e.g. less than 1 month) with an increased risk of exposure to JE based on planned travel duration, season, location, activities, and accommodations.[2]
   b. Travelers going to endemic areas, but who are uncertain of specific destinations, activities, or duration of travel.

C. Booster doses
   a. A booster dose should be given ≥1 year after completion of the primary JE-VC series if ongoing exposure or re-exposure to JE virus is expected.

b. The 2-dose primary series of JE-VC vaccine should be given to persons who received JE-MB (JE-VAX®) † and need a booster.
c. Vaccinated, at-risk laboratory personnel should receive appropriate booster doses of JE vaccine or be evaluated regularly for JE virus-specific neutralizing antibodies to assure adequate titers.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1]

Vaccine	Contains
IXIARO® (JE-VC)	Protamine sulfate, aluminum hydroxide and phosphate buffered saline (sodium chloride, potassium dihydrogen phosphate, disodium hydrogen phosphate)[1]

7. Warnings and Precautions

A. Hypersensitivity to protamine sulfate[1]
B. Other vaccines: Studies of concomitant administration of JE vaccine with hepatitis A vaccine and JE vaccine with rabies vaccine have showed noninferiority compared to administering each vaccine alone. An additional study of concomitant administration of JE vaccine, rabies vaccine and meningococcal conjugate vaccine showed protective responses to all administered vaccines.[3]
C. Pregnancy: No studies of JE-VC in pregnant women have been conducted. Pregnancy is a precaution for use of JE-VC and in most instances, its administration to pregnant women should be deferred. However, pregnant women who must travel to an area where risk for JE virus infection is high should be vaccinated when the theoretical risk of immunization is outweighed by the risk of infection.[2]
D. Newborns: JE vaccine has not been tested in individuals ≤2 months of age.[3] Older adults: In a post-licensure study, seroprotection and gross mean titers were substantially lower among adults ≥65 years of age compared to younger persons. No data exists on the safety or immunogenicity of an additional dose or early booster dose of JE vaccine for adults ≥65 years of age. [3]

8. Other Considerations [1-3]

A. Although ≤1% of JEV infections results in clinical disease, JE is a devastating illness that has a case-fatality rate of 20%–30% and neurologic or psychiatric sequelae in 30%–50% of survivors. No specific treatment exists.[3]
B. In all instances, travelers are advised to take personal precautions to reduce exposure to mosquito bites.[2]
C. The decision to use JE-VC should balance the risks for exposure to the virus and for developing illness, the availability and acceptability of repellents and other alternative measures, and the side effects of vaccination.[2]
D. Risk assessments should be interpreted cautiously because risk can vary within areas and from year to year.[2]

E. Risk of JE for travelers to highly endemic areas during the transmission season can reach 5 to 50 cases per 100,000; the risk for most short-term travelers may be 1 per million or less.[2]
F. Adverse Events: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[4]
G. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses. Immunosuppressive therapies may decrease the immune response to IXIARO®[1]
H. Lactation: Breastfeeding is not a contraindication or precaution to JE vaccine.[3]

9. Side Effects and Adverse Reactions[1]

Adverse Events	Frequency
Infants and Children	
Pain, itching, redness or swelling at the injection site	Up to 20%
Fever	Up to 10%
Allergic reactions	Rare
Adults	
Soreness, redness or itching at the injection site, headache, fatigue	Up to 30%
Vomiting, fever, chills, rash	Up to 5%
Allergic reactions	Rare

10. Storage and Handling

A. IXIARO® is a clear liquid with a white precipitate. Before administration, shake the syringe well to obtain a white, opaque, homogeneous suspension.
B. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
IXIARO®[1]	2°– 8°C (36˚F–46˚F)	Do not freeze. Store in original container. Protect from light.	No natural rubber latex. Do not use after manufacturer's expiration date on product label.

11. References

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12. Appendix

A. N/A

Protocol for Meningococcal Containing Vaccines
MenQuadfi®, Menveo®, Bexsero®, Trumenba®, and Penbraya™

1. What's New

A. Meningococcal ABCWY vaccine, Penbraya™, was added as an alternative vaccine option for individuals 10-25 years of age who are intending to receive both the MenACWY and MenB vaccines at the same visit.
B. Menveo® dosage and administration updated for 1 and 2 vial presentations.[4]
C. Menactra® has been removed from the market, all guidance related to Menactra® removed from protocol.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of meningococcal vaccine according to age-appropriate schedules and high-risk conditions.
B. Meningococcal ACWY vaccines are interchangeable when more than one brand is age-appropriate. [1]
C. Meningococcal B vaccines are not interchangeable. All doses of Meningococcal B must be of the same brand of vaccine.[1]
D. The MenACWY and MenB vaccines may be given simultaneously at different sites if indicated. [1] Alternatively, patients intending to receive both MenACWY and MenB vaccines at the same visit may instead receive the MenABCWY vaccine.[7]
E. Meningococcal vaccines can be given with all other routinely recommended vaccines.[2]

3. Vaccine Schedule

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	11-18 years	
Booster	16-18 years	8 weeks

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
2		8 weeks if 2 doses indicated
Boosters (if person remains at risk)	Aged <7 years at completion of primary series: Single dose at 3 years after primary vaccination and every 5 years thereafter Aged ≥7 years at completion of primary series: Single dose at 5 years after primary vaccination and every 5 years thereafter	

MenB Vaccines (Bexsero®, Trumenba®) Schedule for Healthy Persons*, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	16-23 years	
2		28 days for Bexsero®, 6 months for Trumenba®

*ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. See section 5 for guidance.

MenB Vaccines (Bexsero®, Trumenba®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥10 years	
2		28 days
3*		4 months after dose 2
Boosters (if person remains at risk)		Single dose at 1 year after completion of primary vaccination and every 2–3 years thereafter

*Dose 3 applies to Trumenba® only, not needed if dose 2 was administered at least 6 months after dose 1. If dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3.

MenABCWY Vaccines (Penbraya™) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	10-25 years	
2		6 months

*If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead. If a patient receives MenABCWY vaccine, which includes Trumenba®, then administer:

- Trumenba® for additional MenB dose(s) when MenACWY is not indicated
- Any MenACWY vaccine when MenB is not indicated

4. Licensed Vaccines

Meningococcal ACWY Conjugate Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenACWY-TT[3] (MenQuadfi®)	Neisseria meningitidis serogroup A, C, W, and Y capsular polysaccharide antigens that are individually conjugated to tetanus toxoid protein	0.5-mL single-dose vials	≥2 years	None
MenACWY-CRM[4] (Menveo®)	Neisseria meningitidis serogroup A, C, Y, and W-135 oligosaccharides conjugated individually to Corynebacterium diphtheriae CRM protein	Single-dose 2 vial presentation (gray and orange caps) that requires reconstitution. 0.5-mL dose once reconstituted	2 months-55 years	None
		0.5-mL single-dose 1 vial presentation (pink cap) that does **not** require reconstitution	10-55 years	None

Meningococcal B Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenB-4C (Bexsero®)[5]	Recombinant proteins Neisserial adhesin A (NadA), Neisserial Heparin Binding Antigen (NHBA), and factor H binding protein (fHbp)	0.5-mL prefilled syringes	10-25 years	None
MenB-fHbp (Trumenba®)[6]	Two recombinant lipidated factor H binding protein (fHbp) variants from N. meningitidis serogroup B, one from fHbp subfamily A and one from subfamily B (A05 and B01, respectively)	0.5-mL prefilled syringes	10-25 years	None
Meningococcal ABCWY Vaccine				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenABCWY (Penbraya™)[7]	Neisseria meningitidis serogroup A, C, W, and Y polysaccharides conjugated to tetatnus toxoid and two recombinant lipidated factor H binding protein (fHbp) variants from N. meningitidis serogroup B, one from fHbp subfamily A and one from subfamily B (A05 and B01, respectively)	0.5-mL single-dose diluent in prefilled syringe and vial with lyophilized antigen	10-25 years	None

5. Recommendations for Use

A. Routine use of Meningococcal ACWY vaccine[1]

a. All adolescents 11–18 years of age without contraindications. Preferred age for dose one is 11-12 years with a booster dose at age 16 years. Catch-up vaccination age for dose one is 13–15 years with a booster dose at age 16–18 years. If series started at age 16 or older, no booster dose is indicated.

   i. Children who received MenACWY at age 10 years do not need an additional dose at age 11–12 years but should receive the booster dose at age 16 years. Children who received MenACWY before age 10 years and with no ongoing risk for meningococcal disease for which boosters are recommended should still receive MenACWY according to the recommended adolescent schedule.
- b. Unvaccinated or under vaccinated first-year college students living in residence halls. One dose may be administered to persons 19-21 years who have not received a dose after their 16th birthday. Boosters are not routinely recommended unless there is another indication.
- c. Military recruits 19-21 years of age who have not received a dose after their 16th birthday. Administer one dose with booster every 5 years based on assignment. Vaccine recommendations for military personnel are made by the U.S. Department of Defense.
- d. Booster doses for previously vaccinated persons who become or remain at increased risk. At 3 or 5 years after primary vaccination depending on age at last dose and every 5 years thereafter.

B. Use of Meningococcal ACWY vaccine in high-risk persons[1]
- a. Persons with complement component deficiency or who are taking complement inhibitor medications, with anatomical or functional asplenia, or with HIV should receive 2 doses 8 weeks apart.
- b. Microbiologists routinely exposed to isolates of Neisseria meningitidis, persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men [MSM]), and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic, particularly the meningitis belt in sub-Saharan Africa, should receive 1 dose.
   i. Vaccination is required for entry for persons traveling to Saudi Arabia for the Hajj and Umrah pilgrimages.

C. Use of Meningococcal B vaccine in healthy persons[1]
- a. Vaccination of adolescents and young adults aged 16–23 years with a 2-dose MenB series on the basis of shared clinical decision-making. MenB vaccination is not routinely recommended for all adolescents. Instead, ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision making to discuss MenB vaccination with persons aged 16-23 years who are most likely to benefit.
   i. Pharmacists are authorized to administer MenB vaccine if the following risk factor is present: College students, especially those who are freshmen, attend a 4-year university, live in on-campus housing, or participate in sororities and fraternities

D. Use of Meningococcal B vaccine in high-risk persons[1]
- a. Persons with persistent complement component deficiencies or who are taking complement inhibitor medications, with anatomic or functional asplenia, and Microbiologists routinely exposed to isolates of *Neisseria meningitidis* should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.
   i. A single booster dose for previously vaccinated persons who remain at increased risk should be given at 1 year after completion of primary vaccination and every 2-3 years thereafter.

b. Persons at increased risk during an outbreak (e.g., in community or organizational settings, and among MSM should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.
   i. A single booster dose for previously vaccinated persons and identified at increased risk during an outbreak should be given if ≥1 year after completion of primary series (a ≥ 6-month interval might also be considered by public health).

E. Use of Meningococcal ABCWY vaccine
   a. If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead.
      i. If a patient receives MenABCWY vaccine, which includes Trumenba®, then administer:
         1. Trumenba® for additional MenB dose(s) when MenACWY is not indicated
         2. Any MenACWY vaccine when MenB is not indicated
      ii. The minimum interval between MenABCWY doses is 6 months.
   b. People with prolonged increased risk for serogroup A, C, W, or Y and B meningococcal disease need regular boosters. However, the recommended interval between doses varies by age and vaccine type. MenABCWY vaccine can be used only when both MenACWY and MenB vaccines are indicated at the same visit. Otherwise, MenACWY and MenB vaccines should be given separately as appropriate.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[3-7]

Vaccine	Contains
MenACWY-TT – MenQuadfi®	sodium chloride, sodium acetate, formaldehyde, tetanus toxoid
MenACWY-CRM - Menveo®	formaldehyde, CRM197 protein
MenB-4C - Bexsero®	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
MenB-FHbp - Trumenba®	polysorbate 80, aluminum phosphate, histidine buffered saline
MenABCWY- Penbrayra™	L-histidine, trometamol, sucrose, aluminum phosphate, sodium chloride, and polysorbate 80

7. Warnings and Precautions[3-6]

A. N/A

8. Other Considerations

A. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses. [3-6]
B. Pregnant and lactating women should receive MenACWY vaccine if indicated. However, due to a lack of data, vaccination with MenB should be deferred unless the woman is at increased risk and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks. [1]

C. Lactation: It is not known whether meningococcal vaccines are excreted in human milk. Use with caution in nursing mothers.[1]
D. MenACWY meningococcal vaccines will stimulate protection only against infections caused by organisms from serogroups A, C, Y and W meningococci. They are not protective against serogroup B meningococci.[5,6]
E. Meningococcal vaccine is recommended 2 weeks before or ≥2 weeks after splenectomy surgery for persons ≥7years of age. [1]
F. Immunization with MenQuadfi® or Penbraya™ does not substitute for routine tetanus immunization.[3,7]

9. Side Effects and Adverse Reactions[3-7]

MenACWY Vaccines	
Adverse Event	**Frequency**
Low-grade fever, headache, redness at injection site, dizziness	Up to 40%
Grade 3 - fever, headache, redness at injection site, dizziness	Up to 3%
MenB Vaccines	
Adverse Event	**Frequency**
Headache, fatigue, redness at injection site	Up to 51%
Pain at injection site	Up to 26%
Chills, joint pain	Up to 20%
Fever	Up to 2.5%
MenABCWY Vaccine	
Adverse Event	**Frequency**
Pain at injection site	Up to 89%
Fatigue	Up to 52%
Headache	Up to 47%
Muscle pain	Up to 26%
Injection site redness	Up to 26%
Injection site swelling	Up to 25%
Joint pain	Up to 20%
Chills	Up to 20%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.
B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
MenQuadfi®[3]	Store at 2°to 8°C (36° to 46°F)	Protect from light. Do not use if vaccine has been frozen.	
Menveo®[4] and diluent			After reconstitution, administer Menveo® immediately or store between 2°C and 25°C (36°F and 77°F) for up

			to 8 hours. Shake well before using. Discard reconstituted vaccine if it has been frozen or not used within 8 hours.
Bexsero®[5] and Trumenba®[6]			
Penbraya™[7]		During storage, a white deposit and clear supernatant may be observed in the prefilled syringe containing the MenB Component. Store the carton horizontally to minimize the time necessary to resuspend the MenB Component. Do not freeze. Discard if the carton has been frozen	After reconstitution, administer PENBRAYA immediately or store between 2°C and 30°C (36°F and 86°F) and use within 4 hours. Do not freeze.

10. References

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11. Appendix

A. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making for Meningococcal B Vaccination in Adolescents and Adults: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/vaccines/hcp/admin/downloads/ISD-job-aid-SCDM-mening-b-shared-clinical-decision-making.pdf

Protocol for Pneumococcal Vaccines PCV15 (VAXNEUVANCE™), PCV20 (Prevnar 20®)and Pneumococcal Polysaccharide Vaccine: PPSV23 (Pneumovax®23)

1. What's New

A. The 13-valent pneumococcal conjugate vaccine (PCV13) has been deleted from all sections. Previous children and adolescent schedules containing PCV13 have been updated with new recommendations for use of PCV15, PCV20, and PPSV23.

B. All vaccine schedule tables have been updated to provide additional clarity on recommended subsequent doses, minimum vaccine spacing and the addition of shared clinical decision making, when applicable.

C. Additional information was provided to clarify what conditions should be considered for patients over the age of 65 to qualify for PCV20 via shared clinical decision making.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of pneumococcal conjugate vaccine (PCV) to persons ≥7 years of age according to age-appropriate schedule or high-risk group indication **OR**

B. Administer a 0.5-mL dose, IM or SQ, of pneumococcal polysaccharide vaccine (PPSV) to persons ≥7 years of age according to age-appropriate schedule or high-risk group indication.

C. PCV and PPSV should not be given at the same time. Either vaccine type may be given simultaneously with influenza and most other ACIP-recommended child and adult vaccinations.[4]

3. Vaccine Schedule

A. Routine Schedule

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons ≥ 65 Years of Age Dose-0.5-mL, Route varies by product				
Age	**Previous PCV Vaccination History**	**Previous PPSV Vaccination History**	**Due Now/Route**	**Due Next**
≥ 65 years	Unvaccinated	Unvaccinated	PCV15 IM **or**	PPSV23 IM or SQ ≥ 1 year later‡
			PCV20 IM	Complete*
	Unvaccinated	1 dose (at any age)	PCV15 IM ≥ 1 year later **or**	Complete*
			PCV20 IM ≥ 1 year later	Complete*
	PCV13 only (at any age)	Unvaccinated	PCV20 IM ≥ 1 year later **or**	Complete*
			PPSV23 IM or SQ ≥ 1 year later‡	Complete*
	PCV13 (at any age)	1 dose (at < 65 years old)	PCV20 IM ≥ 5 years after last pneumococcal dose **or**	Complete*
			PPSV23 IM or SQ ≥ 5 years after last pneumococcal dose‡	

	PCV13 (at any age)	1 dose (≥ 65 years old)	The patient and vaccine provider may consider administering PCV 20 via ***shared clinical decision making*** to patients who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 (See Section 5 for additional details).
‡ For adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak, the minimum interval for PPSV23 is ≥ 8 weeks since last PCV13 dose and ≥ 5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥ 1 year since last PCV13 dose and ≥ 5 years since last PPSV23 dose.			

B. Special Conditions Schedule

Pneumococcal Vaccine (PCV15 or PCV20; PPSV23) for Persons 7-18 Years of Age with Immunocompromising Conditions* Dose-0.5-mL, Route varies by product				
Acceptable Age Range	**Previous PCV Vaccination History**	**Previous PPSV23 Vaccination History**	**Due Now/Route** (≥ 8 weeks since last pneumococcal vaccine)	**Due Next**
7-18 years of age with immune-compromising conditions	No previous history of PCV13, PCV15, or PCV20	Unvaccinated	PCV15 IM **or**	Administer PPSV23 in ≥8 weeks.
			PCV20 IM	Complete
		1 dose	PCV15 IM **or**	Revaccinate with PCV20 or PPSV23 in 5 years.
			PCV20 IM	Complete
	≥1 dose of PCV13 or PCV15 before age 6	Unvaccinated	PCV 20 IM **or**	Complete
			PPSV23 IM or SQ	Revaccinate with PCV20 or PPSV23 in 5 years.
	≥1 dose of PCV20 before age 6	Unvaccinated	Complete	
	≥1 dose of PCV13 at or after age 6	Unvaccinated	PCV20 IM **or**	Complete
			PPSV23 IM or SQ	Revaccinate with PCV20 or PPSV23 in 5 years.
		1 dose	PCV20 **or**†	Complete
			PPSV23†	Complete
*Children and adolescents on maintenance dialysis, or with immunocompromising conditions such as nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; or sickle cell disease or other hemoglobinopathies †Vaccination must occur at least 8 weeks after the most recent PCV13 dose and at least 5 years after dose 1 PPSV23				

Protocol for Pneumococcal Vaccines
PCV15 (VAXNEUVANCE™), PCV20 (Prevnar 20®)and
Pneumococcal Polysaccharide Vaccine: PPSV23 (Pneumovax®23)

Pneumococcal Vaccine (PCV15 or PCV20; PPSV23) for Persons 7-18 Years of Age with Chronic Conditions Dose-0.5-mL, Route varies by product**				
Acceptable Age Range	**Previous PCV Vaccination History**	**Previous PPSV23 Vaccination History**	**Due Now/Route** (≥ 8 weeks since last pneumococcal vaccine)	**Due Next**
7-18 years of age with chronic conditions	No previous history of PCV13, PCV15, or PCV20	Unvaccinated	PCV15 IM **or**	Administer PPSV23 in ≥8 weeks.
			PCV20 IM	Complete
		1 dose	PCV15 IM **or**	Complete
			PCV20 IM	Complete
	≥1 dose of PCV13 or PCV15 before age 6	Unvaccinated	PCV 20 IM **or**	Complete
			PPSV23 IM or SQ	Revaccinate with PCV20 or PPSV23 in 5 years.
	≥1 dose of PCV20 before age 6	Unvaccinated	Complete	
	≥1 dose of PCV13 at or after age 6	Unvaccinated	PCV20 IM **or**	Complete
			PPSV23 IM or SQ	Complete
		1 dose	Complete	
**Children and adolescents with cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; or diabetes mellitus				

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with Immunocompromising Conditions* Dose-0.5-mL, Route varies by product				
Age	**Previous PCV Vaccination History**	**Previous PPSV Vaccination History**	**Due Now/Route**	**Due Next**
19-64 years with immune-compromising conditions	Unvaccinated	Unvaccinated	PCV15 IM **or**	PPSV23 IM or SQ ≥ 8 weeks later‡
			PCV20 IM	Complete¥
	Unvaccinated	1 dose	PCV15 IM ≥ 1 year after last PCV dose **or**	Complete¥
			PCV20 IM ≥ 1 year after last PCV dose	Complete¥
	PCV13 only	Unvaccinated	PCV20 IM ≥ 1 year after last PCV dose **or**	Complete¥
			PPSV23 IM or SQ ≥ 8 weeks later‡	Revaccinate with PPSV23 in 5 years.

	PCV13	1 dose	PCV20 IM ≥ 5 years after last PPSV23 dose **or**	Complete¥
			PPSV23 IM or SQ ≥ 5 years after last PPSV23 dose	PCV20 IM ≥ 5 years after last PPSV23 dose
	PCV13	2 doses	PCV20 IM ≥ 5 years after last PPSV23 dose	Complete¥

* Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiencies, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.
‡May use minimum interval of 8 weeks for adults with an immunocompromising condition*, cochlear implant, or cerebrospinal fluid leak.
¥Review pneumococcal vaccine recommendations when patient turns 65 years old

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with Chronic Conditions Dose-0.5-mL, Route varies by product**				
Age	**Previous PCV Vaccination History**	**Previous PPSV Vaccination History**	**Due Now/Route**	**Due Next**
19-64 years with chronic conditions	Unvaccinated	Unvaccinated	PCV15 IM **or**	PPSV23 IM or SQ ≥ 1 year later
			PCV20 IM	Complete
	Unvaccinated	1 dose	PCV15 IM ≥ 1 year after last PPSV dose **or**	Complete
			PCV20 IM ≥ 1 year after last PPSV dose	Complete
	PCV13 only	Unvaccinated	PCV20 IM ≥ 1 year after last PCV dose **or**	Complete
			PPSV23 IM or SQ ≥ 1 year later	Complete¥
	PCV13	1 dose	Complete¥	

**Chronic conditions include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV infection, Hodgkin disease, immunodeficiencies, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, or sickle cell disease or other hemoglobinopathies.
¥Review pneumococcal vaccine recommendations when patient turns 65 years old

Protocol for Pneumococcal Vaccines
PCV15 (VAXNEUVANCE™), PCV20 (Prevnar 20®)and
Pneumococcal Polysaccharide Vaccine: PPSV23 (Pneumovax®23)

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with Cochlear Implant or Cerebrospinal Fluid Leak Dose-0.5-mL, Route varies by product				
Age	**Previous PCV Vaccination History**	**Previous PPSV Vaccination History**	**Due Now/Route**	**Due Next**
19-64 years	Unvaccinated	Unvaccinated	PCV15 IM **or**	PPSV23 IM or SQ ≥ 8 weeks later‡
			PCV20 IM	Complete
	Unvaccinated	1 dose	PCV15 IM ≥ 1 year after last PPSV dose **or**	Complete
			PCV20 IM ≥ 1 year after last PPSV dose	Complete
	PCV13 only	Unvaccinated	PCV20 IM ≥ 1 year after last PCV dose **or**	Complete
			PPSV23 IM or SQ ≥ 8 weeks later‡	Complete¥
	PCV13	1 dose	PCV20 IM ≥ 5 years after last pneumococcal dose **or**	Complete¥
‡May use minimum interval of 8 weeks for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak. ¥Review pneumococcal vaccine recommendations when patient turns 65 years old				

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
Pneumococcal Conjugate Vaccines				
Prevnar 20™ (PCV20) [1]	Sterile suspension of mixture of saccharides of the capsular antigens of S. pneumoniae, individually linked to non-toxic diphtheria CRM197 protein	0.5 mL prefilled syringes	≥ 6 weeks of age	None
VAXNEUVANCE™ (PCV15) [2]		0.5 mL prefilled syringes	≥ 2 months	
Pneumococcal Polysaccharide Vaccine				
Pneumovax 23® (PPSV23) [3]	Pneumococcal Vaccine Polyvalent is a sterile, liquid vaccine consisting of a mixture of purified capsular polysaccharides from Streptococcus pneumoniae	0.5 mL single dose vials	≥ 2 years	None
		0.5 mL prefilled syringes		

5. Recommendations for Use

Protocol for Pneumococcal Vaccines
PCV15 (VAXNEUVANCE™), PCV20 (Prevnar 20®)and
Pneumococcal Polysaccharide Vaccine: PPSV23 (Pneumovax®23)

A. Routine

1. Age 65 years or older:
    b. Not previously received a dose of PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose
        i. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk of invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.
        ii. Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies.
    c. Previously received only PCV7: follow the recommendation above.
    d. Previously received only PCV13: 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
    e. Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.
    f. Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older: 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
    g. Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older: Adults aged 65 or older have the option to receive PCV20 if they previously completed the pneumococcal vaccine series with both PCV13 and PPSV23. This includes one dose of PCV13 at any age and all recommended doses of PPSV23, including one dose at or after age 65. PCV20 is not routinely recommended for these individuals as their risk of disease is lower due to prior vaccinations. Instead, ACIP recommends a PCV20 vaccination for persons aged 65 or older who have received both PCV13 and PPSV23 on the basis of shared clinical decision-making.

    Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision making to discuss PCV20 vaccination with persons aged 65 or older who are most likely to benefit.

    Pharmacists are authorized to administer PCV20 vaccine if one of the following risk factors is present AND at least 5 years has elapsed since last pneumococcal vaccination:
        i. Individuals living in nursing homes or other long-term care facilities.
        ii. Individuals living in areas with low pediatric pneumococcal conjugate vaccine uptake.

iii. Individuals with immunocompromising conditions, cochlear implant, cerebrospinal fluid leak, or more than one of these chronic medical conditions: alcoholism; chronic heart, liver, or lung disease; cigarette smoking; or diabetes.

B. Special Conditions

1. Age 7-18 years:
   A. Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:
      a. Any incomplete series with PCV: no further PCV doses needed
      b. No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV doses)
   B. Cerebrospinal fluid leak, cochlear implant:
      a. No history of either PCV or PPSV23: 1 dose PCV, 1 dose PPSV23 at least 8 weeks later
      b. Any PCV but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV
      c. PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent dose of PPSV23
   C. Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:
      a. No history of either PCV or PPSV23: 1 dose PCV, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
      b. Any PCV but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
      c. PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent PPSV23 dose and a dose 2 of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV
   D. Hematopoietic Stem Cell Transplant[6]: Children aged <19 years who are hematopoietic stem cell transplant (HSCT) recipients are recommended to receive 4 doses of PCV20, starting 3–6 months after HSCT. Administer 3 doses of PCV20, 4 weeks apart starting 3–6 months after HSCT. Administer a fourth PCV20 dose ≥6 months after the third dose of PCV20 or ≥12 months after HSCT, whichever is later.
      a. If PCV20 is not available, 3 doses of PCV15 4 weeks apart, followed by a single dose of PPSV23 ≥1 year after HSCT, can be administered. For patients with chronic graft versus host disease (GVHD) who are receiving PCV15, a fourth dose of PCV15 can be administered in place of PPSV23 because these children are less likely to respond to
      PPSV23. Any PCV but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)

b. A patient's clinical team is best informed to determine the appropriate timing of vaccination.

2. Age 19–64 years:
   A. Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV, Hodgkin disease, immunodeficiency, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplants, or sickle cell disease, or other hemoglobinopathies
      c. Not previously received a PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose.
         a) A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak
         b) Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies
      d. Previously received only PCV7: follow the recommendation above
      e. Previously received only PCV13: 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
      f. Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23
      g. Previously received both PCV13 and PPSV23 but have not completed the recommended series: 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
B. PCV20[1] or PCV15[2]: Persons who experienced an anaphylactic reaction to a previous dose of any diphtheria toxoid-containing vaccine.

7. Warnings and Precautions

A. PPSV23: Care should be exercised when administering to patients with severely compromised cardiovascular or pulmonary function in whom a systemic reaction would pose a significant risk.[3]

8. Other Considerations

A. Adults with previous PPSV23 only: Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23. [4]

B. Lactation: It is not known whether pneumococcal vaccines are excreted in human milk. Use with caution in people who are nursing. [1-3]

C. Pregnancy: Pneumococcal vaccine should be considered for persons at increased risk.[9]

D. Simultaneous administration of PCV15 and PPSV23 is NOT recommended. See section 5, recommendations for use, for the necessary minimum interval between doses. [4,5]

E. Splenectomy, immunocompromising therapy, or cochlear implant: When elective splenectomy, immunocompromising therapy, or cochlear implant placement is being planned, age appropriate PCV vaccination should be completed at least 2 weeks before surgery or initiation of therapy. If vaccine is not administered before surgery, it should be administered ≥2 weeks after surgery. If the patient is unlikely to return, vaccine can be administered in the immediate postoperative period. [7]

F. Children who have experienced invasive pneumococcal disease should receive all recommended doses of a pneumococcal conjugate vaccine as appropriate for their age and underlying condition. The full series of scheduled doses should be completed even if the series is interrupted by an episode of invasive pneumococcal disease. [7]

G. Individuals with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.[1-3]

H. Recipients of Hematopoietic Cell Transplants (HCT): ACIP recommends that patients be revaccinated with three sequential doses of age appropriate PCV vaccine beginning 3–6 months after HCT transplant. A dose of PPSV should be administered ≥8 weeks after the last dose of PCV.[7]

9. Side Effects and Adverse Reactions

PCV20[1], PCV15[2] Adverse Events	**Frequency**
Soreness at the injection site, fatigue	Up to 76%
Headache, muscle pain, joint pain, decreased appetite, local swelling, decreased arm movement	Up to 30%
Vomiting, fever, chills, rash	Up to 30%
Allergic reactions	Rare
PPSV23[3] Adverse Events	**Frequency**
Soreness, redness, swelling at the injection site	Up to 60%
Headache, muscle pain, fatigue	Up to 20%
Nausea, fever, chills	Rare, up to 2%
Allergic Reactions	Rare

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Prevnar 20™ [1]	Store at 2°– 8°C (36°- 46°F)	Store syringes horizontally to minimize re-suspension time; do not freeze	
VAXNEUVANCE™ [2]		Do not freeze. Protect from light.	
Pneumovax® 23[3]		None	

11. References

1. Prevnar 20™ (PCV20). [Package insert]. April 2023. www.fda.gov/media/149987/download. Accessed 14 January 2024.
2. VAXNEUVANCE™ (PCV15). [Package insert]. May 2023. www.fda.gov/media/150819/download. Accessed 14 January 2024.
3. Pneumovax®23 (PPSV23). [Package insert]. October 2021. https://www.fda.gov/media/80547/download. Accessed 14 January 2024.
4. Kobayashi M, Farrar JL, Gierke R, et al. Use of 15-valent pneumococcal conjugate vaccine and 20-valent pneumococcal conjugate vaccine among U.S. children: Updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2022;71(4);109–17. Available at: https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7137a3-H.pdf. Accessed 14 January 2024.
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12. Appendix

A. Centers for Disease Control and Prevention (CDC). Pneumococcal Vaccine Timing. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
B. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making for Pneumococcal Conjugate Vaccine (PCV20) Vaccination in Adults Aged 65 Years or Older: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/vaccines/hcp/admin/downloads/job-aid-SCDM-PCV20-508.pdf

C. Centers for Disease Control and Prevention (CDC). Pneumococcal PneumoRecs VaxAdvisor Mobile App for Vaccine Providers. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html

Protocol for Polio Vaccine (IPOL®)

1. What's New

A. Routine recommendations for adults who are known or suspected to be unvaccinated or incompletely vaccinated were updated to include completion of the 3-dose IPV primary series. The recommendation for adults who are at increased risk for exposure to poliovirus and have completed the primary series was also added.

2. Immunization Protocol

A. Administer 0.5-mL dose, IM or SQ, of polio vaccines as recommended for age, vaccination status, and travel itinerary.

B. May be given with all ACIP-recommended child and adult vaccinations.

3. Vaccine Schedule

A. **Routine schedule for children <18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Recommended Spacing**
1	7 through17 years	
2		4-8 weeks from previous dose
3		6-12 months from previous dose
4		A 4th dose is not necessary if 3rd dose administered at age 4 or older and at least 6 months after the previous dose. A 4th dose is indicated if all previous doses were administered at <4 years or if the 3rd dose was administered <6 months after the second dose. The minimum interval between the 3rd and 4th dose is 6 months.

B. **Accelerated schedule for children <18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	7 through17 years	
2		≥4 weeks after dose 1
3		≥6 months after dose 2

C. **Unvaccinated, incompletely vaccinated, or unknown vaccine status for ≥18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Recommended Spacing**
1	≥18 years	
2		4-8 weeks after dose 1
3		6-12 months after dose 2

D. **Accelerated schedule for unvaccinated, incompletely vaccinated, or unknown vaccine status for ≥18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		≥4 weeks after dose 1*
3		≥4 weeks after dose 2*

* If less than 8 weeks but more than 4 weeks is available before protection is needed, 2 doses of IPV should be administered at least 4 weeks apart. If less than 4 weeks is available before protection is needed, a single dose of IPV is recommended.[5]

E. **Fully vaccinated travelers ≥18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	≥12 months after last dose

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
IPOL®[1]*	Inactivated polio virus (IPV) serotypes 1,2 and 3	5-mL multi-dose vials	≥ 6 weeks	None

*Combination vaccines including polio may also be used according to approved age indication

5. Recommendations for Use

A. Adults known or suspected to be unvaccinated or incompletely vaccinated known or suspected to be unvaccinated or incompletely vaccinated: administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series. Unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children. Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

B. Adults who previously completed the full, routine polio vaccine series and are at increased risk of exposure to poliovirus, should receive a onetime booster dose of polio vaccine IPV. Adults working in health care settings, refugee camps or other humanitarian aid settings in countries bordering a country with circulating poliovirus should also receive a one-time booster dose of IPV.[5] Countries where a booster of IPV is recommended before travel can be found at: https://wwwnc.cdc.gov/travel/notices/alert/global-polio

C. Adults known or suspected to be unvaccinated or incompletely vaccinated known or suspected to be unvaccinated or incompletely vaccinated: administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series. Unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children. Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

D. Adults who have received only one or two doses in the past should get the remaining doses of IPV vaccine administered at least 4 weeks apart.[3] If an adult cannot complete the series before travel departure, an accelerated schedule (doses administered at least 4 weeks apart) is recommended.[3]
E. If a child cannot complete the accelerated schedule before departure, the remaining doses should be given in the visited country, or upon return home, at the intervals recommended in the accelerated schedule.[3]
F. Children completing the accelerated schedule should still receive a final dose of IPV at ≥4 years old, and at least 6 months after the previous dose.[3]

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1]

Vaccine	Contains[3]
IPOL®[1]	calf bovine serum albumin, 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B, M-199 medium

7. Warnings and Precautions

A. Moderate or severe acute illness with or without fever.[4]
B. Although no causal relationship between IPOL® vaccine and Guillain-Barré Syndrome (GBS) has been established, GBS has been temporally related to administration of another inactivated poliovirus vaccine.[1]

8. Other Considerations

A. IPOL® can also be given by the subcutaneous route.[1]
B. Polio vaccine given outside the United States is valid if written documentation indicates that all doses were given after 6 weeks of age and the vaccine received was IPV or trivalent oral poliovirus vaccine (tOPV). Recipients receiving both tOPV and IPV require a total of 4 doses.[5]
C. OPV given before April 1, 2016, can be assumed to be trivalent and valid.[5] OPV doses given in April of 2016, can only be counted as valid if the documentation indicates that it was trivalent.[5] OPV given after May 1, 2016 should not be counted as valid because it was a bivalent or monovalent vaccine.[5]
D. Persons <18 years of age with doses of OPV that do not count should receive IPV to complete the series.[5] Oral polio vaccine (OPV) has been unavailable in the United States since 1999.[5]
E. Travelers staying in a polio-infected country longer than 12 months may receive available poliovirus vaccine (IPV or OPV) in the infected country to meet the departure requirement.[3]
F. Immunodeficiency: IPV may be administered safely to immunocompromised travelers and their household contacts. Although a protective immune response cannot be ensured, IPV might confer some protection to the immunocompromised person.[4] People with certain primary immunodeficiency diseases should not be given live, attenuated OPV and should avoid contact with excreted OPV virus (such as exposure to a child vaccinated with OPV in the previous 6 weeks). Because OPV is no longer given in the United States, this situation

would arise only if a child receives OPV overseas.[5] Revaccination with 3 doses of IPV is recommended 6–12 months after hematopoietic stem cell transplantation.

G. Mild Illness: IPV may be administered to people with diarrhea. Minor upper respiratory illnesses with or without fever, current antimicrobial therapy, and the convalescent phase of acute illness are not contraindications for vaccination.

H. Pregnancy: If a pregnant woman is unvaccinated or incompletely vaccinated and requires immediate protection against polio because of planned travel to a country or area where polio cases are occurring, IPV can be administered as recommended for adults.[5]

I. Breastfeeding: Is not a contraindication to administration of polio vaccine to an infant or mother.[5] It is not known whether polio-containing vaccines are excreted in human milk. Use with caution in nursing mothers.[1]

J. After an interval of 15–40 years, 25%–40% of survivors of paralytic poliomyelitis may experience muscle pain and exacerbation of existing weakness or develop new weakness or paralysis. This disease entity, referred to as post-polio syndrome, has been reported only in persons infected during the era of wild poliovirus circulation. This is not an infectious process.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Any local reaction – pain, redness, induration or swelling at the injection site	Up to 75%
Redness ≥50 mm at injection site	Up to 18%
Severe pain, induration or swelling at the injection site	Up to 9%
Any systemic reaction – fever, malaise, aches, persistent crying, drowsiness	Up to 50%
Severe (grade 3) systemic reactions including fever above 102° F	Up to 3%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
IPOL®[1]	Store at 2°to 8°C (36°to 46°F)	Do not use if vaccine has been frozen. Protect from light.	

11. References

1. IPOL®. Package insert. Swiftwater, PA: Sanofi Pasteur SA; Updated May 1, 2022. https://www.fda.gov/media/75695/download. Accessed April 14, 2023.
2. Use of Inactivated Polio Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR 2023;72(49):1327-30. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7249a3.htm. Accessed 17 January 2024.

3. CDC. Vaccine Excipient Table. November 2021. Available at https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf Accessed 14 Apr 2023.
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12. Appendix

A. N/A

Protocol for Respiratory Syncytial Virus Vaccine (ABRYSVO™, AREXVY™)

1. What's New

A. Added additional clarification regarding Abrysvo™ seasonal administration during the final trimester of pregnancy and additional guidance on subsequent vaccination for future pregnancies.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of respiratory syncytial virus (RSV) vaccine to persons ≥ 60 years of age, using shared clinical decision making, as described in Section 5.

B. May be given with all ACIP-recommended adult vaccinations.

3. Vaccine Schedule

RSV Vaccine (ABRYSVO™, AREXVY™) [1,2] Dose and Route – 0.5-mL IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥60 years	

RSV Vaccine (ABRYSVO™ only) [4] Dose and Route – 0.5-mL IM			
Dose	**Acceptable Age Range**	**Indication**	**Minimum Acceptable Spacing**
1	N/A	Pregnancy	Administer 32 weeks 0 days through 36 weeks and 6 days of pregnancy during or just prior to the start of the RSV season*.

*Vaccine should be administered to pregnant persons during September–January in most of the continental United States, including Oregon, to target vaccine to pregnant persons whose infants will be in their first months of life during the RSV season. Administer RSV vaccine regardless of previous RSV infection. All other pregnant persons: RSV vaccine not recommended. There is currently no ACIP recommendation for RSV vaccination in subsequent pregnancies. No data are available to inform whether additional doses are needed in later pregnancies.

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
ABRYSVO™[1]	60 mcg RSV prefusion F A protein and 60 mcg RSV prefusion F B protein	0.5-mL single-dose diluent in prefilled syringe and vial with lyophilized antigen	≥60 years	No
AREXVY™[2]	120 mcg of the recombinant RSVPreF3 antigen, 25 mcg of MPL and 25 mcg of QS-21	0.5-mL single-dose vial of adjuvant suspension and single-dose vial of lyophilized antigen		

MPL: 3-O-desacyl-4'-monophosphoryl lipid A; QS-21: saponin purified from plant extract *Quillaja Saponaria* Molina

5. Recommendations for Use[3,4]

A. Shared clinical decision making for patients 60 years of age and older: until additional evidence becomes available from post-marketing surveillance clarifying the potential risk (e.g. neurologic inflammatory events, atrial fibrillation), RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease. Pharmacists can

engage in shared clinical decision making to discuss RSV vaccination with persons aged 60 years or older who are most likely to benefit. Pharmacists are authorized to administer RSV vaccine if the patient provides information that one of the following risk factors is present:

Chronic underlying medical conditions
• Lung disease (such as chronic obstructive pulmonary disease and asthma) • Cardiovascular disease (such as congestive heart failure and coronary artery disease) • Moderate or severe immune compromise* • Diabetes mellitus • Neurologic or neuromuscular conditions • Kidney disorders • Liver disorders • Hematologic disorders • Other underlying conditions that a health care provider, including a pharmacist, determines may increase the risk for severe respiratory disease
Other factors
• Frailty† • Advanced age‡ • Residence in a nursing home or other long-term care facility • Other underlying factors that a health care provider, including a pharmacist, determines may increase the risk for severe respiratory disease

*A list of potentially immune compromising conditions is available at:
https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-who-are-immunocompromised.html

† Frailty is a multidimensional geriatric syndrome and reflects a state of increased vulnerability to adverse health outcomes. Although there is no consensus definition, one frequently used tool is the Fried frailty phenotype in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10 pounds or 4.5 kilograms in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity.

‡ Among adults aged ≥ 60 years, RSV incidence increases with advancing age. Although age may be considered in determining an older adult patient's risk for severe RSV-associated disease, there is no specific age threshold at which RSV vaccination is more strongly recommended within the age group of adults aged 60 years.

B. Pregnancy: Administer at 32–36 weeks' gestation during every pregnancy using seasonal administration (September–January in most of the continental United States, including Oregon) for prevention of RSV-associated LRTI in infants aged < 6 months.

6. Contraindications[1,2]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Contains
ABRYSVO™[1]	Tromethamine, tromethamine hydrochloride, sucrose, mannitol, polysorbate 80, sodium chloride, host cell protein and DNA
AREXVY™[2]	Trehalose, sodium chloride, potassium dihydrogen phosphate, dipotassium phosphate, polysorbate 80, disodium phosphate anhydrous, dioleoyl phosphatidylcholine (DOPC), host cell protein and DNA

7. Warnings and Precautions[1,2,4]

A. Individuals with acute, moderate, or severe illness with or without fever should delay immunization until symptoms have improved.

B. Individuals with an immunocompromising condition may experience a diminished immune response to the vaccine.

C. Potential risk of preterm birth. To avoid the potential risk of preterm birth (defined as birth before 37 weeks' gestation), administer Abrysvo™ as indicated only to pregnant individuals at 32 through 36 weeks' gestational age.

8. Other Considerations[1,2,4]

A. Coadministration with other vaccines: Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable. Available data on immunogenicity of coadministration of RSV vaccines and other vaccines is currently limited. Coadministration of RSV and influenza vaccines met noninferiority criteria for immunogenicity except for a lower antibody response to the influenza A Darwin H3N2 strain when ABREXVY™ was administered with an adjuvanted quadrivalent inactivated influenza vaccine. The clinical significance of this is unknown.

Administering RSV vaccines with one or more other adult vaccines during the same visit may increase local or systemic reactogenicity. When determining whether to coadminister other vaccines with the RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preference.

B. Pregnancy and Breastfeeding: RSV vaccines are not approved for individuals <60 years of age. It is unknown if RSV vaccines are excreted in human milk.

C. Nirsevimab administration: Providers who care for pregnant persons should discuss the relative advantages and disadvantages of maternal RSV vaccination and nirsevimab and consider patient preferences when determining whether to vaccinate the pregnant person or to rely on administration of nirsevimab for prevention of RSV in the infant. Nirsevimab administration is recommended for infants aged < 8 months who are born during or are entering their first RSV season and whose mother did not receive a RSV vaccination or vaccination status is unknown; but administration of both products is not needed for most infants.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
ABRYSVO™[1]	
Fatigue	15.5%
Headache	12.8%
Injection site pain	10.5%
Myalgia	10.1%
Adults who are pregnant	
Preeclampsia	1.8% (95% CI 1.4, 2.3)
Gestational hypertension	1.1% (95% CI 0.8, 1.5)
AREXVY™[2]	
Injection site pain	60.9%
Fatigue	33.6%

Myalgia	28.9%
Headache	27.2%
Arthralgia	18.1%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
ABRYSVO™[1]	Store at 2°– 8°C (36°- 46°F)	Store in original carton and protect from light. Do not freeze. Discard if carton has been frozen.	Reconstituted vaccine may **only** be stored at room temperature, 15°– 30°C (59°- 86°F). Discard reconstituted vaccine if not used within 4 hours.
AREXVY™[2]			Reconstituted vaccine may be stored in the refrigerator between 2°– 8°C (36°- 46°F) or at room temperature up to 25°C (77°F). Discard reconstituted vaccine if not used within 4 hours.

11. References

1. Abrysvo™. [Package insert]. October 2023. https://www.fda.gov/media/168889/download. Accessed 10 October 2023.
2. Arexvy™. [Package insert]. May 2023. https://www.fda.gov/media/167805/download. Accessed 13 August 2023.
3. Melgar M, Britton A, Roper LE, et. al. Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR 2023; 72: 793-801. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm. Accessed 13 August 2023.
4. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus-associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices— United States, 2023. MMWR ePub: 9 October 2023. Available at http://dx.doi.org/10.15585/mmwr.mm7241e1. Accessed 9 Oct 2023.

12. Appendix

A. Centers for Disease Control and Prevention. Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2023. Available from: https://www.cdc.gov/vaccines/vpd/rsv/downloads/provider-job-aid-for-older-adults-508.pdf

Protocol for Tetanus Diphtheria Containing Vaccines (Adacel®, Boostrix®, TENIVAC®, and TDVAX™)

1. What's New

A. Updated recommendations to reflect that if Tdap is administered inadvertently to children 10 years of age that the Tdap dose may be counted as the adolescent dose recommended at age 11-12 years. This previously was considered to be an invalid dose.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of tetanus-containing vaccine, according to the age-appropriate schedule and vaccine history.

B. May be given with all ACIP-recommended child and adult vaccinations.

3. Vaccine Schedule

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM		
For unvaccinated persons ≥ 7 years of age[1]*		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥ 7 years	
2		4 weeks after dose 1
3		6 months after dose 2
The preferred schedule is 1 dose of Tdap, followed by either Td or Tdap for dose 2 & 3		
*See appendices for catch-up schedule for partially vaccinated children.		

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM		
Booster schedule for persons ≥ 10 years of age[2]		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
Adolescent booster	11 through18 years	These persons should receive a single dose of Tdap, preferably at age 11–12 years. For persons aged 7–9 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap dose should be administered at age 11–12 years. If a Tdap dose is administered at age ≥10 years, the Tdap dose may count as the adolescent Tdap dose.
Routine booster	≥19 years	Regardless of the interval since their last tetanus or diphtheria toxoid–containing vaccine, persons aged ≥19 years who have never received a dose of Tdap should receive 1 dose of Tdap.
Additional boosters		To ensure continued protection against tetanus and diphtheria, 1 booster dose of either Td or Tdap should be administered every 10 years throughout life.

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM
For Pregnant Persons[2]
Tdap should be administered during **every** pregnancy, at 27-36 weeks' gestation, preferably during the earlier part of the third trimester. Vaccination during the third trimester provides the highest concentration of maternal antibodies to be transferred closer to birth.
Tdap can be given at any time during pregnancy if needed for catch-up or wound management.

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM				
For Wound Management[2]				
History of absorbed tetanus toxoid doses	**Clean, minor wounds**		**All other wounds***	
	Tdap or Td	**TIG#**	**Tdap or Td**	**TIG#**
Unknown or <3 doses	Yes	No	Yes	Yes
≥ 3 doses	Administer if ≥ 10 years since last dose	No	Administer if ≥ 5 years since last dose	No
*Wounds contaminated with dirt, feces, soil or saliva; puncture wounds; avulsions; or wounds from missiles, crushing, burns or frostbite. #Persons with HIV or severe immunodeficiency should receive Tetanus Immune Globulin (TIG), regardless of immunization history or wound severity.				

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range***	**Thimerosal**
Adacel®[3]	Tetanus, diphtheria, and acellular pertussis	Single-dose vials and prefilled syringes containing a 0.5- mL suspension for injection	10-64 years	None
Boostrix®[4]			≥10 years	
TENIVAC®[5]	Tetanus and diphtheria		≥7 years	
TDVAX™[6]		Single-dose vials containing a 0.5- mL suspension for injection		≤0.3 mcg (not as a preservative)
*Off-label use is approved by ACIP				

5. Recommendations for Use

A. Routine use: All persons ≥11 years of age who have not received a dose of Tdap should receive a single dose of Tdap at the first opportunity, regardless of when they last received a Td booster.[1]

B. Catch-up vaccination: Persons who do not have documentation of receiving a series of diphtheria/tetanus-containing vaccine in childhood need a single-dose of Tdap and two doses of either Td or Tdap vaccine.

C. Pregnant persons: No change has been made to the recommendations for routine Tdap immunization during pregnancy. Pregnant persons should receive 1 dose of Tdap during each pregnancy, irrespective of their history of receiving the vaccine. Tdap should be

administered at 27–36 weeks' gestation, preferably during the earlier part of this period, although it may be administered at any time during pregnancy.

D. Wound management: Either Td or Tdap can be used for wound management. Tdap is preferred for persons who haven't previously received Tdap or whose history is unknown.[2]

6. Contraindications

A. Allergy: Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component, including latex (Adacel®, Boostrix®, Tenivac®)

Vaccine	Contains[7]
Adacel®	aluminum phosphate, formaldehyde, 2-phenoxyethanol, glutaraldehyde, tip caps of prefilled syringes may contain latex
Boostrix®	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80, tip caps of prefilled syringes may contain latex
Tenivac®	aluminum phosphate, formaldehyde, sodium chloride, tip caps of prefilled syringes may contain latex
TDVAX™	aluminum phosphate, formaldehyde, thimerosal

B. Encephalopathy: (Tdap) Encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures) not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap. These persons should receive Td in place of Tdap.[5]

7. Warnings and Precautions

A. Neurological disorders: (Tdap) Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized; these precautions are for pertussis components.[1]

B. Guillain-Barré syndrome: Guillain-Barré syndrome <6 weeks after a previous dose of tetanus toxoid-containing vaccine.[1]

C. Arthus-type hypersensitivity: History of Arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid–containing vaccines; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid–containing vaccine.[1]

8. Other Considerations

A. Catch up schedules for 7 through 18 years of age:

i. If patients' vaccination status is unknown or incomplete, guidance for catch-up schedules can be found at https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html

1. For children 7-9 years of age: https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-1.pdf
2. For children and adolescents 10-18 years of age: https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-2.pdf

B. History of disease:

i. Persons who have a history of pertussis should receive a booster dose of Tdap according to the routine recommendation. While pertussis disease likely confers some natural immunity, duration of protection is not long-term.[5]

ii. Tetanus or diphtheria disease does not confer immunity against re-infection. Persons who have a history of a primary series should receive a booster dose during convalescence. Persons without a history of vaccination should begin the 3-dose Tdap/Td series.[1]

C. Inadvertent administration of the incorrect formulation:[1]

i. DTaP is not indicated for persons aged ≥7 years. If DTaP is administered inadvertently to a fully vaccinated child aged 7 through9 years, an adolescent Tdap dose should be administered at age 11 through 12 years.

ii. If DTaP is administered inadvertently to an under-vaccinated child aged 7 through 9 years, this dose should count as the Tdap dose of the catch-up series, and the child should receive an adolescent booster dose of Tdap at age 11 through 12 years.

iii. If DTaP is administered inadvertently to a person aged ≥10 years, this dose should count as the adolescent Tdap dose Routinely administered at age 11 through 12 years.

iv. Children aged 7 through9 years who are fully vaccinated. If Tdap is administered inadvertently, the Tdap dose should not be counted as valid. The adolescent Tdap dose should be administered as recommended when this child is aged 11 through12 years.

v. Children aged 10 years who are fully vaccinated. If Tdap is administered inadvertently, the Tdap dose may be counted as the adolescent dose recommended at age 11 through12 years.

9. Side Effects and Adverse Reactions

Tdap[3,4] Adverse Events	Frequency
Injection site pain	Very common, up to 78%
Other local reactions (redness, swelling)	Less Common, up to 21%
Fever >100. 4°F	Uncommon, up to 5%
Other systemic reactions (fatigue, headache, GI symptoms)	Common, up to 43%

Td[5,6] Adverse Events	Frequency
Injection site pain	Very common, up to 81%
Other local reactions (redness, swelling)	Less Common, up to 26%
Fever >100. 4°F	Uncommon, up to 2%
Other systemic reactions (fatigue, headache, GI symptoms)	Less Common, up to 25%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Adacel®[3] Boostrix®[4] Tenivac®[5]	Store at 2°– 8°C (36°- 46°F)	Do not freeze. Do not use if vaccine has been frozen.	
TDAVAX™[6]			No latex.

11. References

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6. TDVAX™. [Package insert]. November 2018. www.fda.gov/media/76430/download . Accessed 23 July 2023.
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8. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). 20 June 2023. Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed 23 July 2023.

12. Appendix

A. N/A

Protocol for Yellow Fever Vaccine (YF-VAX®)

1. What's New

Updated references to reflect the updated 2024 CDC Yellow Book.

2. Immunization Protocol

A. Administer a 0.5-mL dose, SQ, of yellow fever vaccine to persons ≥7 years of age if indicated.

B. YF-VAX®[3] may be given with all other ACIP-recommended vaccines.

C. **You must be an Oregon-certified Yellow Fever (YF) vaccine provider to administer this vaccine**. More information on Oregon's yellow fever certification can be found at: https://www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/yellfev.aspx

3. Vaccine Schedule

Yellow Fever Vaccine (YF-VAX®)[3] Dose and Route – 0.5-mL SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
Booster[#]		10 years

[#]Not routinely recommended. See Recommendations for use.

4. Licensed Vaccine

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
YF-VAX®[1]	17D-204 strain of YF virus grown in chicken embryos with gelatin and sorbitol as a stabilizer	Vaccine vial, 1 Dose supplied in a package of 5 vials Diluent vial containing sodium chloride, 0.6 mL, supplied separately in a package of 5 vials Vaccine vial, 5 Dose supplied in a package of 1 vial Diluent vial, 3 mL supplied separately in a package of 1 vial	≥9 months	None

5. Recommendations for Use

A. Due to the risk of serious adverse events that can occur following YF vaccine administration, providers should carefully observe the contraindications and consider the precautions to vaccination prior to administration; and vaccinate only persons who are at risk of exposure to YF virus or who require proof of vaccination for country entry.[2]

B. YF vaccine is recommended for persons aged 7 years and older who are traveling to or living in areas at risk for yellow fever virus (YFV) transmission in Central and South America or Africa.[2]

C. Countries or areas with risk of yellow fever transmission are listed at: https://wwwnc.cdc.gov/travel/yellowbook/2024/preparing/yellow-fever-vaccine-malaria-prevention-by-country. Vaccination is also recommended for travel outside the urban areas

of countries that do not officially report the disease but that lie in a yellow fever-endemic zone.[2]

D. Yellow fever vaccination may be required for international travel. Some countries in Africa require evidence of YF vaccination from all entering travelers and some countries may waive the requirements for travelers arriving from areas where there is no current evidence of significant risk for contracting yellow fever and will be staying less than 2 weeks. Some countries require an individual, even if only in transit, to have a valid International Certificate of Vaccination if the individual has been in countries either known or thought to harbor yellow fever virus. The certificate becomes valid 10 days after vaccination with YF vaccine.[2]

E. Laboratory personnel who might be exposed to virulent yellow fever virus or to concentrated preparations of the yellow fever vaccine strain by direct or indirect contact or by aerosols should be vaccinated.[3]

F. Simultaneous Administration of Other Vaccines or Drugs: No evidence exists that inactivated vaccines and YF vaccine interfere with the immune response to the vaccine. Therefore, inactivated vaccines can be administered either simultaneously or at any time before or after YF vaccination. YF vaccine should be administered either simultaneously or 28 days apart from other live viral vaccines because the immune response to one live virus vaccine might be impaired if administered within 28 days of another live-virus vaccine.[6]

G. Booster Dose recommendations: As of July 11, 2016, International Health Regulations NO LONGER require revaccination at intervals of 10 years: a completed International Certificate of Vaccination or Prophylaxis is now valid for the lifetime of the vaccinee. Vaccine administrators should check national requirements.[4]

   a. High-Risk Travel: Travelers who received their last dose of yellow fever vaccine at least 10 years previously and who will be in a higher-risk setting based on season, location, activities, and duration of their travel. This would include travelers who plan to spend a prolonged period in endemic areas or those traveling to highly endemic areas such as rural West Africa during peak transmission season or an area with an ongoing outbreak.
   b. Hematopoietic stem cell transplant recipients: Persons who received a hematopoietic stem cell transplant after receiving a dose of yellow fever vaccine and who are sufficiently immunocompetent to be safely vaccinated should be revaccinated before their next travel that puts them at risk for yellow fever virus infection.
   c. HIV Infection: Persons who were infected with human immunodeficiency virus when they received their last dose of yellow fever vaccine should receive a dose every 10 years if they continue to be at risk for yellow fever virus infection.
   d. Pregnancy: Persons who were pregnant when they received their initial dose of vaccine should receive 1 additional dose before they are next at risk for YF.
   e. Laboratory workers: Individuals who routinely handle wild-type yellow fever virus should have yellow fever virus-specific neutralizing antibody titers measured at least every 10 years to determine if they should receive additional doses of the vaccine. For laboratory workers who are unable to have neutralizing antibody titers measured, yellow fever vaccine should be given every 10 years as long as they remain at risk.

6. Contraindications[1]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

B. History of life-threatening allergic reaction to eating eggs or chicken.
C. History of thymus disorders associated with abnormal immune cell function, such as thymomas or myasthenia gravis.[3]
D. Symptomatic HIV infection.[3]
E. History of primary immunodeficiencies, malignant neoplasms, transplantation, immunosuppressive or immunomodulatory therapies. Persons receiving current or recent radiation therapy or immunosuppressive drugs.[1]
F. Postpone vaccination in case of an acute or febrile disease.[1]

Vaccine	Contains
YF-VAX®[1]	sorbitol, gelatin, sodium chloride, egg protein

7. Warnings and Precautions

WARNING

Yellow fever vaccine-associated viscerotropic disease (YEL–AVD)[1]
YEL-AVD is a severe illness similar to wild-type YF disease, with vaccine virus proliferating and disseminating throughout the host's tissues. To date, two specific risk factors for YEL-AVD have been identified: older age and a history of thymus disease or thymectomy. YEL-AVD has been reported to occur only after the first dose of YF vaccine.

Yellow fever vaccine-associated neurotropic disease (YEL–AND)[1]
YEL-AND is a serious but rarely fatal adverse event that occurs in first-time YF vaccine recipients. YEL-AND represents a conglomeration of clinical syndromes, including meningoencephalitis, Guillain-Barré syndrome, acute disseminated encephalomyelitis, and cranial nerve palsies.

Adults ≥60 years of age[1]
Age ≥60 years is a precaution to receiving YF vaccine, particularly a first-ever dose. The risks of YEL-AVD and YEL-AND are higher in this age group.

A. Avoid vaccinating breastfeeding women against YF. However, when travel of nursing mothers to YF–endemic areas cannot be avoided or postponed, these women should be vaccinated. Some experts recommend breastfeeding women who receive YF vaccine should temporarily suspend breastfeeding, pump, and discard pumped milk for at least 2 weeks after vaccination before resuming breastfeeding. Lactation is a precaution for vaccination, particularly if the breastfeeding infant is <9 months of age, because of the risk of encephalitis.[4]
B. Pregnancy is a precaution, and pregnant persons should avoid travel to a yellow fever-endemic area. If travel is unavoidable and the vaccination risks outweigh the risks of YFV exposure, pregnant persons should be excused and issued a medical waiver to fulfill health regulations. Pregnant persons who must travel to areas where YFV exposure is likely should be vaccinated.[1]
C. Persons ≥60 years of age maybe at increased risk for serious adverse events after vaccination, compared with younger persons. The rate of serious adverse events following

vaccination is 1.5 times higher than the average rate for persons 60–69 years of age and 3 times higher for persons 70 years or older.
If travel is unavoidable, the decision to vaccinate travelers aged ≥60 years needs to be weighed against their destination-specific risk for exposure to YFV. Particular caution should be considered for older travelers receiving YF vaccine for the first time.[1]

D. Asymptomatic HIV infection with moderate immune suppression, i.e., CD4+ T-lymphocyte values of 200 to 499/mm^3 for persons aged ≥6 years old.[4]

8. Other Considerations

A. ACIP recommends that a woman wait 4 weeks after receiving the yellow fever vaccine before conceiving.[3]
B. Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.[5]
C. HIV-infected persons, because vaccination of asymptomatic HIV-infected persons might be less effective, measurement of their neutralizing antibody response to vaccination should be considered before travel. Contact CDC at 970-221-6400 to discuss serologic testing further.[6]
D. Allergic Reactions: less severe or localized manifestations of allergy to eggs or to feathers are not contraindications to vaccine administration and do not usually warrant vaccine skin testing.[1]
E. National YF vaccination requirements are mandatory and are primarily intended to prevent importation into and transmission of YF virus within a given country. Some countries require evidence of vaccination from all entering travelers. International Health Regulations stipulate that a Yellow Fever Stamp-Approved care provider may issue a waiver of yellow fever vaccination to a traveler, if the provider judges that yellow fever vaccination is medically contraindicated. The traveler also should be advised of the possibility that the medical waiver might not be accepted by the destination country. Failure to secure validations can cause a traveler to be quarantined, denied entry, or possibly revaccinated at the point of entry to a country.[4] Country requirements are subject to change at any time; therefore CDC encourages travelers to check with the appropriate embassy or consulate before departure. Because requirements may change, current information should be obtained from the CDC's Travelers' Health website: https://wwwnc.cdc.gov/travel/yellowbook/2024/preparing/yellow-fever-vaccine-malaria-prevention-by-country.
F. All travelers to yellow fever endemic countries should be advised of the risks of the disease and available methods to prevent it, including personal protective measures and vaccine. All travelers should take precautions to avoid mosquito bites to reduce the risk of YF and other vector-borne infectious diseases. These precautions include using insect repellent, wearing permethrin-impregnated clothing, and staying in screened or air conditioned-rooms. Additional information on protection against mosquitoes and other arthropods can be found at: https://wwwnc.cdc.gov/travel/page/avoid-bug-bites

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Local injection site reactions like pain, redness, swelling, rash	Up to 71.9%
Systemic symptoms like fever, tiredness, headache, muscle pain	Up to 30%
Vaccinees over 60 years of age are at increased risk of systemic adverse events and at lower risk of local reactions.	
Yellow Fever Vaccine–Associated Neurologic Disease (YEL-AND) YEL-AND represents a conglomeration of clinical syndromes, including meningoencephalitis, Guillain-Barré syndrome, acute disseminated encephalomyelitis, and, rarely, cranial nerve palsies	0.8/100,000 doses **Age ≥ 60 years:** 2.2/100,000 doses
Yellow Fever Vaccine–Associated Viscerotropic Disease (YEL-AVD) YEL-AVD is a severe illness similar to wild-type YF disease, with vaccine virus proliferating in multiple organs and often leading to multiorgan dysfunction or failure and occasionally death	0.3/100,000 doses **Age ≥ 60 years:** 1.2/100,000 doses

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
YF-VAX®[1]	2° to 8°C (36˚F to 46˚F)	Do not use if vaccine has been frozen.	Use immediately. Reconstituted vaccine not used must be discarded after one hour. Discarded vaccine must be either sterilized or disposed in red hazardous waste containers.

11. References

1. YF-VAX® February 2019 package insert. Available at: https://www.fda.gov/media/76015/download Accessed 13 April 2023.
2. Yellow Fever. In: 2024 Yellow Book: Health Information for International Travel. Gershman, M, Staples, JE. Available at: https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/yellow-fever. Accessed 17 January 2024.
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9. World Health Organization. Vaccine-preventable diseases, Yellow Fever. Available at: https://www.who.int/news-room/fact-sheets/detail/yellow-fever. . Accessed 6 February 2024.

12. Appendix

A. N/A

OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
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AND TRIBAL LIAISON

ARCHIVES DIVISION
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DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/17/2024 9:55 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amends rule to limit labeling exemption to nasal sprays consistent with 2023 SB 450

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
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Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/22/2024
TIME: 9:30 AM
OFFICER: Rachel Melvin

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 392711816
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.
If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name and email address to pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes to amend rule by adding requirements that limit labeling exemption to nasal sprays consistent with the directives of 2023 SB 450.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2023 SB 450 https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/SB450/Enrolled

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The proposed amendment is not expected to affect racial equity in this state.

FISCAL AND ECONOMIC IMPACT:

The proposed amendment has no anticipated fiscal and economic impact.

COST OF COMPLIANCE:

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

There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved with the development of proposed amendment to the rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Proposed amendments are consistent with the legislative mandate of 2023 SB 450, a RAC was not necessary.

AMEND: 855-115-0350

RULE SUMMARY: Proposes amending existing rule by adding that the labeling exemption only applies to nasal sprays as stated in 2023 SB 450.

CHANGES TO RULE:

855-115-0350
Services: Prescribing Practices - Short-acting Opioid Antagonists
(1) A Pharmacist may prescribe any FDA approved short-acting opioid antagonist (e.g., naloxone, nalmefene) and the necessary medical supplies to administer a short-acting opioid antagonist for opiate overdose:¶
(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME); ¶
(b) To an individual seeking a short-acting opioid antagonist; ¶
(c) To an entity seeking a short-acting opioid antagonist.¶
(2) A Pharmacist is not required to label the prescription according to OAR 855-041-1130 if dispensing a FDA approved short-acting opioid antagonist in the form of a nasal spray.¶
(3) The Pharmacist must document the encounter, the prescription and maintain records according to OAR 855-104-0055.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682, ORS 689.684, ~~2023 HB 2395, 2023 SB 450~~ORS 689.802, ORS 689.813

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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/17/2024 9:49 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Permits a supervising Pharmacist fluent in patient language to supervise Intern interpretation during counseling

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/22/2024
TIME: 9:30 AM
OFFICER: Rachel Melvin

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 392711816
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.
If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name and email address to pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

To align with OAR 855-115-0145, this proposed amendment clarifies that a supervising Pharmacist who is also fluent in the language being interpreted may communicate directly with a patient who prefers to communicate in a language other than English or who communicates in signed language without mandating the use of a health care interpreter registered by the Oregon Health Authority.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

ORS 413.558 https://www.oregonlegislature.gov/bills_laws/ors/ors413.html
OAR 855-115-0145 https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=308901
OAR 855-120-0150 https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=304249

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The proposed amendment may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated.

FISCAL AND ECONOMIC IMPACT:

No fiscal or economic impacts are anticipated.

COST OF COMPLIANCE:

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

There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

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

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

The board adopted Division 120 Interns and Preceptors effective 3/1/2024. The resources involved in convening an RAC were not necessary to amend this rule.

AMEND: 855-120-0150

RULE SUMMARY: Proposes amending (1)(c) by incorporating “Pharmacist or” to allow a supervising Pharmacist or a Preceptor who is also fluent in the language being interpreted to communicate with a patient who prefers to communicate in a language other than English or who communicates in signed language without mandating the use of a health care interpreter registered by the Oregon Health Authority. Interns are only permitted to practice pharmacy under the supervision of a Pharmacist or a Healthcare Preceptor with the practice of pharmacy within their scope.

CHANGES TO RULE:

855-120-0150
Prohibited Practices - Intern
(1) An Intern must not:¶
(a) Practice pharmacy as defined in ORS 689.005 except as permitted by the Pharmacist or Healthcare Preceptor who is supervising the Intern;¶
(b) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace; ¶
(c) Communicate (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, unless the Intern is a health care interpreter registered by the Oregon Health Authority under ORS 413.558 or the supervising Pharmacist or Preceptor is also

fluent in the language being interpreted; or¶
(d) Engage in patient care services when the supervising Pharmacist is not trained and qualified to perform the service.¶
(2) Until an Intern has successfully completed their first academic year, an Intern may observe, but must not:¶
(a) Conduct a Drug Utilization Review or Drug Regimen Review;¶
(b) Counsel a patient or the patient's agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in the patient's record or chart;¶
(c) Advise on therapeutic values, content, hazards and use of drugs and devices;¶
(d) Conduct Medication Therapy Management;¶
(e) Practice pursuant to a Clinical Pharmacy Agreement or engage in Collaborative Drug Therapy Management;¶
(f) Practice pursuant to Statewide Drug Therapy Management Protocols;¶
(g) Prescribe a vaccine, drug or device; or ¶
(h) Perform verification as defined in OAR 855-006-0005.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

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SECRETARY OF STATE

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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/17/2024 10:12 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Repeals Div 020 Protocol Compendium

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
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800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/22/2024
TIME: 9:30 AM
OFFICER: Rachel Melvin

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 392711816
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.
If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name and email address to pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes to permanently repeal OAR 855-020-0300 Protocol Compendium which is now located in OAR 855-115-0345.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

OAR 855-115-0345 https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=311546

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

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

FISCAL AND ECONOMIC IMPACT:

The proposed rule repeal has no anticipated fiscal and economic impact.

COST OF COMPLIANCE:

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

The proposed rule repeal will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

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

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

No. The board adopted new Division 115 Pharmacists rules effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

REPEAL: 855-020-0300

RULE SUMMARY: Permanently repeals OAR 855-020-0300 Protocol Compendium. The board adopted Division 115 Pharmacists rules effective 3/1/2024 which replace Division 020. OAR 855-115-0345 includes current versions of the protocols.

CHANGES TO RULE:

~~855-020-0300~~
~~Protocol Compendium~~
~~A Pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium:¶~~
~~(1) Continuation of therapy including emergency refills of insulin (v. 06/2023)¶~~
~~(2) Conditions¶~~
~~(a) Cough and cold symptom management¶~~
~~(A) Pseudoephedrine (v. 06/2021);¶~~
~~(B) Benzonatate (v. 06/2021);¶~~
~~(C) Short-acting beta agonists (v. 06/2021);¶~~
~~(D) Intranasal corticosteroids (v. 06/2021);¶~~
~~(b) Vulvovaginal candidiasis (VVC) (v. 06/2021);¶~~
~~(c) COVID-19 Antigen Self-Test (v. 12/2021); ¶~~
~~(3) Preventative care¶~~
~~(a) Emergency Contraception (v. 06/2021);¶~~
~~(b) Male and female condoms (v. 06/2021);¶~~
~~(c) Tobacco Cessation, Nicotine Replacement Therapy (NRT) and Non-NRT (v. 06/2022);¶~~
~~(d) Travel Medications (v. 06/2023);¶~~
~~(e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);¶~~
~~(f) HIV Pre-exposure Prophylaxis (PrEP) (v. 06/2023); ¶~~

~~(g) Contraception (v. 06/2023); and ¶~~
~~(h) Vaccinations:¶~~
~~(A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 2/2024); ¶~~
~~(B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 2/2024); ¶~~
~~(C) Cholera (v. 2/2024); ¶~~
~~(D) Coronavirus 2019 (v. 2/2024); ¶~~
~~(E) Haemophilus Influenza type b (v. 2/2024)¶~~
~~(F) Hepatitis A containing vaccines (v. 2/2024); ¶~~
~~(G) Hepatitis B containing vaccines (v. 2/2024); ¶~~
~~(H) Human Papillomavirus (v. 2/2024); ¶~~
~~(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 2/2024); ¶~~
~~(J) Influenza - Live Attenuated Influenza Vaccine 2023-24 (v. 2/2024); ¶~~
~~(K) Japanese Encephalitis (v. 2/2024); ¶~~
~~(L) Meningococcal containing vaccines (v. 2/2024); ¶~~
~~(M) Measles Mumps & Rubella containing vaccines (v. 2/2024); ¶~~
~~(N) Pneumococcal (v. 2/2024); ¶~~
~~(O) Polio (v. 2/2024); ¶~~
~~(P) Rabies (v. 2/2024); ¶~~
~~(Q) Respiratory Syncytial Virus (v. 2/2024);¶~~
~~(R) Tetanus Diphtheria containing vaccines (v. 2/2024);¶~~
~~(S) Typhoid (v. 2/2024); ¶~~
~~(T) Varicella containing vaccines (v. 2/2024);¶~~
~~(U) Yellow fever (v. 2/2024); ¶~~
~~(V) Zoster (v. 2/2024).¶~~
~~[Publications referenced are available from the agency.]~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689, ORS 689.696~~

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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/17/2024 2:52 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Updates incorporated standards adopted by reference

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/22/2024
TIME: 9:30 AM
OFFICER: Rachel Melvin

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 392711816
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.
If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name and email address to pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposed amendments incorporate updated standards adopted by reference as required by the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019). Removes outdated terminology related to individuals with intellectual disabilities.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Adopted Standards by Reference- 16 CFR (01/01/2023), 21 CFR (04/01/2023), 21 USC 352 (03/23/2024), 21 USC 353

(03/23/2024) 21 USC 351 (03/23/2024), 21 USC 811 (03/23/2024), 21 USC 812 (03/23/2024), 21 USC 822 (03/23/2024), 21 USC 822a (03/23/2024), 21 USC 827 (03/23/2024), 21 USC 828 (03/23/2024), 42 USC 262 (03/23/2024), United States Pharmacopeia <USP> and National Formulary <NF> (USP NF 2023, Issue 3 v. 2023), Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2024)https://www.hpus.com/ USP 1229.5 (08/01/2022), and DEA Table of Exempted Prescription Products (01/11/2024) https://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf, Accreditation Council on Pharmaceutical Education (ACPE) Accredited Providers of Continuing Pharmacy Education (04/02/2024) https://www.acpe-accredit.org/accredited-providers-by-state/, and Accredited Colleges/Schools of Pharmacy (04/02/2024) https://www.acpe-accredit.org/accredited-programs-by-state/, Accreditation Council for Continuing Medical Education (ACCME) or an ACCME-recognized State Medical Society Accredited Providers of Continuing Medical Education (03/2024) https://accme.org/sites/default/files/2024-03/625_20240326_currently_accredited_cme_providers_upload.xlsx

Terminology- Rosa's Law. Public Law 111-256 (2010) https://www.govinfo.gov/content/pkg/STATUTE-124/pdf/STATUTE-124-Pg2643.pdf. Accessed March 28, 2024.

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

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 AND ECONOMIC IMPACT:

No fiscal impact is anticipated related to adoption of standards by reference.

COST OF COMPLIANCE:

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

There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

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

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Amendments are required per ORS 183.337 pursuant to ORS 475.035 and ORS 475.055.

RULES PROPOSED:

855-006-0005, 855-041-1046, 855-041-1092, 855-041-1145, 855-041-7050, 855-043-0545, 855-043-0740, 855-045-0200, 855-045-0205, 855-080-0020, 855-080-0021, 855-080-0022, 855-080-0023, 855-080-0024, 855-080-0026, 855-080-0028, 855-080-0031, 855-080-0065, 855-080-0070, 855-080-0075, 855-080-0085, 855-115-0125,

855-120-0005, 855-135-0001, 855-139-0145, 855-139-0350, 855-139-0460, 855-141-0350

AMEND: 855-006-0005

RULE SUMMARY: Proposes to amend referenced versions of the United States Code (USC), United States Pharmacopeia (USP), and Homeopathic Pharmacopoeia of the United States (HPUS). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-006-0005
Definitions ¶

As used in OAR Chapter 855:¶
(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. 03/21~~1~~3/202~~3~~4).¶
(2) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.¶
(3) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.¶
(4) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.¶
(5) "Biosimilar" product means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (v. ~~12~~03/2~~8~~3/202~~2~~4).¶
(6) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.¶
(7) "Certified health care interpreter" has the meaning given that term in ORS 413.550.¶
(8) "Certified Oregon Pharmacy Technician" means a person who has taken and passed a national pharmacy technician certification examination offered by the Pharmacy Technician Certification Board (PTCB) or National Healthcareer Association (NHA) and is licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board.¶
(9) "Clinical Pharmacy Agreement" means an agreement between a Pharmacist or pharmacy and a health care organization, or a physician as defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010 that permits the Pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization, or physician or naturopathic physician.¶
(10) "Collaborative Drug Therapy Management" means the participation by a Pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration, and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:¶
(a) Is agreed to by one Pharmacist and one practitioner; or¶
(b) Is agreed to by one or more Pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic, or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.¶
(11) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:¶
(a) As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the Pharmacist and the patient, in the course of professional practice; or¶
(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or¶
(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.¶
(12) "Confidential Information" means any patient information obtained by a Pharmacist or pharmacy.¶
(13) "Consulting Pharmacist" means a Pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.¶
(14) "Counseling" or "Counsel" means communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device. ¶
(15) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.¶

(16) "Custodian of pharmacy records" means a board licensee or registrant who is responsible for the maintenance, care or keeping of pharmacy records based on the services provided by the pharmacy, regardless of whether the records are in that person's actual physical custody and control.¶
(17) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.¶
(18) "Drug Regimen Review" or "DRR" means the process conducted by a Pharmacist who is consulting for a long-term-care facility or other institution, either prior to dispensing or at a later time, with the goal of ensuring that optimal patient outcomes are achieved from the drug therapy.¶
(19) "Drug utilization review" or "DUR" means evaluation of a prescription to identify and resolve potential problems through the review of information provided to the Pharmacist by the patient, patient's agent, prescriber and the patient's record.¶
(20) "Entry system" enables control of access to a secured area.¶
(21) "Final verification" means after prescription information is entered into a pharmacy's electronic system and reviewed by a Pharmacist for accuracy, a physical verification that the drug and drug dosage, device or product selected from a pharmacy's inventory pursuant to the electronic system entry is the prescribed drug and drug dosage, device, or product.¶
(22) "Good standing" means a license or registration that is not suspended, revoked, or otherwise restricted from the practice of pharmacy or subject to a current disciplinary order.¶
(23) "Health care interpreter" has the meaning given that term in ORS 413.550.¶
(24) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.¶
(25) "Individual with limited English proficiency" means a person who, by reason of place of birth or culture, communicates in a language other than English and does not communicate in English with adequate ability to communicate effectively with a health care provider.¶
(26) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 USC 262(k)(4) (v. ~~12~~03/2~~8~~3/202~~2~~4).¶
(27) "Intern" means a person who is enrolled in or has completed a course of study at a board approved college or school of pharmacy and who is licensed with the board as an Intern.¶
(28) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.¶
(29) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.¶
(30) "Misbranded" has the same definition as set forth in 21 USC 352 (v. ~~12~~03/2~~8~~3/202~~2~~4).¶
(31) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.¶
(32) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.¶
(33) "Nationally Certified Exam" means an exam that is approved by the board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible, and valid.¶
(34) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.¶
(35) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:¶
(a) The creation and retention of accurate and complete patient records;¶
(b) Assuming authority and responsibility for product selection of drugs and devices;¶
(c) Developing and maintaining a safe practice setting for the Pharmacist, for pharmacy staff and for the general

public;¶
(d) Maintaining confidentiality of patient information.¶
(36) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (v. USP NF 2023, Issue ~~1~~3), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 202~~3~~4), or any supplement to any of these.¶
(37) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:¶
(a) Cure of a disease;¶
(b) Elimination or reduction of a patient's symptomatology;¶
(c) Arrest or slowing of a disease process; or¶
(d) Prevention of a disease or symptomatology.¶
(38) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.¶
(39) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board.¶
(40) "Practice of clinical pharmacy" means:¶
(a) The health science discipline in which, in conjunction with the patient's other practitioners, a Pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;¶
(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and¶
(c) The practice of pharmacy by a Pharmacist pursuant to a clinical pharmacy agreement.¶
(41) "Practice of pharmacy" is as defined in ORS 689.005.¶
(42) "Prescription drug" or "legend drug" is as defined in ORS 689.005 and:¶
(a) Required by federal law, prior to being dispensed or delivered, to be labeled with "Rx only"; or¶
(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.¶
(43) "Prescription released by the Pharmacist" means, a prescription which has been reviewed by the Pharmacist that does not require further Pharmacist intervention such as reconstitution or counseling.¶
(44) "Prohibited conduct" means conduct by a licensee that:¶
(a) Constitutes a criminal act against a patient or client; or¶
(b) Constitutes a criminal act that creates a risk of harm to a patient or client.¶
(45) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:¶
(a) Assure retention of their purity and potency;¶
(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;¶
(c) Assure security and minimize the risk of their loss through accident or theft;¶
(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;¶
(e) Protect the health, safety and welfare of the Pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.¶
(46) "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.¶
(47) "Reasonable professional judgment" means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities, qualifications, and competencies, after careful review, analysis and consideration of the relevant subject matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion, or conclusion.¶
(48) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (v. ~~12~~03/2~~8~~3/202~~2~~4) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.¶
(49) "Repackage" means the act of taking a drug from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug.¶
(50) "Still image capture" means a specific image captured electronically from a video or other image capture device.¶
(51) "Store and forward" means a video or still image record which is saved electronically for future review.¶
(52) "Supervision by a Pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the Intern, Certified Oregon Pharmacy Technician or

Pharmacy Technician being supervised, coupled with the ability to control and be responsible for the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician's action.¶
(53) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.¶
(54) "Tamper-resistant Prescription" means a form for the purpose of issuing a handwritten or typed prescription, intended to be manually delivered to a pharmacy, which has been developed, and formatted to ensure security, integrity and authenticity using currently accepted technologies. Formatted features may include but are not limited to characteristics such as:¶
(a) The word "void" appears when photocopies are attempted;¶
(b) Background ink which reveals attempted alterations;¶
(c) Heat sensitive ink that changes colors;¶
(d) Penetrating ink to prevent chemical alterations;¶
(e) A watermark which cannot be photocopied;¶
(f) Coin reactive ink that reveals word when rubbed with a coin;¶
(g) Sequential numbering.¶
(55) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.¶
(56) "Verification" means the confirmation by the Pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an Intern, a Certified Oregon Pharmacy Technician, or a Pharmacy Technician. ¶
[Publications: Publications referenced are available for review at the agency or from United States Pharmacopoeia.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.005, ORS 689.151, ORS 689.155, ORS 689.703

AMEND: 855-041-1046

RULE SUMMARY: Proposes to amend referenced versions of the United States Code (USC) and Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-041-1046
Secure and Responsible Drug Disposal ¶

(1) A pharmacy that operates a drug take back collection program or that participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered with the DEA as an authorized collector to collect controlled and non-controlled drugs for destruction.¶
(2) A pharmacy that operates as a Drug Enforcement Agency (DEA) authorized collector must notify the board within 30 days of initiating or terminating the program and must establish and enforce policies and procedures, including but not limited to:¶
(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is accessible to the public, within view of the pharmacy counter and must not be located behind the pharmacy counter; and¶
(b) Provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation, and key accountability; and¶
(c) Personnel training and accountability.¶
(3) A pharmacy must inform consumers to directly deposit drugs into the collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected.¶
(4) A pharmacy must not dispose of drugs from pharmacy stock in a collection receptacle.¶
(5) The liner must be inserted and removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel.¶
(6) Liners that have been removed from a collection receptacle and immediately sealed must be directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution agent (such as registered UPS, FedEx, or USPS) or a reverse wholesaler registered with the DEA and the board.¶
(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to the board in writing within one day of discovery.¶
(8) A pharmacy must maintain all drug disposal records for a minimum of 3 years.¶
(9) Authorized collectors are required to comply with the following federal and state laws:¶
(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236, ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;¶
(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370, and OAR 340-098-0390;¶
(c) 21 CFR 1317.30 (04/01/2022), 21 CFR 1317.35 (04/01/202~~2~~3), 21 CFR 1317.40 (04/01/202~~2~~3), 21 CFR 1317.55 (04/01/202~~2~~3), 21 CFR 1317.60 (04/01/202~~2~~3), 21 CFR 1317.65 (04/01/202~~2~~3), 21 CFR 1317.70 (04/01/202~~2~~3), 21 CFR 1317.75 (04/01/202~~2~~3), 21 CFR 1317.80 (04/01/202~~2~~3), and 21 CFR 1317.85 (04/01/202~~2~~3); and¶
(d) 21 USC 822 (03/20~~3~~/2023~~4~~) and 21 USC 822a (03/20~~3~~/2023~~4~~).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218

AMEND: 855-041-1092

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-041-1092
Retail Drug Outlet Pharmacy Closures: Temporary, Permanent or Emergency
(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a Retail Drug Outlet pharmacy is temporarily closed to the public the pharmacy must:¶
(a) Post notification of closure on each pharmacy entrance as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must include:¶
(A) Estimated period of time the pharmacy will be closed; and¶
(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).¶
(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:¶
(A) Estimated period of time the pharmacy will be closed; and¶
(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).¶
(c) If the pharmacy is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.¶
(d) Federal and state holidays are exempt from the requirements of (1).¶
(2) Permanent Closing. If a Retail Drug Outlet pharmacy is permanently closing to the public, the pharmacy must:¶
(a) Prior to closing, the pharmacy must comply with the following:¶
(A) Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:¶
(i) The last day the pharmacy will be open;¶
(ii) Name, address and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records;¶
(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and¶
(iv) The last day a transfer may be initiated.¶
(B) The notification must be made via:¶
(i) Distribution by direct mail or written notice with each prescription dispensed;¶
(ii) Public notice in a newspaper of general circulation, if available, in the area served by the pharmacy; and¶
(iii) Posting a closing notice on each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).¶
(iv) In addition to (i), (ii) and (iii), the pharmacy may also provide notification via email or text.¶
(C) Provide any new patients filling prescriptions during the 15 calendar day period prior to the pharmacy closing with written notification that includes:¶
(i) The last day the pharmacy will be open;¶
(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records;¶
(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and¶
(iv) The last day a transfer may be initiated.¶
(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/202~~2~~3).¶
(b) On the date of closing or up to 24 hours after the permanent closure begins, the Pharmacist-in-charge must comply with the following:¶
(A) Complete and document an inventory of all controlled substances.¶
(B) If the pharmacy dispenses prescriptions:¶
(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed Pharmacist who will serve as the custodian of records;¶
(ii) Update the pharmacy operating status with each electronic prescribing vendor; and¶
(iii) Remove all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications).¶

(c) After closing. Within 30 calendar days after the closing of the pharmacy, the Pharmacist-in-charge must:¶
(A) Complete and document an inventory of all non-controlled drugs and devices.¶
(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the pharmacy by one or a combination of the following methods:¶
(i) Return to manufacturer or supplier (credit or disposal);¶
(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or¶
(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (04/01/2022~~2~~3), 21 CFR 1304.22 (04/01/2022~~2~~3), 21 CFR 1317.05 (04/01/2022~~2~~3), 21 CFR 1317.90 (04/01/2022~~2~~3) and 21 CFR 1317.95 (04/01/2022~~2~~3).¶
(C) Provide the board a written notice of the closing on a board prescribed form which includes the following information:¶
(i) Date of closing to the public and discontinuance of the business;¶
(ii) Date and time the inventory of all prescription drugs and devices was conducted;¶
(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the pharmacy were transferred or disposed;¶
(iv) If drugs were destroyed, name and license numbers of individuals that who witnessed the destruction;¶
(v) If the pharmacy is registered to possess controlled substances, confirmation that the pharmacy complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2022~~2~~3) for discontinuing operation as a pharmacy that dispenses controlled substances.¶
(vi) The name, address and phone number of the pharmacy that took possession of the pharmacy records or the Oregon licensed Pharmacist who is serve as the custodian of pharmacy records which must be maintained according to OAR 855-041-1160;¶
(vii) Confirmation all pharmacy labels and blank prescriptions were destroyed;¶
(viii) Confirmation all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and¶
(ix) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.¶
(D) Once the pharmacy has notified the board that the pharmacy is permanently closed, the license may not be renewed. The pharmacy may apply for a new license as specified in OAR 855-041-1080.¶
(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.¶
(3) Emergency closing. If a Retail Drug Outlet pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, or other emergency circumstances and the Pharmacist-in-charge cannot provide notification as required in (1), the Pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.¶
(4) Non-resident Retail Drug Outlet pharmacies are exempt from (1)-(3) and must follow laws and rules in the pharmacy's state of residence pertaining to temporary, permanent and emergency closures. The non-resident pharmacy must provide the board a written notice of the closing within 30 calendar days on a form prescribed by the board which includes the following information:¶
(a) Date of closing to the public and discontinuance of the business;¶
(b) If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or Oregon licensed Pharmacist who will serve as the custodian of records for Oregon patients to which the prescriptions, including refill information, and patient medication records were transferred; and¶
(c) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.¶
(5) The board may conduct an inspection to verify all requirements in subsection (1), (2), (3) and (4) of this section have been completed.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 475.035
Statutes/Other Implemented: ORS 689.205

AMEND: 855-041-1145

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-041-1145
New Containers ¶

Each pharmacy must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022~~2~~3), 16 CFR 1701 (01/01/2022~~2~~3), and 16 CFR 1702 (01/01/2022~~2~~3).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-7050

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Removes outdated terminology related to individuals with intellectual disabilities. Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-041-7050
Definitions - Long Term Care Pharmacy ¶

As used in OAR 855-041-7000 through 855-041-7080:¶
(1) "Long term care facility" means a facility with permanent facilities that include inpatient beds, providing medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the director, to provide treatment for two or more unrelated patients. "Long Term Care facility" includes skilled nursing facilities and intermediate care facilities but may not be construed to include facilities licensed and operated pursuant to ORS 443.400 to 443.455.¶
(2) For the purposes of Schedule II prescriptions in 21 CFR 1306.11 (04/01/202~~2~~3), 21 CFR 1306.12 (04/01/202~~2~~3), 21 CFR 1306.13 (04/01/202~~2~~3), 21 CFR 1306.14 (04/01/202~~2~~3), and 21 CFR 1306.15 (04/01/202~~2~~3), the DEA definition of "long term care facility" as defined in 21 CFR 1300.01 (04/01/202~~2~~3) includes "community-based care facilities."¶
(3) "Community Based Care Facility" means a home, facility or supervised living environment licensed or certified or otherwise recognized by an agency of the state of Oregon which provides 24-hour care, supervision, and assistance with medication administration. These include but are not limited to Adult Foster Homes, Residential Care Facilities (RCF), Assisted Living Facilities (ALF), ~~Group Homes for the Developmentally Disabled and Mentally Retarded~~Intermediate Care Facilities for Individuals with Intellectual Disabilities and Inpatient Hospice.¶
(4) "Pharmaceutical Care" means the responsible provision of any or all of the following services by the pharmacist:¶
(a) Develop and maintain policies and procedures for pharmaceutical services;¶
(b) Provide direction and oversight regarding all aspects of the acquisition, disposition, handling, storage, and administration of drugs including but not limited to the following:¶
(A) Receipt and interpretation of physician's orders;¶
(B) Ordering and receiving of medications;¶
(C) Handling of emergency drugs and supplies;¶
(D) Labeling of all drugs;¶
(E) Selection of drug delivery systems;¶
(F) Development of systems to provide timely delivery of drugs and supplies;¶
(G) Monitoring of drug storage conditions and expiration dates;¶
(H) Monitoring accuracy and efficiency of medication administration and compliance with physician's orders;¶
(I) Establishing and monitoring of appropriate record keeping;¶
(J) Accountability of controlled substances;¶
(K) Return, release, and/or destruction of discontinued or outdated drugs; and¶
(L) Compliance with state and federal laws and regulations related to pharmaceutical services and medication management.¶
(c) Provide training and in-service education to facility staff;¶
(d) Perform drug regimen review for each resident on a regularly scheduled basis for the purpose of promoting therapeutic appropriateness and achieving the desired drug therapy outcomes by identifying issues such as:¶
(A) Over-utilization or underutilization;¶
(B) Therapeutic duplication;¶
(C) Drug-disease contraindications;¶
(D) Drug-drug interactions;¶
(E) Incorrect drug, drug dosage or duration of drug treatment;¶
(F) Drug-allergy interaction;¶
(G) Clinical abuse/misuse;¶
(H) Untreated indication;¶
(I) Monitoring and assessing of drug therapy outcomes;¶
(e) Communicate effectively with residents' physicians and facility staff; and¶
(f) Participate in resident care planning. ¶

[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

AMEND: 855-043-0545

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-043-0545
Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery
(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by the practitioner's licensing board.¶
(2) Drugs dispensed from the DPDO must be dispensed in compliance with the requirements of the practitioner's licensing board.¶
(3) A DPDO must comply with all requirements of State or federal law.¶
(4) A DPDO must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/202~~2~~3), 16 CFR 1701 (01/01/202~~2~~3) and 16 CFR 1702 (01/01/202~~2~~3).¶
(5) Dispensed drugs must be packaged by the DPDO, a pharmacy, or a manufacturer registered with the board.¶
(6) A DPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.¶
(7) A DPDO may deliver or mail prescription to the patient if:¶
(a) Proper drug storage conditions are maintained; and¶
(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:¶
(A) Drug name, class and indications;¶
(B) Proper use and storage;¶
(C) Common side effects;¶
(D) Precautions and contraindications; and¶
(E) Significant drug interactions.¶
(8) The DPDO must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.¶
(9) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-043-0740

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-043-0740
Community Health Clinic (CHC) - Dispensing and Drug Delivery ¶

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.¶
(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.¶
(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.¶
(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.¶
(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.¶
(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/202~~2~~3), 16 CFR 1701 (01/01/202~~2~~3) and 16 CFR 1702 (01/01/202~~2~~3).¶
(7) Dispensed drugs must be packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the board.¶
(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.¶
(9) A CHC must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.¶
(10) A CHC may deliver or mail prescription to the patient if:¶
(a) Proper drug storage conditions are maintained; and¶
(b) The CHC offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:¶
(A) Drug name, class and indications;¶
(B) Proper use and storage;¶
(C) Common side effects;¶
(D) Precautions and contraindications; and¶
(E) Significant drug interactions.¶
(11) The CHC must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.¶
(12) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

AMEND: 855-045-0200

RULE SUMMARY: Proposes to amend referenced versions of the United States Pharmacopeia (USP). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-045-0200
Application ¶

(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for use or distribution in Oregon must register with the board as a drug outlet and comply with board regulations.¶
(2) These rules apply to sterile and non-sterile compounding of a drug.¶
(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:¶
(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (05/01/2020 v. 2014);¶
(b) USP <797> Pharmaceutical Compounding-Sterile Preparations (05/01/2020 v. 2008);¶
(c) USP <800> Hazardous Drugs-Handling in Healthcare Settings (07/01/2020 v. 2020);¶
(d) USP <825> Radiopharmaceuticals-Preparation, Compounding, Dispensing, and Repackaging (01~~2~~/01/202~~0 v. 2020~~4); and¶
(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (0~~5~~9/01/202~~0~~3), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (10~~5~~/01/20~~15~~23), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2022), 1231 (12/01/2021), and 1821 (05/01/2017). ¶
[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-045-0205

RULE SUMMARY: Proposes to amend referenced versions of the United States Pharmacopeia (USP). Adds statement that referenced publications are available for review. Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-045-0205
Compliance with New Standards
As an alternative to the requirements in OAR 855-045-0200(3)(a) and (3)(b) registrants may comply with any or all standards contained in: ¶
(1) USP <795> Pharmaceutical Compounding-Non-Sterile Preparations (11/1/202~~2~~3).¶
(2) USP <797> Pharmaceutical Compounding-Sterile Preparations (11/1/202~~2~~3).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-080-0020

RULE SUMMARY: Proposes to amend referenced versions of the United States Code (USC). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0020
Schedules ¶

Pursuant to ORS 475.005(6) those drugs and their immediate precursors classified in Schedules I through V under the Federal Controlled Substances Act, 21 USC 811 (03/20~~0~~3/2023~~4~~), 21 USC 812 (03/20~~0~~3/2023~~4~~) and as amended by the board pursuant to ORS 475.035 are the controlled substances for purposes of regulation and control under the Act. Those schedules are set out in OAR 855-080-0021 through 855-080-0026.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0021

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0021
Schedule I ¶

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.11 (04/01/2022~~2~~3), and unless specifically exempt or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:¶
(a) 1,4-butanediol;¶
(b) Gamma-butyrolactone¶
(c) Methamphetamine, except as listed in OAR 855-080-0022;¶
(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)¶
(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.¶
(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,¶
(A) Methylmethcathinone (Mephedrone);¶
(B) Methylenedioxypyrovalerone (MDPV);¶
(C) Methylenedioxymethylcathinone (Methylone);¶
(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);¶
(E) Fluoromethcathinone (Flephedrone);¶
(F) 4-Methoxymethcathinone (Methedrone).¶
(2) Schedule I also includes any compounds in the following structural classes (2a-2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:¶
(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;¶
(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;¶
(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;¶
(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);¶
(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;¶
(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;¶
(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution

at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;¶
(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;¶
(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;¶
(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and¶
(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.¶
(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) is not an FDA approved drug or is exempted from the definition of controlled substance in ORS 475.005(6)(b)(A)-(E).¶
(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.¶
(5) Schedule I also includes any compounds in the following structural classes (a - b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:¶
(a) Benzodiazepine class: A fused 1,4-diazepine and benzene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Clonazolam, Flualprazolam¶
(b) Thienodiazepine class: A fused 1,4-diazepine and thiophene ring structure with a phenyl connected to the 1,-4-diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Etizolam¶
(6) Exceptions. The following are exceptions to subsection (1) of this rule:¶
(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;¶
(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;¶
(c) The following substances per ORS 475.005(6)(b):¶
(A) The plant Cannabis family Cannabaceae;¶
(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;¶
(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;¶
(D) The seeds of the plant Cannabis family Cannabaceae; or¶
(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph. ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055, ORS 475.065

AMEND: 855-080-0022

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0022
Schedule II ¶

Schedule II consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.12 (04/01/2022~~2~~3) and any quantity of methamphetamine, when in the form of a FDA approved product containing methamphetamine, its salts, isomers, and salts of its isomers as an active ingredient for the purposes of currently accepted medical use. ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055, ORS 475.065

AMEND: 855-080-0023

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0023
Schedule III ¶

Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.13 (04/01/2022~~2~~3). ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 475.973
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0024

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0024
Schedule IV ¶

Schedule IV consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.14 (04/01/2022~~2~~3), unless specifically excepted or listed in another schedule. ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

AMEND: 855-080-0026

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0026
Schedule V ¶

Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.15 (04/01/202~~2~~3); and¶
(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.¶
(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.¶
(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active ingredient.¶
(4) In order to provide non-prescription pseudoephedrine or ephedrine to a purchaser, a pharmacy must:¶
(a) Store all pseudoephedrine and ephedrine behind the pharmacy counter in an area that is inaccessible to the public;¶
(b) Utilize an electronic system meeting the requirements under ORS 475.230;¶
(c) Train individuals who are responsible for providing pseudoephedrine or ephedrine to purchasers on the requirements of the Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177), the Combat Methamphetamine Enhancement Act of 2010, P.L. 111-268, and use of the electronic system as described in ORS 475.230;¶
(d) Ensure that only a Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician provides pseudoephedrine or ephedrine to the purchaser after:¶
(A) Verifying that the purchaser is 18 years of age or older;¶
(B) Verifying the identity of the purchaser with valid government-issued photo identification; and¶
(C) Confirming the purchase is allowed via the electronic system; and¶
(e) Maintain an electronic log for at least three years from the date of the transaction that documents the following elements:¶
(A) Date and time of the purchase;¶
(B) Name, address and date of birth of the purchaser;¶
(C) Form of government-issued photo identification and the identification number used to verify the identity of the purchaser;¶
(D) Name of the government agency that issued the photo identification in (C);¶
(E) Name of product purchased;¶
(F) Quantity in grams of product purchased;¶
(G) Name or initials of Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician who provides the drug; and¶
(H) Signature of the purchaser. The signature of the purchaser may be recorded on a written log that also contains the transaction ID generated by the electronic system.¶
(5) All sales of pseudoephedrine or ephedrine are subject to the following quantity limits and restrictions:¶
(a) No more than 3.6 grams in a 24-hour period, no more than 9 grams in a 30-day period without regard to the number of transactions; and¶
(b) For non-liquids, product packaging is limited to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches.¶
(6) Sections (4) and (5) do not apply to a pseudoephedrine or ephedrine when the drug is dispensed pursuant to a prescription.¶
(7) Each pharmacy, Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/202~~2~~3), 21 CFR 1314.02 (04/01/202~~2~~3), 21 CFR 1314.03 (04/01/202~~2~~3), 21 CFR 1314.05 (04/01/202~~2~~3), 21 CFR 1314.10 (04/01/202~~2~~3), 21 CFR 1314.15 (04/01/202~~2~~3), 21 CFR 1314.20 (04/01/202~~2~~3), 21 CFR 1314.25, (04/01/202~~2~~3); 21 CFR 1314.30 (04/01/202~~2~~3), 21 CFR 1314.35 (04/01/202~~2~~3), 21 CFR 1314.40 (04/01/202~~2~~3), 21 CFR 1314.42 (04/01/202~~2~~3), 21 CFR 1314.45 (04/01/202~~2~~3); and 21 CFR 1314.50 (04/01/202~~2~~3). ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 475.230~~, 2022 HB 4034~~
Statutes/Other Implemented: ORS 475.035, ORS 475.230~~, 2022 HB 4034~~

AMEND: 855-080-0028

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR) and Table of Exempted Prescription Products. Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0028
Excluded or Exempted Substances ¶

(1) The board adopts the excluded substances list found in 21 CFR 1308.22 (04/01/202~~2~~3).¶
(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/202~~2~~3).¶
(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (0~~8/22~~1/11/202~~2~~4) pursuant to 21 CFR 1308.32 (04/01/202~~2~~3).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 475.035
Statutes/Other Implemented: ORS 689.155, ORS 475.035

AMEND: 855-080-0031

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0031
Registration Requirements ¶

(1) Every person who manufactures, delivers, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, delivery or dispensing of any controlled substance within this state must obtain a controlled substance registration annually issued by the State Board of Pharmacy.¶
(2) The board adopts the exceptions to registration for distribution by dispenser to another practitioner pursuant to 21 CFR 1307.11 (04/01/2022~~2~~3).¶
(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/2022~~2~~3). ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.155, ORS 689.205
Statutes/Other Implemented: ORS 475.125

AMEND: 855-080-0065

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0065
Security ¶

(1) All applicants and registrants as applicable to the registration classification must comply with the security requirements of 21 CFR 1301.01 (04/01/202~~2~~3), 21 CFR 1301.02 (04/01/202~~2~~3), 21 CFR 1301.71 (04/01/202~~2~~3), 21 CFR 1301.72 (04/01/202~~2~~3), 21 CFR 1301.73 (04/01/202~~2~~3), 21 CFR 1301.74 (04/01/202~~2~~3), 21 CFR 1301.75 (04/01/202~~2~~3), 21 CFR 1301.76 (04/01/202~~2~~3), 21 CFR 1301.77 (04/01/202~~2~~3), 21 CFR 1301.90 (04/01/202~~2~~3), 21 CFR 1301.91 (04/01/202~~2~~3), 21 CFR 1301.92 (04/01/202~~2~~3), and 21 CFR 1301.93 (04/01/202~~2~~3).¶
(2) The security requirements of (1) of this rule apply to all controlled substances, as defined in these rules, including ephedrine, pseudoephedrine, and phenylpropanolamine.¶
(3) Applicants and registrants must guard against theft and diversion of ephedrine, pseudoephedrine, and phenylpropanolamine.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.135, ORS 475.125

AMEND: 855-080-0070

RULE SUMMARY: Proposes to amend referenced versions of the United States Code (USC) and Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0070
Records and Inventory ¶

(1) All registrants must, as applicable to the registration classification, keep records and maintain inventories in compliance with 21 USC 827 (03/~~15~~23/202~~2~~4); 21 CFR 1304.01 (04/01/202~~2~~3), 21 CFR 1304.02 (04/01/202~~2~~3), 21 CFR 1304.03 (04/01/202~~2~~3), 21 CFR 1304.04 (04/01/202~~2~~3), 21 CFR 1304.05 (04/01/202~~2~~3), 21 CFR 1304.06 (04/01/202~~2~~3); 21 CFR 1304.11 (04/01/202~~2~~3); 21 CFR 1304.21 (04/01/202~~2~~3), 21 CFR 1304.22 (04/01/202~~2~~3), 21 CFR 1304.23 (04/01/202~~2~~3), 21 CFR 1304.24 (04/01/202~~2~~3), 21 CFR 1304.25 (04/01/202~~2~~3), 21 CFR 1304.26 (04/01/202~~2~~3); 21 CFR 1304.31 (04/01/202~~2~~3), 21 CFR 1304.32 (04/01/202~~2~~3), 21 CFR 1304.33 (04/01/202~~2~~3).¶
(2) A written inventory of all controlled substances must be taken by registrants annually within 367 days of the last written inventory.¶
(3) All such records must be maintained for a period of three years.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 475.165

AMEND: 855-080-0075

RULE SUMMARY: Proposes to amend referenced versions of the United States Code (USC) and Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0075
Orders for Schedule I and II Controlled Substances
Controlled substances in Schedules I and II must be distributed by a registrant to another registrant only pursuant to an order form or electronic order in compliance with 21 USC 828 (03/20~~0~~4/202~~3~~4) and 21 CFR 1305.01 (04/01/202~~2~~3), 21 CFR 1305.02 (04/01/202~~2~~3), 21 CFR 1305.03 (04/01/202~~2~~3), 21 CFR 1305.04 (04/01/202~~2~~3), 21 CFR 1305.05 (04/01/202~~2~~3), 21 CFR 1305.06 (04/01/202~~2~~3), 21 CFR 1305.07 (04/01/202~~2~~3); 21 CFR 1305.11 (04/01/202~~2~~3), 21 CFR 1305.12 (04/01/202~~2~~3), 21 CFR 1305.13 (04/01/202~~2~~3), 21 CFR 1305.14 (04/01/202~~2~~3), 21 CFR 1305.15 (04/01/202~~2~~3), 21 CFR 1305.16 (04/01/202~~2~~3), 21 CFR 1305.17 (04/01/202~~2~~3), 21 CFR 1305.18 (04/01/202~~2~~3), 21 CFR 1305.19 (04/01/202~~2~~3), 21 CFR 1305.20 (04/01/202~~2~~3); 21 CFR 1305.21 (04/01/202~~2~~3), 21 CFR 1305.22 (04/01/202~~2~~3), 21 CFR 1305.23 (04/01/202~~2~~3), 21 CFR 1305.24 (04/01/202~~2~~3), 21 CFR 1305.25 (04/01/202~~2~~3), 21 CFR 1305.26 (04/01/202~~2~~3), 21 CFR 1305.27 (04/01/202~~2~~3), 21 CFR 1305.28 (04/01/202~~2~~3), and 21 CFR 1305.29 (04/01/202~~2~~3).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.175

AMEND: 855-080-0085

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-080-0085
Prescription Requirements ¶

(1) Registrants, practitioners and Pharmacists as specified therein in the issuance, preparation, labeling, dispensing, recordkeeping and filing of prescriptions for controlled substances must comply with the provisions of 21 CFR 1306.01 (04/01/202~~2~~3), 21 CFR 1306.02 (04/01/202~~2~~3), 21 CFR 1306.03 (04/01/202~~2~~3), 21 CFR 1306.04 (04/01/202~~2~~3), 21 CFR 1306.05 (04/01/202~~2~~3), 21 CFR 1306.06 (04/01/202~~2~~3), 21 CFR 1306.07 (04/01/202~~2~~3), 21 CFR 1306.08 (04/01/202~~2~~3), 21 CFR 1306.09 (04/01/202~~2~~3); 21 CFR 1306.11 (04/01/202~~2~~3), 21 CFR 1306.12 (04/01/202~~2~~3), 21 CFR 1306.13 (04/01/202~~2~~3), 21 CFR 1306.14 (04/01/202~~2~~3), 21 CFR 1306.15 (04/01/202~~2~~3); 21 CFR 1306.21 (04/01/202~~2~~3), 21 CFR 1306.22 (04/01/202~~2~~3); 21 CFR 1306.23 (04/01/202~~2~~3), 21 CFR 1306.24 (04/01/202~~2~~3), 21 CFR 1306.25 (04/01/202~~2~~3), 21 CFR 1306.27 (04/01/202~~2~~3); and 21 CFR 1304.03(d) (04/01/202~~2~~3).¶
(2) Controlled substances listed in 21 CFR 1308.15 (04/01/202~~2~~3) as schedule V are prescription drugs.¶
(3) Pseudoephedrine and ephedrine may be:¶
(a) Provided to a patient without a prescription under ORS 475.230.¶
(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/202~~2~~3), 21 CFR 1306.22 (04/01/202~~2~~3); 21 CFR 1306.23 (04/01/202~~2~~3), 21 CFR 1306.24 (04/01/202~~2~~3), 21 CFR 1306.25 (04/01/202~~2~~3), and 21 CFR 1306.27 (04/01/202~~2~~3). ¶
(4) For a Schedule II controlled substance prescription, a Pharmacist may:¶
(a) Add the patient's address based on information provided by the patient or patient's agent with appropriate verification;¶
(b) Amend or add the following information after consultation with and agreement of the prescriber:¶
(A) Drug strength; ¶
(B) Dosage form;¶
(C) Drug quantity;¶
(D) Directions for use;¶
(E) Prescriber's address; and¶
(F) Prescriber's DEA registration number.¶
(c) Amend the following information after consultation with and agreement of the prescriber, the:¶
(A) Date the prescription was issued; and¶
(B) Date the prescription can be filled.¶
(d) For (b) and (c), the Pharmacist must document on the prescription the date of the prescriber's authorization, the amendment or addition authorized, and the Pharmacist's identity. ¶
(5) For a Schedule II controlled substance prescription, a Pharmacist must not change the patient's name, the controlled substance prescribed except for generic substitution, and the name or signature of the prescriber. ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.185, ORS 475.188

AMEND: 855-115-0125

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-115-0125
Responsibilities: Drugs, Records and Security
When practicing pharmacy per ORS 689, each Pharmacist must:¶
(1) Ensure the security of prescription drugs, pharmacy and patient records including:¶
(a) Provide adequate safeguards against loss, theft, or diversion; and¶
(b) Ensure only persons authorized by the Pharmacist access the areas where prescription drugs, pharmacy and patient records are stored by restricting access;¶
(2) Ensure that all records are maintained in accordance with state and federal laws and rules;¶
(3) Only receive drugs from an Oregon Registered Drug Outlet (e.g., Wholesaler, Manufacturer or Pharmacy);¶
(4) Comply with the drug storage rules for pharmacies in OAR 855-041-1036;¶
(5) Ensure drugs and devices that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or identified as suspect or illegitimate, or otherwise unfit for dispensing or administration must be documented, quarantined and physically separated from other drugs and devices until they are destroyed or returned to the supplier;¶
(6) Ensure each compounded drug is prepared in compliance with OAR 855-045;¶
(7) Ensure all computer equipment used for the practice of pharmacy:¶
(a) Establishes and maintains a secure connection to patient information to which they have access;¶
(b) Prevents unauthorized access to patient information; and¶
(c) Is configured so information from any patient records are not duplicated, downloaded, or removed from the electronic database if accessed remotely;¶
(8) Document accurately and maintain records in the practice of pharmacy including, but not limited to:¶
(a) Services provided; ¶
(b) The date, time and identification of the licensee and the specific activity or functions performed; and¶
(c) Maintain records pertaining to the acquisition, storage, dispensing or administration, and disposal of drugs and devices; and¶
(9) Ensure reporting of data as required by federal and state regulations, including but not limited to:¶
(a) ALERT Immunization Information System (ALERT-IIS) per ORS 433.090, ORS 433.092, ORS 433.094, ORS 433.095, ORS 433.096, ORS 433.098, ORS 433.100, ORS 433.102, ORS 433.103, and ORS 433.104;¶
(b) Communicable diseases per ORS 433.004; and¶
(c) Vaccine Adverse Event Reporting System (VAERS) per 21 CFR 600.80 (v. 04/01/202~~2~~3).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-120-0005

RULE SUMMARY: Proposes to amend referenced version of Accreditation Council for Pharmacy Education accredited colleges and schools of pharmacy. Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-120-0005
Definitions
(1) "ACPE accredited" means a college or school of pharmacy that is accredited, accredited with probation, pre-candidate or candidate status by Accreditation Council for Pharmacy Education (v. ~~5~~04/02/202~~3~~4) including the Lebanese American University school in Byblos, Lebanon after 2002.¶
(2) "College of Pharmacy or School of Pharmacy (COP or SOP)" means an ACPE accredited college or school of pharmacy.¶
(3) "Healthcare Preceptor" means a pharmacist, or person with an active healthcare license in good standing that can independently practice pharmacy within the scope of their licensure and is licensed by the board to supervise the internship training of a licensed Intern.¶
(4) "Intern" means a person who is enrolled in or has completed a course of study at a board approved college or school of pharmacy and who is licensed with the board as an Intern.¶
(5) "Internship Program" means a professional experiential program that is approved by the board.¶
(6) "Internship Program Supervisor-" is a Pharmacist licensed with the board as a Preceptor who supervises the Internship Program for a COP or SOP located in Oregon.¶
(7) "Other Preceptor" means a person who is not licensed as a pharmacist or other healthcare provider in Oregon and is licensed by the board to supervise the internship training of a licensed Intern.¶
(8) "Preceptor" means a Pharmacist or a person licensed by the board to supervise the internship training of a licensed Intern.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

AMEND: 855-135-0001

RULE SUMMARY: Proposes to amend referenced versions of accredited providers of continuing pharmacy education by the Accreditation Council on Pharmaceutical Education (ACPE) and continuing medical education by the Accreditation Council for Continuing Medical Education (ACCME). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

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. 0~~6~~4/01~~1~~2/202~~2~~4) or continuing medical education (CME) accredited by the Accreditation Council for Continuing Medical Education (ACCME) or an ACCME-recognized State Medical Society (v. ~~6~~03/202~~2~~4) as an American Medical Association (AMA) Category 1 CME program. ¶
(2) "Board-approved program" means a structured continuing pharmacy education program which has been reviewed and approved by the board.¶
(3) "Certificate of completion" means a certificate or other official document issued to a participant certifying the successful completion of a continuing pharmacy education program.¶
(4) "Continuing Pharmacy Education" or "CPE" means an accredited or board-approved program designed to support the continuing development of Pharmacists, Interns, Certified Oregon Pharmacy Technicians or Pharmacy Technicians to maintain and enhance their competence applicable to the practice of pharmacy or the assistance of the practice of pharmacy. ¶
(5) "Contact hour" means sixty minutes of continuing pharmacy education. ¶
(6) "CPE Monitor" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy (NABP) for monitoring continuing pharmacy education that Pharmacists, Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians receive from participating providers;¶
(7) "Cultural competence" means the lifelong process of examining the values and beliefs and developing and applying an inclusive approach to health care practice in a manner that recognizes the content and complexities of provider-patient communication and interaction and preserves the dignity of individuals, families, and communities.¶
(a) Cultural competence applies to all patients.¶
(b) Culturally competent providers do not make assumptions on the basis of an individual's actual or perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital status, socio-economic status, veteran's status, sexual orientation, gender identity, gender expression, gender transition status, level of formal education, physical or mental disability, medical condition or any consideration recognized under federal, state and local law.¶
(8) "Medication error prevention" means the prevention of events that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer. ¶
(9) "Patient safety" means the prevention of healthcare related errors or the elimination or mitigation of patient injury caused by healthcare related errors. ¶
(10) "Pain management education program" means a specific one-hour web-based program developed by the Pain Management Commission of the Oregon Health Authority.¶
(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.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 676.850
Statutes/Other Implemented: ORS 413.450, ORS 413.590, ORS 689.255, ORS 689.285, ORS 689.486, ORS 689.490

AMEND: 855-139-0145

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-139-0145
Outlet: Closure- Temporary, Permanent and Emergency
(1) Temporary Closing. Unless subject to an exemption in OAR 855-139-0145(3), when a RDSP is temporarily closed to the public the RDSP must:¶
(a) Post notification of closure on each RDSP entrance as soon as the need to deviate from the posted hours is known by the RDSP, but no later than 2 hours after the temporary closure begins. The posting must include:¶
(A) Estimated period of time the RDSP will be closed; and¶
(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).¶
(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:¶
(A) Estimated period of time the RDSP will be closed; and¶
(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).¶
(c) If the RDSP is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.¶
(d) Federal and state holidays are exempt from the requirements of (1).¶
(2) Permanent Closing. If a RDSP is permanently closing to the public, the RDSP must:¶
(a) Prior to closing, the RDSP must comply with the following:¶
(A) Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:¶
(i) The last day the RDSP will be open;¶
(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;¶
(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and¶
(iv) The last day a transfer may be initiated.¶
(B) The notification must be made via:¶
(i) Distribution by direct mail or written notification with each prescription dispensed;¶
(ii) Public notice in a newspaper of general circulation, if available, in the area served by the RDSP; and¶
(iii) Posting a closing notice at each building and each RDSP entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).¶
(iv) In addition to (i), (ii) and (iii), the RDSP may also provide notification via email or text.¶
(C) Provide any new patients filling prescriptions during the 15-calendar day period prior to the RDSP closing with written notification that includes:¶
(i) The last day the RDSP will be open;¶
(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;¶
(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and¶
(iv) The last day a transfer may be initiated.¶
(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/202~~2~~3).¶
(b) On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:¶
(A) Complete and document an inventory of all controlled substances.¶
(B) If the RDSP dispenses prescriptions:¶
(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed Pharmacist who will serve as the custodian of records;¶
(ii) Update the RDSP operating status with each electronic prescribing vendor; and¶
(iii) Remove all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications).¶

(c) After closing. Within 30 calendar days after the closing of the RDSP, the pharmacist-in-charge must:¶
(A) Complete and document an inventory of all non-controlled drugs and devices.¶
(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the RDSP by one or a combination of the following methods:¶
(i) Return to manufacturer or supplier (credit or disposal);¶
(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or¶
(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (04/01/2022~~2~~3), 21 CFR 1304.22 (04/01/2022~~2~~3), 21 CFR 1317.05 (04/01/2022~~2~~3), 21 CFR 1317.90 (04/01/2022~~2~~3) and 21 CFR 1317.95 (04/01/2022~~2~~3).¶
(C) Provide the board a written notice of the closing on a board prescribed form which includes the following information:¶
(i) Date of closing to the public and discontinuance of the business;¶
(ii) Date and time the inventory of all prescription drugs and devices was conducted;¶
(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the RDSP were transferred or disposed;¶
(iv) If drugs were destroyed, name and license numbers of individuals who witnessed the destruction;¶
(v) If the RDSP is registered to possess controlled substances, confirmation that the RDSP complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2022~~2~~3) for discontinuing operation as a RDSP that dispenses controlled substances.¶
(vi) If the RDSP dispenses prescriptions, the name, address and phone number of the RDSP or Oregon licensed Pharmacist who will serve as the custodian of records to which the prescriptions, including refill information, and patient medication records were transferred;¶
(vii) Confirmation all RDSP labels and blank prescriptions were destroyed;¶
(viii) Confirmation all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and¶
(ix) Confirmation that each registration certificate issued to the RDSP by the board has been mailed to the board office.¶
(D) Once the RDSP has notified the board that the RDSP is permanently closed, the license may not be renewed. The RDSP may apply for a new license as specified in OAR 855-139-0015.¶
(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.¶
(3) Emergency closing. If the RDSP is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the Pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.¶
(4) The board may conduct an inspection to verify all requirements in subsection (1), (2), and (3) of this section have been completed. ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.700
Statutes/Other Implemented: ORS 689.155, ORS 689.700

AMEND: 855-139-0350

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-139-0350
Dispensing: Containers
Each pharmacy must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/202~~2~~3), 16 CFR 1701 (01/01/202~~2~~3), and 16 CFR 1702 (01/01/202~~2~~3).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-139-0460

RULE SUMMARY: Proposes to amend referenced versions of the United States Code (USC) and Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

855-139-0460
Drugs and Devices: Take-back Program
(1) A RDSP that operates a drug take-back collection program or that participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered with the DEA as an authorized collector to collect controlled and non-controlled drugs for destruction.¶
(2) A RDSP that operates as a Drug Enforcement Agency (DEA) authorized collector must notify the board within 30 days of initiating or terminating the program and must establish and enforce policies and procedures, including but not limited to:¶
(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is accessible to the public, within view of the pharmacy counter and must not be located behind the pharmacy counter; and¶
(b) Provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation, and key accountability; and¶
(c) Personnel training and accountability.¶
(3) A RDSP must inform consumers to directly deposit drugs into the collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected.¶
(4) A RDSP must not dispose of drugs from pharmacy stock in a collection receptacle.¶
(5) The liner must be inserted and removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel.¶
(6) Liners that have been removed from a collection receptacle and immediately sealed must be directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution agent (such as registered UPS, FedEx, or USPS) or a reverse wholesaler registered with the DEA and the board.¶
(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to the board in writing within one day of discovery.¶
(8) A RDSP must maintain all drug disposal records for a minimum of 3 years.¶
(9) Authorized collectors are required to comply with the following federal and state laws:¶
(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236, ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;¶
(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370, and OAR 340-098-0390;¶
(c) 21 CFR 1317.30 (04/01/202~~2~~3), 21 CFR 1317.35 (04/01/202~~2~~3), 21 CFR 1317.40 (04/01/202~~2~~3), 21 CFR 1317.55 (04/01/202~~2~~3), 21 CFR 1317.60 (04/01/202~~2~~3), 21 CFR 1317.65 (04/01/202~~2~~3), 21 CFR 1317.70 (04/01/202~~2~~3), 21 CFR 1317.75 (04/01/202~~2~~3), 21 CFR 1317.80 (04/01/202~~2~~3), and 21 CFR 1317.85 (04/01/202~~2~~3); and¶
(d) 21 USC 822 (03/20~~0~~3/202~~3~~4) and 21 USC 822a (03/20~~0~~3/202~~3~~4).¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218

AMEND: 855-141-0350

RULE SUMMARY: Proposes to amend referenced versions of the Code of Federal Regulations (CFR). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

CHANGES TO RULE:

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 (01/01/202~~2~~3), 16 CFR 1701 (01/01/202~~2~~3), and 16 CFR 1702 (01/01/202~~2~~3). ¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

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503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/17/2024 2:35 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amends rule regarding delegation of final verification

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@bop.oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/22/2024
TIME: 9:30 AM
OFFICER: Rachel Melvin

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 392711816
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.
If you wish to present oral testimony virtually during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your first and last name and email address to pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes adding “drug” and removing “form” in (3).

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

ORS 689.703 Final verification; delegation; rules https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Proposed amendments provide clarity, transparency for licensees/registrants and promotes patient safety, no effects on racial equity are anticipated.

FISCAL AND ECONOMIC IMPACT:

No fiscal impact anticipated. When the board sends the proposed rule to a rulemaking hearing, licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

COST OF COMPLIANCE:

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

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

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

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

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

The resources involved in convening a RAC were not necessary to amend this rule. Board members represent the interests of persons and communities likely to be affected by a proposed rule and were able to provide information necessary to draft the proposed rule.

AMEND: 855-115-0130

RULE SUMMARY: Proposed amendment adds "drug" and removes "form" from OAR 855-115-0130(3). The current rule permits a pharmacist to delegate final verification of a drug dosage "form" to a technician. ORS 689.703 does not permit final verification of the drug dosage "form" by a technician.

CHANGES TO RULE:

855-115-0130
Responsibilities: Practicing Pharmacy for a Drug Outlet
(1) When practicing pharmacy per ORS 689 for a Drug Outlet, each Pharmacist must:¶
(a) Be responsible for the daily conduct, operation, management and control of the Drug Outlet pharmacy;¶
(b) Ensure that only a Pharmacist has access to the Drug Outlet pharmacy when the pharmacy is closed, except as permitted in OAR 855-041-6310;¶
(c) Ensure each prescription contains all the elements required in OAR 855-041 or OAR 855-139; ¶
(d) Ensure the patient record contains the elements required in OAR 855-041 or OAR 855-139;¶
(e) Ensure prescriptions, prescription refills, and drug orders are dispensed:¶
(A) Accurately;¶

(B) To the correct party;¶
(C) Pursuant to a valid prescription; ¶
(D) Pursuant to a valid patient-practitioner relationship; and ¶
(E) For a legitimate medical purpose;¶
(f) Ensure the Drug Outlet pharmacy is operated in a professional manner at all times; ¶
(g) Ensure the drug outlet reports data as required by federal and state regulations, including but not limited to:¶
(A) Prescription Drug Monitoring Program (PDMP) per ORS 413A.890, ORS 413A.895, ORS 413A.896, ORS 413A.898, and OAR 333-023;¶
(B) Death with Dignity per ORS 127.800, ORS 127.805, ORS 127.810, ORS 127.815, ORS 127.820, ORS 127.825, ORS 127.830, ORS 127.835, ORS 127.840, ORS 127.845, ORS 127.850, ORS 127.855, ORS 127.860, ORS 127.865, ORS 127.870, ORS 127.875, ORS 127.880, ORS 127.885, ORS 127.890, ORS 127.892, ORS 127.895, ORS 127.897, and OAR 333-009;¶
(C) Controlled substances per 21 CFR 1301.74 (v. 04/01/202~~2~~3); and¶
(D) Listed chemicals per 21 CFR 1310.05 (v. 04/01/202~~2~~3); and¶
(2) A Pharmacist who utilizes licensees remotely, must comply with OAR 855-041-3200 through OAR 855-041-3250.¶
(3) When engaging in the practice of pharmacy per ORS 689, each Pharmacist may delegate final verification of drug and drug 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.¶
[Publications: Publications referenced are available for review at the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.703

Division 139: Remote Dispensing Site Pharmacy (General Requirements, Prohibited Practices)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Remote Dispensing Site Pharmacy (RDSP) general requirements related to mileage and prohibited practices

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes amending general requirements related to mileage limitations, adding a waiver process and prohibiting pharmacist from verifying prescriptions when the telepharmacy system is malfunctioning.

Documents Relied Upon per ORS 183.335(2)(b)(D): April 2024 Board Meeting Agenda, mailing #F

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. When the board sends the proposed rule to a rulemaking hearing, licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public),Effect on Small Businesses, number and type of small businesses subject to the rule(s), expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s), estimated cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

The proposed rule will have no additional economic impact on state agencies, units of local government, or the public.

The proposed rule applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.

The proposed rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

The proposed rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The resources involved in convening a RAC were not necessary to amend this rule. Board members represent the interests of persons and communities likely to be affected by a proposed rule and were able to provide information necessary to draft the proposed rule.

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

OAR 855-139-0200 – Proposes #4 options for board consideration to amend (2) based on public feedback regarding mileage requirements between the RDSP and RDSP Affiliated Pharmacy.

Option #2-1 proposes to repeal (2) in its entirety.

Option #2-2 proposes to shift the location requirement from the RDSP Affiliated Pharmacy to the supervising pharmacist, allowing a greater distance for the pharmacy as long as the pharmacist remains within 120 miles of the RDSP.

Option #2-3 proposes amending the mileage from "120" to "200" miles.

Option #2-4 proposes adding that a RDSP Affiliated Pharmacy must be located in Oregon and must be located less than "200" miles apart.

Proposes to add (3) by adding requirements for registrants who wish to request a waiver from (2).

OAR 855-139-0600 proposes amending RDSP prohibited practices by adding (5) which prohibits an RDSP from permitting a Pharmacist to verify prescriptions for dispensing when any component of the telepharmacy system is not functioning.

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0200
Outlet: General Requirements

(1) A RDSP Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.

(2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.

(2-1) ~~A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.~~

(2-2) The Pharmacist providing supervision, direction and control of the RDSP and personnel for the RDSP Affiliated Pharmacy must be located less than 120 miles apart via the shortest surface street route from the RDSP.

(2-3) A RDSP Affiliated Pharmacy must be less than ~~120~~ **200** miles apart via the shortest surface street route from the RDSP.

(2-4) A RDSP Affiliated Pharmacy must be located in Oregon and must be **located** less than ~~120~~ **200** miles apart via the shortest surface street route from the RDSP.

(3) Upon written request the board may grant in writing a waiver to (2) if the following parameters are met:

(a) RDSP is co-registered as a Retail Drug Outlet Pharmacy;

(b) RDSP operates as a Retail Drug Outlet Pharmacy at least 50 percent of the location's operating hours; and

(c) The RDSP Affiliated Pharmacy demonstrates that the waiver will further public health or safety or the health and safety of a patient.

(~~3~~**4**) A RDSP and its RDSP 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 each prescription is dispensed in compliance with OAR 855-115, OAR 855-125 and OAR 855-139;

(d) Comply with all applicable federal and state laws and rules;

(e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians authorized to access the RDSP and operate the telepharmacy system;

(f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system and RDSP;

(g) Develop, implement and enforce a continuous quality improvement program for dispensing services from a RDSP 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;

(h) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy; and

(i) Develop, implement and enforce a process for an in person physical inspection of the RDSP by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy. The inspection must utilize the RDSP self-inspection form, be documented, and records retained.

Statutory/Other Authority: ORS 689.205 & 2021 SB 629
Statutes/Other Implemented: 2021 SB 629 & ORS 689.155

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet RDSP must not:

(1) Allow a Certified Oregon Pharmacy Technician or Pharmacy Technician to:

(a) Refuse a request from a patient, patient's agent, or practitioner to interact with a Pharmacist; and

(b) Administer a vaccine.

(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the board pursuant to ORS 689.305;

(3) Compound sterile preparations; or

(4) Repackage drugs.

(5) Permit a Pharmacist to verify prescriptions for dispensing when any component of the telepharmacy system is not functioning.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.700
Statutes/Other Implemented: ORS 689.315, ORS 689.155, ORS 689.700 & 2023 HB 2486

Division 115: Pharmacists (Prescribing: Protocol Compendium)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Continuation of Therapy, Vulvovaginal candidiasis and Coronavirus 2019 protocols, adds new SARS-CoV-2 Antiviral protocol

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes amending Continuation of Therapy protocol by adding early refills of non-controlled opioid use disorder medications to pursuant to 2024 HB 4002 Sections 6, 7 and 9 , proposes amending the term "Vulvovaginal candidiasis" in the current protocol to "Vaginal Itching" and proposes adding new SARS-CoV-2 Antiviral protocol pursuant to 2024 SB 1506. Proposed to amend current version of the Coronavirus 19 protocol.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2024 SB 1506, 2024 HB 4002

Protocol Compendium:

Proposed Continuation of Therapy

Proposed Vaginal Itching

Proposed SARS-CoV-2 Antiviral

Vaccines:

Proposed Coronavirus 19

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal anticipated. Licensees, registrants and stakeholders will have an opportunity to provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): Effect on Small Businesses: Number/Type: Reporting, Recordkeeping and Administrative Activities Cost: Professional Services, Equipment/ Supplies, Labor Cost: The proposed rule amendments will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Subject Matter Experts (SME) are responsible for drafting proposed protocols and the Public Health and Pharmacy Formulary Advisory Committee is responsible for recommending proposed or amended protocols sent to the board for consideration.

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

OAR 855-115-0345 - Proposes to amend the Continuation of Therapy protocol by adding early refills of non-controlled opioid use disorder medications pursuant to directives of 2024 HB 4002 Sections 6,7, and 9, proposes to amend existing protocol for Vulvovaginal candidiasis (VVC) by replacing "Vulvovaginal candidiasis with "Vaginal Itching", proposes adding new protocol SARS-CoV-2 Antiviral pursuant to 2024 SB 1506 to the protocol compendium and proposes to amend current vaccine protocol for Coronavirus 2019.

Division 115
PHARMACISTS

NOTE: The proposed rule below was drafted utilizing the proposed May 2024 rule filing notice. Please note that if any revisions are made in real time during the board meeting on mailing #B1, the version below will need to be amended. *Review the current permanent rule **OAR 855-115-0345**.

855-115-0345 *Review proposed rule filing for **OAR 855-115-0345**
Services: Prescribing - Protocol Compendium

A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, FDA-approved drugs and devices listed in the following compendium, pursuant to a statewide drug therapy management protocol.

(1) Continuation of therapy including emergency refills of insulin **and early refills of opioid use disorder medications** (v. 06**8**/2024)

(2) Conditions

(a) Cough and cold symptom management

(A) Benzonatate (v. 06/2021);

(B) Short-acting beta agonists (v. 06/2021);

(C) Intranasal corticosteroids (v. 06/2021);

(b) ~~Vulvovaginal candidiasis (VVC)~~ **Vaginal Itching** (v. 06**8**/202~~1~~**4**);

(c) COVID-19 Antigen Self-Test (v. 12/2021);

(d) SARS-CoV-2 Antiviral (v. 08/2024)

(3) Preventative care

(a) Emergency Contraception (v. 06/2021);

(b) Male and female condoms (v. 06/2021);

(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT (v. 06/2024);

(d) Travel Medications (v. 06/2024);

(e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);

(f) HIV Pre-exposure Prophylaxis (PrEP) (v.06/2023);

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

(h) Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) (v. 06/2024);

(i) Short-acting Opioid Antagonists (v. 06/2024); and

(j) Vaccines:

(A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 06/2024);

(B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 06/2024);

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

(D) Coronavirus 2019 (v. 06~~8~~/2024);

(E) Haemophilus Influenza type b (v. 06/2024);

(F) Hepatitis A containing vaccines (v. 02/2024);

(G) Hepatitis B containing vaccines (v. 02/2024);

(H) Human Papillomavirus (v. 02/2024);

(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 06/2024);

(J) Influenza - Live Attenuated Influenza Vaccine 2023-24 (v. 02/2024);

(K) Japanese Encephalitis (v. 06/2024);

(L) Meningococcal containing vaccines (v. 06/2024);

(M) Measles Mumps & Rubella containing vaccines (v. 02/2024);

(N) Pneumococcal (v. 06/2024);

(O) Polio (v. 06/2024);

(P) Rabies (v. 02/2024);

(Q) Respiratory Syncytial Virus (v. 06/2024);

(R) Tetanus Diphtheria containing vaccines (v. 06/2024);

(S) Typhoid (v. 02/2024);

(T) Varicella containing vaccines (v. 02/2024);

(U) Yellow fever (v. 06/2024); and

(V) Zoster (v. 02/2024).

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689.205, **2024 HB 4002, 2024 SB 1506**
Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689, **2024 HB 4002, 2024 SB 1506**

CONTINUATION OF THERAPY

Including Emergency Refills of Insulin and Early Refills of Opioid Use Disorder Medications

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Per ORS 689.696, a pharmacist may prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies to a person who has evidence of a previous prescription from a licensed health care provider.
- Per 2024 HB 4002 (Sections 6,7,9), a pharmacist with a may prescribe and dispense early refills of medication for the treatment of opioid use disorder.

- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe:
- Any non-controlled drug or device to a person who has evidence of a previous prescription drug or device from a licensed health care provider in order to:
  - Replace a damaged* prescription drug or device within the original duration of therapy; or
    - Extend a patient's current prescription drug or device (same drug/device, dose and directions) to avoid interruption of treatment.
  - An early refill of a non-controlled drug or device to a person who has evidence of a previous prescription for Opioid Use Disorder from a licensed health care provider in order to:
    - Replace a medication that has been lost, stolen or destroyed within a 12 month period.
    - Refill a medication for which the previous prescription expired in the prior 12 month period.

*The Pharmacist must use their reasonable professional judgment as defined by OAR 855-006-0005 to determine if the drug or device is damaged. This includes physical damage like broken containers or spills, chemical changes like discoloration or unusual odors, and damage from exposure to heat or moisture, which can affect the drug or device's effectiveness and safety.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Continuation of Therapy Patient Intake Form (pg. 2)
- Utilize the standardized Continuation of Therapy Assessment and Treatment Care Pathway (pg. 3)
- Utilize the standardized Continuation of Therapy Prescription Template *optional* (pg. 4)
- Utilize the standardized Patient Informational Handout *optional* (pg. 5)
- Utilize the standardized Continuation of Therapy Provider Fax *optional for insulin/non-insulin and non-opioid use disorder medications, required for opioid use disorder medications* (pg. 6)

PRESCRIBING PARAMETERS

- **For Non-Insulin and Non-Opioid Use Disorder Medication, Medication Related Devices and Supplies:**
  - Quantity sufficient for the circumstances
  - Maximum quantity:
    - Damaged: May not exceed original duration of therapy

        - Extend: May not exceed a 60-day supply
    - Maximum frequency:
        - Damaged: No more than one replacement in a rolling 12-month period per medication
        - Extend: No more than two extensions in a rolling 12-month period per medication

- **For Insulin, Insulin Related Devices and Supplies (excluding pump devices):**
    - Quantity sufficient for the circumstances
    - Maximum quantity: Lesser of a 30-day supply or the smallest available package size
    - Maximum frequency: No more than three extensions in a calendar year (Jan 1- Dec 31)

- **For Opioid Use Disorder Medication (excluding controlled substances):**
    - Quantity consistent with the amount specified in the most recent prescription for the medication
    - Maximum quantity: The amount specified in the most recent prescription for the medication.
    - Maximum frequency:
        - Lost/Stolen/Destroyed: No more than 3 refills in a 12-month period per medication*
        - Prescription expired in prior 12 month period: No more than 1 refill in a 12-month period per medication*

      *In accordance with federal law.

PHARMACIST TRAINING/EDUCATION: None required.

Continuation of Therapy: Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Which medication or medication-related devices and supplies do you need an refill of today?_____ _____	
2.	Why are you unable to obtain a refill from your previous prescriber? _____	
3.	Have you previously had the medication or medication-related devices and supplies needed in #1 prescribed to you by a licensed health care provider? - If yes, what is the name and contact information for your licensed health care provider? _____ - If yes, when was the last time your provider prescribed the medication or medication-related device or supply to you? ___/___/_____	□ Yes □ No
4.	Do you have evidence of a previous prescription for the medication or medication-related device or supply needed in #1 from a licensed health care provider? - If yes, what evidence do you have? □ Prescription Vial □ Medical Record □ Other _____	□ Yes □ No
5.	Have you previously had medication or medication-related device or supplies prescribed to you by a Pharmacist? - If yes, what is the name and contact information for your pharmacist/pharmacy that prescribed to you? _____ - If yes, when was the last time a pharmacist prescribed medication or medication-related device or supply to you? ___/___/_____	□ Yes □ No

Patient Signature_____Date_____
(Parent or Legal Guardian signature needed if patient is under 18 years of age)

To Be Completed by a Pharmacist:

If medication or medication-related device or supply were prescribed/dispensed, please complete the following:

Drug or Device: _____ Directions: _____ Quantity: _____ + 0 refills Evidence: □ Prescription Vial □ Medical Record □ Other	Drug or Device: _____ Directions: _____ Quantity: _____ + 0 refills Evidence: □ Prescription Vial □ Medical Record □ Other
Drug or Device: _____ Directions: _____ Quantity: _____ + 0 refills Evidence: □ Prescription Vial □ Medical Record □ Other	Drug or Device: _____ Directions: _____ Quantity: _____ + 0 refills Evidence: □ Prescription Vial □ Medical Record □ Other

Primary Care Provider (if known) contacted/notified of therapy Date _____/_____/_____

If medication or medication related device or supplies were not prescribed/dispensed/administered, please indicate reason(s) for referral: _____
_____

RPH Signature_____Date_____

Continuation of Therapy
Emergency Refills of Insulin or Insulin-Related Devices
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

1. Does the patient need a medication or medication-related device/supply today?	
☐ Yes. Go to #2	☐ No. Do not prescribe.
2. If insulin-related supplies are needed, do these supplies include insulin pump devices?	
☐ Yes. Refer patient to other HCP	☐ No. Go to #3
3. Does the patient have evidence of a previous prescription for the needed medication or medication-related device or supply from a licensed health care provider?	
☐ Yes. Go to #4	☐ No. Refer patient to local primary care provider (PCP), emergency department (ED) or urgent care.
4. Has the patient received more than: a. one refill of non-insulin medication, medication-related device or supply from a pharmacist in the past rolling 12-months? b. two emergency refills of insulin or insulin-related supplies from a pharmacist in the past calendar year (1/1-12/31)	
☐ Yes. Do not prescribe. Refer patient to local primary care provider (PCP), emergency department (ED) or urgent care.	☐ No. Prescription recommended. Pharmacist must notify the provider.

Please refer to ORS 689.696 for specific laws concerning emergency refills of insulin and associated insulin-related devices and supplies.

RECOMMENDED REGIMEN:

Medication or medication-related device or supply	Notes:
	• Emergency prescribing must be for the same drug or related supply, strength, and dosage as shown by the patient evidence. • Emergency prescribing for non-insulin medications, devices or supplies is limited to a 60-day supply • Emergency prescribing for insulin or insulin-related supplies is limited to the lesser of a 30-day supply or the smallest available package size.

COUNSELING POINTS:

- To help plan, ask your health care provider for a prescription lasting more than 30 days to ensure you always have enough.
- In a case where you know you are going to need a refill while traveling, you may be able to order an additional supply in advance. Some health insurance plans allow for prescription overrides so that you can get a prescription filled early or obtain more than a 30-day supply.
- Keep an up-to-date list of all your prescription medications.

Continuation of Therapy Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Rx

☐ **Drug:** _____
- Directions: _____
- Quantity: _____ + 0 refills

☐ **Drug:** _____
- Directions: _____
- Quantity: _____ + 0 refills

☐ **Drug:** _____
- Directions: _____
- Quantity: _____ + 0 refills

☐ **Drug:** _____
- Directions: _____
- Quantity: _____ + 0 refills

Written Date: _____

Prescriber Name:_____Prescriber Signature: _____

Pharmacy Address:_____Pharmacy Phone: _____

Optional-May be used by pharmacy if desired

Patient Information
Continuation of Therapy

Pharmacy Name: _____Pharmacist Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

Your pharmacist, _____, authorized a refill of the medication, devices and/or supplies listed below to prevent an interruption in your therapy.

- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills

Follow-up and Next Steps

- Please contact your primary care provider to obtain further authorization to fill this medication.

Provider Notification
Continuation of Therapy

Pharmacy Name:_____ Pharmacist Name: _____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

On _____/_____/_____, your patient _____(name) _____/_____/_____ (DOB) was assessed for a refill of the medication, medication-related devices, and supplies listed below at _____ Pharmacy. Your patient was:

☐ **Prescribed medication or medication related devices and supplies**. The prescription(s) issued and dispensed consisted of:

- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
  - Evidence Provided: ☐ Prescription Vial ☐ Medical Record ☐ Other
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
  - Evidence Provided: ☐ Prescription Vial ☐ Medical Record ☐ Other
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
  - Evidence Provided: ☐ Prescription Vial ☐ Medical Record ☐ Other
- ☐ **Drug:** _____
  - Directions: _____
  - Quantity: _____ + 0 refills
  - Evidence Provided: ☐ Prescription Vial ☐ Medical Record ☐ Other

☐ **Referred to**: ☐ Primary care provider (PCP) ☐ Emergency department (ED) ☐ Urgent care for the following reasons:

_____
_____
_____
_____
_____

Medication or medication-related devices and supplies were not prescribed to your patient.

In authorizing this refill, the pharmacist used their professional judgment to meet the patient's medical needs.

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 the pharmacy. The prescription(s) was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

Enrolled
House Bill 4002

Introduced and printed pursuant to House Rule 12.00. Presession filed (at the request of Joint Interim Committee on Addiction and Community Safety Response for Representative Jason Kropf, Senator Kate Lieber)

CHAPTER .....

AN ACT

Relating to the addiction crisis in this state; creating new provisions; amending ORS 51.050, 133.060, 135.050, 135.753, 137.225, 137.300, 153.012, 153.018, 153.019, 153.021, 153.064, 153.992, 221.339, 316.502, 414.609, 414.766, 419C.370, 423.478, 423.483, 423.525, 430.234, 430.384, 430.389, 430.392, 430.399, 430.401, 431A.463, 475.005, 475.235, 475.245, 475.752, 475.814, 475.824, 475.834, 475.854, 475.874, 475.884, 475.894, 475.900, 670.280, 689.005, 743A.168, 750.055 and 750.333; repealing ORS 153.043, 153.062, 293.665, 305.231, 419C.460 and 475.237; and declaring an emergency.

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

BEHAVIORAL HEALTH
(Payment for Substance Use Disorder Treatment)

SECTION 1. Section 2 of this 2024 Act is added to and made a part of ORS chapter 743A.

SECTION 2. (1) As used in this section:

(a) "Group health insurance" has the meaning given that term in ORS 731.098.

(b) "Health benefit plan" has the meaning given that term in ORS 743B.005.

(c) "Substance use disorder" has the meaning given that term in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association.

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

(2) Notwithstanding any provision of ORS 743A.168, an issuer of group health insurance or an individual health benefit plan, other than a health plan that is subject to 42 U.S.C. 18011:

(a) May not impose a requirement for prior authorization or any other form of utilization review for the reimbursement of a covered medication approved by the United States Food and Drug Administration that is prescribed for the purpose of treating a substance use disorder, including but not limited to opioid addiction and opioid withdrawal.

(b) Shall reimburse the cost of refills of medications described in paragraph (a) of this subsection if dispensed by a licensed health care professional who is legally authorized to dispense such medications, including early refills described in section 7 of this section.

(3) Subsection (2) of this section applies to any form of buprenorphine, including but not limited to sublingual, tablet or injectable forms.

(4) This section does not prohibit prior authorization or other utilization review for opioids or opiates prescribed for a purpose other than medication-assisted treatment or the treatment of opiate abuse or addiction.

(5) This section does not prohibit utilization review for the purpose of:

(a) Auditing claims for improper payments, fraud or abuse; or

(b) Reasonable periodic redeterminations about the need for continuing care.

(6) Coverage under this section may be subject to the same terms and conditions that apply to other benefits under the plan except for utilization review as provided in subsection (2) of this section.

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

SECTION 3. ORS 743A.168 is amended to read:

743A.168. (1) As used in this section:

(a) "Behavioral health assessment" means an evaluation by a provider, in person or using telemedicine, to determine a patient's need for behavioral health treatment.

(b) "Behavioral health condition" has the meaning prescribed by rule by the Department of Consumer and Business Services.

(c) "Behavioral health crisis" means a disruption in an insured's mental or emotional stability or functioning resulting in an urgent need for immediate outpatient treatment in an emergency department or admission to a hospital to prevent a serious deterioration in the insured's mental or physical health.

(d) "Facility" means a corporate or governmental entity or other provider of services for the treatment of behavioral health conditions.

(e) "Generally accepted standards of care" means:

(A) Standards of care and clinical practice guidelines that:

(i) Are generally recognized by health care providers practicing in relevant clinical specialties; and

(ii) Are based on valid, evidence-based sources; and

(B) Products and services that:

(i) Address the specific needs of a patient for the purpose of screening for, preventing, diagnosing, managing or treating an illness, injury or condition or symptoms of an illness, injury or condition;

(ii) Are clinically appropriate in terms of type, frequency, extent, site and duration; and

(iii) Are not primarily for the economic benefit of an insurer or payer or for the convenience of a patient, treating physician or other health care provider.

(f) "Group health insurer" means an insurer, a health maintenance organization or a health care service contractor.

(g) "Median maximum allowable reimbursement rate" means the median of all maximum allowable reimbursement rates, minus incentive payments, paid for each billing code for each provider type during a calendar year.

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

(i) "Program" means a particular type or level of service that is organizationally distinct within a facility.

(j) "Provider" means:

(A) A behavioral health professional or medical professional licensed or certified in this state who has met the credentialing requirement of a group health insurer or an issuer of an individual health benefit plan that is not a grandfathered health plan as defined in ORS 743B.005 and is otherwise eligible to receive reimbursement for coverage under the policy;

(B) A health care facility as defined in ORS 433.060;

(C) A residential facility as defined in ORS 430.010;

(D) A day or partial hospitalization program;

(E) An outpatient service as defined in ORS 430.010; or

(F) A provider organization certified by the Oregon Health Authority under subsection (9) of this section.

(k) "Relevant clinical specialties" includes but is not limited to:

(A) Psychiatry;

(B) Psychology;

(C) Clinical sociology;

(D) Addiction medicine and counseling; and

(E) Behavioral health treatment.

(L) "Standards of care and clinical practice guidelines" includes but is not limited to:

(A) Patient placement criteria;

(B) Recommendations of agencies of the federal government; and

(C) Drug labeling approved by the United States Food and Drug Administration.

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

(n) "Valid, evidence-based sources" includes but is not limited to:

(A) Peer-reviewed scientific studies and medical literature;

(B) Recommendations of nonprofit health care provider professional associations; and

(C) Specialty societies.

(2) A group health insurance policy or an individual health benefit plan that is not a grandfathered health plan providing coverage for hospital or medical expenses, other than limited benefit coverage, shall provide coverage for expenses arising from the diagnosis of behavioral health conditions and medically necessary behavioral health treatment at the same level as, and subject to limitations no more restrictive than, those imposed on coverage or reimbursement of expenses arising from treatment for other medical conditions. The following apply to coverage for behavioral health treatment:

(a) The coverage may be made subject to provisions of the policy that apply to other benefits under the policy, including but not limited to provisions relating to copayments, deductibles and coinsurance. Copayments, deductibles and coinsurance for treatment in health care facilities or residential facilities may not be greater than those under the policy for expenses of hospitalization in the treatment of other medical conditions. Copayments, deductibles and coinsurance for outpatient treatment may not be greater than those under the policy for expenses of outpatient treatment of other medical conditions.

(b) The coverage of behavioral health treatment may not be made subject to treatment limitations, limits on total payments for treatment, limits on duration of treatment or financial requirements unless similar limitations or requirements are imposed on coverage of other medical conditions. The coverage of eligible expenses of behavioral health treatment may be limited to treatment that is medically necessary as determined in accordance with this section and no more stringently under the policy than for other medical conditions.

(c) The coverage of behavioral health treatment must include:

(A) A behavioral health assessment;

(B) No less than the level of services determined to be medically necessary in a behavioral health assessment of the specific needs of a patient or in a patient's care plan:

(i) To effectively treat the patient's underlying behavioral health condition rather than the mere amelioration of current symptoms such as suicidal ideation or psychosis; and

(ii) For care following a behavioral health crisis, to transition the patient to a lower level of care;

(C) Treatment of co-occurring behavioral health conditions or medical conditions in a coordinated manner;

(D) Treatment at the least intensive and least restrictive level of care that is safe and most effective and meets the needs of the insured's condition;

(E) A lower level or less intensive care only if it is comparably as safe and effective as treatment at a higher level of service or intensity;

(F) Treatment to maintain functioning or prevent deterioration;

(G) Treatment for an appropriate duration based on the insured's particular needs;

(H) Treatment appropriate to the unique needs of children and adolescents;

(I) Treatment appropriate to the unique needs of older adults; and

(J) Coordinated care and case management as defined by the Department of Consumer and Business Services by rule.

(d) The coverage of behavioral health treatment may not limit coverage for treatment of pervasive or chronic behavioral health conditions to short-term or acute behavioral health treatment at any level of care or placement.

(e) A group health insurer or an issuer of an individual health benefit plan other than a grandfathered health plan shall have a network of providers of behavioral health treatment sufficient to meet the standards described in ORS 743B.505. If there is no in-network provider qualified to timely deliver, as defined by rule, medically necessary behavioral treatment to an insured in a geographic area, the group health insurer or issuer of an individual health benefit plan shall provide coverage of out-of-network medically necessary behavioral health treatment without any additional out-of-pocket costs if provided by an available out-of-network provider that enters into an agreement with the insurer to be reimbursed at in-network rates.

(f) A provider is eligible for reimbursement under this section if:

(A) The provider is approved or certified by the Oregon Health Authority;

(B) The provider is accredited for the particular level of care for which reimbursement is being requested by the Joint Commission or the Commission on Accreditation of Rehabilitation Facilities;

(C) The patient is staying overnight at the facility and is involved in a structured program at least eight hours per day, five days per week; or

(D) The provider is providing a covered benefit under the policy.

(g) A group health insurer or an issuer of an individual health benefit plan other than a grandfathered health plan must use the same methodology to set reimbursement rates paid to behavioral health treatment providers that the group health insurer or issuer of an individual health benefit plan uses to set reimbursement rates for medical and surgical treatment providers.

(h) A group health insurer or an issuer of an individual health benefit plan other than a grandfathered health plan must update the methodology and rates for reimbursing behavioral health treatment providers in a manner equivalent to the manner in which the group health insurer or issuer of an individual health benefit plan updates the methodology and rates for reimbursing medical and surgical treatment providers, unless otherwise required by federal law.

(i) A group health insurer or an issuer of an individual health benefit plan other than a grandfathered health plan that reimburses out-of-network providers for medical or surgical services must reimburse out-of-network behavioral health treatment providers on the same terms and at a rate that is in parity with the rate paid to medical or surgical treatment providers.

(j) Outpatient coverage of behavioral health treatment shall include follow-up in-home service or outpatient services if clinically indicated under criteria and guidelines described in subsection (5) of this section. The policy may limit coverage for in-home service to persons who are homebound under the care of a physician only if clinically indicated under criteria and guidelines described in subsection (5) of this section.

(k)(A) Subject to **section 2 of this 2024 Act and to** the patient or client confidentiality provisions of ORS 40.235 relating to physicians, ORS 40.240 relating to nurse practitioners, ORS 40.230 relating to psychologists, ORS 40.250 and 675.580 relating to licensed clinical social workers and ORS 40.262 relating to licensed professional counselors and licensed marriage and family therapists, a group health insurer or issuer of an individual health benefit plan may provide for review for level of treatment of admissions and continued stays for treatment in health facilities, residential facilities, day or partial hospitalization programs and outpatient services by either staff of a group health insurer or issuer of an individual health benefit plan or personnel under contract to the group health insurer or issuer of an individual health benefit plan that is not a grandfathered health plan, or by a utilization review contractor, who shall have the authority to certify for or deny level of payment.

(B) Review shall be made according to criteria made available to providers in advance upon request.

(C) Review shall be performed by or under the direction of a physician licensed under ORS 677.100 to 677.228, a psychologist licensed by the Oregon Board of Psychology, a clinical social worker licensed by the State Board of Licensed Social Workers or a professional counselor or marriage and family therapist licensed by the Oregon Board of Licensed Professional Counselors and Therapists, in accordance with standards of the National Committee for Quality Assurance or Medicare review standards of the Centers for Medicare and Medicaid Services.

(D) Review may involve prior [*approval*] **authorization**, concurrent review of the continuation of treatment, post-treatment review or any combination of these. However, if prior [*approval*] **authorization** is required, provision shall be made to allow for payment of urgent or emergency admissions, subject to subsequent review. If prior [*approval*] **authorization** is not required, group health insurers and issuers of individual health benefit plans that are not grandfathered health plans shall permit providers, policyholders or persons acting on their behalf to make advance inquiries regarding the appropriateness of a particular admission to a treatment program. Group health insurers and issuers of individual health benefit plans that are not grandfathered health plans shall provide a timely response to such inquiries. Noncontracting providers must cooperate with these procedures to the same extent as contracting providers to be eligible for reimbursement.

(L) Health maintenance organizations may limit the receipt of covered services by enrollees to services provided by or upon referral by providers contracting with the health maintenance organization. Health maintenance organizations and health care service contractors may create substantive plan benefit and reimbursement differentials at the same level as, and subject to limitations no more restrictive than, those imposed on coverage or reimbursement of expenses arising out of other medical conditions and apply them to contracting and noncontracting providers.

(3) **Except as provided in section 2 of this 2024 Act,** this section does not prohibit a group health insurer or issuer of an individual health benefit plan that is not a grandfathered health plan from managing the provision of benefits through common methods, including but not limited to selectively contracted panels, health plan benefit differential designs, preadmission screening, prior authorization of services, utilization review or other mechanisms designed to limit eligible expenses to those described in subsection (2)(b) of this section provided such methods comply with the requirements of this section.

(4) The Legislative Assembly finds that health care cost containment is necessary and intends to encourage health insurance plans designed to achieve cost containment by ensuring that reimbursement is limited to appropriate utilization under criteria incorporated into the insurance, either directly or by reference, in accordance with this section.

(5)(a) Any medical necessity, utilization or other clinical review conducted for the diagnosis, prevention or treatment of behavioral health conditions or relating to service intensity, level of care placement, continued stay or discharge must be based solely on the following:

(A) The current generally accepted standards of care.

(B) For level of care placement decisions, the most recent version of the levels of care placement criteria developed by the nonprofit professional association for the relevant clinical specialty.

(C) For medical necessity, utilization or other clinical review conducted for the diagnosis, prevention or treatment of behavioral health conditions that does not involve level of care placement decisions, other criteria and guidelines may be utilized if such criteria and guidelines are based on the current generally accepted standards of care including valid, evidence-based sources and current treatment criteria or practice guidelines developed by the nonprofit professional association for the relevant clinical specialty. Such other criteria and guidelines must be made publicly available and made available to insureds upon request to the extent permitted by copyright laws.

(b) This subsection does not prevent a group health insurer or an issuer of an individual health benefit plan other than a grandfathered health plan from using criteria that:

(A) Are outside the scope of criteria and guidelines described in paragraph (a)(B) of this subsection, if the guidelines were developed in accordance with the current generally accepted standards of care; or

(B) Are based on advancements in technology of types of care that are not addressed in the most recent versions of sources specified in paragraph (a)(B) of this subsection, if the guidelines were developed in accordance with current generally accepted standards of care.

(c) For all level of care placement decisions, an insurer shall authorize placement at the level of care consistent with the insured's score or assessment using the relevant level of care placement criteria and guidelines as specified in paragraph (a)(B) of this subsection. If the level of care indicated by the criteria and guidelines is not available, the insurer shall authorize the next higher level of care. If there is disagreement about the appropriate level of care, the insurer shall provide to the provider of the service the full details of the insurer's scoring or assessment using the relevant level of care placement criteria and guidelines specified in paragraph (a)(B) of this subsection.

(6) To ensure the proper use of any criteria and guidelines described in subsection (5) of this section, a group health insurer or an issuer of an individual health benefit plan shall provide, at no cost:

(a) A formal education program, presented by nonprofit clinical specialty associations or other entities authorized by the department, to educate the insurer's or the issuer's staff and any individuals described in subsection (2)(k) of this section who conduct reviews.

(b) To stakeholders, including participating providers and insureds, the criteria and guidelines described in subsection (5) of this section and any education or training materials or resources regarding the criteria and guidelines.

(7) This section does not prevent a group health insurer or issuer of an individual health benefit plan that is not a grandfathered health plan from contracting with providers of health care services to furnish services to policyholders or certificate holders according to ORS 743B.460 or 750.005, subject to the following conditions:

(a) A group health insurer or issuer of an individual health benefit plan that is not a grandfathered health plan is not required to contract with all providers that are eligible for reimbursement under this section.

(b) An insurer or health care service contractor shall, subject to subsection (2) of this section, pay benefits toward the covered charges of noncontracting providers of services for behavioral health treatment. The insured shall, subject to subsection (2) of this section, have the right to use the services of a noncontracting provider of behavioral health treatment, whether or not the behavioral health treatment is provided by contracting or noncontracting providers.

(8)(a) This section does not require coverage for:

(A) Educational or correctional services or sheltered living provided by a school or halfway house;

(B) A long-term residential mental health program that lasts longer than 45 days unless clinically indicated under criteria and guidelines described in subsection (5) of this section;

(C) Psychoanalysis or psychotherapy received as part of an educational or training program, regardless of diagnosis or symptoms that may be present;

(D) A court-ordered sex offender treatment program; or

(E) Support groups.

(b) Notwithstanding paragraph (a)(A) of this subsection, an insured may receive covered outpatient services under the terms of the insured's policy while the insured is living temporarily in a sheltered living situation.

(9) The Oregon Health Authority shall establish a process for the certification of an organization described in subsection (1)(j)(F) of this section that:

(a) Is not otherwise subject to licensing or certification by the authority; and

(b) Does not contract with the authority, a subcontractor of the authority or a community mental health program.

(10) The Oregon Health Authority shall adopt by rule standards for the certification provided under subsection (9) of this section to ensure that a certified provider organization offers a distinct and specialized program for the treatment of mental or nervous conditions.

(11) The Oregon Health Authority may adopt by rule an application fee or a certification fee, or both, to be imposed on any provider organization that applies for certification under subsection (9) of this section. Any fees collected shall be paid into the Oregon Health Authority Fund established in ORS 413.101 and shall be used only for carrying out the provisions of subsection (9) of this section.

(12) The intent of the Legislative Assembly in adopting this section is to reserve benefits for different types of care to encourage cost effective care and to ensure continuing access to levels of care most appropriate for the insured's condition and progress in accordance with this section. This section does not prohibit an insurer from requiring a provider organization certified by the Oregon Health Authority under subsection (9) of this section to meet the insurer's credentialing requirements as a condition of entering into a contract.

(13) The Director of the Department of Consumer and Business Services and the Oregon Health Authority, after notice and hearing, may adopt reasonable rules not inconsistent with this section that are considered necessary for the proper administration of this section. The director shall adopt rules making it a violation of this section for a group health insurer or issuer of an individual health benefit plan other than a grandfathered health plan to require providers to bill using a specific billing code or to restrict the reimbursement paid for particular billing codes other than on the basis of medical necessity.

(14) This section does not:

(a) Prohibit an insured from receiving behavioral health treatment from an out-of-network provider or prevent an out-of-network behavioral health provider from billing the insured for any unreimbursed cost of treatment.

(b) Prohibit the use of value-based payment methods, including global budgets or capitated, bundled, risk-based or other value-based payment methods.

(c) Require that any value-based payment method reimburse behavioral health services based on an equivalent fee-for-service rate.

SECTION 4. ORS 414.766 is amended to read:

414.766. (1) Notwithstanding ORS 414.065 and 414.690, a coordinated care organization must provide behavioral health services to its members that include but are not limited to all of the following:

(a) For a member who is experiencing a behavioral health crisis:

(A) A behavioral health assessment; and

(B) Services that are medically necessary to transition the member to a lower level of care;

(b) At least the minimum level of services that are medically necessary to treat a member's underlying behavioral health condition rather than a mere amelioration of current symptoms, such as suicidal ideation or psychosis, as determined in a behavioral health assessment of the member or specified in the member's care plan;

(c) Treatment of co-occurring behavioral health disorders or medical conditions in a coordinated manner;

(d) Treatment at the least intensive and least restrictive level of care that is safe and effective and meets the needs of the individual's condition;

(e) For all level of care placement decisions, placement at the level of care consistent with a member's score or assessment using the relevant level of care placement criteria and guidelines;

(f) If the level of placement described in paragraph (e) of this subsection is not available, placement at the next higher level of care;

(g) Treatment to maintain functioning or prevent deterioration;

(h) Treatment for an appropriate duration based on the individual's particular needs;

(i) Treatment appropriate to the unique needs of children and adolescents;

(j) Treatment appropriate to the unique needs of older adults;

(k) Treatment that is culturally and linguistically appropriate;

(L) Treatment that is appropriate to the unique needs of gay, lesbian, bisexual and transgender individuals and individuals of any other minority gender identity or sexual orientation;

(m) Coordinated care and case management as defined by the Department of Consumer and Business Services by rule; [*and*]

(n) Mental health wellness appointments as prescribed by the Oregon Health Authority by rule**; and**

(o) Medications and refills of medications prescribed for the treatment of opioid use disorder and any co-occurring substance use disorder or mental health condition, including early refills as described in section 7 of this 2024 Act.

(2) If there is a disagreement about the level of care required by subsection (1)(e) or (f) of this section, a coordinated care organization shall provide to the behavioral health treatment provider full details of the coordinated care organization's scoring or assessment, to the extent permitted by the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164, ORS 192.553 to 192.581 or other state or federal laws limiting the disclosure of health information.

(3) The Oregon Health Authority shall adopt by rule a list of behavioral health services that may not be subject to prior authorization.

SECTION 5. ORS 431A.463 is amended to read:

431A.463. **(1) As used in this section, "medication-assisted treatment" means any medication, and the dispensing or administering of the medication, that is approved by the United States Food and Drug Administration on or before January 1, 2024, for the treatment of substance use disorders, and that is used for that purpose, including opioid and opiate addiction.**

[*(1)*] **(2)** The Oregon Health Authority shall prohibit coordinated care organizations and public payers of health insurance[*, when reimbursing the cost of medication-assisted treatment for treating substance use disorders, including opioid and opiate addiction,*] from requiring prior authorization [*of payment during the first 30 days of medication-assisted treatment*] **for the reimbursement of the costs of medication-assisted treatment**.

(3) Notwithstanding subsection (2) of this section, a coordinated care organization may require prior authorization of a brand name drug for medication-assisted treatment if a generic equivalent is available to substitute for a prescribed brand name drug. As used in this subsection, a different formulation of the medication is not a generic equivalent.

[*(2)*] **(4)** The authority may adopt rules to carry out this section.

(Pharmacist Prescribing and Dispensing of Opioid Use Disorder Medication Refills)

SECTION 6. Sections 7 and 8 of this 2024 Act are added to and made a part of ORS chapter 689.

SECTION 7. (1) As used in this section:

(a) "Early refill" means:

(A) Up to three refills of a current prescription for a medication that a patient has lost or that has been stolen or destroyed; or

(B) One refill in a 12 month period of a medication for which the previous prescription expired in the prior 12 month period.

(b) "Refill" means a supply of a medication consistent with the amount specified in the most recent prescription for the medication.

(2) A pharmacist may prescribe and dispense to a patient, to the extent permitted by federal law, an early refill of a medication for the treatment of opioid use disorder in accordance with subsection (3) of the section.

(3) A pharmacist who prescribes and dispenses early refills under this section shall:

(a) Complete a patient assessment to determine whether the prescription is appropriate;

(b) Document the patient visit and include notations regarding evidence of the patient's previous prescription from the patient's licensed health care provider, information relating to the patient's treatment and other relevant information; and

(c) Notify the patient's primary care provider, and the licensed health care provider who made the previous prescription, of the pharmacist's dispensing of early refills, to the extent permitted by state and federal law.

(4) Notations in a record documenting evidence of a patient's previous prescription under subsection (3)(b) of this section constitute verification of a valid prescription.

(5) The State Board of Pharmacy shall adopt rules to carry out this section, including but not limited to rules to allow a:

(a) Pharmacist to apply for and obtain a registration number from the Drug Enforcement Administration of the United States Department of Justice as a mid-level practitioner; and

(b) Pharmacy to store on the premises medications for the treatment of opioid use disorder.

(6) In adopting rules to carry out this section, the board shall consult with the Public Health and Pharmacy Advisory Formulary Committee described in ORS 689.649.

SECTION 8. (1) As used in this section, "prescription drug locker" means a mechanical device that serves as an extension of a retail drug outlet's will call or point of sale area in which completed patient-specific prescription drugs, devices and related supplies and nonprescription drugs, devices and related supplies are stored for pickup.

(2) A prescription drug locker located within this state and at the same physical address as the retail drug outlet with which the prescription drug locker is associated:

(a) Is considered part of the retail drug outlet and is not required to obtain a license or registration from the State Board of Pharmacy; and

(b) Is not required to obtain a registration from the Drug Enforcement Administration of the United States Department of Justice.

(3) A prescription drug locker located within this state but at a physical address other than the physical address of the retail drug outlet with which the prescription drug locker is associated is considered a remote dispensing site pharmacy and must obtain a registration from the Drug Enforcement Administration in order to dispense controlled substances.

(4) The board may adopt rules to carry out this section.

SECTION 9. 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 State Board of Pharmacy.

(3) "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.

(4) "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.

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

(6) “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.

(7) “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.

(8) “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.

(9) “Distribute” means the delivery of a drug other than by administering or dispensing.

(10) “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.

(11) “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.

(12) “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.

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

(14) “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.

(15) “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.

(16) “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.

(17) “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.

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

(19) “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.

(20) “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.

(21) "Manufacturer" means a person engaged in the manufacture of drugs.

(22) "Nonprescription drug outlet" means a business or other establishment that is open to the general public for the sale or nonprofit distribution of nonprescription drugs and is registered under ORS 689.305.

(23) "Nonprescription drugs" means drugs that may be sold without a prescription and that 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.

(24) "Person" means an individual, corporation, partnership, association or other legal entity.

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

(26) "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.

(27) "Pharmacy technician" means a person licensed by the board who assists in the practice of pharmacy pursuant to rules of the board.

(28) "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.

(29) "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;

(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**; and**

(p) The prescribing and dispensing of early refills of medication for the treatment of opioid use disorder pursuant to section 7 of this 2024 Act.

(30) "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.

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

(32) "Prescription drug" or "legend drug" means a drug that 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.

(33) "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.

(34) "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.

(35) "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.

(36) "Third-party logistics provider" means an entity that:

(a) Provides or coordinates warehousing of, or other logistics services for, a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser of the product; and

(b) Does not take ownership of, or have responsibility to direct the sale or disposition of, the product.

(37) "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.

(38) "Wholesale distributor drug outlet" means a person, other than a manufacturer, manufacturer's colicensed partner, third-party logistics provider or repackager, as defined in 21 U.S.C. 360eee(16), that is engaged in wholesale distribution, as defined in 21 U.S.C. 353(e)(4).

(Access to Addiction Treatment
by Members of Coordinated Care Organizations)

SECTION 10. ORS 414.609 is amended to read:

414.609. (1) A coordinated care organization that contracts with the Oregon Health Authority must maintain a network of providers**, including but not limited to addiction treatment providers,** sufficient in numbers and areas of practice and geographically distributed in a manner to ensure that the health services provided under the contract are reasonably accessible to members.

(2) A member may transfer from one organization to another organization no more than once during each enrollment period.

(Alcohol and Drug Policy Commission Study)

SECTION 11. (1) The Alcohol and Drug Policy Commission created under ORS 430.221 shall conduct a study of barriers to and best practices for:

(a) Youth accessing opioid use disorder treatment; and

(b) Increasing access to opioid use disorder medications, including:

(A) Opioid use disorder medication treatment interventions and the prescribing of opioid use disorder medication in emergency departments; and

(B) Increasing the number of providers of opioid use disorder treatment statewide.

(2) In studying the barriers to and best practices for youth accessing opioid use disorder treatment under subsection (1)(a) of this section, the commission shall collaborate with participating state agencies, as defined in ORS 430.221, and the System of Care Advisory Council established in ORS 418.978.

(3) No later than September 30, 2024, the commission shall provide to the interim committees of the Legislative Assembly related to health a report on the status of the study and any preliminary recommendations that the commission has developed.

(4) No later than September 15, 2025, the commission shall report to the interim committees of the Legislative Assembly related to behavioral health, in the manner provided in ORS 192.245:

(a) A strategic plan to improve the access of youth to opioid use disorder treatment;

(b) A strategic plan that includes evidence-based and evidence-informed strategies for increasing the number of opioid use disorder treatment providers statewide and expanding the capacity of the opioid use disorder treatment system in this state;

(c) Recommendations for reducing the barriers to accessing opioid use disorder treatment, including barriers to the provision of opioid use disorder treatment interventions in emergency departments; and

(d) Needed changes to address obstacles encountered by behavioral health providers when seeking health insurance reimbursement for opioid use disorder medications, including but not limited to:

(A) Requiring providers to use specialty pharmacies instead of purchasing medications directly from vendors and billing the insurers;

(B) Limiting the coverage of opioid use disorder treatment to specific forms of medications, such as sublingual or injectable forms;

(C) Imposing limits on the amount of an opioid use disorder medication that may be dispensed during a single visit; and

(D) Obstacles identified from data regarding insurance claim denials, including retroactive denials, of reimbursement for opioid use disorder medications.

SECTION 12. Section 11 of this 2024 Act is repealed on January 2, 2026.

(Certified Community Behavioral Health Clinic Program)

SECTION 13. Section 14 of this 2024 Act is added to and made a part of ORS chapter 413.

SECTION 14. (1) The certified community behavioral health clinic program is established in the Oregon Health Authority for the purpose of certifying community behavioral health

clinics that meet criteria adopted by the authority by rule to receive prospective fixed cost-based rates, as provided in subsection (4) of this section, for services provided to medical assistance enrollees.

(2) The authority shall appoint an advisory committee, as described in ORS 183.333, to advise the authority in the adoption of rules to carry out this section. The Director of the Oregon Health Authority shall appoint to the advisory committee 15 individuals who represent a diverse constituency and are knowledgeable about certified community behavioral health clinic delivery systems, patient-centered primary care home delivery systems, integrated health care or health care quality. At least five members of the advisory committee must be current or former consumers of the type of behavioral health services that are typically provided by certified community behavioral health clinics or family members, representatives or advocates for such consumers. Rules adopted by the authority:

(a) Must be consistent with the criteria adopted by the United States Department of Health and Human Services for certified community behavioral health clinics; and

(b) Shall ensure that certified community behavioral health clinics provide, either directly or by referral through formal relationships with other providers, all of the services required by the criteria adopted by the United States Department of Health and Human Services for certified community behavioral health clinics.

(3) If the authority adopts requirements for certified community behavioral health clinics that are in addition to the criteria described in subsection (2)(a) of this section, the authority shall:

(a) Provide funding to the clinics sufficient to reimburse the costs of the additional requirements; or

(b) Have a process for granting allowable variances to one or more of the requirements.

(4)(a) A certified community behavioral health clinic shall complete the federally required cost report for the authority to review and approve the clinic's prospective fixed cost-based rate for a patient encounter.

(b) The authority shall regularly adjust the prospective fixed cost-based rate at intervals consistent with federal guidance. A certified community behavioral health clinic may request a rate adjustment if a clinic changes the clinic's scope of services.

(c) The authority shall adopt and provide to certified community behavioral health clinics guidance on the development of fixed rates and billing. The fixed rate must include but is not limited to:

(A) An estimate of the projected cost of anticipated expansions of the certified community behavioral health clinic program or the populations served by the program; and

(B) The cost of the technology and data systems needed by each clinic to track and measure outcomes and other data that the authority requires to be tracked or measured.

(d) The authority shall review federal guidance on rate setting for clinics that are dually certified as federally qualified health centers, as defined in 42 U.S.C. 1396d(l)(2), and as certified community behavioral health clinics and provide recommendations to such dually certified clinics about how the clinics can best bill for services.

(5) In any geographic region of this state that is served by both a certified community behavioral health clinic and a community mental health program:

(a) Before the authority may approve the certification of a certified community behavioral health clinic, the certified community behavioral health clinic and the community mental health program shall enter into a written agreement concerning collaboration between the clinic and the program in the coordination of services that are provided by both the clinic and the program.

(b) The authority shall develop a plan to ensure:

(A) Coordination of services between the clinic and the program to minimize service redundancies; and

(B) Financial efficiencies to maximize financial benefits.

(6) This section does not require a clinic that is eligible for certification under this section to apply for certification. Participation in the certified community behavioral health clinic program is voluntary.

SECTION 15. (1) Prior to January 15, 2025, the Oregon Health Authority shall begin preparing a draft state plan amendment to submit to the Centers for Medicare and Medicaid Services to implement the certified community behavioral health clinic program established in section 14 of this 2024 Act.

(2) Prior to the expiration of the community behavioral health clinic demonstration program described in section 223 of the Protecting Access to Medicare Act of 2014 (P.L. 113-93), as amended, the authority shall seek federal approval for an amendment to the Medicaid state plan to allow the state to receive federal financial participation in the costs of the certified community behavioral health clinic program established in section 14 of this 2024 Act.

(3) The authority shall explore all prospective rate methodologies allowed for the certified community behavioral health clinic model by the Centers for Medicare and Medicaid Services.

(Joint Task Force on Regional Behavioral Health Accountability)

SECTION 16. (1) The Joint Task Force on Regional Behavioral Health Accountability is established to make recommendations to the Legislative Assembly to improve the governance of behavioral health systems and strengthen evidence-based and equitable funding decisions and accountability of behavioral health systems.

(2) The task force consists of 26 members appointed as follows:

(a) The President of the Senate shall appoint two members from among members of the Senate, one from the majority party and one from the minority party.

(b) The Speaker of the House of Representatives shall appoint two members from among members of the House of Representatives, one from the majority party and one from the minority party.

(c) The Chief Justice of the Supreme Court shall appoint one member from the Judicial Department.

(d) The Governor shall appoint 21 members as follows:

(A) One member representing the Oregon Health Authority;

(B) One member representing the Alcohol and Drug Policy Commission;

(C) One member representing the Department of Human Services;

(D) One member representing coordinated care organizations;

(E) One member representing providers of psychiatric care in clinical settings;

(F) One member representing Oregon counties;

(G) One member representing Oregon cities;

(H) One member who provides county mental health services or who represents county mental health providers;

(I) One member from a large labor organization representing behavioral health workers;

(J) One member who is a behavioral health provider or who represents private and nonprofit behavioral health providers;

(K) One member who provides nonprofit substance use disorder treatment or who represents nonprofit substance use disorder treatment providers;

(L) One member from a large labor organization representing nurses;

(M) One member who is a licensed doctor or who represents licensed doctors with experience in behavioral health or substance use disorder treatment programs, care delivery or funding;

(N) One member from a business coalition representing the hospital industry;

(O) One member from a business coalition representing the insurance industry;

(P) One member from a business coalition representing pharmacists;

(Q) One member representing a consumer of behavioral health services;

(R) One member with extensive experience in Oregon Indian tribes and a deep understanding of Oregon's rural and urban tribal populations, appointed after consultation with the Commission on Indian Services;

(S) One member who is an emergency response transportation provider;

(T) One member representing long term care facilities; and

(U) One member with experience in regional behavioral health system governance.

(3) The task force, in collaboration with any other task forces that are charged with scopes of work that overlap or intersect with the charges of the Joint Task Force on Regional Behavioral Health Accountability, shall develop recommendations to:

(a) Improve collaboration and accountability across federal, state and local behavioral health and substance use disorder treatment programs and funding;

(b) Ensure equitable outcomes in publicly supported treatment settings across Oregon communities;

(c) Provide greater cost efficiencies in the continuum of care of Oregon's behavioral health system; and

(d) Establish broad access to methadone and other opioid use disorder medications through mobile devices, telehealth and pharmacy-based services to measurably increase the engagement statewide of individuals with opioid use disorder in opioid use disorder treatment.

(4) Recommendations developed under subsection (3) of this section should include:

(a) Any statutory changes needed to ensure that federal, state and local funds are being spent to maximize outcomes and resource efficiency;

(b) Policy changes recommended based on a comparative analysis of policies in other states that spend less on treatment but demonstrate better behavioral health and substance use disorder treatment outcomes, including better outcomes for groups that are disproportionately impacted by health inequities; and

(c) Any governance changes that would facilitate greater alignment of spending decisions between federal, state and local behavioral health and substance use disorder treatment programs.

(5) A majority of the voting members of the task force constitutes a quorum for the transaction of business.

(6) Official action by the task force requires the approval of a majority of the voting members of the task force.

(7) The task force shall elect one of its members to serve as chairperson.

(8) If there is a vacancy for any cause, the appointing authority shall make an appointment to become immediately effective.

(9) The task force shall meet at times and places specified by the call of the chairperson or of a majority of the voting members of the task force.

(10) The task force may adopt rules necessary for the operation of the task force.

(11)(a) The task force shall provide draft recommendations developed under subsections (3) and (4) of this section to the interim committees of the Legislative Assembly related to health no later than September 15, 2025.

(b) The task force shall submit a final report of the task force's recommendations, in the manner provided by ORS 192.245, to the interim committees of the Legislative Assembly related to health no later than December 15, 2025.

(12) The Legislative Policy and Research Director shall provide staff support to the task force, including by:

(a) Researching and providing analysis on current behavioral health funding streams that support the continuum of care across Oregon communities;

(b) Reviewing strategies that have been successful in other states, including through the use of federal Medicaid waivers or Medicaid demonstration projects;

(c) Reviewing data related to the challenges faced by individuals receiving substance use disorder treatment in publicly supported treatment settings; and

(d) Reviewing the responsibilities of county and state agencies and the accountability of county and state agencies for providing behavioral health and substance use disorder treatment.

(13) Members of the Legislative Assembly appointed to the task force are nonvoting members of the task force and may act in an advisory capacity only.

(14) Members of the task force who are not members of the Legislative Assembly are not entitled to compensation or reimbursement for expenses and serve as volunteers on the task force.

(15) All agencies of state government, as defined in ORS 174.111, are directed to assist the task force in the performance of the duties of the task force and, to the extent permitted by laws relating to confidentiality, to furnish information and advice the members of the task force consider necessary to perform their duties.

SECTION 17. Section 16 of this 2024 Act is repealed on January 2, 2026.

(Task Force on Improving the Safety of Behavioral Health Workers)

SECTION 18. (1) The Task Force on Improving the Safety of Behavioral Health Workers is established.

(2) The task force consists of 17 members appointed as follows:

(a) The President of the Senate shall appoint two members from among members of the Senate.

(b) The Speaker of the House of Representatives shall appoint two members from among members of the House of Representatives.

(c) The President and the Speaker shall jointly appoint:

(A) Four employers of behavioral health workers including one from county government;

(B) Two behavioral health workers;

(C) Two representatives of organized labor representing behavioral health workers;

(D) One consumer of behavioral health services;

(E) One representative of the state protection and advocacy system described in ORS 192.517 (1); and

(F) One representative of the Oregon State Hospital or the Oregon Health Authority on behalf of the hospital.

(d) The Governor shall appoint two members from the Occupational Safety and Health Division of the Department of Consumer and Business Services.

(3) The task force shall produce a set of recommendations for improving the safety of behavioral health workers.

(4) A majority of the voting members of the task force constitutes a quorum for the transaction of business.

(5) Official action by the task force requires the approval of a majority of the voting members of the task force.

(6) The task force shall elect one of its members to serve as chairperson.

(7) If there is a vacancy for any cause, the appointing authority shall make an appointment to become immediately effective.

(8) The task force shall meet at times and places specified by the call of the chairperson or of a majority of the voting members of the task force.

(9) The task force may adopt rules necessary for the operation of the task force.

(10) No later than September 1, 2024, the task force shall submit to the interim committees of the Legislative Assembly related to health a preliminary report containing draft policy recommendations to address the safety concerns that are prevalent in the behavioral health industry including recommendations, by type of behavioral health facility or workplace setting, for:

(a) Physical and structural security requirements;

(b) Safe staffing levels;

(c) Standards and procedures for reporting assaults;

(d) Best practices for worker safety training including minimum requirements for training on workplace safety protocols;

(e) Minimum standards for safety protocols and procedures;

(f) Strategies to ensure compliance with all worker safety and training requirements; and

(g) Potential sources of funding to mitigate the costs incurred by implementing any of the recommendations.

(11) No later than December 1, 2024, the task force shall report the task force's final recommendations, in the manner provided by ORS 192.245, to the interim committees of the Legislative Assembly related to health.

(12) The Legislative Policy and Research Director shall provide staff support to the task force and the Legislative Counsel shall provide legal support for the task force recommendations including but not limited to drafting proposed legislative changes.

(13) Members of the Legislative Assembly appointed to the task force are nonvoting members of the task force and may act in an advisory capacity only.

(14) Members of the task force who are not members of the Legislative Assembly or appointed by the Governor shall be paid compensation and reimbursed for actual and necessary travel and other expenses incurred by them in the performance of their official duties on the task force in the manner and amounts provided for in ORS 292.495.

(15) All agencies of state government, as defined in ORS 174.111, are directed to assist the task force in the performance of the duties of the task force and, to the extent permitted by laws relating to confidentiality, to furnish information and advice the members of the task force consider necessary to perform their duties.

SECTION 19. Section 18 of this 2024 Act is repealed on January 2, 2026.

(United We Heal Medicaid Payment Program)

SECTION 20. (1) The United We Heal Medicaid Payment Program is established in the Oregon Health Authority. The goal of the program is to increase the available behavioral health care workforce in this state. The authority shall provide supplemental medical assistance payments to eligible behavioral health care providers to enable the providers to access enhanced apprenticeship and training programs and opportunities by participating in a labor-management training trust.

(2) The authority shall prescribe by rule eligibility criteria for receiving the payments consistent with the goal of the program expressed in subsection (1) of this section.

(3) To participate in the program, a behavioral health provider must enter into a memorandum of understanding with the authority specifying how the payments will be used. The authority shall terminate payments if the provider fails to abide by or violates the terms of the memorandum of understanding. A provider may request a contested case proceeding to challenge a termination.

(Conforming Amendments)

SECTION 21. ORS 750.055 is amended to read:

750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

(a) ORS 705.137, 705.138 and 705.139.

(b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.

(c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not including ORS 732.582, and ORS 732.650 to 732.689.

(d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(e) ORS 734.014 to 734.440.

(f) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 742.542.

(g) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.020, 743.022, 743.023, 743.025, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788, 743.790 and 743B.221.

(h) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.169, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252, 743A.260, 743A.310 and 743A.315 and section 2, chapter 771, Oregon Laws 2013**, and section 2 of this 2024 Act**.

(i) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195, 743B.197, 743B.200, 743B.202, 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800.

(j) The following provisions of ORS chapter 744:

(A) ORS 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;

(B) ORS 744.602 to 744.665, relating to the regulation of insurance consultants; and

(C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

(k) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

(2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:

(a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.

(b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.

(3) For the purposes of this section, health care service contractors are insurers.

(4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.

(5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

(b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.

(6) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.

SECTION 22. ORS 750.055, as amended by section 21, chapter 771, Oregon Laws 2013, section 7, chapter 25, Oregon Laws 2014, section 82, chapter 45, Oregon Laws 2014, section 9, chapter 59, Oregon Laws 2015, section 7, chapter 100, Oregon Laws 2015, section 7, chapter 224, Oregon Laws 2015, section 11, chapter 362, Oregon Laws 2015, section 10, chapter 470, Oregon Laws 2015, section 30, chapter 515, Oregon Laws 2015, section 10, chapter 206, Oregon Laws 2017, section 6, chapter 417, Oregon Laws 2017, section 22, chapter 479, Oregon Laws 2017, section 10, chapter 7, Oregon Laws 2018, section 69, chapter 13, Oregon Laws 2019, section 38, chapter 151, Oregon Laws 2019, section 5, chapter 441, Oregon Laws 2019, section 85, chapter 97, Oregon Laws 2021, section 12, chapter 37, Oregon Laws 2022, section 5, chapter 111, Oregon Laws 2023, and section 2, chapter 152, Oregon Laws 2023, is amended to read:

750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

(a) ORS 705.137, 705.138 and 705.139.

(b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.

(c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not including ORS 732.582, and ORS 732.650 to 732.689.

(d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(e) ORS 734.014 to 734.440.

(f) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 742.542.

(g) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.020, 743.022, 743.023, 743.025, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788, 743.790 and 743B.221.

(h) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.169, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252, 743A.260, 743A.310 and 743A.315 **and section 2 of this 2024 Act**.

(i) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195, 743B.197, 743B.200, 743B.202, 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800.

(j) The following provisions of ORS chapter 744:

(A) ORS 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;

(B) ORS 744.602 to 744.665, relating to the regulation of insurance consultants; and

(C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

(k) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

(2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:

(a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.

(b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.

(3) For the purposes of this section, health care service contractors are insurers.

(4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.

(5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

(b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.

(6) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.

SECTION 23. ORS 750.333 is amended to read:

750.333. (1) The following provisions apply to trusts carrying out a multiple employer welfare arrangement:

(a) ORS 705.137, 705.138 and 705.139.

(b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.268, 731.296 to 731.316, 731.324, 731.328, 731.378, 731.386, 731.390, 731.398, 731.406, 731.410, 731.414, 731.418 to 731.434, 731.454, 731.484, 731.486, 731.488, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.804, 731.808 and 731.844 to 731.992.

(c) ORS 733.010 to 733.050, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(d) ORS 734.014 to 734.440.

(e) ORS 742.001 to 742.009, 742.013, 742.016, 742.061 and 742.065.

(f) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.020, 743.023, 743.028, 743.029, 743.053, 743.405, 743.406, 743.524, 743.526, 743.535 and 743B.221.

(g) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.024, 743A.034, 743A.036, 743A.040, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.169, 743A.170, 743A.175, 743A.180, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252, 743A.260 and 743A.310 **and section 2 of this 2024 Act**.

(h) ORS 743B.001, 743B.003 to 743B.127 (except 743B.125 to 743B.127), 743B.195, 743B.197, 743B.200, 743B.202, 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.310, 743B.320, 743B.321, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343, 743B.344, 743B.345, 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.451, 743B.453, 743B.470, 743B.505, 743B.550, 743B.555 and 743B.601.

(i) The following provisions of ORS chapter 744:

(A) ORS 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;

(B) ORS 744.602 to 744.665, relating to the regulation of insurance consultants; and

(C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

(j) ORS 746.005 to 746.140, 746.160 and 746.220 to 746.370.

(2) For the purposes of this section:

(a) A trust carrying out a multiple employer welfare arrangement is an insurer.

(b) References to certificates of authority are references to certificates of multiple employer welfare arrangement.

(c) Contributions are premiums.

(3) The provision of health benefits under ORS 750.301 to 750.341 is the transaction of health insurance.

(4) The Department of Consumer and Business Services may adopt rules that are necessary to implement the provisions of ORS 750.301 to 750.341.

DELIVERY OF CONTROLLED SUBSTANCES
(Delivery Definition Based on State v. Boyd)

SECTION 24. ORS 475.005 is amended to read:

475.005. As used in ORS 475.005 to 475.285 and 475.752 to 475.980, unless the context requires otherwise:

(1) "Abuse" means the repetitive excessive use of a drug short of dependence, without legal or medical supervision, which may have a detrimental effect on the individual or society.

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

(a) A practitioner or an authorized agent thereof; or

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

(3) "Administration" means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

(4) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser. It does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman.

(5) "Board" means the State Board of Pharmacy.

(6) "Controlled substance":

(a) Means a drug or its immediate precursor classified in Schedules I through V under the federal Controlled Substances Act, 21 U.S.C. 811 to 812, as modified under ORS 475.035. The use of the term "precursor" in this paragraph does not control and is not controlled by the use of the term "precursor" in ORS 475.752 to 475.980.

(b) Does not include:

(A) The plant Cannabis family Cannabaceae;

(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;

(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;

(D) The seeds of the plant Cannabis family Cannabaceae;

(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph; or

(F) Psilocybin or psilocin, but only if and to the extent that a person manufactures, delivers, or possesses psilocybin, psilocin, or psilocybin products in accordance with the provisions of ORS 475A.210 to 475A.722 and rules adopted under ORS 475A.210 to 475A.722.

(7) "Counterfeit substance" means a controlled substance or its container or labeling, which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, delivered or dispensed the substance.

(8) "Deliver" or "delivery" means the actual, constructive or attempted transfer **of, or possession with the intent to transfer**, other than by administering or dispensing, from one person to another**,** [*of*] a controlled substance, whether or not there is an agency relationship.

(9) "Device" means instruments, apparatus or contrivances, including their components, parts or accessories, intended:

(a) For use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals; or

(b) To affect the structure of any function of the body of humans or animals.

(10) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, and includes the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

(11) "Dispenser" means a practitioner who dispenses.

(12) "Distributor" means a person who delivers.

(13) "Drug" means:

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

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals;

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

(d) Substances intended for use as a component of any article specified in paragraph (a), (b) or (c) of this subsection; however, the term does not include devices or their components, parts or accessories.

(14) "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 any similar apparatus having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities.

(15) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, 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 substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance:

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

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

(16) "Person" includes a government subdivision or agency, business trust, estate, trust or any other legal entity.

(17) "Practitioner" means physician, dentist, veterinarian, scientific investigator, licensed nurse practitioner, physician assistant or other person licensed, registered or otherwise permitted by law to dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state but does not include a pharmacist or a pharmacy.

(18) "Prescription" means a written, oral or electronically transmitted direction, given by a practitioner 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. Any label affixed to a drug prepared under written, oral or electronically transmitted direction shall prominently display a warning that the removal thereof is prohibited by law.

(19) "Production" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance.

(20) "Research" means an activity conducted by the person registered with the federal Drug Enforcement Administration pursuant to a protocol approved by the United States Food and Drug Administration.

(21) "Ultimate user" means a person who lawfully possesses a controlled substance for the use of the person or for the use of a member of the household of the person or for administering to an animal owned by the person or by a member of the household of the person.

(22) "Usable quantity" means:

(a) An amount of a controlled substance that is sufficient to physically weigh independent of its packaging and that does not fall below the uncertainty of the measuring scale; or

(b) An amount of a controlled substance that has not been deemed unweighable, as determined by a Department of State Police forensic laboratory, due to the circumstances of the controlled substance.

(23) **"Within 30 feet," "within 500 feet" and** "within 1,000 feet" [*means*] **mean** a straight line measurement in a radius extending for [*1,000*] **the specified number of** feet or less in every direction from a specified location or from any point on the boundary line of a specified unit of property.

(Delivery in Certain Locations)

SECTION 25. ORS 475.900 is amended to read:

475.900. (1) A violation of ORS 475.752, 475.806 to 475.894, 475.904 or 475.906 shall be classified as crime category 8 of the sentencing guidelines grid of the Oregon Criminal Justice Commission if:

(a) The violation constitutes delivery or manufacture of a controlled substance and involves substantial quantities of a controlled substance. For purposes of this paragraph, the following amounts constitute substantial quantities of the following controlled substances:

(A) Five grams or more of a mixture or substance containing a detectable amount of heroin;

(B) Five grams or more or 25 or more user units of a mixture or substance containing a detectable amount of fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy;

(C) Ten grams or more of a mixture or substance containing a detectable amount of cocaine;

(D) Ten grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers or salts of its isomers;

(E) Two hundred or more user units of a mixture or substance containing a detectable amount of lysergic acid diethylamide;

(F) Sixty grams or more of a mixture or substance containing a detectable amount of psilocybin or psilocin; or

(G) Five grams or more or 25 or more pills, tablets or capsules of a mixture or substance containing a detectable amount of:

(i) 3,4-methylenedioxyamphetamine;

(ii) 3,4-methylenedioxymethamphetamine; or

(iii) 3,4-methylenedioxy-N-ethylamphetamine.

(b) The violation constitutes possession, delivery or manufacture of a controlled substance and the possession, delivery or manufacture is a commercial drug offense. A possession, delivery or manufacture is a commercial drug offense for purposes of this subsection if it is accompanied by at least three of the following factors:

(A) The delivery was of heroin, fentanyl, cocaine, methamphetamine, lysergic acid diethylamide, psilocybin or psilocin and was for consideration;

(B) The offender was in possession of $300 or more in cash;

(C) The offender was unlawfully in possession of a firearm or other weapon as described in ORS 166.270 (2), or the offender used, attempted to use or threatened to use a deadly or dangerous weapon as defined in ORS 161.015, or the offender was in possession of a firearm or other deadly or dangerous weapon as defined in ORS 161.015 for the purpose of using it in connection with a controlled substance offense;

(D) The offender was in possession of materials being used for the packaging of controlled substances such as scales, wrapping or foil, other than the material being used to contain the substance that is the subject of the offense;

(E) The offender was in possession of drug transaction records or customer lists;

(F) The offender was in possession of stolen property;

(G) Modification of structures by painting, wiring, plumbing or lighting to facilitate a controlled substance offense;

(H) The offender was in possession of manufacturing paraphernalia, including recipes, precursor chemicals, laboratory equipment, lighting, ventilating or power generating equipment;

(I) The offender was using public lands for the manufacture of controlled substances;

(J) The offender had constructed fortifications or had taken security measures with the potential of injuring persons; or

(K) The offender was in possession of controlled substances in an amount greater than:

(i) Three grams or more of a mixture or substance containing a detectable amount of heroin;

(ii) Three grams or more or 15 or more user units of a mixture or substance containing a detectable amount of fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy;

(iii) Eight grams or more of a mixture or substance containing a detectable amount of cocaine;

(iv) Eight grams or more of a mixture or substance containing a detectable amount of methamphetamine;

(v) Twenty or more user units of a mixture or substance containing a detectable amount of lysergic acid diethylamide;

(vi) Ten grams or more of a mixture or substance containing a detectable amount of psilocybin or psilocin; or

(vii) Four grams or more or 20 or more pills, tablets or capsules of a mixture or substance containing a detectable amount of:

(I) 3,4-methylenedioxyamphetamine;

(II) 3,4-methylenedioxymethamphetamine; or

(III) 3,4-methylenedioxy-N-ethylamphetamine.

(c) The violation constitutes a violation of ORS 475.848, 475.852, 475.868, 475.872, 475.878, 475.882, 475.888, 475.892 or 475.904.

(d) The violation constitutes manufacturing methamphetamine and the manufacturing consists of:

(A) A chemical reaction involving one or more precursor substances for the purpose of manufacturing methamphetamine; or

(B) Grinding, soaking or otherwise breaking down a precursor substance for the purpose of manufacturing methamphetamine.

(e) The violation constitutes a violation of ORS 475.906 (1) or (2) that is not described in ORS 475.907.

(2) A violation of ORS 475.752 or 475.806 to 475.894 shall be classified as crime category 7 of the sentencing guidelines grid of the Oregon Criminal Justice Commission if the violation constitutes delivery for consideration of heroin, cocaine, fentanyl, methamphetamine or 3,4-methylenedioxyamphetamine, 3,4-methylenedioxymethamphetamine or 3,4-methylenedioxy-N-ethylamphetamine and:

(a) The person knows, or reasonably should have known, that the delivery is occurring within 500 feet of the real property comprising a treatment facility;

(b) The person knows, or reasonably should have known, that the delivery is occurring within 500 feet of the real property comprising a temporary residence shelter; or

(c) The delivery occurs within 30 feet of the real property comprising a public park.

[*(2)*] **(3)** A violation of ORS 475.752 or 475.806 to 475.894 shall be classified as crime category 6 of the sentencing guidelines grid of the Oregon Criminal Justice Commission if:

(a) The violation constitutes delivery of heroin, cocaine, fentanyl, methamphetamine or 3,4-methylenedioxyamphetamine, 3,4-methylenedioxymethamphetamine or 3,4-methylenedioxy-N-ethylamphetamine and is for consideration.

(b) The violation constitutes possession of substantial quantities of a controlled substance. For purposes of this paragraph, the following amounts constitute substantial quantities of the following controlled substances:

(A) Five grams or more of a mixture or substance containing a detectable amount of heroin;

(B) Five grams or more or 25 or more user units of a mixture or substance containing a detectable amount of fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy;

(C) Ten grams or more of a mixture or substance containing a detectable amount of cocaine;

(D) Ten grams or more of a mixture or substance containing a detectable amount of methamphetamine;

(E) Two hundred or more user units of a mixture or substance containing a detectable amount of lysergic acid diethylamide;

(F) Sixty grams or more of a mixture or substance containing a detectable amount of psilocybin or psilocin; or

(G) Five grams or more or 25 or more pills, tablets or capsules of a mixture or substance containing a detectable amount of:

(i) 3,4-methylenedioxyamphetamine;

(ii) 3,4-methylenedioxymethamphetamine; or

(iii) 3,4-methylenedioxy-N-ethylamphetamine.

(4) A violation of ORS 475.752 or 475.806 to 475.894 shall be classified as crime category 5 of the sentencing guidelines grid of the Oregon Criminal Justice Commission if the violation constitutes delivery of heroin, cocaine, fentanyl, methamphetamine or 3,4-methylenedioxyamphetamine, 3,4-methylenedioxymethamphetamine or 3,4-methylenedioxy-N-ethylamphetamine and:

(a) The person knows, or reasonably should have known, that the delivery is occurring within 500 feet of the real property comprising a treatment facility;

(b) The person knows, or reasonably should have known, that the delivery is occurring within 500 feet of the real property comprising a temporary residence shelter; or

(c) The delivery occurs within 30 feet of the real property comprising a public park.

[*(3)*] **(5)** Any felony violation of ORS 475.752 or 475.806 to 475.894 not contained in [*subsection (1) or (2)*] **subsections (1) to (4)** of this section shall be classified as crime category 4 of the sentencing guidelines grid of the Oregon Criminal Justice Commission if the violation involves delivery or manufacture of a controlled substance.

[*(4)*] **(6)** In order to prove a commercial drug offense, the state shall plead in the accusatory instrument sufficient factors of a commercial drug offense under [*subsections (1) and (2)*] **subsection (1)** of this section. The state has the burden of proving each factor beyond a reasonable doubt.

[*(5)*] **(7)** As used in this section[*,*]**:**

(a) "Mixture or substance" means any mixture or substance, whether or not the mixture or substance is in an ingestible or marketable form at the time of the offense.

(b) "Public park" means a park operated by the state, a county, a city or a park and recreation district.

(c) "Temporary residence shelter" means a building that provides shelter on a temporary basis for individuals and families who lack permanent housing.

(d) "Treatment facility" has the meaning given that term in ORS 430.306.

(Reevaluation of Release Guidelines)

SECTION 26. No later than June 1, 2024, the Chief Justice of the Supreme Court, with input from a criminal justice advisory committee appointed by the Chief Justice, shall reevaluate and update the release guidelines for the pretrial release orders established under ORS 135.233 for persons arrested for or charged with delivery or manufacture of a controlled substance.

SECTION 27. Section 26 of this 2024 Act is repealed on January 2, 2025.

(Conforming Amendments)

SECTION 28. ORS 475.752 is amended to read:

475.752. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture or deliver a controlled substance. Any person who violates this subsection with respect to:

(a) A controlled substance in Schedule I, is guilty of a Class A felony, except as otherwise provided in ORS 475.886 and 475.890.

(b) A controlled substance in Schedule II, is guilty of a Class B felony, except as otherwise provided in ORS 475.878, 475.880, 475.882, 475.904 and 475.906.

(c) A controlled substance in Schedule III, is guilty of a Class C felony, except as otherwise provided in ORS 475.904 and 475.906.

(d) A controlled substance in Schedule IV, is guilty of a Class B misdemeanor.

(e) A controlled substance in Schedule V, is guilty of a Class C misdemeanor.

(2) Except as authorized in ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to create or deliver a counterfeit substance. Any person who violates this subsection with respect to:

(a) A counterfeit substance in Schedule I, is guilty of a Class A felony.

(b) A counterfeit substance in Schedule II, is guilty of a Class B felony.

(c) A counterfeit substance in Schedule III, is guilty of a Class C felony.

(d) A counterfeit substance in Schedule IV, is guilty of a Class B misdemeanor.

(e) A counterfeit substance in Schedule V, is guilty of a Class C misdemeanor.

(3) It is unlawful for any person knowingly or intentionally to possess a controlled substance unless the substance was obtained directly from, or pursuant to a valid prescription or order of, a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980. Any person who violates this subsection with respect to:

(a) A controlled substance in Schedule I, is guilty of a Class E violation, except as otherwise provided in ORS 475.854, 475.874 and 475.894 and subsection (7) of this section.

(b) A controlled substance in Schedule II, is guilty of a Class E violation, except as otherwise provided in ORS 475.814, 475.824, 475.834 or 475.884 or subsection (8) of this section.

(c) A controlled substance in Schedule III, is guilty of a Class E violation.

(d) A controlled substance in Schedule IV, is guilty of a Class E violation.

(e) A controlled substance in Schedule V, is guilty of a violation.

(4) It is an affirmative defense in any prosecution under this section for manufacture, possession or delivery of the plant of the genus Lophophora commonly known as peyote that the peyote is being used or is intended for use:

(a) In connection with the good faith practice of a religious belief;

(b) As directly associated with a religious practice; and

(c) In a manner that is not dangerous to the health of the user or others who are in the proximity of the user.

(5) The affirmative defense created in subsection (4) of this section is not available to any person who has possessed or delivered the peyote while incarcerated in a correctional facility in this state.

(6)(a) Notwithstanding subsection (1) of this section, a person who unlawfully manufactures or delivers a controlled substance in Schedule IV and who thereby causes death to another person is guilty of a Class C felony.

(b) For purposes of this subsection, causation is established when the controlled substance plays a substantial role in the death of the other person.

(7) Notwithstanding subsection (3)(a) of this section:

(a) Unlawful possession of a controlled substance in Schedule I is a Class A misdemeanor if the person possesses:

(A) Forty or more user units of a mixture or substance containing a detectable amount of lysergic acid diethylamide; or

(B) Twelve grams or more of a mixture or substance containing a detectable amount of psilocybin or psilocin.

(b) Unlawful possession of a controlled substance in Schedule I is a Class B felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 [*(2)(b)*] **(3)(b)**.

(8) Notwithstanding subsection (3)(b) of this section:

(a) Unlawful possession of a controlled substance in Schedule II is a Class A misdemeanor if the person possesses one gram or more or five or more user units of a mixture or substance containing a detectable amount of fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy.

(b) Unlawful possession of a controlled substance in Schedule II is a Class C felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 [*(2)(b)*] **(3)(b)**.

SECTION 29. ORS 475.854 is amended to read:

475.854. (1) It is unlawful for any person knowingly or intentionally to possess heroin.

(2)(a) Unlawful possession of heroin is a Class E violation.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of heroin is a Class A misdemeanor if the person possesses one gram or more of a mixture or substance containing a detectable amount of heroin.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of heroin is a Class B felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 [*(2)(b)*] **(3)(b)**.

SECTION 30. ORS 475.874 is amended to read:

475.874. (1) It is unlawful for any person knowingly or intentionally to possess 3,4-methylenedioxymethamphetamine.

(2)(a) Unlawful possession of 3,4-methylenedioxymethamphetamine is a Class E violation.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of 3,4-methylenedioxymethamphetamine is a Class A misdemeanor if the person possesses one gram or more or five or more pills, tablets or capsules of a mixture or substance containing a detectable amount of:

(A) 3,4-methylenedioxyamphetamine;

(B) 3,4-methylenedioxymethamphetamine; or

(C) 3,4-methylenedioxy-N-ethylamphetamine.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of 3,4-methylenedioxymethamphetamine is a Class B felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 [*(2)(b)*] **(3)(b)**.

SECTION 31. ORS 475.884 is amended to read:

475.884. (1) It is unlawful for any person knowingly or intentionally to possess cocaine unless the substance was obtained directly from, or pursuant to[,] a valid prescription or order of**,** a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2)(a) Unlawful possession of cocaine is a Class E violation.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of cocaine is a Class A misdemeanor if the person possesses two grams or more of a mixture or substance containing a detectable amount of cocaine.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of cocaine is a Class C felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 [*(2)(b)*] **(3)(b)**.

SECTION 32. ORS 475.894 is amended to read:

475.894. (1) It is unlawful for any person knowingly or intentionally to possess methamphetamine unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2)(a) Unlawful possession of methamphetamine is a Class E violation.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of methamphetamine is a Class A misdemeanor if the person possesses two grams or more of a mixture or substance containing a detectable amount of methamphetamine.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of methamphetamine is a Class C felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 [*(2)(b)*] **(3)(b)**.

(Applicability)

SECTION 33. The amendments to ORS 475.005, 475.752, 475.854, 475.874, 475.884, 475.894 and 475.900 by sections 24, 25 and 28 to 32 of this 2024 Act apply to conduct occurring on or after the effective date of this 2024 Act.

POSSESSION OF CONTROLLED SUBSTANCES
(Drug Enforcement Misdemeanor Provisions)

SECTION 34. Section 35 of this 2024 Act is added to and made a part of ORS 475.752 to 475.980.

SECTION 35. (1) Unlawful possession of a controlled substance constituting a drug enforcement misdemeanor under ORS 475.752 (3)(a), (b), (c) or (d), 475.814 (2)(a), 475.824 (2)(a), 475.834 (2)(a), 475.854 (2)(a), 475.874 (2)(a), 475.884 (2)(a) or 475.894 (2)(a) is punishable as described in this section.

(2)(a) When imposing a sentence for the crime described in this section:

(A) The court may decide to not suspend the imposition or execution of any part of the sentence, and impose a term of incarceration in accordance with ORS 137.010 (7) of up to 180 days, only upon the request of the defendant.

(B) If the defendant has not requested to be sentenced under subparagraph (A) of this paragraph, or if the court has decided not to sentence the defendant under subparagraph (A) of this paragraph, the court shall suspend the imposition of any sentence of incarceration and, notwithstanding ORS 137.010 (4), impose a sentence of supervised probation of a definite period of up to 18 months.

(b) When imposing a sentence of probation under this section, the court may not order as a condition of probation that the defendant serve a sentence of incarceration or confinement in the county jail.

(c) Notwithstanding ORS 135.050, 137.010 (7), 161.635 and 161.665, the court may not include in the judgment of conviction for the crime described in this section a requirement that the defendant pay a fine, cost, assessment or attorney fee.

(d) ORS 137.540 (2)(a) does not apply to sentences imposed under this section.

(3)(a) Structured, intermediate sanctions as described in ORS 137.593 may be imposed in accordance with rules adopted under ORS 137.595 when a condition of a term of probation imposed under this section has been violated.

(b) Upon a finding that the person on probation has violated a condition of probation imposed under this section, the court may impose a sanction, which may include days in jail.

(c) The total amount of jail that a person may receive pursuant to structured, intermediate sanctions, or a court-imposed sanctions, on a probation imposed under this section is

30 days. Any term of incarceration imposed as a sanction must allow for early release to a treatment facility.

(d) The court may extend the length of a probation sentence imposed under this section if the person on probation consents to the extension. The total term of probation may not exceed five years.

(4)(a) Notwithstanding ORS 137.545 (5)(a)(B) and 137.593, upon the court's revocation of a sentence of probation imposed under this section, the court may impose as a revocation sentence up to 180 days' incarceration. For any sentence of incarceration imposed under this paragraph, the court shall authorize early release to an inpatient or outpatient drug and alcohol treatment program as described in paragraph (b) of this subsection.

(b) Upon imposing a revocation sentence of incarceration under this subsection, the court shall commit the person to the custody of the supervisory authority under ORS 137.124. The county community corrections agency shall monitor when an inpatient or outpatient drug and alcohol treatment program becomes available for the person and shall notify the person when a program is available. In order to be released early to the program, the person must enter into a revocation release agreement subject to such conditions as determined by the county community corrections agency. If the person violates the terms of the revocation release agreement, the county community corrections agency may cause the person to return to jail to serve the remainder of the incarceration sentence originally imposed.

(c) When a person has been released to an inpatient or outpatient drug and alcohol treatment program under paragraph (b) of this subsection, each day that the person is in the community and subject to the revocation release agreement shall count toward the total term of incarceration imposed as a revocation sentence.

(d) When imposing a revocation sentence of incarceration under this section, the court shall order, and may not deny, that the person receive credit for time served for any day that the person was previously incarcerated on the charge.

(Deflection Programs)

SECTION 36. (1) Law enforcement agencies in this state are encouraged to, in lieu of citation or arrest, or after citation or arrest but before referral to the district attorney, refer a person to a deflection program when the person is suspected of committing, or has been cited or arrested for, unlawful possession of a controlled substance constituting a drug enforcement misdemeanor under section 35 of this 2024 Act.

(2) District attorneys in this state are encouraged to divert for assessment, treatment and other services, in lieu of conviction, cases involving unlawful possession of a controlled substance constituting a drug enforcement misdemeanor under section 35 of this 2024 Act.

(3) If a deflection program is established, the program coordinator shall be responsible for providing notification that a person has completed the program to those entities responsible for sealing records under section 54 of this 2024 Act, including but not limited to law enforcement agencies, district attorneys and courts.

(4) As used in this section, "deflection program" has the meaning given that term in section 37 of this 2024 Act.

SECTION 37. (1) The Oregon Criminal Justice Commission shall establish a statewide system for tracking simple, clear and meaningful data concerning deflection program outcomes, including connections to social services and criminal justice system avoidance, and other data deemed relevant that is timely and easily accessed to inform best practices and improve outcomes for individual program participants.

(2)(a) No later than 12 months after the effective date of this 2024 Act, the commission shall conduct a study to determine best practices for deflection programs and make recommendations for funding of the Oregon Behavioral Health Deflection Program described in

section 76 of this 2024 Act. In making the recommendations described in this paragraph, the commission shall consider the best available information and projections regarding deflection programs in this state.

(b) No later than 18 months after the effective date of this 2024 Act, the commission shall develop standards and best practices for deflection programs in this state based on information received from the programs and pursuant to sections 76 and 77 of this 2024 Act.

(3) The commission shall maintain a list of deflection programs operating within this state, and shall make the list publicly available on the website of the commission.

(4) As used in this section, "deflection program" means a collaborative program between law enforcement agencies and behavioral health entities that assists individuals who may have substance use disorder, another behavioral health disorder or co-occurring disorders, to create community-based pathways to treatment, recovery support services, housing, case management or other services.

SECTION 38. ORS 133.060 is amended to read:

133.060. (1) **Except as provided in subsections (3) and (4) of this section,** a person who has been served with a criminal citation shall appear before a magistrate of the county in which the person was cited at the time, date and court specified in the citation, which shall not be later than 30 days after the date the citation was issued.

(2) If the cited person fails to appear at the time, date and court specified in the criminal citation, and a complaint or information is filed, the magistrate shall issue a warrant of arrest, upon application for its issuance, upon the person's failure to appear.

(3)(a) Notwithstanding subsection (1) of this section, during a period of statewide emergency, the date specified in a criminal citation on which a person served with the citation shall appear may be more than 30 days after the date the citation was issued.

(b) During a period of statewide emergency, the presiding judge of a circuit court may, upon the motion of a party or the court's own motion, and upon a finding of good cause, postpone the date of appearance described in paragraph (a) of this subsection for all proceedings within the jurisdiction of the court.

(c) The presiding judge may delegate the authority described in paragraph (b) of this subsection to another judge of the court.

(d) Nothing in this subsection affects the rights of a defendant under the Oregon and United States Constitutions.

(e) As used in this subsection, "period of statewide emergency" means the period of time during which any declaration of a state of emergency under ORS 401.165, public health emergency under ORS 433.441 or catastrophic disaster under Article X-A, section 1, of the Oregon Constitution, issued by the Governor, and any extension of the declaration, is in effect, and continuing for 60 days after the declaration and any extension is no longer in effect.

(4) Notwithstanding subsection (1) of this section, the date specified in a criminal citation on which a person served with the citation shall appear may be more than 30 days after the date the citation was issued for purposes of allowing the person to participate in a deflection program as defined in section 37 of this 2024 Act.

(Drug Enforcement Misdemeanor Conforming Amendments)

SECTION 39. ORS 475.752, as amended by section 28 of this 2024 Act, is amended to read:

475.752. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture or deliver a controlled substance. Any person who violates this subsection with respect to:

(a) A controlled substance in Schedule I, is guilty of a Class A felony, except as otherwise provided in ORS 475.886 and 475.890.

(b) A controlled substance in Schedule II, is guilty of a Class B felony, except as otherwise provided in ORS 475.878, 475.880, 475.882, 475.904 and 475.906.

(c) A controlled substance in Schedule III, is guilty of a Class C felony, except as otherwise provided in ORS 475.904 and 475.906.

(d) A controlled substance in Schedule IV, is guilty of a Class B misdemeanor.

(e) A controlled substance in Schedule V, is guilty of a Class C misdemeanor.

(2) Except as authorized in ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to create or deliver a counterfeit substance. Any person who violates this subsection with respect to:

(a) A counterfeit substance in Schedule I, is guilty of a Class A felony.

(b) A counterfeit substance in Schedule II, is guilty of a Class B felony.

(c) A counterfeit substance in Schedule III, is guilty of a Class C felony.

(d) A counterfeit substance in Schedule IV, is guilty of a Class B misdemeanor.

(e) A counterfeit substance in Schedule V, is guilty of a Class C misdemeanor.

(3) It is unlawful for any person knowingly or intentionally to possess a controlled substance unless the substance was obtained directly from, or pursuant to a valid prescription or order of, a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980. Any person who violates this subsection with respect to:

(a) A controlled substance in Schedule I, is guilty of a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**, except as otherwise provided in ORS 475.854, 475.874 and 475.894 and subsection (7) of this section.

(b) A controlled substance in Schedule II, is guilty of a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**, except as otherwise provided in ORS 475.814, 475.824, 475.834 or 475.884 or subsection (8) of this section.

(c) A controlled substance in Schedule III, is guilty of a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**.

(d) A controlled substance in Schedule IV, is guilty of a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**.

(e) A controlled substance in Schedule V, is guilty of a violation.

(4) It is an affirmative defense in any prosecution under this section for manufacture, possession or delivery of the plant of the genus Lophophora commonly known as peyote that the peyote is being used or is intended for use:

(a) In connection with the good faith practice of a religious belief;

(b) As directly associated with a religious practice; and

(c) In a manner that is not dangerous to the health of the user or others who are in the proximity of the user.

(5) The affirmative defense created in subsection (4) of this section is not available to any person who has possessed or delivered the peyote while incarcerated in a correctional facility in this state.

(6)(a) Notwithstanding subsection (1) of this section, a person who unlawfully manufactures or delivers a controlled substance in Schedule IV and who thereby causes death to another person is guilty of a Class C felony.

(b) For purposes of this subsection, causation is established when the controlled substance plays a substantial role in the death of the other person.

(7) Notwithstanding subsection (3)(a) of this section:

(a) Unlawful possession of a controlled substance in Schedule I is a Class A misdemeanor if the person possesses:

(A) Forty or more user units of a mixture or substance containing a detectable amount of lysergic acid diethylamide; or

(B) Twelve grams or more of a mixture or substance containing a detectable amount of psilocybin or psilocin.

(b) Unlawful possession of a controlled substance in Schedule I is a Class B felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 (3)(b).

(8) Notwithstanding subsection (3)(b) of this section:

(a) Unlawful possession of a controlled substance in Schedule II is a Class A misdemeanor if the person possesses one gram or more or five or more user units of a mixture or substance containing a detectable amount of fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy.

(b) Unlawful possession of a controlled substance in Schedule II is a Class C felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 (3)(b).

SECTION 40. ORS 475.814 is amended to read:

475.814. (1) It is unlawful for any person knowingly or intentionally to possess hydrocodone unless the hydrocodone was obtained directly from, or pursuant to a valid prescription or order of, a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2)(a) Unlawful possession of hydrocodone is a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of hydrocodone is a Class A misdemeanor if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses 40 or more pills, tablets, capsules or user units of a mixture or substance containing a detectable amount of hydrocodone.

SECTION 41. ORS 475.824 is amended to read:

475.824. (1) It is unlawful for any person knowingly or intentionally to possess methadone unless the methadone was obtained directly from, or pursuant to a valid prescription or order of, a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2)(a) Unlawful possession of methadone is a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of methadone is a Class A misdemeanor if the person possesses 40 or more user units of a mixture or substance containing a detectable amount of methadone.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of methadone is a Class C felony if the possession is a commercial drug offense under ORS 475.900 (1)(b).

SECTION 42. ORS 475.834 is amended to read:

475.834. (1) It is unlawful for any person knowingly or intentionally to possess oxycodone unless the oxycodone was obtained directly from, or pursuant to a valid prescription or order of, a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2)(a) Unlawful possession of oxycodone is a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of oxycodone is a Class A misdemeanor if the person possesses 40 or more pills, tablets, capsules or user units of a mixture or substance containing a detectable amount of oxycodone.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of oxycodone is a Class C felony if the possession is a commercial drug offense under ORS 475.900 (1)(b).

SECTION 43. ORS 475.854, as amended by section 29 of this 2024 Act, is amended to read:

475.854. (1) It is unlawful for any person knowingly or intentionally to possess heroin.

(2)(a) Unlawful possession of heroin is a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of heroin is a Class A misdemeanor if the person possesses one gram or more of a mixture or substance containing a detectable amount of heroin.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of heroin is a Class B felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 (3)(b).

SECTION 44. ORS 475.874, as amended by section 30 of this 2024 Act, is amended to read:

475.874. (1) It is unlawful for any person knowingly or intentionally to possess 3,4-methylenedioxymethamphetamine.

(2)(a) Unlawful possession of 3,4-methylenedioxymethamphetamine is a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of 3,4-methylenedioxymethamphetamine is a Class A misdemeanor if the person possesses one gram or more or five or more pills, tablets or capsules of a mixture or substance containing a detectable amount of:

(A) 3,4-methylenedioxyamphetamine;

(B) 3,4-methylenedioxymethamphetamine; or

(C) 3,4-methylenedioxy-N-ethylamphetamine.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of 3,4-methylenedioxymethamphetamine is a Class B felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 (3)(b).

SECTION 45. ORS 475.884, as amended by section 31 of this 2024 Act, is amended to read:

475.884. (1) It is unlawful for any person knowingly or intentionally to possess cocaine unless the substance was obtained directly from, or pursuant to a valid prescription or order of, a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2)(a) Unlawful possession of cocaine is a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of cocaine is a Class A misdemeanor if the person possesses two grams or more of a mixture or substance containing a detectable amount of cocaine.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of cocaine is a Class C felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 (3)(b).

SECTION 46. ORS 475.894, as amended by section 32 of this 2024 Act, is amended to read:

475.894. (1) It is unlawful for any person knowingly or intentionally to possess methamphetamine unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2)(a) Unlawful possession of methamphetamine is a [*Class E violation*] **drug enforcement misdemeanor punishable as described in section 35 of this 2024 Act**.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of methamphetamine is a Class A misdemeanor if the person possesses two grams or more of a mixture or substance containing a detectable amount of methamphetamine.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of methamphetamine is a Class C felony if:

(A) The possession is a commercial drug offense under ORS 475.900 (1)(b); or

(B) The person possesses a substantial quantity under ORS 475.900 (3)(b).

SECTION 46a. ORS 135.753 is amended to read:

135.753. (1) If the court directs the charge or action to be dismissed, the defendant, if in custody, shall be discharged. If the defendant has been released, the release agreement is exonerated and security deposited shall be refunded to the defendant.

(2) An order for the dismissal of a charge or action, as provided in ORS 135.703 to 135.709 and 135.745 to 135.757, is a bar to another prosecution for the same crime if the crime is a Class B or C misdemeanor; but it is not a bar if the crime charged is a Class A misdemeanor**, a misdemeanor described in section 35 of this 2024 Act** or a felony.

(3) If any charge or action is dismissed for the purpose of consolidation with one or more other charges or actions, then any such dismissal shall not be a bar to another prosecution for the same offense.

(Supervision Duty and Funding)

SECTION 47. ORS 423.478 is amended to read:

423.478. (1) The Department of Corrections shall:

(a) Operate prisons for offenders sentenced to terms of incarceration for more than 12 months;

(b) Provide central information and data services sufficient to:

(A) Allow tracking of offenders; and

(B) Permit analysis of correlations between sanctions, supervision, services and programs, and future criminal conduct; and

(c) Provide interstate compact administration and jail inspections.

(2) Subject to ORS 423.483, each county, in partnership with the department, shall assume responsibility for community-based supervision, sanctions and services for offenders convicted of felonies, designated drug-related misdemeanors or designated person misdemeanors**, or persons who have entered into a probation agreement on a drug enforcement misdemeanor pursuant to section 52 of this 2024 Act,** who are:

(a) On parole;

(b) On probation;

(c) On post-prison supervision;

(d) Sentenced, on or after January 1, 1997, to 12 months or less incarceration;

(e) Sanctioned, on or after January 1, 1997, by a court or the State Board of Parole and Post-Prison Supervision to 12 months or less incarceration for violation of a condition of parole, probation or post-prison supervision; or

(f) On conditional release under ORS 420A.206.

(3) Notwithstanding the fact that the court has sentenced a person to a term of incarceration, when an offender is committed to the custody of the supervisory authority of a county under ORS 137.124 (2) or (4), the supervisory authority may execute the sentence by imposing sanctions other than incarceration if deemed appropriate by the supervisory authority. If the supervisory authority releases a person from custody under this subsection and the person is required to report as a sex offender under ORS 163A.010, the supervisory authority, as a condition of release, shall order the person to report to the Department of State Police, a city police department or a county sheriff's office or to the supervising agency, if any:

(a) When the person is released;

(b) Within 10 days of a change of residence;

(c) Once each year within 10 days of the person's birth date;

(d) Within 10 days of the first day the person works at, carries on a vocation at or attends an institution of higher education; and

(e) Within 10 days of a change in work, vocation or attendance status at an institution of higher education.

(4) As used in this section:

(a) "Attends," "institution of higher education," "works" and "carries on a vocation" have the meanings given those terms in ORS 163A.005.

(b) "Designated drug-related misdemeanor" means:

(A) Unlawful possession of a Schedule I controlled substance under ORS 475.752 (3)(a);

(B) Unlawful possession of a Schedule II controlled substance under ORS 475.752 (3)(b);

(C) Unlawful possession of a Schedule III controlled substance under ORS 475.752 (3)(c);

(D) Unlawful possession of a Schedule IV controlled substance under ORS 475.752 (3)(d);

(E) Unlawful possession of a Schedule I controlled substance under ORS 475.752 (7)(a);

[*(A)*] **(F)** Unlawful possession of fentanyl under ORS 475.752 (8)(a);

(G) Unlawful possession of hydrocodone under ORS 475.814 (2)(a);

(H) Unlawful possession of hydrocodone under ORS 475.814 (2)(b);

(I) Unlawful possession of methadone under ORS 475.824 (2)(a);

[*(B)*] **(J)** Unlawful possession of methadone under ORS 475.824 (2)(b);

(K) Unlawful possession of oxycodone under ORS 475.834 (2)(a);

[*(C)*] **(L)** Unlawful possession of oxycodone under ORS 475.834 (2)(b);

(M) Unlawful possession of heroin under ORS 475.854 (2)(a);

[*(D)*] **(N)** Unlawful possession of heroin under ORS 475.854 (2)(b);

(O) Unlawful possession of 3,4-methylenedioxymethamphetamine under ORS 475.874 (2)(a);

[*(E)*] **(P)** Unlawful possession of 3,4-methylenedioxymethamphetamine under ORS 475.874 (2)(b);

(Q) Unlawful possession of cocaine under ORS 475.884 (2)(a);

[*(F)*] **(R)** Unlawful possession of cocaine under ORS 475.884 (2)(b); [*or*]

(S) Unlawful possession of methamphetamine under ORS 475.894 (2)(a); or

[*(G)*] **(T)** Unlawful possession of methamphetamine under ORS 475.894 (2)(b).

(c) "Designated person misdemeanor" means:

(A) Assault in the fourth degree constituting domestic violence if the judgment document is as described in ORS 163.160 (4);

(B) Menacing constituting domestic violence if the judgment document is as described in ORS 163.190 (3); or

(C) Sexual abuse in the third degree under ORS 163.415.

SECTION 48. ORS 423.483 is amended to read:

423.483. (1)(a) The baseline funding for biennia beginning after June 30, 1999, is the current service level for the expenses of providing management, support services, supervision and sanctions for offenders described in ORS 423.478 (2). At a minimum, each biennium's appropriation must be established at this baseline.

(b) The baseline funding described in paragraph (a) of this subsection:

(A) May not be decreased as a result of a reduction under ORS 137.633.

(B) May not be increased as a result of community-based sanctions, services and programs that are funded under section 53, chapter 649, Oregon Laws 2013.

(2) If the total state community corrections appropriation is less than the baseline calculated under subsection (1) of this section, a county may discontinue participation by written notification to the director 180 days prior to implementation of the change. If a county discontinues participation, the responsibility for correctional services transferred to the county and the portion of funding made available to the county under ORS 423.530 revert to the Department of Corrections. Responsibility for supervision of and provision of correctional services to misdemeanor offenders does not revert to the department under any circumstances except those of offenders convicted of designated drug-related misdemeanors or designated person misdemeanors**, or of persons who have entered into a probation agreement on a drug enforcement misdemeanor pursuant to section 52 of this 2024 Act**.

(3) As used in this section:

(a) "Current service level" means the calculated cost of continuing current legislatively funded programs, phased in programs and increased caseloads minus one-time costs, decreased caseloads, phased out programs and pilot programs with the remainder adjusted for inflation as determined by the Legislative Assembly in its biennial appropriation to the Department of Corrections.

(b) "Designated drug-related misdemeanor" has the meaning given that term in ORS 423.478.

(c) "Designated person misdemeanor" has the meaning given that term in ORS 423.478.

SECTION 49. ORS 423.483, as amended by section 22, chapter 649, Oregon Laws 2013, section 3, chapter 140, Oregon Laws 2015, and section 2, chapter 341, Oregon Laws 2023, is amended to read:

423.483. (1)(a) The baseline funding for biennia beginning after June 30, 1999, is the current service level for the expenses of providing management, support services, supervision and sanctions for offenders described in ORS 423.478 (2). At a minimum, each biennium's appropriation must be established at this baseline.

(b) The baseline funding described in paragraph (a) of this subsection may not be decreased as a result of a reduction under ORS 137.633.

(2) If the total state community corrections appropriation is less than the baseline calculated under subsection (1) of this section, a county may discontinue participation by written notification to the director 180 days prior to implementation of the change. If a county discontinues participation, the responsibility for correctional services transferred to the county and the portion of funding made available to the county under ORS 423.530 revert to the Department of Corrections. Responsibility for supervision of and provision of correctional services to misdemeanor offenders does not revert to the department under any circumstances except those of offenders convicted of designated drug-related misdemeanors or designated person misdemeanors**, or of persons who have entered into a probation agreement on a drug enforcement misdemeanor pursuant to section 52 of this 2024 Act**.

(3) As used in this section:

(a) "Current service level" means the calculated cost of continuing current legislatively funded programs, phased in programs and increased caseloads minus one-time costs, decreased caseloads, phased out programs and pilot programs with the remainder adjusted for inflation as determined by the Legislative Assembly in its biennial appropriation to the Department of Corrections.

(b) "Designated drug-related misdemeanor" has the meaning given that term in ORS 423.478.

(c) "Designated person misdemeanor" has the meaning given that term in ORS 423.478.

SECTION 50. ORS 423.525 is amended to read:

423.525. (1) A county, group of counties or intergovernmental corrections entity shall apply to the Director of the Department of Corrections in a manner and form prescribed by the director for funding made available under ORS 423.500 to 423.560. The application shall include a community corrections plan. The Department of Corrections shall provide consultation and technical assistance to counties to aid in the development and implementation of community corrections plans.

(2)(a) From July 1, 1995, until June 30, 1999, a county, group of counties or intergovernmental corrections entity may make application requesting funding for the construction, acquisition, expansion or remodeling of correctional facilities to serve the county, group of counties or intergovernmental corrections entity. The department shall review the application for funding of correctional facilities in accordance with criteria that consider design, cost, capacity, need, operating efficiency and viability based on the county's, group of counties' or intergovernmental corrections entity's ability to provide for ongoing operations.

(b)(A) If the application is approved, the department shall present the application with a request to finance the facility with financing agreements to the State Treasurer and the Director of the Oregon Department of Administrative Services. Except as otherwise provided in subparagraph (B) of this paragraph, upon approval of the request by the State Treasurer and the Director of the Oregon Department of Administrative Services, the facility may be financed with financing agreements, and certificates of participation issued pursuant thereto, as provided in ORS 283.085 to 283.092. All decisions approving or denying applications and requests for financing under this section are final. No such decision is subject to judicial review of any kind.

(B) If requests to finance county correctional facility projects are submitted after February 22, 1996, and the requests have not been approved by the department on the date a session of the Legislative Assembly convenes, the requests are also subject to the approval of the Legislative Assembly.

(c) After approval but prior to the solicitation of bids or proposals for the construction of a project, the county, group of counties or intergovernmental corrections entity and the department shall enter into a written agreement that determines the procedures, and the parties responsible, for the awarding of contracts and the administration of the construction project for the approved correctional facility. If the parties are unable to agree on the terms of the written agreement, the Governor shall decide the terms of the agreement. The Governor's decision is final.

(d) After approval of a construction project, the administration of the project shall be conducted as provided in the agreement required by paragraph (c) of this subsection. The agreement must require at a minimum that the county, group of counties or intergovernmental corrections entity shall submit to the department any change order or alteration of the design of the project that, singly or in the aggregate, reduces the capacity of the correctional facility or materially changes the services or functions of the project. The change order or alteration is not effective until approved by the department. In reviewing the change order or alteration, the department shall consider whether the implementation of the change order or alteration will have any material adverse impact on the parties to any financing agreements or the holders of any certificates of participation issued to fund county correctional facilities under this section. In making its decision, the department may rely on the opinions of the Department of Justice, bond counsel or professional financial advisers.

(3) Notwithstanding ORS 283.085, for purposes of this section, "financing agreement" means a lease purchase agreement, an installment sale agreement, a loan agreement or any other agreement to finance a correctional facility described in this section, or to refinance a previously executed financing agreement for the financing of a correctional facility. The state is not required to own or operate a correctional facility in order to finance it under ORS 283.085 to 283.092 and this section. The state, an intergovernmental corrections entity, county or group of counties may enter into any agreements, including, but not limited to, leases and subleases, that are reasonably necessary or generally accepted by the financial community for purposes of acquiring or securing financing as authorized by this section. In financing county correctional facilities under this section, "property rights" as used in ORS 283.085 includes leasehold mortgages of the state's rights under leases of correctional facilities from counties.

(4) Notwithstanding any other provision of state law, county charter or ordinance, a county may convey or lease to the State of Oregon, acting by and through the Department of Corrections, title to interests in, or a lease of, any real property, facilities or personal property owned by the county for the purpose of financing the construction, acquisition, expansion or remodeling of a correctional facility. Upon the payment of all principal and interest on, or upon any other satisfaction of, the financing agreement used to finance the construction, acquisition, expansion or remodeling of a correctional facility, the state shall reconvey its interest in, or terminate and surrender its leasehold of, the property or facilities, including the financed construction, acquisition, expansion or remodeling, to the county. In addition to any authority granted by ORS 283.089, for the purposes of obtaining financing, the state may enter into agreements under which the state may grant to trustees or lenders leases, subleases and other security interests in county property conveyed or leased to the state under this subsection and in the property or facilities financed by financing agreements.

(5) In connection with the financing of correctional facilities, the Director of the Oregon Department of Administrative Services may bill the Department of Corrections, and the Department of Corrections shall pay the amounts billed, in the same manner as provided in ORS 283.089. As required by ORS 283.091, the Department of Corrections and the Oregon Department of Administrative Services shall include in the Governor's budget all amounts that will be due in each fiscal period under financing agreements for correctional facilities. Amounts payable by the state under a financing agreement for the construction, acquisition, expansion or remodeling of a correctional facility are limited to available funds as defined in ORS 283.085, and no lender, trustee, certificate holder or county has any claim or recourse against any funds of the state other than available funds.

(6) The director shall adopt rules that may be necessary for the administration, evaluation and implementation of ORS 423.500 to 423.560. The standards shall be sufficiently flexible to foster the development of new and improved supervision or rehabilitative practices and maximize local control.

(7) When a county assumes responsibility under ORS 423.500 to 423.560 for correctional services previously provided by the department, the county and the department shall enter into an intergovernmental agreement that includes a local community corrections plan consisting of program descriptions, budget allocation, performance objectives and methods of evaluating each correctional service to be provided by the county. The performance objectives must include in dominant part reducing future criminal conduct. The methods of evaluating services must include, to the extent of available information systems resources, the collection and analysis of data sufficient to determine the apparent effect of the services on future criminal conduct.

(8) All community corrections plans shall comply with rules adopted pursuant to ORS 423.500 to 423.560, and shall include but need not be limited to an outline of the basic structure and the supervision, services and local sanctions to be applied to offenders convicted of felonies, designated drug-related misdemeanors and designated person misdemeanors**, or persons who have entered into a probation agreement on a drug enforcement misdemeanor pursuant to section 52 of this 2024 Act,** who are:

(a) On parole;

(b) On probation;

(c) On post-prison supervision;

(d) Sentenced, on or after January 1, 1997, to 12 months or less incarceration;

(e) Sanctioned, on or after January 1, 1997, by a court or the State Board of Parole and Post-Prison Supervision to 12 months or less incarceration for a violation of a condition of parole, probation or post-prison supervision; and

(f) On conditional release under ORS 420A.206.

(9) All community corrections plans shall designate a community corrections manager of the county or counties and shall provide that the administration of community corrections under ORS 423.500 to 423.560 shall be under such manager.

(10) No amendment to or modification of a county-approved community corrections plan shall be placed in effect without prior notice to the director for purposes of statewide data collection and reporting.

(11) The obligation of the state to provide funding and the scheduling for providing funding of a project approved under this section is dependent upon the ability of the state to access public security markets to sell financing agreements.

(12) No later than January 1 of each odd-numbered year, the Department of Corrections shall:

(a) Evaluate the community corrections policy established in ORS 423.475, 423.478, 423.483 and 423.500 to 423.560; and

(b) Assess the effectiveness of local revocation options.

(13) As used in this section, "designated drug-related misdemeanor" and "designated person misdemeanor" have the meanings given those terms in ORS 423.478.

(Conditional Discharge)

SECTION 51. Section 52 of this 2024 Act is added to and made a part of ORS 475.752 to 475.980.

SECTION 52. (1)(a) When a person is charged with unlawful possession of a controlled substance under ORS 475.752 (3)(a), (b), (c) or (d), 475.814 (2)(a), 475.824 (2)(a), 475.834 (2)(a), 475.854 (2)(a), 475.874 (2)(a), 475.884 (2)(a) or 475.894 (2)(a) constituting a drug enforcement misdemeanor as described in section 35 of this 2024 Act, the person is eligible to enter, and subject to paragraphs (b) and (c) of this subsection may request to enter, into a probation agreement as described in this section.

(b) The district attorney may object to the defendant's entry into a probation agreement under this section. After hearing the reasons for the objection, the court may deny the person's entry if the probation agreement would not serve the needs of the person or the protection and welfare of the community.

(c) A person may request to enter into a probation agreement under this section no later than 30 days after the person's first appearance, unless the court authorizes a later date for good cause shown. For purposes of this paragraph, the filing of a demurrer, a motion to suppress or a motion for an omnibus hearing does not constitute good cause.

(d) When a person enters into a probation agreement under this section, the court shall defer further proceedings on the charge described in paragraph (a) of this subsection and place the person on probation. The terms of the probation shall be defined by a probation agreement.

(e) A person may enter into a probation agreement under this section on the charge described in paragraph (a) of this subsection regardless of whether the person is charged with other offenses within the same charging instrument or as part of a separate charging instrument, but the proceedings on the other offenses continue in the normal course and are not deferred.

(2)(a) A probation agreement described in this section carries the understanding that if the defendant fulfills the terms of the agreement, the charge described in subsection (1)(a) of this section that is the subject of the agreement will be dismissed with prejudice.

(b) The initial term of probation shall be 12 months, subject to early termination by the court. The terms of the probation shall include the general conditions of probation described in ORS 137.540 (1) and a requirement that the defendant complete a substance abuse evaluation and any treatment recommended by the evaluator. The court may impose sanctions of up to a total of 30 days of imprisonment upon finding that the person has violated the conditions of probation. Structured, intermediate sanctions as described in ORS 137.593 may be imposed in accordance with rules adopted under ORS 137.595 when the conditions of a term of probation described in this section have been violated.

(c) The agreement must contain a waiver of the following rights of the defendant with respect to each criminal charge:

(A) The right to a speedy trial and trial by jury;

(B) The right to present evidence on the defendant's behalf;

(C) The right to confront and cross-examine witnesses against the defendant;

(D) The right to contest evidence presented against the defendant, including the right to object to hearsay evidence; and

(E) The right to appeal from a judgment of conviction resulting from an adjudication of guilt entered under subsection (3) of this section, unless the appeal is based on an allegation that the sentence exceeds the maximum allowed by law or constitutes cruel and unusual punishment.

(d) The agreement may not contain a requirement that the defendant enter a plea of guilty or no contest on any charge in the accusatory instrument.

(e) The fact that a person has entered into a probation agreement under this section does not constitute an admission of guilt and is not sufficient to warrant a finding or adjudication of guilt by a court.

(f) Police reports or other documents associated with the criminal charges in a court file other than the probation agreement may not be admitted into evidence, and do not establish a factual basis for finding the defendant guilty, unless the court resumes criminal proceedings and enters an adjudication of guilt under subsection (3) of this section.

(3) Upon violation of a term or condition of the probation agreement, the court may impose a sanction or may resume the criminal proceedings and may find the defendant guilty of the charge that is the subject of the agreement in accordance with the waiver of rights in the agreement. The defendant may not contest the sufficiency of the evidence establishing the defendant's guilt of the offenses in the accusatory instrument.

(4) Upon the conclusion or early termination of the probation period, if the court has received notice from the district attorney or a supervising officer that the person has fulfilled the terms and conditions of the probation agreement, the court shall discharge the

person and dismiss the charge that is the subject of the agreement. Discharge and dismissal under this section shall be without adjudication of guilt and is not a conviction for purposes of this section or for purposes of disqualifications or disabilities imposed by law upon conviction of a crime.

(5) In the event that the period of probation under this section expires, but the court has not received notice that the terms and conditions of the probation agreement have been fulfilled and no probation violation proceeding was initiated prior to the expiration of the period of probation, the court may not discharge the person and dismiss the proceedings against the person. The court shall instead issue an order requiring the person to appear and to show cause why the court should not enter an adjudication of guilt as described in subsection (3) of this section due to the failure of the person to fulfill the terms and conditions of the probation agreement prior to expiration of the period of probation. At the hearing on the order to show cause, after considering any evidence or argument from the district attorney and the person, the court may:

(a) Order a new period of probation to allow the person to fulfill the terms and conditions of the probation agreement; or

(b) Enter an adjudication of guilt as described in subsection (3) of this section.

SECTION 53. ORS 475.245 is amended to read:

475.245. (1)(a) Whenever a person is charged with an offense listed in subsection (5) of this section, the court, with the consent of the district attorney and the person, may defer further proceedings and place the person on probation. The terms of the probation shall be defined by a probation agreement.

(b) A probation agreement carries the understanding that if the defendant fulfills the terms of the agreement, the criminal charges filed against the defendant will be dismissed with prejudice.

(c) The agreement must contain a waiver of the following rights of the defendant with respect to each criminal charge:

(A) The right to a speedy trial and trial by jury;

(B) The right to present evidence on the defendant's behalf;

(C) The right to confront and cross-examine witnesses against the defendant;

(D) The right to contest evidence presented against the defendant, including the right to object to hearsay evidence; and

(E) The right to appeal from a judgment of conviction resulting from an adjudication of guilt entered under subsection (2) of this section, unless the appeal is based on an allegation that the sentence exceeds the maximum allowed by law or constitutes cruel and unusual punishment.

(d) The agreement must include a requirement that the defendant pay any restitution owed to the victim as determined by the court, and any fees for court-appointed counsel ordered by the court under ORS 135.050.

(e) The agreement may not contain a requirement that the defendant enter a plea of guilty or no contest on any charge in the accusatory instrument.

(f) Entering into a probation agreement does not constitute an admission of guilt and is not sufficient to warrant a finding or adjudication of guilt by a court.

(g) Police reports or other documents associated with the criminal charges in a court file other than the probation agreement may not be admitted into evidence, and do not establish a factual basis for finding the defendant guilty, unless the court resumes criminal proceedings and enters an adjudication of guilt under subsection (2) of this section.

(2) Upon violation of a term or condition of the probation agreement, the court may **impose sanctions of up to a total of 30 days of imprisonment, or** resume the criminal proceedings and may find the defendant guilty of the offenses in the accusatory instrument in accordance with the waiver of rights in the probation agreement. The defendant may not contest the sufficiency of the evidence establishing the defendant's guilt of the offenses in the accusatory instrument.

(3) Upon fulfillment of the terms and conditions of the probation agreement, the court shall discharge the person and dismiss the proceedings against the person. Discharge and dismissal under

this section shall be without adjudication of guilt and is not a conviction for purposes of this section or for purposes of disqualifications or disabilities imposed by law upon conviction of a crime. There may be only one discharge and dismissal under this section with respect to any person.

(4) In the event that the period of probation under this section expires, but the terms and conditions of the probation agreement have not been fulfilled and no probation violation proceeding was initiated prior to the expiration of the period of probation, the court may not discharge the person and dismiss the proceedings against the person. The court shall instead issue an order requiring the person to appear and to show cause why the court should not enter an adjudication of guilt as described in subsection (2) of this section due to the failure of the person to fulfill the terms and conditions of the probation agreement prior to expiration of the period of probation. At the hearing on the order to show cause, after considering any evidence or argument from the district attorney and the person, the court may:

(a) Order a new period of probation to allow the person to fulfill the terms and conditions of the probation agreement; or

(b) Enter an adjudication of guilt as described in subsection (2) of this section.

(5) This section applies to the following offenses:

(a) Possession of a controlled substance under ORS 475.752 (3), 475.814, 475.824, 475.834, 475.854, 475.874, 475.884 or 475.894;

(b) Unlawfully possessing a prescription drug under ORS 689.527 (6);

(c) Unlawfully possessing marijuana plants, usable marijuana, cannabinoid products, cannabinoid concentrates or cannabinoid extracts as described in ORS 475C.337 or 475C.341, if the offense is a misdemeanor or felony;

(d) Endangering the welfare of a minor under ORS 163.575 (1)(b);

(e) Frequenting a place where controlled substances are used under ORS 167.222; and

(f) A property offense that is motivated by a dependence on a controlled substance or a marijuana item as defined in ORS 475C.009.

(Expungement)

SECTION 54. (1) Within 60 days of receiving verification from a deflection program coordinator that a person has completed a deflection program, after being referred to the program due to the alleged commission of unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35 of this 2024 Act, a law enforcement agency or district attorney shall seal all records related to the person's participation in the program, the alleged conduct that resulted in the referral to the program and, if applicable, the citation for the offense, and a court shall seal all electronic records that may have been created concerning the offense. Records sealed under this subsection are not subject to disclosure under ORS 192.311 to 192.478 or any other law.

(2) After two years have elapsed from the date that a person is cited for unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35 of this 2024 Act, and if no further prosecutorial action on the citation has occurred, within 60 days after the conclusion of the two year time period, any law enforcement agency or district attorney that possesses records related to the citation, and any court that possesses electronic records related to the citation, shall seal the records. Records sealed under this subsection are not subject to disclosure under ORS 192.311 to 192.478 or any other law.

(3)(a) Notwithstanding ORS 137.225, when a person successfully completes a probation agreement and the court discharges the person and dismisses the proceedings against the person under section 52 (4) of this 2024 Act, the court shall, within 90 days after the dismissal, enter an order sealing all records related to the arrest or citation and the criminal proceedings. The clerk of the court shall forward a copy of the order, or a certified copy if requested, to such agencies as directed by the court.

(b) Notwithstanding ORS 137.225, when the court receives notice that a defendant has successfully completed a term of probation for unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35 of this 2024 Act, the court shall, within 90 days after the notification, enter an order sealing all records related to the arrest or citation and the criminal proceedings. The clerk of the court shall forward a copy of the order, or a certified copy if requested, to such agencies as directed by the court.

(4)(a) Notwithstanding ORS 137.225, after three years have passed from the date of entry of judgment of conviction for unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35 of this 2024 Act, the court shall, within 60 days after the three year period has concluded, enter an order sealing all records related to the arrest or citation, charges and conviction. The clerk of the court shall forward a copy of the order, or a certified copy if requested, to such agencies as directed by the court.

(b) Notwithstanding ORS 137.225, after three years have passed since the dismissal of a unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35 of this 2024 Act, if the court has not sealed records of the offense under subsection (2) or (3) of this section, the court shall, within 60 days after the three year period has concluded, enter an order sealing all records related to the arrest or citation and any criminal proceedings. The clerk of the court shall forward a copy of the order, or a certified copy if requested, to such agencies as directed by the court.

(5)(a) The State Court Administrator shall develop a standardized form for obtaining the information necessary for all entities to seal records as required by subsections (3) and (4) of this section.

(b) When a person enters into a probation agreement under section 52 of this 2024 Act, or is convicted of unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35 of this 2024 Act, the district attorney and the defense attorney shall ensure that a copy of the form described in paragraph (a) of this subsection is completed and submitted to the court.

SECTION 55. ORS 137.225 is amended to read:

137.225. (1)(a) At any time after the person becomes eligible as described in paragraph (b) of this subsection, any person convicted of an offense who has fully complied with and performed the sentence of the court for the offense, and whose conviction is described in subsection (5) of this section, by motion may apply to the court where the conviction was entered for entry of an order setting aside the conviction. A person who is still under supervision as part of the sentence for the offense that is the subject of the motion has not fully complied with or performed the sentence of the court.

(b) A person is eligible to file a motion under paragraph (a) of this subsection:

(A) For a Class B felony, seven years from the date of conviction or the release of the person from imprisonment for the conviction sought to be set aside, whichever is later.

(B) For a Class C felony, five years from the date of conviction or the release of the person from imprisonment for the conviction sought to be set aside, whichever is later.

(C) For a Class A misdemeanor, three years from the date of conviction or the release of the person from imprisonment for the conviction sought to be set aside, whichever is later.

(D) For a Class B or Class C misdemeanor, a violation or the finding of a person in contempt of court, one year from the date of conviction or finding or the release of the person from imprisonment for the conviction or finding sought to be set aside, whichever is later.

(c) If no accusatory instrument is filed, at any time after 60 days from the date the prosecuting attorney indicates that the state has elected not to proceed with a prosecution or contempt proceeding, an arrested, cited or charged person may apply to the court in the county in which the person was arrested, cited or charged, for entry of an order setting aside the record of the arrest, citation or charge.

(d) At any time after an acquittal or a dismissal other than a dismissal described in paragraph (c) of this subsection, an arrested, cited or charged person may apply to the court in the county in which the person was arrested, cited or charged, for entry of an order setting aside the record of the arrest, citation or charge.

(e) Notwithstanding paragraph (b) of this subsection, a person whose sentence of probation was revoked may not apply to the court for entry of an order setting aside the conviction for which the person was sentenced to probation for a period of three years from the date of revocation or until the person becomes eligible as described in paragraph (b) of this subsection, whichever occurs later.

(f) A person filing a motion under this section is not required to pay the filing fee established under ORS 21.135.

(2)(a) A copy of the motion shall be served upon the office of the prosecuting attorney who prosecuted the offense, or who had authority to prosecute the charge if there was no accusatory instrument filed. The prosecuting attorney may object to a motion filed under subsection (1)(a) of this section and shall notify the court and the person of the objection within 120 days of the date the motion was filed with the court.

(b) When a prosecuting attorney is served with a copy of a motion to set aside a conviction under subsection (1)(a) of this section, the prosecuting attorney shall provide a copy of the motion and notice of the hearing date to the victim, if any, of the offense by mailing a copy of the motion and notice to the victim's last-known address.

(c) When a person makes a motion under this section, the person shall forward to the Department of State Police a full set of the person's fingerprints on a fingerprint card or in any other manner specified by the department.

(d) When a person makes a motion under subsection (1)(a) of this section, the person must pay a fee to the Department of State Police for the purpose of the department performing a criminal record check. The department shall establish a fee in an amount not to exceed the actual cost of performing the criminal record check. If the department is required to perform only one criminal record check for the person, the department may only charge one fee, regardless of the number of counties in which the person is filing a motion to set aside a conviction, arrest, charge or citation under this section. The department shall provide a copy of the results of the criminal record check to the prosecuting attorney.

(e) The prosecuting attorney may not charge the person a fee for performing the requirements described in this section.

(3)(a) If an objection is received to a motion filed under subsection (1)(a) of this section, the court shall hold a hearing, and may require the filing of such affidavits and may require the taking of such proofs as the court deems proper. The court shall allow the victim to make a statement at the hearing. If the person is otherwise eligible for relief under this section, the court shall grant the motion and enter an order as described in paragraph (b) of this subsection unless the court makes written findings, by clear and convincing evidence, that the circumstances and behavior of the person, from the date of the conviction the person is seeking to set aside to the date of the hearing on the motion, do not warrant granting the motion due to the circumstances and behavior creating a risk to public safety. When determining whether the person's circumstances and behavior create a risk to public safety, the court may only consider criminal behavior, or violations of regulatory law or administrative rule enforced by civil penalty or other administrative sanction that relate to the character of the conviction sought to be set aside. The court may not consider nonpunitive civil liability, monetary obligations and motor vehicle violations. Upon granting the motion, the court shall enter an appropriate order containing the original arrest or citation charge, the conviction charge, if different from the original, the date of charge, the submitting agency and the disposition of the charge. Upon the entry of the order, the person for purposes of the law shall be deemed not to have been previously convicted, and the court shall issue an order sealing the record of conviction and other official records in the case, including the records of arrest, citation or charge.

(b) The court shall grant a motion filed under subsection (1)(c) or (d) of this section, or under subsection (1)(a) of this section if no objection to the motion is received, and shall enter an appro-

priate order containing the original arrest or citation charge, the conviction charge, if applicable and different from the original, the date of charge, the submitting agency and the disposition of the charge. Upon the entry of the order, the person for purposes of the law shall be deemed not to have been previously convicted, arrested, cited or charged, and the court shall issue an order sealing all official records in the case, including the records of arrest, citation or charge, whether or not the arrest, citation or charge resulted in a further criminal proceeding.

(4) The clerk of the court shall forward a certified copy of the order to such agencies as directed by the court. A certified copy must be sent to the Department of Corrections when the order concerns a conviction. Upon entry of the order, the conviction, arrest, citation, charge or other proceeding shall be deemed not to have occurred, and the person may answer accordingly any questions relating to its occurrence.

(5) The provisions of subsection (1)(a) of this section apply to a conviction for:

(a) A Class B felony, except for a violation of ORS 166.429 or any crime classified as a person felony as defined in the rules of the Oregon Criminal Justice Commission.

(b) Any misdemeanor, Class C felony or felony punishable as a misdemeanor pursuant to ORS 161.705.

(c) An offense constituting a violation under state law or local ordinance.

(d) An offense committed before January 1, 1972, that, if committed after that date, would qualify for an order under this section.

(e) The finding of a person in contempt of court.

(6) Notwithstanding subsection (5) of this section, the provisions of subsection (1)(a) of this section do not apply to a conviction for:

(a) Criminal mistreatment in the second degree under ORS 163.200 if the victim at the time of the crime was 65 years of age or older.

(b) Criminal mistreatment in the first degree under ORS 163.205 if the victim at the time of the crime was 65 years of age or older, or when the offense constitutes child abuse as defined in ORS 419B.005.

(c) Endangering the welfare of a minor under ORS 163.575 (1)(a), when the offense constitutes child abuse as defined in ORS 419B.005.

(d) Criminally negligent homicide under ORS 163.145, when that offense was punishable as a Class C felony.

(e) Assault in the third degree under ORS 163.165 (1)(h).

(f) Any sex crime, unless:

(A) The sex crime is listed in ORS 163A.140 (1)(a) and:

(i) The person has been relieved of the obligation to report as a sex offender pursuant to a court order entered under ORS 163A.145 or 163A.150; and

(ii) The person has not been convicted of, found guilty except for insanity of or found to be within the jurisdiction of the juvenile court based on a crime for which the court is prohibited from setting aside the conviction under this section; or

(B) The sex crime constitutes a Class C felony and:

(i) The person was under 16 years of age at the time of the offense;

(ii) The person is:

(I) Less than two years and 180 days older than the victim; or

(II) At least two years and 180 days older, but less than three years and 180 days older, than the victim and the court finds that setting aside the conviction is in the interests of justice and of benefit to the person and the community;

(iii) The victim's lack of consent was due solely to incapacity to consent by reason of being less than a specified age;

(iv) The victim was at least 12 years of age at the time of the offense;

(v) The person has not been convicted of, found guilty except for insanity of or found to be within the jurisdiction of the juvenile court based on a crime for which the court is prohibited from setting aside the conviction under this section; and

(vi) Each conviction or finding described in this subparagraph involved the same victim.

(7) Notwithstanding subsection (5) of this section, the provisions of subsection (1) of this section do not apply to:

(a) A conviction for a state or municipal traffic offense.

(b) A person convicted, within the following applicable time period immediately preceding the filing of the motion pursuant to subsection (1) of this section, of any other offense, excluding motor vehicle violations **and unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35 of this 2024 Act**, whether or not the other conviction is for conduct associated with the same criminal episode that caused the arrest, citation, charge or conviction that is sought to be set aside:

(A) For a motion concerning a Class B felony, seven years.

(B) For a motion concerning a Class C felony, five years.

(C) For a motion concerning a Class A misdemeanor, three years.

(D) For a motion concerning a Class B or Class C misdemeanor a violation or a finding of contempt of court, one year.

(c) A single violation, other than a motor vehicle violation, within the time period specified in paragraph (b) of this subsection is not a conviction under this subsection. Notwithstanding subsection (1) of this section, a conviction that has been set aside under this section shall be considered for the purpose of determining whether paragraph (b) of this subsection is applicable.

(d) A person who at the time the motion authorized by subsection (1) of this section is pending before the court is under charge of commission of any crime.

(8) The provisions of subsection (1)(c) or (d) of this section do not apply to an arrest or citation for driving while under the influence of intoxicants if the charge is dismissed as a result of the person's successful completion of a diversion agreement described in ORS 813.200.

(9) The provisions of subsection (1) of this section apply to convictions, arrests, citations and charges that occurred before, as well as those that occurred after, September 9, 1971. There is no time limit for making an application.

(10) For purposes of any civil action in which truth is an element of a claim for relief or affirmative defense, the provisions of subsection (3) of this section providing that the conviction, arrest, citation, charge or other proceeding be deemed not to have occurred do not apply and a party may apply to the court for an order requiring disclosure of the official records in the case as may be necessary in the interest of justice.

(11)(a) Upon motion of any prosecutor or defendant in a case involving records sealed under this section, supported by affidavit showing good cause, the court with jurisdiction may order the reopening and disclosure of any records sealed under this section for the limited purpose of assisting the investigation of the movant. However, such an order has no other effect on the orders setting aside the conviction or the arrest, citation or charge record.

(b) Notwithstanding paragraph (a) of this subsection, when an arrest, citation or charge described in subsection (1)(c) of this section is set aside, a prosecuting attorney may, for the purpose of initiating a criminal proceeding within the statute of limitations, unseal the records sealed under this section by notifying the court with jurisdiction over the charge, record of arrest or citation. The prosecuting attorney shall notify the person who is the subject of the records of the unsealing under this paragraph by sending written notification to the person's last known address.

(12) The State Court Administrator shall create forms to be used throughout the state for motions and proposed orders described in this section.

(13) As used in this section:

(a) "Affidavit" includes a declaration under penalty of perjury.

(b) "Sex crime" has the meaning given that term in ORS 163A.005.

(Other Amendments Related to Expungement)

SECTION 56. ORS 135.050 is amended to read:

135.050. (1) Suitable counsel for a defendant shall be appointed by a municipal, county or justice court if:

(a) The defendant is before a court on a matter described in subsection (5) of this section;

(b) The defendant requests aid of counsel;

(c) The defendant provides to the court a written and verified financial statement; and

(d) It appears to the court that the defendant is financially unable to retain adequate representation without substantial hardship in providing basic economic necessities to the defendant or the defendant's dependent family.

(2) Suitable counsel for a defendant shall be appointed by a circuit court if:

(a) The defendant is before the court on a matter described in subsection (5) of this section;

(b) The defendant requests aid of counsel;

(c) The defendant provides to the court a written and verified financial statement; and

(d)(A) The defendant is determined to be financially eligible under ORS 151.485 and the standards established by the Oregon Public Defense Commission under ORS 151.216; or

(B) The court finds, on the record, substantial and compelling reasons why the defendant is financially unable to retain adequate representation without substantial hardship in providing basic economic necessities to the defendant or the defendant's dependent family despite the fact that the defendant does not meet the financial eligibility standards established by the commission.

(3) Appointed counsel may not be denied to any defendant merely because the defendant's friends or relatives have resources adequate to retain counsel or because the defendant has deposited or is capable of depositing security for release. However, appointed counsel may be denied to a defendant if the defendant's spouse has adequate resources which the court determines should be made available to retain counsel.

(4) The defendant's financial statement under subsection (1) or (2) of this section shall include, but not be limited to:

(a) A list of bank accounts in the name of defendant or defendant's spouse, and the balance in each;

(b) A list of defendant's interests in real property and those of defendant's spouse;

(c) A list of automobiles and other personal property of significant value belonging to defendant or defendant's spouse;

(d) A list of debts in the name of defendant or defendant's spouse, and the total of each; and

(e) A record of earnings and other sources of income in the name of defendant or defendant's spouse, and the total of each.

(5) Counsel must be appointed for a defendant who meets the requirements of subsection (1) or (2) of this section and who is before a court on any of the following matters:

(a) Charged with a crime.

(b) For a hearing to determine whether an enhanced sentence should be imposed when such proceedings may result in the imposition of a felony sentence.

(c) For extradition proceedings under the provisions of the Uniform Criminal Extradition Act.

(d) For any proceeding concerning an order of probation, including but not limited to the revoking or amending thereof.

(6) Unless otherwise ordered by the court, the appointment of counsel under this section shall continue during all criminal proceedings resulting from the defendant's arrest through acquittal or the imposition of punishment. The court having jurisdiction of the case may not substitute one appointed counsel for another except pursuant to the policies, procedures, standards and guidelines of the Oregon Public Defense Commission under ORS 151.216.

(7) If, at any time after the appointment of counsel, the court having jurisdiction of the case finds that the defendant is financially able to obtain counsel, the court may terminate the appointment of counsel. If, at any time during criminal proceedings, the court having jurisdiction of the case finds that the defendant is financially unable to pay counsel whom the defendant has retained, the court may appoint counsel as provided in this section.

(8)**(a) Except as provided in paragraph (b) of this subsection,** the court may order the defendant in a circuit court to pay to the Public Defense Services Account established by ORS 151.225, through the clerk of the court, in full or in part the administrative costs of determining the eligibility of the defendant for appointed counsel and the costs of the legal and other services that are related to the provision of appointed counsel under ORS 151.487.

(b) A court may not enter an order described in paragraph (a) of this subsection when the defendant is charged only with unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35 of this 2024 Act.

(9) In addition to any criminal prosecution, a civil proceeding may be initiated by any public body which has expended moneys for the defendant's legal assistance within two years of judgment if the defendant was not qualified in accordance with subsection (1) or (2) of this section for legal assistance.

(10) The civil proceeding shall be subject to the exemptions from execution as provided for by law.

(11) As used in this section unless the context requires otherwise, "counsel" includes a legal advisor appointed under ORS 135.045.

(Repealing Class E Violation Provisions)

SECTION 57. ORS 51.050 is amended to read:

51.050. (1) Except as otherwise provided in this section, in addition to the criminal jurisdiction of justice courts already conferred upon and exercised by them, justice courts have jurisdiction of all offenses committed or triable in their respective counties. The jurisdiction conveyed by this section is concurrent with any jurisdiction that may be exercised by a circuit court or municipal court.

(2) In any justice court that has not become a court of record under ORS 51.025, a defendant charged with a misdemeanor shall be notified immediately after entering a plea of not guilty of the right of the defendant to have the matter transferred to the circuit court for the county where the justice court is located. The election shall be made within 10 days after the plea of not guilty is entered, and the justice shall immediately transfer the case to the appropriate court.

(3) A justice court does not have jurisdiction over the trial of any felony or a designated drug-related misdemeanor as defined in ORS 423.478. [*A justice court does not have jurisdiction over Class E violations.*] Except as provided in ORS 51.037, a justice court does not have jurisdiction over offenses created by the charter or ordinance of any city.

SECTION 58. ORS 137.300 is amended to read:

137.300. (1) The Criminal Fine Account is established in the General Fund. Except as otherwise provided by law, all amounts collected in state courts as monetary obligations in criminal actions shall be deposited by the courts in the account. All moneys in the account are continuously appropriated to the Department of Revenue to be distributed by the Department of Revenue as provided in this section. The Department of Revenue shall keep a record of moneys transferred into and out of the account.

(2) The Legislative Assembly shall first allocate moneys from the Criminal Fine Account for the following purposes, in the following order of priority:

(a) Allocations for public safety standards, training and facilities.

(b) Allocations for criminal injuries compensation and assistance to victims of crime and children reasonably suspected of being victims of crime.

(c) Allocations for the forensic services provided by the Oregon State Police, including, but not limited to, services of the Chief Medical Examiner.

(d) Allocations for the maintenance and operation of the Law Enforcement Data System.

(3) After making allocations under subsection (2) of this section, the Legislative Assembly shall allocate moneys from the Criminal Fine Account for the following purposes:

(a) Allocations to the Law Enforcement Medical Liability Account established under ORS 414.815.

(b) Allocations to the State Court Facilities and Security Account established under ORS 1.178.

(c) Allocations to the Department of Corrections for the purpose of planning, operating and maintaining county juvenile and adult corrections programs and facilities and drug and alcohol programs.

(d) Allocations to the Oregon Health Authority for the purpose of grants under ORS 430.345 for the establishment, operation and maintenance of alcohol and drug abuse prevention, early intervention and treatment services provided through a county.

(e) Allocations to the Oregon State Police for the purpose of the enforcement of the laws relating to driving under the influence of intoxicants.

(f) Allocations to the Arrest and Return Account established under ORS 133.865.

(g) Allocations to the Intoxicated Driver Program Fund established under ORS 813.270.

(h) Allocations to the State Court Technology Fund established under ORS 1.012.

[*(4) Notwithstanding subsections (2) and (3) of this section, the Legislative Assembly shall allocate all moneys deposited into the Criminal Fine Account as payment of fines on Class E violations to the Drug Treatment and Recovery Services Fund established under ORS 430.384.*]

[*(5)*] **(4)** It is the intent of the Legislative Assembly that allocations from the Criminal Fine Account under subsection (3) of this section be consistent with historical funding of the entities, programs and accounts listed in subsection (3) of this section from monetary obligations imposed in criminal proceedings. Amounts that are allocated under subsection (3)(c) of this section shall be distributed to counties based on the amounts that were transferred to counties by circuit courts during the 2009-2011 biennium under the provisions of ORS 137.308, as in effect January 1, 2011.

[*(6)*] **(5)** Moneys in the Criminal Fine Account may not be allocated for the payment of debt service obligations.

[*(7)*] **(6)** The Department of Revenue shall deposit in the General Fund all moneys remaining in the Criminal Fine Account after the distributions listed in subsections (2)[*,*] **and** (3) [*and (4)*] of this section have been made.

[*(8)*] **(7)** The Department of Revenue shall establish by rule a process for distributing moneys in the Criminal Fine Account. The department may not distribute more than one-eighth of the total biennial allocation to an entity during a calendar quarter.

SECTION 59. ORS 153.012 is amended to read:

153.012. Violations are classified for the purpose of sentencing into the following categories:

(1) Class A violations.

(2) Class B violations.

(3) Class C violations.

(4) Class D violations.

[*(5) Class E violations.*]

[*(6)*] **(5)** Unclassified violations as described in ORS 153.015.

[*(7)*] **(6)** Specific fine violations as described in ORS 153.015.

SECTION 60. ORS 153.018 is amended to read:

153.018. (1) The penalty for committing a violation is a fine. The law creating a violation may impose other penalties in addition to a fine but may not impose a term of imprisonment.

(2) Except as otherwise provided by law, the maximum fine for a violation committed by an individual is:

(a) $2,000 for a Class A violation.

(b) $1,000 for a Class B violation.

(c) $500 for a Class C violation.

(d) $250 for a Class D violation.

[*(e) $100 for a Class E violation.*]

[*(f)*] **(e)** $2,000 for a specific fine violation, or the maximum amount otherwise established by law for the specific fine violation.

(3) If a special corporate fine is specified in the law creating the violation, the sentence to pay a fine shall be governed by the law creating the violation. Except as otherwise provided by law, if a special corporate fine is not specified in the law creating the violation, the maximum fine for a violation committed by a corporation is:

(a) $4,000 for a Class A violation.

(b) $2,000 for a Class B violation.

(c) $1,000 for a Class C violation.

(d) $500 for a Class D violation.

SECTION 61. ORS 153.019 is amended to read:

153.019. (1) Except as provided in ORS 153.020, [*153.062 and 430.391,*] the presumptive fines for violations are:

(a) $440 for a Class A violation.

(b) $265 for a Class B violation.

(c) $165 for a Class C violation.

(d) $115 for a Class D violation.

[*(e) $100 for a Class E violation.*]

(2) The presumptive fine for a specific fine violation is:

(a) The amount specified by statute as the presumptive fine for the violation; or

(b) An amount equal to the greater of 20 percent of the maximum fine prescribed for the violation, or the minimum fine prescribed by statute for the violation.

(3) Any surcharge imposed under ORS 1.188 shall be added to and made a part of the presumptive fine.

SECTION 62. ORS 153.021 is amended to read:

153.021. (1) Unless a specific minimum fine is prescribed for a violation, and except as otherwise provided by law, the minimum fine a court shall impose for a violation that is subject to the presumptive fines established by ORS 153.019 (1) or 153.020 are as follows:

(a) $225 for a Class A violation.

(b) $135 for a Class B violation.

(c) $85 for a Class C violation.

(d) $65 for a Class D violation.

[*(e) $45 for a Class E violation.*]

(2) Notwithstanding subsection (1) of this section, a court may waive payment of the minimum fine described in this section, in whole or in part, if the court determines that requiring payment of the minimum fine would be inconsistent with justice in the case. In making its determination under this subsection, the court shall consider:

(a) The financial resources of the defendant and the burden that payment of the minimum fine would impose, with due regard to the other obligations of the defendant; and

(b) The extent to which that burden could be alleviated by allowing the defendant to pay the fine in installments or subject to other conditions set by the court.

(3) This section does not affect the manner in which a court imposes or reduces monetary obligations other than fines.

(4) The Department of Revenue or Secretary of State may audit any court to determine whether the court is complying with the requirements of this section. In addition, the Department of Revenue or Secretary of State may audit any court to determine whether the court is complying with the requirements of ORS 137.145 to 137.159 and 153.640 to 153.680. The Department of Revenue or Secretary of State may file an action under ORS 34.105 to 34.240 to enforce the requirements of this section and of ORS 137.145 to 137.159 and 153.640 to 153.680.

SECTION 63. ORS 153.064 is amended to read:

153.064. (1) Except as provided in subsection (2) of this section, a warrant for arrest may be issued against a person who fails to make a first appearance on a citation for a violation, or fails to appear at any other subsequent time set for trial or other appearance, only if the person is charged with failure to appear in a violation proceeding under ORS 153.992.

(2) If a person fails to make a first appearance on a citation for a violation [*other than a Class E violation*], or fails to appear at any other subsequent time set for trial or other appearance on a violation [*other than a Class E violation*], the court may issue an order that requires the defendant to appear and show cause why the defendant should not be held in contempt. The show cause order may be mailed to the defendant by certified mail, return receipt requested. If service cannot be accomplished by mail, the defendant must be personally served. If the defendant is served and fails to appear at the time specified in the show cause order, the court may issue an arrest warrant for the defendant for the purpose of bringing the defendant before the court.

SECTION 64. ORS 153.992 is amended to read:

153.992. (1) A person commits the offense of failure to appear in a violation proceeding if the person has been served with a citation issued under this chapter for a violation [*other than a Class E violation*] and the person knowingly fails to do any of the following:

(a) Make a first appearance in the manner required by ORS 153.061 within the time allowed.

(b) Make appearance at the time set for trial in the violation proceeding.

(c) Appear at any other time required by the court or by law.

(2) Failure to appear on a violation citation is a Class A misdemeanor.

SECTION 65. ORS 221.339 is amended to read:

221.339. (1) A municipal court has concurrent jurisdiction with circuit courts and justice courts over all violations committed or triable in the city where the court is located.

(2) Except as provided in subsections (3) and (4) of this section, municipal courts have concurrent jurisdiction with circuit courts and justice courts over misdemeanors committed or triable in the city. Municipal courts may exercise the jurisdiction conveyed by this section without a charter provision or ordinance authorizing that exercise.

(3) Municipal courts have no jurisdiction over felonies[,] **or** designated drug-related misdemeanors as defined in ORS 423.478 [*or Class E violations*].

(4) A city may limit the exercise of jurisdiction over misdemeanors by a municipal court under this section by the adoption of a charter provision or ordinance, except that municipal courts must retain concurrent jurisdiction with circuit courts over:

(a) Misdemeanors created by the city's own charter or by ordinances adopted by the city, as provided in ORS 3.132; and

(b) Traffic crimes as defined by ORS 801.545.

(5) Subject to the powers and duties of the Attorney General under ORS 180.060, the city attorney has authority to prosecute a violation of any offense created by statute that is subject to the jurisdiction of a municipal court, including any appeal, if the offense is committed or triable in the city. The prosecution shall be in the name of the state. The city attorney shall have all powers of a district attorney in prosecutions under this subsection.

SECTION 65a. ORS 316.502 is amended to read:

316.502. (1) The net revenue from the tax imposed by this chapter, after deducting refunds and amounts described in ORS 285B.630[,] **and** 285C.635 [*and 305.231*], shall be paid over to the State Treasurer and held in the General Fund as miscellaneous receipts available generally to meet any expense or obligation of the State of Oregon lawfully incurred.

(2) A working balance of unreceipted revenue from the tax imposed by this chapter may be retained for the payment of refunds, but such working balance shall not at the close of any fiscal year exceed the sum of $1 million.

(3) Moneys are continuously appropriated to the Department of Revenue to make:

(a) The refunds authorized under subsection (2) of this section; and

(b) The refund payments in excess of tax liability authorized under ORS 315.133, 315.174, 315.262, 315.264, 315.266, 315.273, 315.519 and 316.090 and section 3, chapter 589, Oregon Laws 2021.

SECTION 66. ORS 419C.370 is amended to read:

419C.370. (1) The juvenile court may enter an order directing that all cases involving:

(a) Violation of a law or ordinance relating to the use or operation of a motor vehicle, boating laws or game laws be waived to criminal or municipal court;

(b) An offense classified as a violation [*other than a Class E violation*] under the laws of this state or a political subdivision of this state be waived to municipal court if the municipal court has agreed to accept jurisdiction; and

(c) A misdemeanor that entails theft, destruction, tampering with or vandalism of property be waived to municipal court if the municipal court has agreed to accept jurisdiction.

(2) Cases waived under subsection (1) of this section are subject to the following:

(a) That the criminal or municipal court prior to hearing a case, other than a case involving a parking violation, in which the defendant is or appears to be under 18 years of age notify the juvenile court of that fact; and

(b) That the juvenile court may direct that any such case be waived to the juvenile court for further proceedings.

(3)(a) When a person who has been waived under subsection (1)(c) of this section is convicted of a property offense, the municipal court may impose any sanction authorized for the offense except for incarceration. The municipal court shall notify the juvenile court of the disposition of the case.

(b) When a person has been waived under subsection (1) of this section and fails to appear as summoned or is placed on probation and is alleged to have violated a condition of the probation, the juvenile court may recall the case to the juvenile court for further proceedings. When a person has been returned to juvenile court under this paragraph, the juvenile court may proceed as though the person had failed to appear as summoned to the juvenile court or had violated a juvenile court probation order under ORS 419C.446.

(4) Records of cases waived under subsection (1)(c) of this section are juvenile records for purposes of expunction under ORS 419A.260 to 419A.271.

SECTION 67. ORS 430.384 is amended to read:

430.384. (1) The Drug Treatment and Recovery Services Fund is established in the State Treasury, separate and distinct from the General Fund. Interest earned by the Drug Treatment and Recovery Services Fund shall be credited to the fund.

(2) The Drug Treatment and Recovery Services Fund shall consist of:

[*(a) Moneys deposited into the fund pursuant to ORS 305.231;*]

[*(b)*] **(a)** Moneys appropriated or otherwise transferred to the fund by the Legislative Assembly;

[*(c)*] **(b)** Moneys allocated from the Oregon Marijuana Account, pursuant to ORS 475C.726 (3)(b); **and**

[*(d) Moneys allocated from the Criminal Fine Account pursuant to ORS 137.300 (4); and*]

[*(e)*] **(c)** All other moneys deposited into the fund from any source.

(3) Moneys in the fund shall be continuously appropriated to the Oregon Health Authority for the purposes set forth in ORS 430.389.

(4)(a) Pursuant to subsection [*(2)(b)*] **(2)(a)** of this section, the Legislative Assembly shall appropriate or transfer to the fund an amount sufficient to fully fund the grants program required by ORS 430.389.

(b) The total amount deposited and transferred into the fund shall not be less than $57 million for the first year ORS 430.383 to 430.390 and 430.394 are in effect.

(c) In each subsequent year, the minimum transfer amount set forth in paragraph (b) of this subsection shall be increased by not less than the sum of:

(A) $57 million multiplied by the percentage, if any, by which the monthly averaged U.S. City Average Consumer Price Index for the 12 consecutive months ending August 31 of the prior calendar year exceeds the monthly index for the fourth quarter of the calendar year 2020; and

(B) The annual increase, if any, in moneys distributed pursuant to ORS 475C.726 (3)(b).

SECTION 68. ORS 430.389 is amended to read:

430.389. (1) The Oversight and Accountability Council shall approve grants and funding provided by the Oregon Health Authority in accordance with this section to implement Behavioral Health Resource Networks and increase access to community care. A Behavioral Health Resource Network is an entity or collection of entities that individually or jointly provide some or all of the services described in subsection (2)(e) of this section.

(2)(a) The authority shall establish an equitable:

(A) Process for applying for grants and funding by agencies or organizations, whether government or community based, to establish Behavioral Health Resource Networks for the purposes of immediately screening the acute needs of individuals with substance use, including those who also have a mental illness, and assessing and addressing any ongoing needs through ongoing case management, harm reduction, treatment, housing and linkage to other care and services.

(B) Evaluation process to assess the effectiveness of Behavioral Health Resource Networks that receive grants or funding.

(b) Recipients of grants or funding must be licensed, certified or credentialed by the state, including certification under ORS 743A.168 (9), or meet criteria prescribed by rule by the authority under ORS 430.390. A recipient of a grant or funding under this subsection may not use the grant or funding to supplant the recipient's existing funding.

(c) The council and the authority shall ensure that residents of each county have access to all of the services described in paragraph (e) of this subsection.

(d) Applicants for grants and funding may apply individually or jointly with other network participants to provide services in one or more counties.

(e) A network must have the capacity to provide the following services and any other services specified by the authority by rule but no individual participant in a network is required to provide all of the services:

(A) Screening by certified addiction peer support or wellness specialists or other qualified persons designated by the council to determine a client's need for immediate medical or other treatment to determine what acute care is needed and where it can be best provided, identify other needs and link the client to other appropriate local or statewide services, including treatment for substance use and coexisting health problems, housing, employment, training and child care. Networks shall provide this service 24 hours a day, seven days a week, every calendar day of the year through a telephone line or other means. Networks may rely on the statewide telephone hotline established by the authority under ORS 430.391 for telephone screenings during nonbusiness hours such as evenings, weekends and holidays. Notwithstanding paragraph (c) of this subsection, only one grantee in each network within each county is required to provide the screenings described in this subparagraph.

(B) Comprehensive behavioral health needs assessment, including a substance use screening by a certified alcohol and drug counselor or other credentialed addiction treatment professional. The assessment shall prioritize the self-identified needs of a client.

(C) Individual intervention planning, case management and connection to services. If, after the completion of a screening, a client indicates a desire to address some or all of the identified needs, a case manager shall work with the client to design an individual intervention plan. The plan must address the client's need for substance use treatment, coexisting health problems, housing, employment and training, child care and other services.

(D) Ongoing peer counseling and support from screening and assessment through implementation of individual intervention plans as well as peer outreach workers to engage directly with marginalized community members who could potentially benefit from the network's services.

(E) Assessment of the need for, and provision of, mobile or virtual outreach services to:

(i) Reach clients who are unable to access the network; and

(ii) Increase public awareness of network services.

(F) Harm reduction services and information and education about harm reduction services.

(G) Low-barrier substance use treatment.

(H) Transitional and supportive housing for individuals with substance use.

(f) If an applicant for a grant or funding under this subsection is unable to provide all of the services described in paragraph (e) of this subsection, the applicant may identify how the applicant intends to partner with other entities to provide the services, and the authority and the council may facilitate collaboration among applicants.

(g) All services provided through the networks must be evidence-informed, trauma-informed, culturally specific, linguistically responsive, person-centered and nonjudgmental. The goal shall be to address effectively the client's substance use and any other social determinants of health.

(h) The networks must be adequately staffed to address the needs of people with substance use within their regions as prescribed by the authority by rule, including, at a minimum, at least one person in each of the following categories:

(A) Alcohol and drug counselor certified by the authority or other credentialed addiction treatment professional;

(B) Case manager;

(C) Addiction peer support specialist certified by the authority;

(D) Addiction peer wellness specialist certified by the authority;

(E) Recovery mentor, certified by the Mental Health and Addiction Certification Board of Oregon or its successor organization; and

(F) Youth support specialist certified by the authority.

(i) Verification of a screening by a certified addiction peer support specialist, wellness specialist or other person in accordance with paragraph (e)(A) of this subsection shall promptly be provided to the client by the entity conducting the screening. If the client executes a valid release of information, the entity shall provide verification of the screening to the authority or a contractor of the authority and the authority or the authority's contractor shall forward the verification to [*the court, in the manner prescribed by the Chief Justice of the Supreme Court, to satisfy the conditions for dismissal under ORS 153.062 or 475.237*] **any entity the client has authorized to receive the verification**.

(3)(a) If moneys remain in the Drug Treatment and Recovery Services Fund after the council has committed grants and funding to establish behavioral health resource networks serving every county in this state, the council shall authorize grants and funding to other agencies or organizations, whether government or community based, and to the nine federally recognized tribes in this state and service providers that are affiliated with the nine federally recognized tribes in this state to increase access to one or more of the following:

(A) Low-barrier substance use treatment that is evidence-informed, trauma-informed, culturally specific, linguistically responsive, person-centered and nonjudgmental;

(B) Peer support and recovery services;

(C) Transitional, supportive and permanent housing for persons with substance use;

(D) Harm reduction interventions including, but not limited to, overdose prevention education, access to short-acting opioid antagonists, as defined in ORS 689.800, and sterile syringes and stimulant-specific drug education and outreach; or

(E) Incentives and supports to expand the behavioral health workforce to support the services delivered by behavioral health resource networks and entities receiving grants or funding under this subsection.

(b) A recipient of a grant or funding under this subsection may not use the grant or funding to supplant the recipient's existing funding.

(4) In awarding grants and funding under subsections (1) and (3) of this section, the council shall:

(a) Distribute grants and funding to ensure access to:

(A) Historically underserved populations; and

(B) Culturally specific and linguistically responsive services.

(b) Consider any inventories or surveys of currently available behavioral health services.

(c) Consider available regional data related to the substance use treatment needs and the access to culturally specific and linguistically responsive services in communities in this state.

(d) Consider the needs of residents of this state for services, supports and treatment at all ages.

(5) The council shall require any government entity that applies for a grant to specify in the application details regarding subgrantees and how the government entity will fund culturally specific organizations and culturally specific services. A government entity receiving a grant must

make an explicit commitment not to supplant or decrease any existing funding used to provide services funded by the grant.

(6) In determining grants and funding to be awarded, the council may consult the comprehensive addiction, prevention, treatment and recovery plan established by the Alcohol and Drug Policy Commission under ORS 430.223 and the advice of any other group, agency, organization or individual that desires to provide advice to the council that is consistent with the terms of this section.

(7) Services provided by grantees, including services provided by a Behavioral Health Resource Network, shall be free of charge to the clients receiving the services. Grantees in each network shall seek reimbursement from insurance issuers, the medical assistance program or any other third party responsible for the cost of services provided to a client and grants and funding provided by the council or the authority under this section may be used for copayments, deductibles or other out-of-pocket costs incurred by the client for the services.

(8) Subsection (7) of this section does not require the medical assistance program to reimburse the cost of services for which another third party is responsible in violation of 42 U.S.C. 1396a(25).

SECTION 69. ORS 430.392 is amended to read:

430.392. (1) The Division of Audits of the office of the Secretary of State shall conduct performance audits and financial reviews as provided in this section, regarding the uses of the Drug Treatment and Recovery Services Fund and the effectiveness of the fund in achieving the purposes of the fund and the policy objectives of ORS 430.383. Recipients of grants or funds under ORS 430.389 shall keep accurate books, records and accounts that are subject to inspection and audit by the division.

(2) The division shall monitor and report on the progress in implementing any recommendations made in the audit or financial review. The division shall follow up on recommendations as part of recurring audit work or as an activity separate from other audit activity. When following up on recommendations, the division may request from the appropriate agency evidence of implementation.

(3) The audits set forth in this section shall be conducted pursuant to the provisions of ORS chapter 297, except to the extent any provision of ORS chapter 297 conflicts with any provision of ORS [*293.665 and 305.231 and*] 430.383 to 430.390 and 430.394, in which case the provisions of ORS [*293.665 and 305.231 and*] 430.383 to 430.390 and 430.394 shall control.

(4) No later than December 31, 2023, the division shall perform a:

(a) Real-time audit, as prescribed by the division, which shall include an assessment of the relationship between the Oversight and Accountability Council and the Oregon Health Authority, the relationship between the council and recipients of grants or funding and the structural integrity of ORS [*293.665 and 305.231 and*] 430.383 to 430.390 and 430.394, including but not limited to assessing:

(A) Whether the organizational structure of the council contains conflicts or problems.

(B) Whether the rules adopted by the council are clear and functioning properly.

(C) Whether the council has sufficient authority and independence to achieve the council's mission.

(D) Whether the authority is fulfilling the authority's duties under ORS 430.384, 430.387, 430.390 and 430.391.

(E) Whether there are conflicts of interest in the process of awarding grants or funding.

(F) Whether there are opportunities to expand collaboration between the council and state agencies.

(G) Whether barriers exist in data collection and evaluation mechanisms.

(H) Who is providing the data.

(I) Other areas identified by the division.

(b) Financial review, which shall include an assessment of the following:

(A) Whether grants and funding are going to organizations that are culturally responsive and linguistically specific, including an assessment of:

(i) The barriers that exist for grant and funding applicants who are Black, Indigenous or People of Color.

(ii) The applicants that were denied and why.

(iii) Whether grants and other funding are being disbursed based on the priorities specified in ORS 430.389.

(iv) For government entities receiving grants or funding under ORS 430.389, the government entities' subgrantees and whether the governmental entity supplanted or decreased any local funding dedicated to the same services after receiving grants or funds under ORS 430.389.

(v) What proportion of grants or funds received by grantees and others under ORS 430.389, was devoted to administrative costs.

(B) The organizations and agencies receiving grants or funding under ORS 430.389 and:

(i) Which of the organizations and agencies are Behavioral Health Resource Network entities.

(ii) The amount each organization and agency received.

(iii) The total number of organizations and agencies that applied for grants or funding.

(iv) The amount of moneys from the fund that were used to administer the programs selected by the council.

(v) The moneys that remained in the Drug Treatment and Recovery Services Fund after grants and funding were disbursed.

(5) No later than December 31, 2025, the division shall conduct a performance audit, which must include an assessment of the following:

(a) All relevant data regarding the implementation of ORS [*153.062 and*] 430.391, including demographic information on individuals who receive citations [*subject to ORS 153.062 and 430.391*] **for a drug enforcement misdemeanor described in section 35 of this 2024 Act** and whether the citations resulted in connecting the individuals with treatment.

(b) The functioning of:

(A) Law enforcement and the courts in relation to [*Class E violation citations*] **drug enforcement misdemeanors described in section 35 of this 2024 Act**;

(B) The telephone hotline operated by the authority;

(C) Entities providing verification of screenings under ORS 430.389; and

(D) The grants and funding systems between the council, the authority and recipients of grants or funding, including by gathering information about which entities are receiving grants or funding and what the grants or funding are used for, the process of applying for grants or funding and whether the process is conducive to obtaining qualified applicants for grants or funding who are from communities of color.

(c) Disparities shown by demographic data and whether the citation data reveals a disproportionate use of citations in communities most impacted by the war on drugs.

(d) Whether ORS [*153.062,*] 430.389 and 430.391 reduce the involvement in the criminal justice system of individuals with substance use.

(e) Training opportunities provided to law enforcement officials regarding services that are available and how to connect individuals to the services.

(f) The efficacy of issuing citations as a method of connecting individuals to services.

(g) The role of the implementation of ORS 430.383 to 430.390 and 430.394 in reducing overdose rates.

(h) Outcomes for individuals receiving treatment and other social services under ORS 430.389, including, but not limited to, the following:

(A) Whether access to care increased since December 3, 2020, and, if data is available, whether, since December 3, 2020:

(i) The number of drug and alcohol treatment service providers increased.

(ii) The number of culturally specific providers increased.

(iii) Access to harm reduction services has increased.

(iv) More individuals are accessing treatment than they were before December 3, 2020.

(v) Access to housing for individuals with substance use has increased.

(B) Data on Behavioral Health Resource Networks and recipients of grants and funding under ORS 430.389, including:

(i) The outcomes of each network or recipient, including but not limited to the number of clients with substance use receiving services from each network or recipient, the average duration of client participation and client outcomes.

(ii) The number of individuals seeking assistance from the network or recipients who are denied or not connected to substance use treatment and other services, and the reasons for the denials.

(iii) The average time it takes for clients to access services and fulfill their individual intervention plan and the reason for any delays, such as waiting lists at referred services.

(iv) Whether average times to access services to which clients are referred, such as housing or medically assisted treatment, have decreased over time since December 3, 2020.

(v) Demographic data on clients served by Behavioral Health Resource Networks, including self-reported demographic data on race, ethnicity, gender and age.

(i) Each recipient of a grant or funding.

(j) Other areas identified by the division for ascertaining best practices for overdose prevention.

(6) The division shall conduct periodic performance audits and financial reviews pursuant to the division's annual audit plan and taking into consideration the risks of the program.

SECTION 69a. ORS 430.392, as amended by section 11, chapter 248, Oregon Laws 2023, is amended to read:

430.392. (1) The Division of Audits of the office of the Secretary of State shall conduct performance audits and financial reviews as provided in this section, regarding the uses of the Drug Treatment and Recovery Services Fund and the effectiveness of the fund in achieving the purposes of the fund and the policy objectives of ORS 430.383. Recipients of grants or funds under ORS 430.389 shall keep accurate books, records and accounts that are subject to inspection and audit by the division.

(2) The division shall monitor and report on the progress in implementing any recommendations made in the audit or financial review. The division shall follow up on recommendations as part of recurring audit work or as an activity separate from other audit activity. When following up on recommendations, the division may request from the appropriate agency evidence of implementation.

(3) The audits set forth in this section shall be conducted pursuant to the provisions of ORS chapter 297, except to the extent any provision of ORS chapter 297 conflicts with any provision of ORS [*293.665 and 305.231 and*] 430.383 to 430.390 and 430.394, in which case the provisions of ORS [*293.665 and 305.231 and*] 430.383 to 430.390 and 430.394 shall control.

(4) The division shall conduct periodic performance audits and financial reviews pursuant to the division's annual audit plan and taking into consideration the risks of the program.

SECTION 70. ORS 475.235 is amended to read:

475.235. (1) It is not necessary for the state to negate any exemption or exception in ORS 475.005 to 475.285 and 475.752 to 475.980 in any complaint, information, indictment or other pleading or in any trial, hearing or other proceeding under ORS 475.005 to 475.285 and 475.752 to 475.980. The burden of proof of any exemption or exception is upon the person claiming it.

(2) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under ORS 475.005 to 475.285 and 475.752 to 475.980, the person is presumed not to be the holder of the registration or form. The burden of proof is upon the person to rebut the presumption.

(3)(a) When a controlled substance is at issue in a criminal proceeding before a grand jury, at a preliminary hearing, in a proceeding on a district attorney's information[*, during a proceeding on a Class E violation*] or for purposes of an early disposition program, it is prima facie evidence of the identity of the controlled substance if:

(A) A sample of the controlled substance is tested using a presumptive test for controlled substances;

(B) The test is conducted by a law enforcement officer trained to use the test or by a forensic scientist; and

(C) The test is positive for the particular controlled substance.

(b) When the identity of a controlled substance is established using a presumptive test for purposes of a criminal proceeding before a grand jury, a preliminary hearing, a proceeding on a district attorney's information or an early disposition program, the defendant, upon notice to the district attorney, may request that the controlled substance be sent to a state police forensic laboratory for analysis. [*The defendant may not make a request under this paragraph concerning a controlled substance at issue in a proceeding on a Class E violation.*]

(4) Notwithstanding any other provision of law, in all prosecutions in which an analysis of a controlled substance or sample was conducted, a certified copy of the analytical report signed by the director of a state police forensic laboratory or the analyst or forensic scientist conducting the analysis shall be admitted as prima facie evidence of the results of the analytical findings unless the defendant has provided notice of an objection in accordance with subsection (5) of this section.

(5) If the defendant intends to object at trial to the admission of a certified copy of an analytical report as provided in subsection (4) of this section, not less than 15 days prior to trial the defendant shall file written notice of the objection with the court and serve a copy on the district attorney.

(6) As used in this section:

(a) "Analyst" means a person employed by the Department of State Police to conduct analysis in forensic laboratories established by the department under ORS 181A.150.

(b) "Presumptive test" includes, but is not limited to, chemical tests using Marquis reagent, Duquenois-Levine reagent, Scott reagent system or modified Chen's reagent.

SECTION 71. ORS 670.280 is amended to read:

670.280. (1) As used in this section:

(a) "License" includes a registration, certification or permit.

(b) "Licensee" includes a registrant or a holder of a certification or permit.

(2) Except as provided in ORS 342.143 (3) or 342.175 (3), a licensing board, commission or agency may not deny, suspend or revoke an occupational or professional license solely for the reason that the applicant or licensee has been convicted of a crime, but it may consider the relationship of the facts which support the conviction and all intervening circumstances to the specific occupational or professional standards in determining the fitness of the person to receive or hold the license. [*There is a rebuttable presumption as to each individual applicant or licensee that an existing or prior conviction for conduct that has been classified or reclassified as a Class E violation does not make an applicant for an occupational or professional license or a licensee with an occupational or professional license unfit to receive or hold the license.*]

(3) Except as provided in ORS 342.143 (3) and 342.175 (3), a licensing board, commission or agency may deny an occupational or professional license or impose discipline on a licensee based on conduct that is not undertaken directly in the course of the licensed activity, but that is substantially related to the fitness and ability of the applicant or licensee to engage in the activity for which the license is required. In determining whether the conduct is substantially related to the fitness and ability of the applicant or licensee to engage in the activity for which the license is required, the licensing board, commission or agency shall consider the relationship of the facts with respect to the conduct and all intervening circumstances to the specific occupational or professional standards. [*There is a rebuttable presumption as to each individual applicant or licensee that an existing or prior conviction for conduct that has been classified or reclassified as a Class E violation is not related to the fitness and ability of the applicant or licensee to engage in the activity for which the license is required.*]

SECTION 72. ORS 153.043, 153.062, 293.665, 305.231, 419C.460 and 475.237 are repealed.

(Operative Dates and Applicability)

SECTION 73. (1) Sections 34 to 37, 51, 52 and 54 this 2024 Act, the amendments to ORS 51.050, 133.060, 135.050, 135.753, 137.225, 137.300, 153.012, 153.018, 153.019, 153.021, 153.064, 153.992, 221.339, 316.502, 419C.370, 423.478, 423.483, 423.525, 430.384, 430.389, 430.392, 475.235, 475.752, 475.814, 475.824, 475.834, 475.854, 475.874, 475.884, 475.894 and 670.280 by sections 38 to

50 and 55 to 71 of this 2024 Act and the repeal of ORS 153.043, 153.062, 293.665, 305.231, 419C.460 and 475.237 by section 72 of this 2024 Act become operative on September 1, 2024.

(2) The Oregon Criminal Justice Commission, the Judicial Department, the Department of Corrections, law enforcement agencies and district attorneys may take any action before the operative date specified in subsection (1) of this section that is necessary for those entities to exercise, on and after the operative date specified in subsection (1) of this section, all of the powers, duties and functions imposed on the entities under sections 34 to 37, 51, 52 and 54 this 2024 Act, the amendments to ORS 51.050, 133.060, 135.050, 135.753, 137.225, 137.300, 153.012, 153.018, 153.019, 153.021, 153.064, 153.992, 221.339, 316.502, 419C.370, 423.478, 423.483, 423.525, 430.384, 430.389, 430.392, 475.235, 475.752, 475.814, 475.824, 475.834, 475.854, 475.874, 475.884, 475.894 and 670.280 by sections 38 to 50 and 55 to 71 of this 2024 Act and the repeal of ORS 153.043, 153.062, 293.665, 305.231, 419C.460 and 475.237 by section 72 of this 2024 Act.

SECTION 74. Sections 35, 52 and 54 this 2024 Act, the amendments to ORS 51.050, 135.050, 135.753, 137.300, 153.012, 153.018, 153.019, 153.021, 153.064, 153.992, 221.339, 316.502, 419C.370, 423.478, 423.483, 423.525, 430.384, 430.389, 430.392, 475.235, 475.752, 475.814, 475.824, 475.834, 475.854, 475.874, 475.884, 475.894 and 670.280 by sections 39 to 50 and 56 to 71 of this 2024 Act and the repeal of ORS 153.043, 153.062, 293.665, 305.231, 419C.460 and 475.237 by section 72 of this 2024 Act apply to conduct constituting an offense occurring, or alleged to have occurred, on or after September 1, 2024.

DATA TRACKING

SECTION 75. (1) For purposes of tracking racial or other demographic disparities in enforcement, the Oregon Criminal Justice Commission shall collect and analyze the following data concerning deflections, arrests, charges and convictions for unlawful possession of a controlled substance and delivery of a controlled substance offenses:

(a) The date and location of each deflection and arrest;

(b) The specific offense for which each person was arrested, charged or convicted; and

(c) Demographic data for each person deflected, arrested, charged or convicted.

(2) Beginning no later than August 31, 2025, and annually thereafter, the commission shall provide a report to the interim committees of the Legislative Assembly related to the judiciary, in the manner described in ORS 192.245, containing an analysis of the data described in this section.

(3) In carrying out the commission's duties under this section, the commission may use any information concerning deflections obtained as part of carrying out the duties of the commission under section 37 of this 2024 Act or as part of the grant program application, monitoring and evaluation process described in sections 76 and 77 of this 2024 Act.

(4) Data reported under this section shall be used only for statistical purposes and not for any other purpose. The data reports may not contain information that reveals the identity of any individual. Data collected by government agencies or held by the Oregon Criminal Justice Commission under this section that may reveal the identity of any individual is exempt from public disclosure in any manner.

(5) The Oregon Criminal Justice Commission may adopt rules to carry out the provisions of this section.

OREGON BEHAVIORAL HEALTH DEFLECTION PROGRAM

SECTION 76. (1) As used in this section, "deflection program" means a collaborative program between law enforcement agencies and behavioral health entities that assists individuals who may have substance use disorder, another behavioral health disorder or co-

occurring disorders, to create community-based pathways to treatment, recovery support services, housing, case management or other services.

(2) The Oregon Behavioral Health Deflection Program is established within the Improving People's Access to Community-based Treatment, Supports and Services Grant Review Committee established under ORS 430.234. The program consists of grants awarded by the committee to counties and federally recognized tribal governments to fund deflection programs.

(3)(a) The purpose of the program described in this section is to:

(A) Address the need for more deflection programs to assist individuals whose behavioral health conditions, including substance use disorder, lead to interactions with law enforcement, incarceration, conviction and other engagement with the criminal justice system.

(B) Track and report data concerning deflection program outcomes in order to determine the best practices for deflection programs within this state.

(b) ORS 430.230 to 430.236 do not apply to the program described in this section.

(4)(a) The committee shall develop a grant application process for awarding grants under this section.

(b) An application for a grant under this section may be submitted by a county or the designee of a county, or by a tribal government or designee of a tribal government. Only one application per county may be submitted, but the application may request funding multiple programs within a county.

(c) Prior to submitting an application for a grant under this section, the applicant shall coordinate with all partners of the development and administration of the proposed deflection program to ensure that the partners have the resources necessary to implement the deflection program. The partners shall include at least a district attorney, a law enforcement agency, a community mental health program established under ORS 430.620 and a provider from a Behavioral Health Resource Network established under ORS 430.389. Partners may also include a treatment provider, a local mental health authority, a tribal government, a peer support organization, a court or a local government body.

(d) An application for a grant under this section must contain:

(A) A description of the coordination with program partners required by paragraph (c) of this subsection that has occurred;

(B) A description of the individuals who would be eligible for the program and what qualifies as a successful outcome, formulated in cooperation with the program partners described in paragraph (c) of this subsection;

(C) A description of how the program for which the applicant is seeking funding is culturally and linguistically responsive, trauma-informed and evidence-based;

(D) A description of a plan to address language access barriers when communicating program referral options and program procedures to non-English speaking individuals; and

(E) A description of how the program coordinator will communicate with program partners concerning persons participating in the program and any other matter necessary for the administration of the program.

(5) To be eligible for funding under this section, a deflection program:

(a) Must be coordinated by or in consultation with a community mental health program, a local mental health authority or a federally recognized tribal government;

(b) Must have a coordinator with the following program coordinator duties:

(A) Convening deflection program partners as needed for the operation of the program;

(B) Managing grant program funds awarded under this section; and

(C) Tracking and reporting data required by the Oregon Criminal Justice Commission under section 37 of this 2024 Act;

(c) Must involve the partners described in subsection (4)(c) of this section; and

(d) May involve a partnership with one or more of the following entities:

(A) A first responder agency other than a law enforcement agency;

(B) A community provider;

(C) A treatment provider;

(D) A community-based organization;

(E) A case management provider;

(F) A recovery support services provider; or

(G) Any other individual or entity deemed necessary by the program coordinator to carry out the purposes of the deflection program, including individuals with lived experience with substance use disorder, a behavioral health disorder or co-occurring disorders.

(6) During a grant application period established by the committee, the maximum proportion of grant funds available to an applicant shall be determined as follows:

(a) The proportion of grant funds available to an applicant other than a tribal government shall be determined based on the county formula share employed by the Oversight and Accountability Council established under ORS 430.388, but an applicant may not receive less than $150,000.

(b) The committee shall determine the proportion of funds available to an applicant that is a federally recognized tribal government.

(7)(a) Grant funds awarded under this section may be used for:

(A) Deflection program expenses including but not limited to law enforcement employees, deputy district attorneys and behavioral health treatment workers, including peer navigators and mobile crisis and support services workers.

(B) Behavioral health workforce development.

(C) Capital construction of behavioral health treatment infrastructure.

(b) Notwithstanding paragraph (a) of this subsection, the committee may award planning grants for the development of deflection programs.

(c) The committee may allocate up to three percent of program funds to support grantee data collection and analysis or evaluation of outcome measures.

(8) The Oregon Criminal Justice Commission shall provide staff support to the grant program.

(9) The committee and the commission may adopt rules to carry out the provisions of this section.

SECTION 77. (1)(a) The Improving People's Access to Community-based Treatment, Supports and Services Grant Review Committee established under ORS 430.234, in cooperation with the Oregon Criminal Justice Commission and the Oregon Health Authority, shall monitor the progress of and evaluate program outcomes for applicants that receive grant funds as part of the Oregon Behavioral Health Deflection Program established under section 76 of this 2024 Act.

(b) The committee shall share with the commission any data described in paragraph (a) of this subsection that the commission requires to carry out the commission's duties under section 37 of this 2024 Act.

(2) Beginning no later than September 30, 2025, the committee shall annually report, in the manner described in ORS 192.245 and in conjunction with the report required under ORS 430.245 (3), the findings of the evaluation described in subsection (1) of this section to the relevant interim committees of the Legislative Assembly.

SECTION 78. The Oregon Behavioral Health Deflection Program Account is established in the State Treasury, separate and distinct from the General Fund. All moneys in the account are continuously appropriated to the Oregon Criminal Justice Commission for the purpose of carrying out the provisions of sections 76 and 77 of this 2024 Act.

SECTION 79. ORS 430.234 is amended to read:

430.234. (1) The Improving People's Access to Community-based Treatment, Supports and Services Grant Review Committee is established in the Oregon Criminal Justice Commission consisting of [*19*] **21** members as follows:

(a) The Director of the Oregon Health Authority, or the director's designee.

(b) The Director of the Department of Corrections, or the director's designee.

(c) The Chief Justice of the Supreme Court, or the Chief Justice's designee.

(d) The executive director of the Oregon Criminal Justice Commission or the director's designee.

(e) Two members of the Oregon Criminal Justice Commission, to be appointed by the chair of the commission.

[*(e)*] **(f)** The Director of the Housing and Community Services Department or the director's designee.

[*(f)*] **(g)** Nine members appointed by the Governor including:

(A) A district attorney.

(B) An attorney specializing in defense of individuals with mental health or substance use disorders.

(C) A chief of police.

(D) A county commissioner.

(E) A director of a hospital that provides acute mental health treatment.

(F) A representative of a community-based mental health treatment facility or a practitioner in a community-based mental health treatment facility.

(G) A representative of a community-based substance use disorder treatment facility or a practitioner in a community-based substance use disorder treatment facility.

(H) A sheriff.

(I) A representative of a federally recognized Indian tribe.

[*(g)*] **(h)** One nonvoting member appointed by the President of the Senate from among members of the Senate.

[*(h)*] **(i)** One nonvoting member appointed by the Speaker of the House of Representatives from among members of the House of Representatives.

[*(i)*] **(j)** Three members of the public that represent the age demographics of the target population.

(2) A majority of the voting members of the committee constitutes a quorum for the transaction of business.

(3) The directors of the Oregon Criminal Justice Commission and the Oregon Health Authority or their designees shall serve as cochairpersons.

(4) If there is a vacancy for any cause, the appointing authority shall make an appointment to become effective immediately.

(5) The committee shall meet at times and places specified by the call of the cochairpersons or a majority of the voting members of the committee.

(6) The Oregon Criminal Justice Commission shall provide staff support to the committee.

(7) Legislative members of the committee shall be entitled to payment of compensation and expenses under ORS 171.072, payable from funds appropriated to the Legislative Assembly.

(8) Members of the committee who are not members of the Legislative Assembly are not entitled to compensation but may be reimbursed for actual and necessary travel and other expenses incurred by the member in the performance of the member's official duties in the manner and amount provided in ORS 292.495.

(9) All agencies of state government, as defined in ORS 174.111, are directed to assist the committee in the performance of the duties of the committee and, to the extent permitted by laws relating to confidentiality, to furnish information and advice that the members of the committee consider necessary to perform their duties.

EXPANSION OF WELFARE HOLDS

SECTION 80. ORS 430.399 is amended to read:

430.399. (1) Any person who is intoxicated or under the influence of controlled substances in a public place may be sent home or taken to a sobering facility or to [*a treatment*] **an appropriate** facility by a police officer **or a member of a mobile crisis intervention team as defined in ORS 430.626**. If the person is incapacitated, the person shall be taken by the police officer **or team**

member to an appropriate [*treatment*] facility or sobering facility. If the health of the person appears to be in immediate danger, or the police officer **or team member** has reasonable cause to believe the person is dangerous to self or to any other person, the person shall be taken by the police officer **or team member** to an appropriate [*treatment*] facility or sobering facility. A person shall be deemed incapacitated when in the opinion of the police officer **or team member** the person is unable to make a rational decision as to acceptance of assistance.

(2) When a person is taken to [*a treatment*] **an appropriate** facility, the director of the [*treatment*] facility shall determine whether the person shall be admitted as a patient, referred to another [*treatment*] facility or a sobering facility or denied referral or admission. If the person is incapacitated or the health of the person appears to be in immediate danger, or if the director has reasonable cause to believe the person is dangerous to self or to any other person, the person must be admitted. The person shall be discharged within [*48*] **72** hours unless the person has applied for voluntary admission to the [*treatment*] facility.

(3) When a person is taken to a sobering facility, the staff of the sobering facility shall, consistent with the facility's comprehensive written policies and procedures, determine whether or not the person shall be admitted into the sobering facility. A person who is admitted shall be discharged from the sobering facility within 24 hours.

(4) In the absence of any appropriate [*treatment*] facility or sobering facility, or if a sobering facility determines that a person should not be admitted to the sobering facility, an intoxicated person or a person under the influence of controlled substances who would otherwise be taken by [*the*] **a** police officer to [*a treatment*] **an appropriate** facility or sobering facility may be taken to the city or county jail where the person may be held until no longer intoxicated, under the influence of controlled substances or incapacitated.

(5) An intoxicated person or person under the influence of controlled substances, when taken into custody by the police officer for a criminal offense, shall immediately be taken to the nearest appropriate [*treatment*] facility when the condition of the person requires emergency medical treatment.

(6) The records of a person at [*a treatment*] **an appropriate** facility or sobering facility may not, without the person's consent, be revealed to any person other than the director and staff of the [*treatment*] facility or sobering facility. A person's request that no disclosure be made of admission to a [*treatment*] facility or sobering facility shall be honored unless the person is incapacitated or disclosure of admission is required by ORS 430.397.

SECTION 80a. ORS 430.401 is amended to read:

430.401. [*(1)*] A police officer, **person acting under the authority of a mobile crisis intervention team as defined in ORS 430.626,** physician, naturopathic physician, physician assistant, nurse practitioner, judge, treatment facility, treatment facility staff member or sobering facility [*that is registered with the Oregon Health Authority under ORS 430.262 based on a written request for registration received by the authority before January 1, 2016*], or the staff of the sobering facility, may not be held criminally or civilly liable for actions pursuant to ORS 430.315, 430.335, 430.397 to 430.401 and 430.402 provided the actions are in good faith, on probable cause and without malice.

[*(2) A sobering facility registered with the authority under ORS 430.262 based on a written request for registration received by the authority on or after January 1, 2016, and the staff of the sobering facility, may not be held criminally or civilly liable for actions pursuant to ORS 430.315, 430.335, 430.397 to 430.401 and 430.402 provided the actions are in good faith, on probable cause and without gross negligence.*]

OPIOID USE DISORDER MEDICATION GRANT PROGRAM

SECTION 81. As used in sections 81 to 86 of this 2024 Act:

(1) "Commission" means the Oregon Criminal Justice Commission.

(2) "Local correctional facility" has the meaning given that term in ORS 169.005.

(3) "Tribal correctional facility" means a jail or prison in Oregon that is operated by a federally recognized tribe and confines persons for more than 36 hours.

SECTION 82. (1) The Oregon Jail-Based Medications for Opioid Use Disorder Grant Program is established in the Oregon Criminal Justice Commission to provide opioid use disorder treatment and transition planning services to persons in custody in local correctional facilities and tribal correctional facilities.

(2) The commission, in collaboration with the Oregon Health Authority, shall administer the grant program. At minimum, the commission and authority shall collaborate to provide grant recipients support with technical assistance and best practices.

SECTION 83. (1) The Oregon Criminal Justice Commission shall award grants to cities and counties in Oregon that operate a local correctional facility and to federally recognized tribes in Oregon that operate a tribal correctional facility.

(2) Applicants may submit an individual application or a joint application in partnership with other local correctional facilities or tribal correctional facilities.

(3) At least 10 percent of total moneys awarded to grant recipients must be awarded to local correctional facilities in rural areas, as defined by the commission by rule, or tribal correctional facilities. If any amount of the 10 percent is not awarded during an initial application cycle, the remaining amount may be awarded to any otherwise eligible local correctional facility or tribal correctional facility under a supplemental application cycle.

(4) The commission may enter a contract with a third party to provide statewide technical assistance to grant recipients.

(5) The commission shall consider geographic equity when awarding grant funds.

SECTION 84. Moneys awarded to grant recipients under section 83 of this 2024 Act may be used to:

(1) Provide medication, telemedicine or any other reasonable treatment to persons in custody with an opioid use disorder.

(2) Develop or operate mobile or nonmobile opioid treatment units.

(3) Administer screenings for opioid use disorder or risk of acute withdrawal.

(4) Facilitate transition planning services for persons in custody who seek or receive opioid use disorder treatment.

(5) Undertake any other actions reasonably calculated to mitigate operational or structural barriers to providing opioid use disorder treatment in local correctional facilities or tribal correctional facilities, including but not limited to mitigating any lack of secure storage for medication.

SECTION 85. The Oregon Criminal Justice Commission shall adopt rules necessary to administer sections 81 to 86 of this 2024 Act. The rules, at minimum, must:

(1) Establish a methodology for reviewing and approving grant applications and awarding grants.

(2) Require applicants to submit a statement acknowledging that any grant funds received must be expended in accordance with the allowable uses described in section 84 of this 2024 Act.

(3) Require applicants to submit a letter of commitment from each administrator of a local correctional facility or tribal correctional facility who is associated with the application, committing to participate in good faith in the grant program.

(4) Define "rural" for purposes of section 83 (3) of this 2024 Act.

SECTION 86. (1) The Oregon Criminal Justice Commission shall convene an advisory committee to evaluate applications and make recommendations to the commission for the awarding of grants under section 83 of this 2024 Act.

(2) The chairperson of the commission shall exercise discretion to appoint members to serve on the advisory committee.

SECTION 87. (1) The Oregon Jail-Based Medications for Opioid Use Disorder Fund is established in the State Treasury, separate and distinct from the General Fund. Interest

earned by the Oregon Jail-Based Medications for Opioid Use Disorder Fund shall be credited to the fund. The fund consists of moneys appropriated or otherwise transferred to the fund by the Legislative Assembly.

(2) Moneys in the fund are continuously appropriated to the Oregon Criminal Justice Commission for the purposes of carrying out sections 81 to 86 of this 2024 Act.

SECTION 88. No later than December 1, 2024, the Oregon Criminal Justice Commission shall submit a report, in the manner provided in ORS 192.245, to the interim committees of the Legislative Assembly related to the judiciary and health care. The report must include:

(1) The name of each recipient of a grant under section 83 of this 2024 Act and the amount of moneys each grant recipient has received to date.

(2) Opportunities, if any, for local correctional facilities or tribal correctional facilities to obtain medications for opioid use disorder from state agencies.

(3) Any other information relevant to the provision of opioid use disorder treatment to persons in custody in local correctional facilities or tribal correctional facilities.

SECTION 89. Section 88 of this 2024 Act is repealed on January 2, 2025.

CAPTIONS

SECTION 90. The unit captions used in this 2024 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 2024 Act.

EMERGENCY CLAUSE

SECTION 91. This 2024 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2024 Act takes effect on its passage.

Passed by House February 29, 2024

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

.....
Dan Rayfield, Speaker of House

Passed by Senate March 1, 2024

.....
Rob Wagner, President of Senate

Received by Governor:

.....M.,....., 2024

Approved:

.....M.,....., 2024

.....
Tina Kotek, Governor

Filed in Office of Secretary of State:

.....M.,....., 2024

.....
LaVonne Griffin-Valade, Secretary of State

CONDITIONS

VAGINAL ITCHING

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 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe a single course of treatment for non-complicated vaginal itching.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Vaginal Itching Intake Form (pg. 2)
- Utilize the standardized Vaginal Itching Assessment and Treatment Care Pathway (pg. 3-6)
- Utilize the standardized Vaginal Itching Prescription Template *optional* (pg. 7)

Vaginal Itching Self-Screening Intake Form
(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred 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 _____

1.	Has a provider ever diagnosed you with a yeast infection? If so, how recently? _____ How many have you experienced within the last year? _____ How many have you experienced within your lifetime? _____ Have you ever experienced a difficult to treat yeast infection or had treatment not work? What treatments (if any) have you tried for past and/or current yeast infections? Please list them here: _____ _____	□ Yes □ No □ Not sure □ Yes □ No □ Not sure
2.	Symptom review: - Soreness, burning, or itchy vaginal area - Abnormal discharge (color, smell, consistency, etc.) - Pain with urination - Fever - Pain in the lower abdomen and/or back - Other symptoms: _____	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
3.	Have you ever been sexually active? If so, how recently? _____	□ Yes □ No
4.	Have you ever been tested for OR diagnosed with a sexually transmitted infection? If yes, when? _____	□ Yes □ No □ Not sure
5.	When was the first day of your last menstrual period?	Date: _____
6.	Are you currently pregnant?	□ Yes □ No □ Not sure
7.	Are you using any of the following contraceptive devices? 1. Vaginal sponge 2. Diaphragm 3. Intrauterine device (IUD)	 □ Yes □ No □ Yes □ No □ Yes □ No
8.	Have you used antibiotics in the last month?	□ Yes □ No □ Not sure
9.	Has a provider ever diagnosed you with an autoimmune disease? If yes, list them here: _____ _____	□ Yes □ No □ Not sure
10.	Do you have diabetes?	□ Yes □ No □ Not sure
11.	Have you ever been diagnosed with a heart rhythm condition (or QT prolongation)? If yes, list them here: _____	□ Yes □ No □ Not sure
12.	Do you have any other medical problems? If yes, list them here: _____ _____	□ Yes □ No □ Not sure
13.	Are you currently taking any medications, supplements, and/or vitamins? If yes, list them here: _____ _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

Standardized Assessment and Treatment Care Pathway
Vaginal Itching

1) Vaginal itching and Sexually Transmitted Infection (STI) Screen (Form Qs: #1-5)

a. Reoccurrence: If 4 or more episodes within 12 months or recurrent symptoms within 2 months → **Refer**

b. Symptoms inconsistent with vaginal itching: Pain with urination, fever, pain in the lower abdomen and/or back, symptoms consistent with STI, or any other inconsistencies.

If YES to any of these symptoms → **Refer**

2) Pregnancy Screen (Form Qs: #5-6)

a. 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?

b. Have you had a baby in the last 4 weeks?

c. Did you have a miscarriage or abortion in the last 7 days?

d. Did your last menstrual period start within the past 7 days?

e. Have you abstained from sexual intercourse since your last menstrual period or delivery?

f. Have you been using a reliable contraceptive method consistently and correctly?

If YES to AT LEAST ONE of these questions and is free of pregnancy symptoms, proceed to next step.

If NO to ALL of these questions, pregnancy cannot be ruled out → **Refer**

3) Medication and Disease State Screen (Form Qs: #7-13)

a. Are you using the following contraceptive devices: vaginal sponge, diaphragm, IUD → **Refer**

b. Do you have diabetes or other immunosuppressed conditions? → **Refer**

c. Are you taking corticosteroids or immunosuppressive medications, including antineoplastics? → **Refer**

4) Assess and Initiate Antifungal Therapy:

All therapies are equally effective in treating uncomplicated vaginal itchingChoice of therapy should be based on patient safety, preference, availability, and cost.

All therapy is limited to one course of treatment.

a. *Oral therapy*. If indicated, the pharmacist shall issue a prescription for fluconazole and counsel on side effects and follow-up.
   - Fluconazole 150mg tablet, #1

b. *Topical therapy*. If indicated, the pharmacist shall discuss the most appropriate option with the patient, issue a prescription, and counsel on side effects and follow-up of any one of the following treatments:
   - Clotrimazole (various strengths/formulations)
   - Miconazole (various strengths/formulations)
   - Tioconazole (various strengths/formulations)

5) Complete Patient Encounter

Advise: Patient should seek medical advice from a care provider if symptoms do not resolve in 7-14 days.
Encourage: Routine health screenings, STI prevention, etc.
Document: All required elements

Standardized Assessment and Treatment Care Pathway
Vaginal Itching

Medication options/considerations:

- ***Fluconazole***[1]:
  - *Dose and directions*: 150mg Tablet, quantity #1; Take one tablet by mouth one time. If symptoms do not resolve after 1 week, contact your primary care provider.
  - *Warnings/Precautions*: Potential patient harm is associated with known side effects of taking fluconazole. It is well tolerated, but may cause symptoms such as nausea, vomiting, dizziness, and headache. More rare side effects may include:
    - Prolonged QT interval which could lead to Torsades de Pointes. This is rarely a concern unless a patient is taking multiple QT prolonging drugs, has a preexisting heart condition, or known prolonged QT interval.
    - Hepatic toxicity (i.e. hepatitis, cholestasis, fulminant hepatic failure, etc.). Monitor liver function tests of patients with known impaired hepatic function
    - Hypersensitivity reactions: Use with caution in patients with hypersensitivity to other azoles
    - Skin reactions: Monitor for rash development
  - *Metabolism*: **Inhibits** CYP2C19 (strong), CYP2C9 (moderate), CYP3A4 (moderate)
  - *Contraindications for fluconazole use: (consider other therapy)*
    - Prolonged QT interval
    - Multiple QT prolonging drugs
    - Impaired hepatic function
    - Hypersensitivity reactions: Use with caution in patients with hypersensitivity to other azoles
    - Other interacting medications

- ***Clotrimazole***[2]*:*
  - *Dose and directions*:
    - Cream: If symptoms do not resolve after 1 week, contact your primary care provider.
      - 1%: One applicatorful inserted intravaginally at night daily for 7 days.
      - 2%: One applicatorful inserted intravaginally at night daily for 3 days.
      - 10%: One applicatorful to be inserted intravaginally at night as a single dose.
  - *Warnings/Precautions*: It is well tolerated, but may cause symptoms such as irritation and burning.
  - *Drug Interactions:*
    - Progesterone: may diminish the therapeutic effect of Progesterone (*Risk X: Avoid combination)*
    - Sirolimus: may increase the serum concentration of Sirolimus (*Risk C: Monitor therapy)*
    - Tacrolimus (systemic): may increase the serum concentration of Tacrolimus (Systemic) (*Risk C: Monitor therapy)*
  - *Contraindications for clotrimazole use: (consider other therapy)*
    - Progesterone
    - Sirolimus
    - Tacrolimus (systemic)
    - Other interacting medications

- ***Miconazole[3]:***
    - *Dose and directions*:
        - Suppository Capsule: If symptoms do not resolve after 1 week, contact your primary care provider.
            - 100mg: one capsule inserted intravaginally at night daily for 7 days.
            - 200mg: one capsule inserted intravaginally at night daily for 3 days.
            - 1,200mg: one capsule to be inserted intravaginally at night as a single dose.
        - Cream: If symptoms do not resolve after 1 week, contact your primary care provider.
            - 2%: One applicatorful inserted intravaginally at night daily for 7 days.
            - 4%: One applicatorful inserted intravaginally at night daily for 3 days.
    - *Warnings/Precautions*: It is well tolerated, but may cause symptoms such as irritation and burning.
    - *Drug Interactions:*
        - Progesterone: may diminish the therapeutic effect of Progesterone (*Risk X: Avoid combination)*
        - Vitamin K Antagonists (i.e. warfarin): may increase the serum concentration of Vitamin K Antagonists (*Risk D: Consider therapy modification)*
        - Sulfonylureas: may inhibit the metabolism of oral sulfonylureas
    - *Contraindications for miconazole use: (consider other therapy)*
        - Progesterone
        - Vitamin K Antagonists (i.e. warfarin)
        - Sulfonylureas
        - Other interacting medications
- ***Tioconazole[4]:***
    - *Dose and directions*:
        - Ointment: If symptoms do not resolve after 1 week, contact your primary care provider.
            - 6.5%: One applicatorful to be inserted intravaginally at night as a single dose.
    - *Warnings/Precautions*: It is well tolerated, but may cause symptoms such as irritation and burning.
    - *Drug Interactions:*
        - Progesterone: may diminish the therapeutic effect of Progesterone (*Risk X: Avoid combination)*
    - *Contraindications for tioconazole use: (consider other therapy)*
        - Progesterone
        - Other interacting medications

References:

1. Fluconazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Updated February 12, 2020. Accessed February 14, 2020.
2. Clotrimazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Updated February 14, 2020. Accessed February 15, 2020.
3. Miconazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Updated February 17, 2020. Accessed February 17, 2020.
4. Tioconazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Updated November 22, 2019. Accessed February 15, 2020.
5. Peter G. Pappas, Carol A. Kauffman, David R. Andes, Cornelius J. Clancy, Kieren A. Marr, Luis Ostrosky-Zeichner, Annette C. Reboli, Mindy G. Schuster, Jose A. Vazquez, Thomas J. Walsh, Theoklis E. Zaoutis, Jack D. Sobel, Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America, Clinical Infectious Diseases, Volume 62, Issue 4, 15 February 2016, Pages e1–e50, https://doi.org/10.1093/cid/civ933

Vaginal Itching Prescription

Optional -May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Rx

Drug:

Sig:

Quantity:

Refills: 0

DAW: ____

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

CONDITIONS

SARS-CoV-2 Antiviral
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 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe the SARS-CoV-2 Antiviral nirmatrelvir/ritonavir.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized SARS-CoV-2 Antiviral:
    - Patient Intake Form (pg. x-x)
    - Assessment and Treatment Care Pathway (pg. x-x)
    - Prescription Template *optional* (pg. X)
    - Provider Notification (pg. x)

PHARMACIST TRAINING/EDUCATION:

- Pharmacist must be familiar with how to access patient laboratory data to assess renal and hepatic function.
- Review PAXLOVID resources for healthcare providers, available at:
  - Pfizer: https://paxlovid.pfizerpro.com/
  - FDA: PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers
- A minimum of 1 hour of training **is recommended.**
  - CDC Webinar: Diagnostic Testing and Treatment Guidelines for COVID-19 and Influenza
  - APhA CPE: Oral Antivirals for COVID-19: Practical Considerations for Patient Selection, Evaluation for Safe Use, Monitoring and Referral
  - APhA Certificate Program: Pharmacy-Based Test And Treat Certificate Training Program (20 hours)

SARS-CoV-2 Antiviral Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

If you have any of the following, please go directly to the emergency room or have someone call 911.

□ New confusion □ Difficulty breathing □ Pain or pressure in the chest
□ Cannot stay awake □ Gray or blue-colored skin, lips, or nail beds □ Fast heart rate or palpitations
□ If you are on oxygen and have greater oxygen needs

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Theirs, Ze/Hir/Hirs, Other_____Height_____Weight____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? □ Yes □ No Insurance Provider Name _____
Any allergies to medications? □ Yes □ No If yes, please list _____
Which of the following best describes your racial or ethnic identity? Please check **ALL** that apply.
□ Black/African American □ Hispanic or Latino/a/x □ American Indian or Alaska Native □ Asian □ Other
□ Native Hawaiian/Pacific Islander □ Middle Eastern/North African □ White □ Not specified
Are you houseless, or live in a shelter, encampment, or transitional housing? □ Yes □ No

Background Information:

1.	Have you 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 □ No
2.	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. Obesity	□ Yes □ No
	Q. Physically inactive	□ Yes □ No
	R. Pregnancy or recent pregnancy	□ Yes □ No
	S. Smoking, current or former	□ Yes □ No
	T. Transplant of organ or bone marrow	□ Yes □ No
	U. Stroke or brain bleed	□ Yes □ No

SARS-CoV-2 Antiviral Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

	V. Problematic drug or alcohol use……. W. Tuberculosis…… X. Other: _____	□ Yes □ No □ Yes □ No □ Yes □ No
3.	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
4.	Do you have any known medication allergies? If yes, list them here: | | | | | | | |	□ Yes □ No
6.	Do you take any medicines, including herbs or supplements? If yes, list them here: | | | | | | | | | | | | | | | |	□ Yes □ No (notify Pharmacist if more space needed)
7.	Do you take any medicines that you do not remember the name of?	□ Yes □ No
8.	Please write the names of all pharmacies you have filled prescriptions with in the last 90 days: Pharmacy (location):_____ Pharmacy (location):_____ Pharmacy (location):_____ Pharmacy (location):_____	

Signature_____ Date ____/_____/_____

TO BE COMPLETED BY PHARMACIST:

1. SARS-CoV2 test (if intern or pharmacy technician performed the test they may fill in #1)
   a. Manufacturer: _____ Lot #:_____ Expiration Date: ___/___/_____
   b. Test performed by: _____ Date: ___/___/_____ Time: _____:_____ AM / PM (circle one)
   c. Result: □ Reactive □ Non-Reactive □ Indeterminate
2. Weight _____ lbs.
   a. *If applicable* to verify obesity as only risk factor: Height __ ft. ___ in., BMI _____
3. 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
4. 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 SARS-CoV-2 ANTIVIRAL WAS PRESCRIBED, COMPLETE THE FOLLOWING:

1. 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
2. Healthcare Provider (if known) contacted/notified of therapy: □ Yes Date ____/_____/_____ □ Not Applicable

RPH Signature_____Date ____/_____/_____

Standardized Assessment and Treatment Care Pathway
SARS-CoV-2 Antiviral

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

a. Age < 18 years → **Refer to healthcare provider**
b. 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 CLIA-waived, EUA-authorized, FDA-cleared, or FDA-approved SARS-CoV-2 molecular or antigen test completed by Pharmacist (or Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician)* today?

   NOTE: Results that are indeterminate or inconclusive results can suggest the presence of SARS-CoV-2 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.

   *Per 2024 SB 1506: A Pharmacist may delegate to an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician who is under the Pharmacist's supervision the administrative and technical tasks of performing a SARS-CoV-2 molecular or antigen test.

b. Onset of mild to moderate COVID-19 symptoms within past 5 days?

   NOTE: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea, vomiting; or diarrhea

If YES to *BOTH* Steps 2a **AND** 2b, *proceed to Step 3*.

3) Risk of Progression to Severe COVID-19 Screen (Self-screening Patient Intake Form #3, REALD demographics)

a. Did the patient attest to at least one risk factor in #3 on the Self-screening Patient Intake Form, which places an individual at high risk of progression to severe COVID-19?

   NOTE: Pharmacist must obtain or calculate BMI to verify obesity if #3.P. is the *only* risk factor checked "Yes" on #3 of the Self-screening Patient Intake Form. A BMI ≥30 is a risk factor for severe disease.

b. Does the patient identify as Black, African American, Hispanic, Latino/a/x, American Indian/Alaska Native, Asian, Asian American, or Pacific Islander?

NOTE: People of racial and ethnic minority groups are most harmed by health inequities due to racial, ethnic and socioeconomic disparities. These health inequities place these individuals at high risk of progression to severe COVID-19.

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.

If YES to *EITHER* Step 3a, 3b, **OR** 3c, *proceed to Step 4*; otherwise, PAXLOVID is not indicated under this protocol.

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 → Advise patient to seek care from medical provider for further evaluation.
If YES to *EITHER* Step 4b **OR** 4c, *proceed to Step 5*; otherwise, PAXLOVID is not indicated under this protocol → Advise patient to seek care from medical provider for further evaluation.

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.

Standardized Assessment and Treatment Care Pathway
SARS-CoV-2 Antiviral

If YES to *EITHER* Step 5a **OR** 5b, *proceed to Step* 6; otherwise, PAXLOVID is not indicated under this protocol → Advise patient to seek care from medical provider for further evaluation.

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 → Advise patient to seek care from medical provider for further evaluation.

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 using product labeling or other drug interaction tool?

If YES to Step 7a **AND** *NO* to Step 7b, *proceed to Step 8*; otherwise, PAXLOVID is not indicated under this protocol → Advise patient to seek care from medical provider for further evaluation.

8) 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.

9) Notify primary care provider (if known) within 5 days of receipt of therapy

SARS-CoV-2 Antiviral Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Rx

☐ Drug: Paxlovid™ (nirmatrelvir 300 mg/ ritonavir 100 mg)

- Sig: Take two tablets of nirmatrelvir 150 mg (300 mg) and one tablet of ritonavir 100 mg twice daily for 5 days
- Quantity: #30
- Refills: none

☐ Drug: Paxlovid™ (renal dosing - nirmatrelvir 150 mg/ ritonavir 100 mg)

- Sig: Take one tablet of nirmatrelvir 150 mg 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:_____
_____
_____
_____

Provider Notification
SARS-CoV-2 Antiviral

Pharmacy Name:_____ Pharmacist Name: _____

Pharmacy Address:_____

Pharmacy Phone: _____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) was:

Prescribed the SARS-CoV2 Antiviral, Paxlovid™, at our Pharmacy noted above on ___/___/_____. The prescription issued and dispensed consisted of (check one):

- ☐ Paxlovid™ (nirmatrelvir 300 mg and ritonavir 100 mg)
  - Sig: Take two tablets of nirmatrelvir 150 mg (300 mg) and one tablet of ritonavir 100 mg twice daily for 5 days, #30, no refills
- ☐ Paxlovid™ (renal dosing- nirmatrelvir 150 mg and ritonavir 100 mg)
  - Sig: Take one tablet of nirmatrelvir 150 mg and one tablet of ritonavir 100 mg twice daily for 5 days, #20, no refills

Your patient was informed that an office visit with you or another provider on your team is recommended after finishing the course of treatment.

If you have further questions, please contact the prescribing pharmacy.

The prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

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.

Enrolled
Senate Bill 1506

Printed pursuant to Senate Interim Rule 213.28 by order of the President of the Senate in conformance with presession filing rules, indicating neither advocacy nor opposition on the part of the President (at the request of Senate Interim Committee on Health Care)

CHAPTER .....

AN ACT

Relating to pharmacy; creating new provisions; amending ORS 243.144, 243.877, 689.005 and 743A.051; and prescribing an effective date.

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

SECTION 1. Section 2 of this 2024 Act is added to and made a part of ORS chapter 414.

SECTION 2. Notwithstanding ORS 414.065 and 414.690, medical assistance provided to a member of a coordinated care organization or a medical assistance recipient who is not enrolled in a coordinated care organization shall include the testing and treatment, as described in section 4 of this 2024 Act, performed or provided by a pharmacist.

SECTION 3. Section 4 of this 2024 Act is added to and made a part of ORS chapter 689.

SECTION 4. (1) Consistent with the protocols adopted by the State Board of Pharmacy by rule, as recommended by the Public Health and Pharmacy Formulary Advisory Committee, a pharmacist may test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and prescribe, dispense and administer treatment, including drug therapy, for SARS-CoV-2.

(2) When testing for SARS-CoV-2, a pharmacist may use:

(a) A screening procedure that can be safely performed by a pharmacist; and

(b) A test that:

(A) Guides the pharmacist's clinical decision-making;

(B) Is determined by the Centers for Medicare and Medicaid Services to qualify as a waived test under the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578, 42 U.S.C. 201 and 263a) or federal regulations adopted pursuant to the Clinical Laboratory Improvement Amendments of 1988 or is approved by the United States Food and Drug Administration; and

(C) Is approved by the board by rule for use under this section.

(3) A pharmacist may delegate to a pharmacy technician or an intern under the pharmacist's supervision the administrative and technical tasks of performing a task described in subsection (2) of this section.

(4) The board may adopt rules as necessary to carry out this section.

SECTION 5. 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 State Board of Pharmacy.

(3) "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.

(4) "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.

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

(6) "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.

(7) "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.

(8) "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.

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

(10) "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.

(11) "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.

(12) "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.

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

(14) "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.

(15) "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.

(16) "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.

(17) "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.

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

(19) "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.

(20) "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.

(21) "Manufacturer" means a person engaged in the manufacture of drugs.

(22) "Nonprescription drug outlet" means a business or other establishment that is open to the general public for the sale or nonprofit distribution of nonprescription drugs and is registered under ORS 689.305.

(23) "Nonprescription drugs" means drugs that may be sold without a prescription and that 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.

(24) "Person" means an individual, corporation, partnership, association or other legal entity.

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

(26) "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.

(27) "Pharmacy technician" means a person licensed by the board who assists in the practice of pharmacy pursuant to rules of the board.

(28) "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.

(29) "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;

(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[.]**; and**

(p) The testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the prescribing, dispensing and administering of treatment for SARS-CoV-2 pursuant to section 4 of this 2024 Act and rules adopted by the board pursuant to section 4 of this 2024 Act.

(30) "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.

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

(32) "Prescription drug" or "legend drug" means a drug that 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.

(33) "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.

(34) "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.

(35) "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.

(36) "Third-party logistics provider" means an entity that:

(a) Provides or coordinates warehousing of, or other logistics services for, a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser of the product; and

(b) Does not take ownership of, or have responsibility to direct the sale or disposition of, the product.

(37) "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.

(38) "Wholesale distributor drug outlet" means a person, other than a manufacturer, manufacturer's colicensed partner, third-party logistics provider or repackager, as defined in 21 U.S.C. 360eee(16), that is engaged in wholesale distribution, as defined in 21 U.S.C. 353(e)(4).

SECTION 6. ORS 689.005, as amended by section 5 of this 2024 Act, 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 State Board of Pharmacy.

(3) "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.

(4) "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.

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

(6) "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.

(7) "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.

(8) "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.

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

(10) "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.

(11) "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.

(12) "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.

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

(14) "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.

(15) "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.

(16) "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.

(17) "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.

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

(19) "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.

(20) "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.

(21) "Manufacturer" means a person engaged in the manufacture of drugs.

(22) "Nonprescription drug outlet" means a business or other establishment that is open to the general public for the sale or nonprofit distribution of nonprescription drugs and is registered under ORS 689.305.

(23) "Nonprescription drugs" means drugs that may be sold without a prescription and that 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.

(24) "Person" means an individual, corporation, partnership, association or other legal entity.

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

(26) "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.

(27) "Pharmacy technician" means a person licensed by the board who assists in the practice of pharmacy pursuant to rules of the board.

(28) "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.

(29) "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;

(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[*; and*]

[*(p) The testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the prescribing, dispensing and administering of treatment for SARS-CoV-2 pursuant to section 4 of this 2024 Act and rules adopted by the board pursuant to section 4 of this 2024 Act*].

(30) "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.

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

(32) "Prescription drug" or "legend drug" means a drug that 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.

(33) "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.

(34) "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.

(35) "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.

(36) "Third-party logistics provider" means an entity that:

(a) Provides or coordinates warehousing of, or other logistics services for, a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser of the product; and

(b) Does not take ownership of, or have responsibility to direct the sale or disposition of, the product.

(37) "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.

(38) "Wholesale distributor drug outlet" means a person, other than a manufacturer, manufacturer's colicensed partner, third-party logistics provider or repackager, as defined in 21 U.S.C. 360eee(16), that is engaged in wholesale distribution, as defined in 21 U.S.C. 353(e)(4).

SECTION 7. ORS 743A.051 is amended to read:

743A.051. **(1)** Notwithstanding any provisions of a health benefit plan as defined in ORS 743B.005, whenever the plan provides for payment or reimbursement for a service that is within the lawful scope of practice of a pharmacist, the insurer:

[*(1)*] **(a)** May provide payment or reimbursement for the service when the service is provided by a pharmacist; and

[*(2)*] **(b)** Shall provide, in the same manner as would be provided for any other health care provider, payment or reimbursement for:

[*(a)(A)*] **(A)(i)** The prescription of emergency refills of insulin and associated insulin-related devices and supplies as described in ORS 689.696; and

[*(B)*] **(ii)** The service provided by the pharmacist;

[*(b)(A)*] **(B)(i)** The prescription, dispensation and administration of preexposure and postexposure prophylactic antiretroviral therapies pursuant to ORS 689.704 and any rules adopted by the State Board of Pharmacy under ORS 689.645 and 689.704; and

[*(B)*] **(ii)** The service provided by the pharmacist; [*and*]

(C)(i) The testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the prescribing, dispensing and administering of treatment for SARS-CoV-2 pursuant to section 4 of this 2024 Act; and

(ii) The service provided by the pharmacist; and

[*(c)(A)*] **(D)(i)** The prescription and dispensation of other prescription drugs by a licensed pharmacist if the State Board of Pharmacy or any state law authorizes the drug to be prescribed and dispensed by pharmacists licensed under ORS chapter 689; and

[*(B)*] **(ii)** The service provided by the pharmacist.

[*(3)*] **(2)** This section is exempt from ORS 743A.001.

SECTION 8. ORS 743A.051, as amended by section 7 of this 2024 Act, is amended to read:

743A.051. (1) Notwithstanding any provisions of a health benefit plan as defined in ORS 743B.005, whenever the plan provides for payment or reimbursement for a service that is within the lawful scope of practice of a pharmacist, the insurer:

(a) May provide payment or reimbursement for the service when the service is provided by a pharmacist; and

(b) Shall provide, in the same manner as would be provided for any other health care provider, payment or reimbursement for:

(A)(i) The prescription of emergency refills of insulin and associated insulin-related devices and supplies as described in ORS 689.696; and

(ii) The service provided by the pharmacist;

(B)(i) The prescription, dispensation and administration of preexposure and post-exposure prophylactic antiretroviral therapies pursuant to ORS 689.704 and any rules adopted by the State Board of Pharmacy under ORS 689.645 and 689.704; and

(ii) The service provided by the pharmacist; **and**

[*(C)(i) The testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the prescribing, dispensing and administering of treatment for SARS-CoV-2 pursuant to section 4 of this 2024 Act; and*]

[*(ii) The service provided by the pharmacist; and*]

[*(D)(i)*] **(C)(i)** The prescription and dispensation of other prescription drugs by a licensed pharmacist if the State Board of Pharmacy or any state law authorizes the drug to be prescribed and dispensed by pharmacists licensed under ORS chapter 689; and

(ii) The service provided by the pharmacist.

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

SECTION 9. ORS 243.144 is amended to read:

243.144. Benefit plans offered by the Public Employees' Benefit Board that reimburse the cost of medical and other health services and supplies must comply with the requirements for health benefit plan coverage described in:

(1) ORS 743A.058;

(2) ORS 743A.140;

(3) ORS 743A.141;

(4) ORS 743B.256;

(5) ORS 743B.287 (4);

(6) ORS 743B.420;

(7) ORS 743B.423;

(8) ORS 743B.601;

(9) ORS 743B.810; [*and*]

(10) ORS 743A.325**; and**

(11) ORS 743A.051 (2)(c).

SECTION 10. ORS 243.144, as amended by section 9 of this 2024 Act, is amended to read:

243.144. Benefit plans offered by the Public Employees' Benefit Board that reimburse the cost of medical and other health services and supplies must comply with the requirements for health benefit plan coverage described in:

(1) ORS 743A.058;
(2) ORS 743A.140;
(3) ORS 743A.141;
(4) ORS 743B.256;
(5) ORS 743B.287 (4);
(6) ORS 743B.420;
(7) ORS 743B.423;
(8) ORS 743B.601;
(9) ORS 743B.810; **and**
(10) ORS 743A.325[*; and*]
[*(11) ORS 743A.051 (2)(c)*].

SECTION 11. ORS 243.877 is amended to read:

243.877. Benefit plans offered by the Oregon Educators Benefit Board that reimburse the cost of medical and other health services and supplies must comply with the requirements for health benefit plan coverage described in:

(1) ORS 743A.058;
(2) ORS 743A.140;
(3) ORS 743A.141;
(4) ORS 743B.256;
(5) ORS 743B.287 (4);
(6) ORS 743B.420;
(7) ORS 743B.423;
(8) ORS 743B.601;
(9) ORS 743B.810; [*and*]
(10) ORS 743A.325[.]**; and**
(11) ORS 743A.051 (2)(c).

SECTION 12. ORS 243.877, as amended by section 11 of this 2024 Act, is amended to read:

243.877. Benefit plans offered by the Oregon Educators Benefit Board that reimburse the cost of medical and other health services and supplies must comply with the requirements for health benefit plan coverage described in:

(1) ORS 743A.058;
(2) ORS 743A.140;
(3) ORS 743A.141;
(4) ORS 743B.256;
(5) ORS 743B.287 (4);
(6) ORS 743B.420;
(7) ORS 743B.423;
(8) ORS 743B.601;
(9) ORS 743B.810; **and**
(10) ORS 743A.325[*; and*]
[*(11) ORS 743A.051 (2)(c)*].

SECTION 13. The amendments to ORS 243.144, 243.877, 689.005 and 743A.051 by sections 6, 8, 10 and 12 of this 2024 Act become operative on June 30, 2026.

SECTION 14. (1) The amendments to ORS 243.144 by section 9 of this 2024 Act apply to benefit plans issued, renewed or extended on or after October 1, 2024.

(2) The amendments to ORS 243.877 by section 11 of this 2024 Act apply to benefit plans issued, renewed or extended on or after October 1, 2024.

(3) The amendments to ORS 743A.051 by section 7 of this 2024 Act apply to health benefit plans issued, renewed or extended on or after October 1, 2024.

SECTION 15. Sections 2 and 4 of this 2024 Act are repealed on June 30, 2026.

SECTION 16. **(1) Sections 2 and 4 of this 2024 Act and the amendments to ORS 243.144, 243.877, 689.005 and 743A.051 by sections 5, 7, 9 and 11 of this 2024 Act become operative on October 1, 2024.**

(2) The Oregon Health Authority, the Oregon Educators Benefit Board, the Public Employees' Benefit Board and the State Board of Pharmacy may take any action before the operative date specified in this section that is necessary to enable the authority and the boards to exercise, on or after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the authority and the boards by sections 2 and 4 of this 2024 Act and the amendments to ORS 243.144, 243.877, 689.005 and 743A.051 by sections 5, 7, 9 and 11 of this 2024 Act.

SECTION 17. **This 2024 Act takes effect on the 91st day after the date on which the 2024 regular session of the Eighty-second Legislative Assembly adjourns sine die.**

Passed by Senate February 20, 2024

.....
Obadiah Rutledge, Secretary of Senate

.....
Rob Wagner, President of Senate

Passed by House February 28, 2024

.....
Dan Rayfield, Speaker of House

Received by Governor:

.....M.,....., 2024

Approved:

.....M.,....., 2024

.....
Tina Kotek, Governor

Filed in Office of Secretary of State:

.....M.,....., 2024

.....
LaVonne Griffin-Valade, Secretary of State

Protocol for Coronavirus 19 Vaccines (Moderna, Novavax, Pfizer-BioNTech)

1. What's New

A. Individuals ≥ 65 years and older should receive an additional dose of the 2023-2024 COVID-19 vaccine (Moderna, Novavax, or Pfizer-BioNTech) at least four months after the receipt of a previous 2023-2024 COVID-19 dose.

B. There is a new formulation of COVID-19 Vaccine (Comirnaty by Pfizer-BioNTech) that is supplied in a pre-filled single dose glass syringe. The glass syringe is stored in the refrigerator and cannot be frozen.

C. ACIP no longer categorizes Pfizer and Moderna as preferred Coronavirus 19 (COVID-19) vaccines for the 2023-2024 season. Individuals ages 12 years and older may receive either the 2023-2024 mRNA (Moderna or Pfizer-BioNTech) or the 2023-2024 adjuvanted (Novavax) vaccine, as appropriate.

2. Immunization Protocol

A. Administer one or more doses of the updated 2023–2024 Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine based on level of immunocompetency, age, and previous vaccination status. See Section 3 for vaccine volume and dosing schedule based on age and vaccine formulation.[1-6]

B. COVID-19 vaccine may be administered concomitantly with other vaccines. There is no need to separate COVID-19 vaccine from other vaccinations by 2 weeks.

3. Vaccine Schedule[1-6]

A. **Vaccine Schedule for Immunocompetent Individuals**

Table 1A: Immunocompetent Individuals Ages 6 Months through 4 Years*

Note - The PREP Act, 11th Amendment allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2024. Otherwise, pharmacists are only permitted to vaccinate persons ≥ 7 years per ORS 689.645.

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023-2024 Formula) Vaccine Doses Indicated	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors	Interval Between Doses
Unvaccinated	Moderna	2	0.25 mL/ 25 mcg	Dark blue cap; Green label	Dose 1 and Dose 2: 4-8 weeks‡
	OR				
	Pfizer-BioNTech	3	0.3 mL/ 3 mcg	Yellow cap; Yellow label	Dose 1 and Dose 2: 3-8 weeks‡ Dose 2 and Dose 3: At least 8 weeks
1 dose any Moderna	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	4-8 weeks after last dose‡

2 or more doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 8 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/ 3 mcg	Yellow cap; Yellow label	Dose 1: 3-8 weeks after last dose‡ Dose 1 and Dose 2: At least 8 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	Yellow cap; Yellow label	At least 8 weeks after last dose
3 or more doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	Yellow cap; Yellow label	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

*Per FDA authorization, all COVID-19 vaccine doses in this age group should be homologous. In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:

- Same vaccine not available at the vaccination site at the time of the clinic visit
- Previous dose unknown
- Person would otherwise not receive a recommended vaccine dose
- Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

Table 1B: Immunocompetent Individuals Ages 5 through 11 years§

Note - The PREP Act, 11th Amendment allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2024. Otherwise, pharmacists are only permitted to vaccinate persons ≥ 7 years per ORS 689.645.

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023-2024 Formula) Vaccine Doses Indicated	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors	Interval Between Doses
Unvaccinated	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	-
	OR				
	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	Blue cap; Blue label	-
1 or more doses any mRNA	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	Blue cap; Blue label	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

§ For children who transition from age 4 years to age 5 years during the initial vaccination series:

- **Moderna series:** Children are recommended to complete the 2-dose series with the updated 2023–2024 Formula Moderna COVID-19 Vaccine, 0.25 mL/25 mcg (dark blue cap; green label), as per the FDA EUA; there is no dosage change.
- **Pfizer-BioNTech series:** Children who received 1 or 2 doses of Pfizer-BioNTech vaccine for ages 6 months–4 years, 0.3 mL/3 mcg (yellow cap; yellow label) are recommended to receive 1 dose of the updated 2023—2024 Formula Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg (blue cap; blue label) on or after turning age 5 years. If the 10 mcg dose is the second dose, administer 3–8 weeks after the first dose; if it is the third dose, administer at least 8 weeks after the second dose. Alternatively, these children may complete the 3-dose series with the updated 2023–2024 Formula Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 mcg (yellow cap; yellow label), as per the FDA EUA.

Table 1C: Immunocompetent Individuals Ages 12 years and older

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023-2024 Formula) Vaccine Doses Indicated	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors¶	Interval Between Doses
Unvaccinated	Moderna	1	0.5 mL/ 50 mcg	Dark blue cap; Blue label	-
	OR				
	Novavax	2	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	Dose 1 and Dose 2: 3-8 weeks‡
	OR				
	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	Gray cap; gray label	-
1 or more doses any mRNA; 1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses	Moderna	1	0.50 mL/ 50 mcg	Dark blue cap; Blue label	At least 8 weeks after last dose
	OR				
	Novavax	1	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	Gray cap; Gray label	At least 8 weeks after last dose
People ages 65 years and older should receive 1 additional dose of any updated (2023-2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 4 months following the last recommended dose of updated 2023-2024 COVID-19 vaccine. For initial vaccination with updated 2023-2024 Formula Novavax COVID-19 vaccine, the 2-dose series should be completed before administration of the additional dose. If Moderna is used, administer 0.5 mL/50 mcg; if Novavax is used, administer 0.5 mL/5 mcg rS protein and 50 mcg Matrix-M adjuvant; if Pfizer-BioNTech is used, administer 0.3 mL/30 mcg.					

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two; for people ages 12 years and older, Original monovalent Novavax COVID-19 Vaccine doses,

alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent Novavax vaccine doses.

‡ An 8-week interval between the first and second COVID-19 vaccine (Moderna, Novavax, and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

¶The updated 2023-2024 formula Moderna and Pfizer-BioNTech COVID-19 vaccines are also available in a prefilled, single-dose syringe for individuals 12 years and older.

B. Vaccine Schedule for Individuals with Moderately or Severely Immunocompromising Conditions

Table 2A: Age 6 months through 4 years with Moderately or Severely Immunocompromising Conditions*

See section 5a for list of immunocompromising conditions.

Note - The PREP Act, 11th Amendment allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2024. Otherwise, pharmacists are only permitted to vaccinate persons ≥ 7 years per ORS 689.645.

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023-2024 Formula) Vaccine Doses Indicated¥	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors	Interval Between Doses
Unvaccinated	Moderna	3	0.25 mL/ 25 mcg	Dark blue cap; Green label	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	OR				
	Pfizer-BioNTech	3	0.3 mL/ 3 mcg	Yellow cap; Yellow label	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 8 weeks
1 dose any Moderna	Moderna	2	0.25 mL/ 25 mcg	Dark blue cap; Green label	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 4 weeks after last dose
3 or more doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 8 weeks after last dose

1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/ 3 mcg	Yellow cap; Yellow label	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 8 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	Yellow cap; Yellow label	At least 8 weeks after last dose
3 or more doses any Pfizer BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	Yellow cap; Yellow label	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

- ¥Children ages 6 months through 4 years who are moderately or severely immunocompromised may receive 1 additional dose of a homologous updated 2023–2024 Formula mRNA vaccine at least 2 months after the last updated 2023–2024 mRNA vaccine dose. Further additional homologous updated 2023–2024 mRNA dose(s) may be administered by a pharmacist with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated 2023–2024 mRNA vaccine dose. For Moderna, administer 0.25 mL/25 mcg (dark blue cap; green label); for Pfizer-BioNTech, administer 0.3 mL/3 mcg (dark blue cap; green label) for all doses.
- **Pfizer-BioNTech series:** Children are recommended to receive an updated 2023-–2024 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg (blue cap; blue label) for all doses received on or after turning age 5 years. Alternatively, they may complete the 3-dose series with updated 2023–2024 Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 mcg (yellow cap; yellow label).

Table 2B: Ages 5 through 11 years with Moderately or Severely Immunocompromising Conditions *

See section 5a for list of immunocompromising conditions.

Note - The PREP Act, 11th Amendment allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2024. Otherwise, pharmacists are only permitted to vaccinate persons ≥ 7 years per ORS 689.645.

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023-2024 Formula) Vaccine Doses Indicated±	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors	Interval Between Doses
Unvaccinated	Moderna	3	0.25 mL/ 25mcg	Dark blue cap; Green label	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	OR				
	Pfizer-BioNTech	3	0.3 mL/ 10 mcg	Blue cap; Blue label	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks

1 dose any Moderna	Moderna	2	0.25 mL/ 25 mcg	Dark blue cap; Green label	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 4 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/ 10 mcg	Blue cap; Blue label	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	Blue cap; Blue label	At least 4 weeks after last dose
3 or more doses any mRNA vaccine	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	Blue cap; Blue label	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

±Children ages 5–11 years who are moderately or severely immunocompromised may receive 1 additional dose of updated 2023–2024 Moderna COVID-19 Vaccine, 0.25mL/25 mcg (dark blue cap; green label) or updated 2023–2024 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg (blue cap; blue label) at least 2 months after the last updated 2023–2024 mRNA vaccine dose indicated in Table 2B. Further additional dose(s) may be administered by a pharmacist with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated (2023–2024 Formula) mRNA vaccine dose.

* For children who transition from age 4 years to age 5 years during the initial vaccination series:

- **Moderna series:** Children are recommended to receive an updated 2023-–2024 Moderna COVID-19 Vaccine, 0.25 mL/25 mcg (dark blue cap; green label) for all doses.
- **Pfizer-BioNTech series:** Children are recommended to receive an updated 2023-–2024 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg (blue cap; blue label) for all doses received on or after turning age 5 years. Alternatively, they may complete the 3-dose series with updated 2023–2024 Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 mcg (yellow cap; yellow label).

Table 2C: Ages 12 years and older with Moderately or Severely Immunocompromising Conditions *
See section 5a for list of immunocompromising conditions.

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023-2024 Formula) Vaccine Doses Indicated‡§	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors¶	Interval Between Doses
Unvaccinated	Moderna	3	0.5 mL/ 50 mcg	Dark blue cap; Blue label	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	OR				
	Novavax	2	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	Dose 1 and Dose 2: 3 weeks
	OR				
	Pfizer-BioNTech	3	0.3 mL/ 30 mcg	Gray cap; Gray label	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks
1 dose any Moderna	Moderna	2	0.5 mL/ 50 mcg	Dark blue cap; Blue label	Dose 1: 4 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.5 mL/ 50 mcg	Dark blue cap; Blue label	At least 4 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/ 30 mcg	Gray cap; Gray label	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 4 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	Gray cap; Gray label	At least 4 weeks after last dose

3 or more doses any mRNA vaccine	Moderna	1	0.5 mL/ 50 mcg	Dark blue cap; Blue label	At least 8 weeks after last dose
	OR				
	Novavax	1	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	Gray cap; Gray label	At least 8 weeks after last dose
1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses	Moderna	1	0.5 mL/ 50 mcg	Dark blue cap; Blue label	At least 8 weeks after last dose
	OR				
	Novavax	1	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	Gray cap; Gray label	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two; for people ages 12 years and older, Original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent Novavax vaccine doses.

‡Apart from the administration of additional doses, the FDA EUA for the updated 2023–2024 Novavax COVID-19 vaccine does not provide for a specific vaccination schedule for people who are moderately or severely immunocompromised. People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of an updated 2023–2024 Moderna COVID-19 Vaccine, 0.5 mL/50 mcg (dark blue cap; blue label), an updated 2023–2024 Novavax COVID-19 Vaccine; or an updated 2023-–2024 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/30 mcg (gray cap; gray label) at least 2 months following the last recommended updated 2023-–2024 vaccine dose. Further additional dose(s) may be administered by a pharmacist with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated 2023–-2024 COVID-19 vaccine dose.

§Administration of additional doses is as follows:

- **People ages 12–64 years who are moderately or severely immunocompromised may** receive 1 additional dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 2 months after the last dose of an updated 2023–2024 COVID-19 vaccine as indicated in Table 2C. Pharmacist may administer further additional dose(s) with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated 2023–2024 COVID-19 vaccine dose.

- **People ages 65 years and older who are moderately or severely immunocompromised should** receive 1 additional dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 2 months after the last dose of an updated 2023–2024 vaccine as indicated in Table 2C. Pharmacist may administer further additional dose(s) with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated 2023–2024 COVID-19 vaccine dose.

- For all age groups, the dosage for the additional doses is as follows: Moderna, 0.5 mL/50 ug; Novavax, 0.5 mL/5 mcg rS protein and 50 mcg Matrix-M adjuvant; Pfizer-BioNTech, 0.3 mL/30 ug.

¶ The updated 2023–-2024 Moderna and Pfizer-BioNTech COVID-19 vaccines are also available in a prefilled, single-dose syringe for people ages 12 years and older.

*For children who transition from age 11 years to age 12 years during the initial vaccination series:

- **Moderna series:** Children are recommended to receive an updated 2023–2024 Moderna COVID-19 Vaccine, 0.5 mL/50mcg (dark blue cap; blue label) for all doses received on or after turning age 12 years. Alternatively, they may complete the 3-dose series with an updated 2023–2024 Moderna COVID-19 Vaccine for children ages 5–11 years, 0.25 mL/25mcg (dark blue cap; green label).
- **Pfizer-BioNTech series:** Children are recommended to receive an updated 2023–-2024 Formula Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/30 mcg (gray cap; gray label) for all doses received on or after turning age 12 years. Alternatively, they may complete the 3-dose series with an updated 2023–2024 Pfizer-BioNTech COVID-19 Vaccine for children ages 5–11 years, 0.3 mL/10 mcg (blue cap; blue label).

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Cap/Label Color
Pfizer-BioNTech 2023-2024 formulation[1]	mRNA	0.9 mL, 3 dose vial 0.3 mL, single dose vial	3-4 years 5-11 years	Yellow Cap Blue Cap
Pfizer-BioNTech COMIRNATY®[3] 2023-2024 formulation	mRNA	0.3 mL, single dose vial 0.3 mL, prefilled syringe	≥ 12 years	Gray Cap
Moderna 2023-2024 formulation[2]	mRNA	0.25 mL, single dose vial	3-11 years	Blue Cap/Green Label
Moderna SPIKEVAX® 2023-2024 formulation[4]	mRNA	2.5 mL, 5 dose vial 0.5 mL, single dose vial 0.5 mL, prefilled syringe	≥ 12 years	Blue Cap/Blue Label
NVX-CoV2373[3] (NOVAVAX® 2023-2024 formulation)[5]	Protein subunit	2.5 mL, 5-dose vial	≥ 12 years	Royal Blue Cap

5. Recommendations for Use[1-8]

A. **<u>Vaccine Schedule for Immunocompetent Individuals</u>**

Ages 6 months–4 years

1. <u>Unvaccinated:</u> 2 or 3 homologous (i.e., from the same manufacturer) updated 2023–2024 mRNA vaccine doses, depending on vaccine manufacturer (i.e., Moderna, Pfizer-BioNTech).
2. <u>Previously received an incomplete series of Original monovalent or bivalent mRNA vaccine doses:</u> Complete the vaccination series with 1 or 2 homologous updated 2023–2024 mRNA vaccine doses, depending on vaccine manufacturer and the number of previous vaccine doses.

3. Previously received all doses in the initial vaccination series with Original monovalent or bivalent mRNA vaccine: 1 homologous updated 2023–2024 mRNA vaccine dose.
4. Special situations for children ages 6 months–4 years: COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended. In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:
    - Same vaccine not available at the vaccination site at the time of the clinic visit
    - Previous dose unknown
    - Person would otherwise not receive a recommended vaccine dose
    - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication.
5. The **extended interval** consideration applies only to the following people who are not moderately or severely immunocompromised:
    - Ages 6 months–4 years, depending on their vaccination history
    - Ages 12 years–64 years and receiving a 2-dose Novavax series

    The **minimum interval** between the first and second doses continues to be recommended for:
    - People who are moderately or severely immunocompromised
    - People ages 65 years and older receiving Novavax vaccine
    - Situations when the fullest possible protection needs to be achieved sooner (e.g., increased concern about an individual's higher risk for severe disease)

Ages 5–11 years

1. Unvaccinated or previously received any number of Original monovalent or bivalent mRNA vaccine doses: 1 dose of an updated 2023–2024 mRNA vaccine from either manufacturer (i.e., Moderna or Pfizer-BioNTech).

Ages 12 years and older

1. Unvaccinated: 1 dose of an updated 2023–2024 mRNA COVID-19 vaccine (i.e., Moderna, Pfizer-BioNTech) OR 2 doses of the updated 2023–2024 Novavax vaccine.
2. Previously received 1 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
3. Previously received 1 or more doses of Original monovalent Novavax vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated 2023–2024 Formula COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
4. Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
5. Special situation for people ages 65 years and older: People ages 65 years and older should receive 1 additional dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 4 months following the previous dose of an updated 2023–2024 COVID-19 vaccine. For initial vaccination with the updated 2023–2024 Novavax COVID-19 Vaccine, the 2-dose series should be completed before administration of the additional dose.
6. The **extended interval** consideration applies only to the following people who are not moderately or severely immunocompromised:
    - Ages 6 months–4 years, depending on their vaccination history
    - Ages 12 years–64 years and receiving a 2-dose Novavax series

Protocol for Coronavirus 19 Vaccines
(Moderna, Novavax, Pfizer-BioNTech)

The **minimum interval** between the first and second doses continues to be recommended for:

- People who are moderately or severely immunocompromised
- People ages 65 years and older receiving Novavax vaccine
- Situations when the fullest possible protection needs to be achieved sooner (e.g., increased concern about an individual's higher risk for severe disease)

a. <u>Vaccine Schedule for Individuals with Moderately or Severely Immunocompromising Conditions</u>

Conditions causing moderate to severe immunodeficiency include[¥]:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of Chimeric antigen receptor (CAR)-T-cell or hematopoietic cell transplant (HCT) within 2 years of transplantation or taking immunosuppression therapy
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day)
- Alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

¥Individuals with immunocompromising conditions not listed above, may receive subsequent vaccination doses with a prescription from a healthcare provider.

Ages 6 months through 4 years

1. <u>Unvaccinated:</u> 3 homologous (i.e., from the same manufacturer) updated 2023–2024 mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech).
2. <u>Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses:</u> Complete the 3-dose series with 2 or 1 homologous updated 2023–2024 mRNA vaccine doses, respectively.
3. <u>Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses:</u> 1 dose of a homologous updated 2023–2024 mRNA vaccine.
4. <u>Special situations for children ages 6 months–4 years:</u> COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended. In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:
    - Same vaccine not available at the vaccination site at the time of the clinic visit
    - Previous dose unknown
    - Person would otherwise not receive a recommended vaccine dose
    - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication.

5. Additional doses: May receive 1 or more additional homologous updated 2023–2024 mRNA vaccine doses with a prescription issued by a healthcare provider.

Ages 5 through 11 years

1. Unvaccinated: 3 homologous (i.e., from the same manufacturer) updated 2023–2024 mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech).
2. Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete the 3-dose series with 2 or 1 homologous updated 2023–2024 mRNA vaccine doses, respectively.
3. Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of an updated 2023–2024 mRNA vaccine from either manufacturer.
4. Additional doses: May receive 1 or more additional updated 2023–2024 mRNA vaccine doses from either manufacturer with a prescription issued by a healthcare provider.

Ages 12 years and older

1. Unvaccinated: 3 homologous (i.e., from the same manufacturer) updated 2023–2024 mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech) OR 2 updated 2023–2024 Novavax vaccine doses.
2. Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete the 3-dose series with 2 or 1 homologous updated 2023–2024 mRNA vaccine doses, respectively.
3. Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
4. Previously received 1 or more Original monovalent Novavax vaccine doses, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
5. Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
6. Additional doses:
    - People ages 12–64 years may receive 1 or more additional doses of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) with a prescription issued by a healthcare provider.
    - People ages 65 years and older should receive 1 additional dose of any updated 2023-2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 2 months after receipt of a previous updated 2023-2024 COVID-19 vaccine. Individuals 65 years and older may receive further additional doses of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) with a prescription issued by a healthcare provider.

6. Contraindications

a. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1-5]

Protocol for Coronavirus 19 Vaccines
(Moderna, Novavax, Pfizer-BioNTech)

Vaccine	Contains
Pfizer-BioNtech 2023-2024 formulation[1] (yellow cap and border)[1]	Lipids (0.04 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]-N,N itetradecylacetamide, 0.01 mg 1,2-distearoyl-snglycero-3-phosphocholine, and 0.02 mg cholesterol), 9.4 mg sucrose, 0.02 mg tromethamine, and 0.12 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 1.88 mg sodium chloride per dose.
Pfizer-BioNtech 2023-2024 formulation[1] (blue cap and border)	Lipids (0.14 mg ((4- hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.03 mg 1,2- distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 31 mg sucrose, 0.06 mg tromethamine, and 0.4 mg tromethamine hydrochloride.
Pfizer-BioNtech COMIRNATY® 2023-2024 formulation[3] (gray cap and border)	Lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate),0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose
Moderna 2023-2024 formulation[2] (dark blue cap and green border)	Total lipid content of 0.5 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC]), 0.13 mg tromethamine, 0.62 mg tromethamine hydrochloride, 0.011 mg acetic acid, 0.049 mg sodium acetate trihydrate, and 21.8 mg sucrose.
Moderna SPIKEVAX® 2023-2024 formulation[4] (dark blue cap and border)	Total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose.
NVA-CoV2373 (NOVAVAX® 2023-2024 formulation)[5]	Cholesterol, phosphatidylcholine, potassium dihydrogen phosphate (3.85 µg), potassium chloride (2.25 µg), disodium hydrogen phosphate dihydrate (14.7 µg), disodium hydrogen phosphate heptahydrate (2.465 mg), sodium dihydrogen phosphate monohydrate (0.445 mg), sodium chloride (8.766 mg) and polysorbate 80 (0.050 mg). The vaccine contains a recombinant form of the SARS-CoV-2 spike protein produced from baculovirus infected Sf9 (fall armyworm) insect cells and Matrix-M™ adjuvant is composed of Fraction-A (42.5 µg) and Fraction-C (7.5 µg) of saponin extracts from the soapbark tree, Quillaja saponaria Molina. The pH is adjusted with sodium hydroxide or hydrochloric acid.

7. **Warnings and Precautions[8]**
    a. History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intravenous, intramuscular or subcutaneous).

b. Persons who have a contraindication to additional doses of mRNA COVID-19 vaccines are considered to have a precaution to the Novavax vaccine. A single dose may be given in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist. This additional dose could be considered after a minimum interval of 28 days after the mRNA COVID-19 vaccine dose. See Appendix A for additional information.
c. Moderate or severe acute illness.
d. Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided.

8. **Other Considerations**[8]
   a. Individuals with known COVID-19 infection should wait until their symptoms have resolved and criteria have been met to discontinue isolation. Persons who have a history of COVID-19 disease should be vaccinated if otherwise indicated. If desired, persons with acute COVID-19 may wait up to 90 days to receive vaccination, as reinfection within 90 days is uncommon. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.
   b. Individuals who received monoclonal antibodies or convalescent plasma during COVID-19 treatment may be vaccinated as soon as their symptoms have resolved.
   c. Individuals with a known community or outpatient setting COVID-19 exposure should wait until the end of their quarantine period before seeking vaccination to avoid potentially exposing healthcare personnel.
   d. Individuals who have been exposed to COVID-19 living in congregate settings, including long-term care, homeless shelters, or correctional institutions, where exposure or transmission can occur repeatedly over a long period of time may be vaccinated without completing a quarantine period.
   e. Ask patient to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint. Individuals with a history of severe allergic reactions should be asked to remain for 30 minutes.
   f. CDC recommends that vaccine for children aged 5–17 years of age with history of Multisystem Inflammatory Syndrome of Children (MIS-C) be delayed for 90 days after their diagnosis of MIS-C. Providers should inform individuals that the risk of reinfection, and therefore the potential benefit from vaccination, may increase with time following initial infection.
   g. COVID-19 vaccination is recommended for all people of childbearing age, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.
   h. Persons who are trying to become pregnant do not need to avoid pregnancy after receiving COVID-19 vaccine. There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine.
   i. Persons with underlying medical conditions who have no contraindications may receive COVID-19 vaccine.
   j. Children 3 years through 4 years of age should complete a multi-dose initial series (2 doses of Moderna vaccine or 3 doses of Pfizer-BioNtech vaccine) with at least one dose of the

2023–2024 COVID-19 mRNA vaccines. Doses for adults and immunocompromised persons ≥5 years of age may receive any age-appropriate authorized product.

9. Side Effects and Adverse Reactions

a. COVID-19 vaccines appear to be more reactogenic than most. Inform patient that symptoms of immune system activation are normal (see Table) and should improve without intervention in 12-24 hours.

Pfizer-BioNtech [1,3] and Moderna[2,4] Adverse Events	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 93%
Systemic events (fatigue, headache, muscle ache, joint pain)	Very common, up to 77%
Fever	Up to 16%
Lymphadenopathy*	Up to 20%
Serious adverse events	Uncommon, up to 1% (similar to placebo group)

*Lymph node swelling in the underarm is more common after the booster dose than after the initial series.

Novavax[5] Adverse Events	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 82%
Systemic events (fatigue, muscle pain, headache, nausea)	Very common, up to 62%
Fever	Uncommon, up to 6%

10. Storage and Handling

a. Store medications according to OAR 855-041-1036.

b. For Pfizer-BioNtech vaccine only: thaw, if needed. The single dose pre-filled glass syringe (COMIRNATY) CANNOT be frozen and stored in the refrigerator. The yellow cap formulation requires reconstitution; the blue and gray cap formulations are ready to administer.[1,3]

c. For Moderna vaccine only: thaw vaccine prior to administration.[2,4]

Vaccine	**Temp**	**Storage Issues**	**Notes**
Pfizer-BioNtech [1,3]	-90° to -60° C (-130° to -76° F)	Vaccine may be stored until the expiration date.	Do not freeze the single dose pre-filled glass syringe (discard if frozen)
	2° to 8° C (36° to 46° F)	**Adolescent/adult 2023-2024 formulation (blue or gray cap vial OR single dose pre-filled plastic pre-filled syringe):** store in the refrigerator for up to 10 weeks	
		Pediatric 2023-2024 formulation (yellow cap): before mixing, the vaccine may	

		be stored in the refrigerator for up to 10 weeks.	
		Adolescent/adult 2023-2024 formulation (single dose pre-filled glass syringe): Store in the refrigerator until printed expiration date on carton	
	Ambient temperatures	**Adolescent/adult 2023-2024 formulation (blue or gray cap vial OR single dose pre-filled glass syringe OR single dose pre-filled plastic syringe):** vaccine may be held at room temperature for up to 12 hours	
		Pediatric 2023-2024 formulation (yellow cap): once mixed, vaccine may be held at room temperature for up to 12 hours	
Moderna[2,4]	-50° to -15° C (-58° to 5° F)	Vaccine is viable until the expiration date.	For multi-dose vials, once stopper has been punctured, all doses must be used within 12 hours. Do not refreeze once thawed. Protect vaccine from light.
	2° to 8° C (36° to 46° F)	Vaccine is viable under refrigeration for up to 30 days.	
	Ambient temperatures	Unpunctured vials of vaccine is viable for up to 24 hours at room temperature	
Novavax[5]	2°– 8°C (36° to 46° F)	No expiration date is printed on vial or carton. Lookup the expiration date of the batch/Lot number at www.novavaxcovidvaccine.com enter "United States" as the "country/region."	Once vial stopper has been punctured, store vial at 2° to 25° C (36° to 77° F) for use within 12 hours. Discard the vial 12 hours after first puncture. Do not freeze. Protect vaccine from light.

11. References

1. Pfizer-BioNTech COVID-19 Vaccine, 2023–2024 formulation. Emergency use authorization (EUA) fact sheet, 11 Sep 2023. Available at: https://www.fda.gov/media/167211/download. Accessed 14 Sep 2023.
2. Moderna COVID-19 vaccine, 2023–2024 formulation. Emergency use authorization (EUA) fact sheet and prescribing information, 11 Sep 2023. Available at: https://www.fda.gov/media/167208/download. Accessed 14 Sep 2023.
3. Pfizer-BioNTech Comirnaty, 2023–2024 formulation. Package insert, September 11, 2023. Available at: https://www.fda.gov/media/151707/download. Accessed 24 Jan 2024.

4. Moderna Spikevax, 2023–2024 formulation. Package insert, 11 Sep 2023. Available at: https://www.fda.gov/media/155675/download. Accessed 14 Sep 2023.
5. Novavax, Inc. Full emergency use authorization (EUA) prescribing information, 3 Oct 2023. Available at: https://www.fda.gov/media/159897/download. Accessed 9 Oct 2023.
6. Centers for Disease Control and Prevention. (2024, April 4). ACIP Vaccine Recommendations and Schedules. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/acip/recommendations.html. Accessed 1 March 2024.
7. Wallace M. Evidence to Recommendations Framework: 2023–2024 (Monovalent, XBB Containing) COVID-19 Vaccine. PowerPoint presentation, 12 Sep 2023. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf. Accessed 14 Sep 2023.
8. Interim clinical considerations for use of COVID-19 vaccines in the United States, November 22, 2023. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html. Accessed 13 Apr 2024.

12. **Appendix**
    a. COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, April 2024: https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-immunization-schedule-ages-6months-older.pdf

Division 135: Continuing Pharmacy Education (Definitions & General Requirements)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends accredited program definition by adding continuing veterinary medical education definition and requirements

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes to amend continuing education definition by adding continuing veterinary medical education accredited by the American Association of Veterinary State Boards Registry of Approved Continuing Education (AAVSB-RACE) as a medical program and amends CPE General Requirements.

Documents Relied Upon per ORS 183.335(2)(b)(D): April 2024 Board Meeting, mailing #G

- American Association of Veterinary State Boards (AAVSB) Registry of Approved Continuing Education (RACE) Standards for Approved Providers of Continuing Veterinary Medical Education- https://www.aavsb.org/ce-services/race/review-the-race-standards
- Registry of AAVSB-RACE approved CE courses- https://courses.cebroker.com/search/or/veterinarian

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 amendments may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal or economic impacts are anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The resources involved in convening a RAC we not necessary to amend these rules.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):
855-135-0001 - Proposes to add continuing veterinary medical education (CVME) accredited by the American Association of Veterinary State Boards Registry of Approved Continuing Education (AAVSB-RACE) as a medical program to CPE Definitions.

855-135-0010 – Proposes adding AAVSB RACE approved medical program to general requirements when calculating CPE credit requirements.

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**:**

(a) ~~c~~**C**ontinuing pharmacy education that is accredited by the Accreditation Council on Pharmaceutical Education (ACPE) (v. 06/01/2022)**;** ~~or~~

(b) ~~c~~**C**ontinuing medical education (CME) accredited by the Accreditation Council for Continuing Medical Education (ACCME) or an ACCME-recognized State Medical Society (v. 6/2022) as an American Medical Association (AMA) Category 1 CME program**; or**

(c) Continuing veterinary medical education (CVME) accredited by the American Association of Veterinary State Boards Registry of Approved Continuing Education (AAVSB-RACE) as a medical 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 413.450, ORS 413.590, ORS 689.255, ORS 689.285, ORS 689.486 & ORS 689.490

855-135-0010
Continuing Pharmacy Education Programs: General Requirements

(1) CPE programs must consist of subject matter pertinent to pharmacy including:

(a) Socioeconomic aspects of healthcare;

(b) Legal aspects of healthcare;

(c) Properties and actions of drugs and dosage forms;

(d) Etiology, characteristics, therapeutics, and prevention of disease states; or

(e) General topics related to pharmacy.

(2) Time spent in the following activities may be included in the calculation of CPE credit:

(a) A program delivered by an instructor or a panel of instructors;

(b) A structured CPE discussion, workshop or demonstration;

(c) A structured CPE question and answer session;

(d) An ACPE accredited program or board-approved program;

(e) An ACCME AMA Category 1 accredited program or **AAVSB RACE approved medical program** up to the following limits per renewal cycle:

(A) 10 hours of CPE for Pharmacists;

(B) 6 hours of CPE for Certified Oregon Pharmacy Technicians and Pharmacy Technicians.

(f) A policy discussion at an Oregon Board of Pharmacy meeting up to a maximum of 2 hours of law CPE per renewal cycle.

(3) Time spent in the following activities must not be included in the calculation of CPE credit:

(a) Welcoming remarks;

(b) Meals or social functions;

(c) Business sessions (e.g. voting, treasury report, strategic plan);

(d) Unstructured discussion, workshops, and demonstrations;

(e) Unstructured question and answer sessions;

(f) Degree programs;

(g) Non-ACPE approved certificate programs;

(h) Licensing or certification examinations;

(i) Skills training programs;

(j) Software training programs;

(k) Learning assessments;

(l) Program evaluations; and

(m) Attending CPE programs for which credit was not granted by the provider.

(4) For each accredited or board-approved program, the licensee must retain a certificate of completion for each completed program that includes:

(a) Licensee name;

(b) Title, activity date, and activity number of the program;

(c) Topic designation (e.g. law, patient safety, pain);

(d) Name of the program provider;

(e) Number of contact hours earned by topic designation; and

(f) Statement of credit granted to the participant.

(5) For each accredited or board-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or a certificate of completion is uploaded to the licensee's electronic licensing record with the board prior to submission of the license renewal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.255, ORS 689.285 & ORS 689.490

Divisions: 006/041/043/045/183: Drug Compounding

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural review; Repeals Division 45 and creates new Division 183 for Drug Compounding

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 45 and creates a new Division 183 for Drug Compounding. Adds additional general requirements for Drug Outlet Pharmacies, Dispensing Practitioner Drug Outlets (DPDO), Correctional Facilities (CF) and Community Health Clinics (CHC) related to dispensing compounded drugs in Divisions 041 and 043. These rules apply to the preparation and dispensing of compounded drugs from a Drug Outlet. These rules do not apply to the preparation and direct administration of compounded drugs by a healthcare provider.

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

USP Chapters: USP Compounding Compendium

Designated Person Responsibilities: ASHP List

Flavoring:

- USP <795> Adding Flavor to Conventionally Manufactured Nonsterile Products (v. 11/2022)

- USP <795> FAQs #21 (v. 11/2023)

Sterile Compounding Technology:

- ISMP Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology (2016 and 2022)

- Pedersen CA, Schneider PJ, Ganio MC, Scheckelhoff DJ. ASHP National Survey of Pharmacy Practice in Hospital Settings: Dispensing and Administration-2020. Am J Health Syst Pharm. 2021 Jun 7;78(12):1074-1093. DOI: 10.1093/ajhp/zxab120. PMID: 33754638; PMCID: PMC8083667.

- Moniz TT, Chu S, Tom C, Lutz P, Arnold A, Gura KM, Patterson A. Sterile Product Compounding Using an I.V. Compounding Workflow Management System at a Pediatric Hospital. Am J Health Syst Pharm. 2014 Aug 1;71(15):1311-7. DOI: 10.2146/ajhp130649. PMID: 25027539.

- Speth SL, Fields DB, Schlemmer CB, Harrison C. Optimizing I.V. Work-Flow. Am J Health Syst Pharm. 2013; 70(23):2076,2078-80. DOI: 10.2146/ajhp120738

- Deng Y, Lin AC, Hingl J, Huang G, Altaye M, Maynard H, Mayhaus D, Penm J. Risk factors for I.V. Compounding Errors When Using an Automated Workflow Management System. Am J Health Syst Pharm. 2016 Jun 15;73(12):887-93. DOI: 10.2146/ajhp150278. PMID: 27261239.

- NV: NAC 639.67017 Use of automated compounding devices.

Sterile Compounding Accreditation: PCAB/ACHC, NABP, TJC

Standard Operating Procedures: ASHP List 795 797

Compounded Drug Recalls: CA Law 4126.9. Recall of Nonsterile Compounded Drugs; 4127.8. Pharmacies that Compound Sterile Drug Products; Recalls; Requirements

Requirements For Use by a Veterinarian: Compounding Animal Drugs from Bulk Drug Substances Guidance for Industry (August 2022), Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

Essential Copies: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (January 2018), FDA drug shortages database, ASHP drug shortages database

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): The proposed new rules and existing rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): On 8/4/2023 board staff sent out an email notification via GovDelivery to 19,647 licensee and registrant subscribers and 3,882 rulemaking interested party subscribers requesting fiscal and economic impact of the proposed rules. A Workgroup was utilized in the development of the proposed rules. Workgroup members provided estimated fiscal and economic impact of the proposed rules on 05/16/2023 and 07/18/2023. All Workgroup and board meetings where proposed rules were discussed were noticed to the public and public comment was requested. The board noticed the proposed rules for rulemaking hearing on 6/16/2023; however, the board was seeking public comment only and did not intend to adopt the rules in August 2023. The public had an opportunity to provide estimated fiscal impact information during the public comment period from 6/16/2023 – 7/26/2023.

To comply, Drug Outlet pharmacies, DPDOs, CFs and CHCs who engage in compounding will need to pay for access to the USP Compounding Compendium which is estimated to cost $250 per year per user.

-The board received estimated fiscal impact statements from six different licensee/registrant/stakeholders who provided a wide range of estimated costs that could potentially cost their organizations/patients/customers anywhere from $1.00 to $10 Million to comply with the proposed rules.

- Related to sterile compounding technology- Compounding Workgroup members stated that in their experience, barcoding and imaging technology procurement, implementation, ongoing maintenance, and training is estimated to cost between $30,000 - $130,000 initially and $50,000 annually. This type of technology is typically customized, requires specialized training and requires extra staff to operate.

- Related to sterile compounding accreditation/certification through PCAB/ACHC, NABP and TJC- Compounding Workgroup members stated in their experience, the estimated cost is between $4,500 to $17,500 depending on the vendor for a three-year accreditation/certification.

Interested parties will have an additional opportunity to provide fiscal and economic impact statements during future rulemaking.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): (1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small

businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) The proposed new rules and existing rule amendments will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed new rules and existing amendments apply to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.

(b) The rulemaking imposes the same mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) In order to comply, Drug Outlet pharmacies, DPDOs, CFs and CHCs who identify as a small business and engage in compounding will need to pay for access to the USP Compounding Compendium which is estimated to cost $250 per year per user.

Describe how small businesses were involved in development of the rules ORS 183.335: Licensees and registrants identify as small businesses were sent an email notice of proposed rulemaking via GovDelivery and had an opportunity to provide public comment when the proposed rules were noticed for rulemaking hearing on 6/16/2023. On 08/04/2023 the board sent out an email communication via GovDelivery to licensees and registrants requesting fiscal impact information on the proposed rules and small businesses had an opportunity to provide estimated fiscal information.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not consulted. The board directed staff to convene a Drug Compounding Workgroup consisting of Subject Matter Experts who had expertise related to drug compounding to assist with the development of proposed rules/amendments. The Compounding Workgroup held meetings on 2/21/2023, 4/18/2023, 5/16/2023, 6/20/2023 and 7/18/2023 and provided expertise and information that board staff utilized to draft proposed rules related to drug compounding.

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

Proposed new rules and existing rule amendments are a result of the board's 2022-2026 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety. USP 795 (v. 11/1/2022) and USP 797 (v. 11/1/2022) become enforceable on 11/1/2023. Board rules related to compounding must be updated to reflect the new standards.

OAR 855-041-1018 - Proposed amendments add compliance requirements related to dispensing compounded preparations and radiopharmaceutical prescriptions.

OAR 855-043-0545 - Proposed amendment adds compliance requirements for a DPDO who dispenses compounded preparations.

OAR 855-043-0630 - Proposed amendments include revising "shall" to "must" and adds that a correctional facility must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

OAR 855-043-0740 - Proposed amendment adds that a CHC must ensure that compounded preparations are dispensed in compliance with OAR 855-183

OAR 855-045-0200 – Repeals rule

OAR 855-045-0210 – Repeals rule

OAR 855-045-0220 – Repeals rule

OAR 855-045-0240 – Repeals rule

OAR 855-045-0270 – Repeals rule

OAR 855-183-0001 - Proposed rule revises and relocates existing rule OAR 855-045-0200 to OAR 855-183-0001 related to applicability.

OAR 855-183-0005 - Proposed rule revises and relocates rule OAR 855-006-0005(11) to OAR 855-183-0005 and adds new language related to compounding definitions.

OAR 855-183-0010 - Proposed new rule adds general designation requirements for each Drug Outlet that practices drug compounding.

OAR 855-183-0050 - Proposed rule revises and relocates existing rule OAR 855-045-0220 to OAR 855-183-0050 related to personnel requirements.

OAR 855-183-0200 - Proposed rule revises and relocates existing rule OAR 855-045-0200(3) to OAR 855-183-0200 and adds general requirements for drug compounding.

OAR 855-183-0205 - Proposed new rule adds compounding technology requirements related to Automated Compounding Devices (ACDs).

OAR 855-183-0370 - Proposed new rule adds delivery requirements for each Drug Outlet Pharmacy who ships or delivers compounded preparations.

OAR 855-183-0400 - Proposed rule revises and relocates existing rule OAR 855-045-0240 to OAR 855-183-0400 related to labeling requirements for compounded non-sterile preparations (CNSPs).

OAR 855-183-0410 - Proposed rule revises and relocates existing rule OAR 855-045-0240 to OAR 855-183-0410 related to labeling requirements for compounded sterile preparations.

OAR 855-183-0420 - Proposed new rule adds labeling requirements for Compounded Non-Sterile Preparations (CNSPs) and Compounded Sterile Preparations (CSPs) for future use.

OAR 855-183-0450 - Proposed new rule adds drug disposal requirements for hazardous and infectious waste.

OAR 855-183-0500 - Proposed rule revises and relocates existing rule OAR 855-045-0220 to OAR 855-183-0500 related to policies and procedures for registrants who practice drug compounding.

OAR 855-183-0520 - Proposed new rule adds requirements for compounded drug recalls.

OAR 855-183-0550 - Proposed rule revises and relocates existing rule OAR 855-045-0270 to OAR 855-183-0550 related to general records requirements.

OAR 855-183-0560 - Proposed rule revises and relocates existing rule OAR 855-045-0270(2) to OAR 855-183-0560 related to master formulation records (MFR) for compounded non-sterile preparations.

OAR 855-183-0565 - Proposed rule revises and relocates existing rule OAR 855-045-0270(2) to OAR 855-183-0565 related to master formulation records (MFR) for compounded sterile preparations.

OAR 855-183-0570 - Proposed rule revises and relocates existing rule OAR 855-045-0270(3) to OAR 855-183-0570 related to requirements for compounding records for compounded non-sterile preparations.

OAR 855-183-0575 - Proposed rule revises and relocates existing rule OAR 855-045-0270(3) to OAR 855-183-0575 related to requirements for compounding records for compounded sterile preparations.

OAR 855-183-0600 - Proposed new rule adds prohibited practices related to compounded drug preparation.

OAR 855-183-0700 - Proposed new rule adds requirements for compounding services related to preparation according to FDA approved labeling.

OAR 855-183-0710 - Proposed new rule adds requirements for compounding services related to copies of an approved drug.

OAR 855-183-0730 - Proposed new rule adds requirements for compounding services related to use by a veterinarian.

NOTES:

- History of rule package review
  - June/July 2023: The rules were sent to rulemaking at the June 2023 board meeting for the July 2023 rulemaking hearing for public comment only.
  - August 2023: The board reviewed OAR 855-006-0005, OAR 855-041-1018, OAR 855-043-0545, OAR 855-043-0630, OAR 855-043-0740, OAR 855-183-0001, OAR 855-183-0005 and OAR 855-183-0010.
  - December 2023: The board reviewed OAR 855-183-0050 through the beginning of OAR 855-183-0200.
  - February 2024: The board reviewed a portion of OAR 855-183-0200.
  - April 2024: The board reviewed OAR 855-183-0200 through OAR 855-183-0700.
  - June 2024: The board will continue its review of OAR 855-183, **focusing discussion on OAR 855-183-0710 and OAR 855-183-0730.**

- Highlights/Markup
  - Rule language highlighted in yellow denote staff proposed amendments made since the rule package was sent to rulemaking at the June 2023 board meeting for the July 2023 rulemaking hearing for public comment only.
  - **The markup** in this package is in comparison to the current rules for Div 006, 041, 043, and 045.

Division 6
DEFINITIONS

855-006-0005 ***View the entire rule of current version of Definitions**
Definitions

(11) "Compounding" means the **process of combining, admixing, diluting, pooling, reconstituting, or otherwise altering a drug product or bulk drug substance to create a new preparation.** ~~preparation, mixing, assembling, packaging, or labeling of a drug or device:~~

(a) **For non-sterile preparations, compounding does not include reconstituting according to the manufacturers labeling.** ~~As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the Pharmacist and the patient, in the course of professional practice; or~~

(b) **For sterile preparations, compounding includes repackaging.** ~~For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or~~

~~(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.~~

Division 41
OPERATION OF PHARMACIES

855-041-1018
NOTE: *The Board adopted amendments to this rule at the December 2023 board meeting to be effective 3/1/2024. The mark-up shown below is against the language effective 3/1/2024.*

A drug outlet pharmacy must:

(1) Ensure each:

(a) Prescription is dispensed in compliance with OAR 855-041, OAR 855-115, OAR 855-120, OAR 855-125, OAR 855-139, OAR 855-141 and OAR 855-143;

(b) Controlled substance is dispensed in compliance with OAR 855-080;

(c) Compounded preparation is dispensed in compliance with OAR 855-~~045~~**183**; and

(d) Radiopharmaceutical is dispensed in compliance with OAR 855-042.

(2) Comply with all applicable federal and state laws and rules;

(3) Ensure all licensees are trained to appropriately perform their duties prior to engaging or assisting in the practice of pharmacy.

(4) Ensure each licensed and non-licensed individual only perform duties they are licensed and trained to perform.

(5) Be responsible for the actions of each licensed and non-licensed individual.

(6) Establish, maintain and enforce the drug outlet written procedures required in OAR 855-041-1040.

(7) Comply with the Pharmacist's determination in OAR 855-115-0120(1)(k);

(8) Develop, implement and enforce a continuous quality improvement program for dispensing services from a Drug Outlet Pharmacy designed to objectively and systematically:

(a) Monitor, evaluate, document the quality and appropriateness of patient care;

(b) Improve patient care; and

(c) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence.

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

Division 43
PRACTITIONER DISPENSING

855-043-0545
Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery

(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by the practitioner's licensing board.

(2) Drugs dispensed from the DPDO must be dispensed in compliance with the requirements of the practitioner's licensing board.

(3) A DPDO must comply with all requirements of State or federal law.

(4) A DPDO must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

(5) Dispensed drugs must be packaged by the DPDO, a pharmacy, or a manufacturer registered with the board.

(6) A DPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(7) A DPDO may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(8) The DPDO must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(9) The DPDO must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

(~~9~~**10**) **Unless an exemption applies,** ~~E~~each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed ~~unless an exemption applies~~.

[~~Publications:~~ Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.305

855-043-0630
Correctional Facility **(CF)** - Drug Delivery and Control
NOTE: The Board adopted amendments to this rule related to short-acting opioid antagonists in October 2023 effective upon filing.

(1) Policies and Procedures: The Pharmacist and the practitioner representing the facility are responsible for establishing written policies and procedures for medication management including, but not limited to, drug procurement, dispensing, administration, labeling, medication counseling, drug utilization review, medication records, parenterals, emergency and nonroutine dispensing procedures, stop orders, over-the-counter drugs, security, storage and disposal of drugs withing the facility. Policies and

procedures must be reviewed and updated annually by the Pharmacist and the practitioner, maintained in the facility; and be made available to the board for inspection. The facility must submit to the board for approval~~,~~ the name of any employee Pharmacist or a written agreement between the Pharmacist and the facility regarding drug policies and procedures. The facility must notify the board of any change of Pharmacist within 15 days of the change.

(2) Dispensing: Prescription drugs must be dispensed by a Pharmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system. **The Correctional Facility (CF) must ensure that compounded preparations are dispensed in compliance with OAR 855-183.**

(3) Unit Dose Dispensing System. The "Unit Dose Dispensing System" is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stock from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled:

(a) A unit dose dispensing system must:

(A) By nature of the system;

(i) Provide for separation of medications by patient name and location; and

(ii) Provide for separating medications by day of administration.

(B) By means of an individual patient medication record:

(i) Record the drug and dosing regimen of those drugs dispensed by the pharmacy;

(ii) Record the actual doses dispensed and returned to the pharmacy;

(iii) Record the date of the original order and the date the order is discontinued;

(iv) Provide a means for the Pharmacist to verify the prescriber's original order;

(v) Provide a means for the Pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient; and

(vi) Provide a mechanism to easily identify those drugs dispensed by pharmacy that are controlled substances.

(b) Each CF utilizing a unit dose dispensing system must establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies must be available in the pharmacy for inspection by the board:

(A) Proper utilization of the unit dose system requires that, in as far as is practicable, all medications be in unit dose packaging when dispensed.

(B) Controlled substances may be included in the unit dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.

(C) Drugs not dispensed in unit dose packaging must be labeled in accordance with (4).

(c) The Pharmacist must certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.

(d) All medication must be stored in a locked area or locked cart.

(4) Labeling: Except as described in SB 450 (2023), prescription drugs dispensed in individual containers or medication cards must be labeled with the following information:

(a) Name and identifying number of the patient/inmate;

(b) Name, strength, and quantity of the drug dispensed. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(c) Name of the prescriber;

(d) Initials of the dispenser and the date of dispensing;

(e) Directions for use;

(f) Auxiliary labels and cautionary statements as required;

(g) Manufacturer's expiration date, or an earlier date if preferable; and

(h) Name of the pharmacy.

(5) Patient counseling:

(a) Upon receipt of a prescription drug order and following review by the Pharmacist of the patient's record, the Pharmacist must initiate and provide oral counseling to the patient or to the patient's agent or care giver in all ambulatory care settings and for discharge medications in institutions:

(A) Upon request; or

(B) On matters which a reasonable and prudent Pharmacist would deem significant; or

(C) Whenever the drug prescribed has not previously been dispensed to the patient; or

(D) Whenever the patient's medication record shows the drug has not been previously dispensed to the patient in the same dosage, form, strength or with the same written directions.

(b) When counseling is provided it must include information that a reasonable and prudent Pharmacist would deem necessary to provide for the safe and effective use of the drug. Such information may include the following:

(A) The name and description of the drug;

(B) The dosage form, dose, route of administration, and duration of drug therapy;

(C) The intended use of the drug and expected actions;

(D) Special directions and precautions for preparation, administration, and use by the patient;

(E) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(F) The possible dangers of taking the drug with alcohol, or taking the drug and then operating a motor vehicle or other hazardous machinery;

(G) Techniques for self-monitoring drug therapy;

(H) Proper storage;

(I) Prescription refill information;

(J) Action to be taken in the event of a missed dose; and

(K) Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Patient counseling must be in person whenever practicable. Whenever the prescription is delivered outside the confines of the pharmacy by mail or other third-party delivery, counseling must be in writing and by free access to the Pharmacist by phone.

(d) Subsections (a) and (b) of this section must not apply to those prescription drug orders for inpatients in hospitals or institutions where the drug is to be administered by a nurse or other individual authorized to administer drugs.

(e) Notwithstanding the requirements set forth in subsection (a), a Pharmacist is not required to provide oral counseling when a patient refuses the Pharmacist 's attempt to counsel, or when the Pharmacist, on

a case-by-case basis and in the exercise of professional judgment, determines that another form of counseling would be more effective.

(f) Board rules for patient counseling must be observed for **each inmate /** patient~~/inmates~~ who self-administer**s** or who ~~are~~ **is** ~~given~~ **dispensed** prescription drugs when they are released from the CF.

(6) Administration: Drugs must be administered to **each** inmate/ patient~~s~~ by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined by the Oregon State Board of Nursing in OAR 851-045-0060. Drugs selected by **a** registered nurse~~s~~ from ~~manufacturer's container or Pharmacist's~~ **a** bulk drug container~~s~~ **as defined in OAR 855-043-0610** must not be administered by **an** unlicensed person~~s~~, except under certain emergency and nonroutine situations as described in the facility's policies and procedures.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, 2023 SB 450

855-043-0740
Community Health Clinic (CHC) - Dispensing and Drug Delivery

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.

(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.

(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.

(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.

(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

(7) Dispensed drugs must be packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the board.

(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(9) A CHC must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

(10) A CHC may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The CHC offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(11) The CHC must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(12) The CHC must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

(13) **Unless an exemption applies,** ~~E~~each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is ~~dispensed unless an exemption applies~~.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

Division ~~45~~ **183**
DRUG COMPOUNDING

~~855-045-0200~~ **855-183-0001**
~~Application~~ **Applicability**

Effective XX/XX/20XX:

(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for ~~use or~~ **dispensing, delivery or** distribution in Oregon must register with the board as a drug outlet and comply with board regulations.

(2) These rules apply to sterile and non-sterile compounding of a drug **for humans and animals**.

(3) Entities that are registered with FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act in 21 USC 353b (04/10/2023) must register with the board as a manufacturer in OAR 855-060.

~~(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:~~

~~(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (05/01/2020 v. 2014);~~

~~(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (05/01/2020 v. 2008);~~

~~(c) USP <800> Hazardous Drugs—Handling in Healthcare Settings (07/01/2020 v. 2020);~~

~~(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging (12/01/2020 v. 2020); and~~

~~(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2016), 1231 (12/01/2021), and 1821 (05/01/2017).~~

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

855-183-0005
Definitions

Effective XX/XX/20XX:

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

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

~~855-045-0210~~ **855-183-0010**
~~Registration~~ **Designation**

Effective XX/XX/20XX:

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

~~(1) A non-resident drug outlet that distributes a non-patient specific compounded drug into Oregon must be registered with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.~~

~~(2) A resident drug outlet that distributes a non-patient specific human compounded drug within or outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.~~

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

~~855-045-0220~~ **855-183-0050**
Personnel ~~and Responsibilities~~

Effective XX/XX/20XX:

(1) All personnel who prepare and supervise the preparation of a compound must **obtain the education,** ~~complete appropriate~~ training**, and experience to demonstrate competency as required by the USP standards applicable to the preparation of compounded sterile and non-sterile products** and be capable and qualified to perform assigned duties **prior to independently engaging in compounding**.

(2) Training must be conducted by qualified individuals on a continuing basis and with sufficient frequency required by applicable USP standards to ensure that compounding personnel remain familiar with operations and policies and procedures.

(3) The training must be documented and records retained according to OAR 855-183-0550.

(4) Each Drug Outlet must ensure:

(a) For non-sterile compounding, personnel in the compounding area are authorized to be in the area by the person providing supervision when compounding activities are occurring.

(b) For sterile compounding, personnel in the compounding area are authorized by the person providing supervision to be in the area.

(c) The annual self-inspection is completed using the board's Compounding Self-Inspection Form by July 1 and retained for board inspection.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

~~(2) The Pharmacist-in-Charge (PIC) and the drug outlet must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR 855-045-0200(3) for all aspects of the compounding operation according to the type of compounding performed and must include written procedures for:~~

~~(a) Personnel qualifications, to include training, evaluation and requalification;~~
~~(b) Hand hygiene;~~

~~(c) Garbing;~~

~~(d) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;~~

~~(e) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;~~

~~(f) Components, to include selection, handling, and storage;~~

~~(g) Creating master formulation records, with documented pharmacist approval;~~

~~(h) Creating compounding records;~~

~~(i) Establishing beyond-use dates (BUDs);~~

~~(j) Continuous quality assurance program and quality controls, to include release testing, end-product evaluation, and quantitative/qualitative testing;~~

~~(k) Completed compounded preparations, to include handling, packaging, storage and transport;~~

~~(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug.~~

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

855-183-0200
Requirements: General

~~855-045-0200~~
~~Application~~

Effective XX/XX/20XX:

(~~3~~**1**)All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:

(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations **(11/01/2022) and all chapters referenced therein, including but not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 659 (04/01/2021), 797 (11/01/2022), 800 (07/01/2020), 1112 (2013), 1163 (12/01/2020), and 1231 (12/01/2021)** ~~(05/01/2020 v. 2014)~~;

POLICY DISCUSSION: Flavoring

(b) USP <797> Pharmaceutical Compounding—Sterile Preparations **(11/01/2022) and all chapters referenced therein, including but not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018), 659 (04/01/2021), 788 (05/01/2013), 789 (08/01/2015), 800 (07/01/2020), 825 (12/01/2020), 1066 (08/01/2015), 1085 (12/01/2020), 1113 (2013), 1116 (2013), 1163 (12/01/2020), 1197 (05/01/2021), 1207 (08/01/2016), 1223 (05/01/2018), 1225 (08/01/2017), 1228.1 (08/01/2016), 1228.4 (11/01/2019), 1229 (08/01/2022), 1229.1 (2013), 1229.4 (05/01/2018), 1229.5 (08/01/2022), 1229.8 (05/01/2018), and 1229.9 (08/01/2016)** ~~(05/01/2020 v. 2008)~~;

(c) USP <800> Hazardous Drugs—Handling in Healthcare Settings **(07/01/2020) and all chapters referenced therein, including but not limited to Chapters 795 (11/01/2022), and 797 (11/01/2022)** ~~(07/01/2020 v. 2020)~~;

(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging **(12/01/2020) and all chapters referenced therein, including but not limited to Chapters 71 (2013), 85 (05/01/2018), 659 (04/01/2021), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1113 (2013), 1116 (2013), and 1163 (12/01/2020)** ~~(12/01/2020 v. 2020)~~; and

~~(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2016), 1231 (12/01/2021), and 1821 (05/01/2017).~~

(2) A drug must only be compounded and dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs except as provided in OAR 855-183-0730. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

NOTE: Remove 'except as provided in OAR 855-183-0730' if board does not send OAR 855-183-0730 to rulemaking.

(3) A drug may be compounded for a commercially available product according to OAR 855-183-0710.

NOTE: Remove (3) if board does not send OAR 855-183-0710 to rulemaking.

(4-1-1) Beginning July 1, 2025, verification of compounded non-sterile preparations (CNSPs) and compounded sterile preparations (CSPs) must utilize a system that incorporates barcoding to verify ingredients.

(4-1-2) Verification of compounded sterile preparations (CSPs) may use a system that incorporates imaging or gravimetrics to verify ingredient quantity and finished CSP volumes.

(4-2) Verification of compounded non-sterile preparations (CNSPs) and compounded sterile preparations (CSPs) may utilize a system that incorporates:

(a) Barcoding to verify ingredients; and

(b) Imaging or gravimetrics to verify ingredient quantity and finished volumes.

(4-3) Verification of compounded sterile preparations (CSPs) may utilize a system that incorporates:

(a) Barcoding to verify ingredients; and

(b) Imaging or gravimetrics to verify ingredient quantity and finished CSP volumes.

POLICY DISCUSSION: May vs. must with implementation dates

(5) It is recommended that verification of CNSPs and CSPs not rely solely on the verification of components after they have been added to the final container. This includes methods such as proxy verification and the syringe pull-back method.

POLICY DISCUSSION: Recommendation vs. must (prohibited practice) with implementation dates

(6) Beginning July 1, 2025, a Drug Outlet that prepares CSPs from non-sterile ingredients must maintain current:

(a) Compounding Pharmacy Accreditation through the Pharmacy Compounding Accreditation Board (PCAB) provided by the Accreditation Commission for Health Care (ACHC);

(b) Compounding Pharmacy Accreditation through the National Association of Boards of Pharmacy (NABP); or

(c) Medication Compounding Certification through The Joint Commission.

POLICY DISCUSSION: May vs. must with implementation dates

(7) For CNSPs, the compounding area must have a visible line of demarcation to designate the area used for compounding. Other activities may not occur in this area when compounding is occurring.

POLICY DISCUSSION: May vs. must with implementation dates

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

855-183-0205

Technology: Automated Compounding Devices (ACDs)

Effective XX/XX/20XX:

(1) For the purposes of this rule, an "automated compounding device" is a device that compounds, measures, and/or packages a specified quantity of individual components in a predetermined sequence for a sterile preparation.

(2) A Drug Outlet Pharmacy, DPDO, CF or CHC may use an Automated Compounding Device (ACD) to:

(a) Assist with the compounding of a CSP; or

(b) Produce a final CSP.

(3) If a Drug Outlet Pharmacy, DPDO, CF or CHC uses an ACD as described in (1), the outlet must establish and maintain written policies and procedures, in addition to the policies and procedures established and maintained pursuant to OAR 855-183-0500, that address:

(a) The qualifications and training that a person must have to operate the ACD;

(b) The routine maintenance and cleaning required to be performed on the ACD which, at a minimum, satisfies the requirements for maintenance and cleaning established by the manufacturer of the ACD; and

(c) The testing required to be performed on the ACD to ensure that the ACD is measuring and dispensing the components of the compounded drug product and preparing the final compounded drug product within tolerances of not more than plus or minus 5 percent.

(4) If a Drug Outlet Pharmacy, DPDO, CF or CHC uses an ACD to assist with the compounding of a drug product for parenteral nutrition, the Drug Outlet Pharmacy, DPDO, CF or CHC must establish safe maximum limits for each additive that may be used in compounding such a drug product. The outlet must ensure that:

(a) The ACD will not allow compounding the drug product for parenteral nutrition if a maximum limit for an additive will be exceeded until a Pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order; or

(b) If an ACD cannot be programmed to not allow the compounding process as described in (a):

(A) The ACD is equipped with an audible alarm or some other mechanism that will alert the Pharmacist if a maximum limit for an additive has been exceeded; and

(B) The Drug Outlet Pharmacy, DPDO, CF or CHC has written policies and procedures to prevent the continuation of the compounding process once a maximum limit for an additive has been exceeded until a Pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

(5) If the Drug Outlet Pharmacy, DPDO, CF or CHC uses a computerized order entry system in conjunction with the ACD, the pharmacy must ensure that the computerized order entry system will cease processing the order if a maximum limit for an additive will be exceeded until a Pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

(6) A Drug Outlet Pharmacy, DPDO, CF or CHC must make and maintain records that evidence compliance by the outlet with the policies and procedures required by this section.

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

855-183-0370
Delivery

Effective XX/XX/20XX:

Each Drug Outlet Pharmacy, DPDO, CF and CHC, must ensure the environmental control, stability, and sterility of all preparations shipped. Therefore, any compounded preparation must be shipped or delivered to a patient or patient's agent in appropriate temperature-controlled delivery containers and stored appropriately according to USP <659> Packaging and Storage Requirements (04/01/2021). Information on appropriate storage must be provided to the patient or patient's agent.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

~~855-045-0240~~ **855-183-0400**
Labeling: ~~of~~ Compounded ~~Drugs~~ Non-Sterile Preparations (CNSPs)

Effective XX/XX/20XX:

In addition to the labeling requirements specified in **USP <795> (11/01/2022),** OAR 855-041, **OAR 855-043, and 855-139,** the label of a **CNSP** ~~compounded drug dispensed or distributed~~ must **prominently and legibly** contain the following, at a minimum:

~~(1) The generic or official name of each active ingredient;~~

(~~2~~**1**) The strength ~~or concentration~~ of each active ingredient~~, to include primary solution for a sterile parenteral preparation~~;

(~~3~~**2**) The ~~dosage form and~~ route of administration;

~~(4) Rate of infusion, for a sterile parenteral preparation;~~

~~(5) The total quantity of the drug product;~~

~~(6) A beyond-use date (BUD), compliant with standards required in OAR 855-045-0200(3); and~~

(3) Indication that the preparation is compounded.

(~~7~~**4**) Handling, storage or drug-specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.

(5) Compounding facility name and contact information if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

~~855-045-0240~~ **855-183-0410**
Labeling: ~~of~~ **Compounded** ~~Drugs~~ **Sterile Preparations (CSPs)**

Effective XX/XX/20XX:

In addition to the labeling requirements specified in **in USP <797> (11/01/2022),** OAR 855-041, **OAR 855-043 and 855-139,** the label of a **CSP** ~~compounded drug dispensed or distributed~~ must **prominently and legibly** contain the following, at a minimum:

~~(1) The generic or official name of each active ingredient;~~

(~~2~~**1**) The strength ~~or concentration~~ of each active ingredient, to include **the identity of the** ~~primary~~ **base** solution for a sterile parenteral preparation;

(~~3~~**2**) The ~~dosage form and~~ route of administration;

(~~4~~**3**) Rate of infusion **or titration parameters**, for a sterile parenteral preparation;

~~(5) The total quantity of the drug product;~~

~~(6) A beyond-use date (BUD), compliant with standards required in OAR 855-045-0200(3); and~~

(4) Indication that the preparation is compounded.

(~~7~~**5**) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.

(6) Compounding facility name and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

855-183-0420
Labeling: Batch Preparation

Effective XX/XX/20XX:

The label of a CNSP and CSP that is prepared in anticipation of a patient-specific prescription must contain the following:

(1) The name, strength or concentration, and quantity of each active ingredient used in the compounded drug preparation;

(2) The total quantity or volume of the compounded drug preparation;

(3) Internal lot number;

(4) The assigned beyond-use date (BUD);

(5) Indication that the preparation is compounded; and

(6) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary;

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

855-183-0450
Disposal

Effective XX/XX/20XX:

The Drug Outlet Pharmacy, DPDO, CF and CHC must ensure the disposal of hazardous pharmaceutical waste is in accordance with applicable state and federal laws and USP <800> Hazardous Drugs – Handling in Healthcare Settings (07/01/2020).

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

855-183-0500
Policies & Procedures

~~855-045-0220~~
~~Personnel and Responsibilities~~

Effective XX/XX/20XX:

~~(2) The Pharmacist-in-Charge (PIC) and the~~ **Each** ~~d~~**D**rug ~~o~~**O**utlet **Pharmacy, DPDO, CF and CHC** must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR **855-183-0200** ~~855-045-0200(3)~~ for all aspects of the compounding operation according to the type of compounding performed **(e.g., CNSP, CSP Type 1, 2 or 3)** and must include written procedures for:

(~~a~~**1**) Personnel qualifications, to include training~~, evaluation and requalification~~ **and ongoing competency assessment**;

(~~b~~**2**) Hand hygiene;

(~~c~~**3**) Garbing;

(~~d~~**4**) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;

(~~e~~**5**) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;

(~~f~~**6**) Components, to include selection, **receipt,** handling, ~~and~~ storage **and disposal**;

(~~g~~**7**) Creating master formulation records, with documented ~~pharmacist~~ approval **by a Pharmacist for a Drug Outlet Pharmacy or prescriber with prescribing and dispensing privileges for a DPDO, CF or CHC**;

(~~h~~**8**) Creating compounding records;

(~~i~~**9**) Establishing ~~beyond-use dates (~~BUDs~~)~~;

(10) Labeling;

(~~j~~**11**) Continuous quality assurance program and quality controls, to include**:**

(a) ~~r~~**R**elease testing, end-product evaluation, and quantitative/qualitative testing;

(b) Complaint handling process;

(c) Adverse event and error reporting process; and

(d) Recall procedure; and

(~~k~~**12**) Completed compounded preparations, to include handling, packaging, storage and transport**.**~~;~~

~~(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug.~~

NOTE: Consider adding 'The recall procedure must include notification to the board within 10 business days in the event of a patient-level recall of a compounded drug.' to (11)(d) if board does not send OAR 855-183-0520 to rulemaking.

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

855-183-0520
Recalls

Effective XX/XX/20XX:

(1) Each Drug Outlet Pharmacy, DPDO, CF and CHC that determines a recall is warranted must immediately issue a recall and immediately initiate communication with each recipient Drug Outlet, prescriber and patient receiving the recalled drug that was dispensed or intended for use in this state and document each attempt. Initial communication must be completed:

(a) Within 12 hours of the recall if use or exposure to the recalled compounded drug will cause serious adverse health consequences or death. If confirmation that the recipient received the communication cannot be established within this timeframe, the outlet must make two additional attempts to provide communication within 24 hours of the initial attempt.

(b) Within 36 hours of the recall if use or exposure to the recalled compounded drug might cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. If confirmation that the recipient received the communication cannot be established within this timeframe, the outlet must make two additional attempts to provide communication within 24 hours of the initial attempt.

(2) If the recalled drug is not likely to cause adverse health consequences, the recipient Drug Outlet, prescriber or patient receiving the recalled drug that was dispensed or intended for use in this state, must be notified within 72 hours of the recall and the outlet must document the notification.

(3) In the event that all attempts to inform the recipient are unsuccessful in (1), the outlet must send notification via certified mail.

(4) A Drug Outlet Pharmacy, DPDO, CF or CHC that has been advised that a patient has been harmed by using a compounded product potentially attributable to the outlet must report the event to MedWatch within 72 hours of the outlet being advised.

(5) The board must be notified of a recall in (1) on a form provided by the board within 10 business days of issuing the recall.

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

~~855-045-0270~~ **855-183-0550**
Records: General Requirements

Effective XX/XX/20XX:

~~(1) All records must be maintained in written or electronic format, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if then retrievable within three business days. Required records include, but are not limited to:~~
In addition to record-keeping and reporting requirements of OAR 855, the following records must be maintained:

(1) All dispensing of CNSP and CSPs.

(2) Any other records required to conform to and demonstrate compliance with USP standards and federal law.

(3) Required records include, but are not limited to:

(a) Standard operating procedures, including documented annual review;

(b) Personnel training according to the type of compounding performed, ~~including~~ competency assessment~~,~~ and qualification records, ~~including~~ **and** corrective actions for any failures~~, including gloved fingertip and thumb sampling test and aseptic manipulation validation~~. The ~~pharmacy~~ **outlet** must maintain a training record for each person, including temporary personnel, who compound preparations~~. At a minimum, the record must contain:~~

~~(A) Name and signature of the person receiving the training;~~

~~(B) Documentation of initial and continuing competency evaluation, to include dates and results of required elements outlined in the outlet's policies and procedures; and~~

~~(C) Name and signature of the pharmacist who is designated as responsible for validation of the completion of all training.~~

(c) Engineering and environmental control records, including equipment, calibration, certification, environmental air and surface monitoring procedures and results, as well as documentation of any corrective actions taken; and

(d) Cleaning**, sanitizing** and disinfecting of all compounding areas and equipment.

(e) Receipt, handling, storage and disposal of components;

(~~2~~**f**) Master formulation records **for all**~~, including as appropriate~~:

(A) CNSPs;

(B) CSPs prepared for more than one patient;

(C) CSPs prepared from a non-sterile ingredient;

(g) Compounding records for all:

(A) CNSPs;

(B) CSPs; and

(C) Immediate-use CSPs prepared for more than one patient; and

(h) Release testing, end-product evaluation and quantitative/qualitative testing.

(4) Information related to complaints and adverse events including corrective actions taken.

(5) Results of investigations including corrective actions taken and recalls.

~~(a) The name, strength and dosage form of the preparation;~~

~~(b) Physical description of the final preparation;~~

~~(c) Ingredient identities and amounts;~~

~~(d) Complete instructions for preparing the product, including equipment, supplies, and a description of the compounding steps;~~

~~(e) Calculations needed to determine and verify quantities of components and doses of ingredients;~~

~~(f) Compatibility and stability information, including references;~~

~~(g) Beyond-use date (BUD) assignment and storage requirements, including reference source;~~

~~(h) Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration;~~

~~(i) Quality control procedures and expected results; and~~

~~(j) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.~~

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

~~(l) Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used;~~

~~(m) Total quantity compounded;~~

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

~~(o) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;~~

~~(p) Records of dispensing or transfer of all compounded preparations; and~~

~~(q) Any other information required by the pharmacy's policies and procedures.~~

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

855-183-0560
Records: Master Formulation Records (MFR) for CNSP

Effective XX/XX/20XX:

In addition to the MFR requirements specified in USP <795> (11/01/2022), the MFR for a CNSP must contain the following, at a minimum:

(1) Appropriate calculations to determine and verify quantities and concentrations of components and strength or activity of the Active Pharmaceutical Ingredients (APIs);

(2) Compatibility and stability information, including USP or other available references;

(3) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate;

(4) Other information needed to describe the compounding process and ensure repeatability; and

(5) Any other information required by the outlet's policies and procedures.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

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

Effective XX/XX/20XX:

If a MFR is required for a CSP in USP <797> (11/01/2022), the MFR for a CSP must contain the requirements specified in the standard and the following, at a minimum:

(1) Appropriate calculations to determine and verify quantities and concentrations of components, and if performing non-sterile to sterile compounding the strength or activity of the APIs;

(2) Compatibility and stability information, including USP or other available references;

(3) Quality control procedures that include the expected results and limits of tolerability for quantitative results;

(4) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(5) Any other information required by the outlet's policies and procedures.
[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

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

~~855-045-0270~~
~~Records~~

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

Effective XX/XX/20XX:

In addition to the CR requirements specified in USP <795> (11/01/2022), the CR for a CNSP must contain the following, at a minimum:

(~~l~~**1**) Pharmacist **or prescriber with prescribing and dispensing privileges performance and** documented verification **that each of the following are correct:** ~~of compounded product accuracy including the correct~~

(a) ~~f~~**F**ormula~~;~~;

(b) ~~c~~**C**alculations **to determine and verify quantities and/or concentrations of components and strength or activity of each API;**~~;~~

(c) ~~q~~**Q**uantities ~~and the correct measurements and drugs used~~;

(d) Compounding technique; and

(e) Accurate preparation of the CNSP.

(~~m~~**2**) **Final yield** ~~Total quantity compounded~~;

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

(~~o~~**3**) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;

(~~p~~**4**) Records of dispensing or transfer of all compounded preparations; and

(~~q~~**5**) Any other information required by the ~~pharmacy~~ **outlet**'s policies and procedures.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

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

~~855-045-0270~~
~~Records~~

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

Effective XX/XX/20XX:

In addition to the CR requirements specified in USP <797> (11/01/2022), the CR for a CSP must contain the following, at a minimum:

(~~l~~**1**) Pharmacist **or prescriber with prescribing and dispensing privileges performance and** documented verification **that each of the following are correct:** ~~of compounded product accuracy including the correct~~

(a) ~~f~~**F**ormula~~;~~;

(b) ~~c~~**C**alculations **to determine and verify quantities and/or concentrations of components and strength or activity of each API;**~~;~~

(c) ~~q~~**Q**uantities ~~and the correct measurements and drugs used~~;

(d) Compounding technique; and

(e) Accurate preparation of the CNSP.

(~~m~~**2**) **Final yield** ~~Total quantity compounded~~;

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

(~~o~~**3**) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;

(~~p~~**4**) Records of dispensing or transfer of all compounded preparations; and

(~~q~~**5**) Any other information required by the ~~pharmacy~~ **outlet**'s policies and procedures.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

855-183-0600
Prohibited Practices

Effective XX/XX/20XX:

The following practices are prohibited in the compounding of a drug preparation:

(1) Carpet in compounding area; and

(2) Animals in the compounding area.

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

855-183-0700
Preparation According to FDA Labeling

Effective XX/XX/20XX:

Compounding does not include:

(1) Mixing, reconstituting, or other such acts that are performed in accordance with directions contained in FDA-approved labeling or supplemental materials provided by the product's manufacturer.
(2) Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's FDA-approved labeling when the:

(a) Product is prepared as a single dose for an individual patient; and

(b) Labeling includes information for the diluent, the resultant strength, the container closure system and BUD.

(3) Docking and activation of a proprietary bag and vial system in accordance with the FDA-approved labeling for immediate administration to an individual patient.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

855-183-0710
Service: Copies of an Approved Drug

Effective XX/XX/20XX:

A Drug Outlet Pharmacy, DPDO, CF, CHC or outsourcing facility may only compound a drug preparation that is essentially a copy of a FDA-approved drug if:

(1) The compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. The relevant change and the significant clinical difference produced for the patient must be indicated on the prescription.

(2) The FDA-approved drug is identified as currently in shortage on the:

(a) FDA drug shortages database published on the FDA website, www.accessdata.fda.gov/scripts/drugshortages/default.cfm; or

(b) American Society of Health-System Pharmacists (ASHP) shortages database published on the ASHP website, www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages.

(3) The Drug Outlet is unable to obtain the approved drug from a Wholesale Distributor Drug Outlet. Documentation of good faith effort must be retained by the Drug Outlet.

POLICY DISCUSSION: FDA Guidance Essential Copies

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

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

Effective XX/XX/20XX:

(1) This rule only applies to drugs compounded by a Drug Outlet Pharmacy intended for non-food producing animal use by licensed veterinarians.

(2) A Drug Outlet Pharmacy may compound drugs intended for non-food producing animal use:

(a) Based on a patient-specific prescription from a licensed veterinarian.

(b) For in-office use (e.g., office stock) by a licensed veterinarian, specifically for a single treatment episode, not to exceed 120-hour supply.

(3) The compounded preparations must not be distributed by an entity other than the Drug Outlet Pharmacy that compounded such veterinary drug preparations.

POLICY DISCUSSION: FDA Guidance Compounding Animal Drugs Section III-B.

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

~~855-045-0200~~
~~Application~~

~~(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for use or distribution in Oregon must register with the board as a drug outlet and comply with board regulations.~~

(2) These rules apply to sterile and non-sterile compounding of a drug.

(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:

(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (05/01/2020 v. 2014);

(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (05/01/2020 v. 2008);

(c) USP <800> Hazardous Drugs—Handling in Healthcare Settings (07/01/2020 v. 2020);

(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging (12/01/2020 v. 2020); and

(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2022), 1231 (12/01/2021), and 1821 (05/01/2017).

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

855-045-0210
Registration

(1) A non-resident drug outlet that distributes a non-patient specific compounded drug into Oregon must be registered with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.
(2) A resident drug outlet that distributes a non-patient specific human compounded drug within or outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.

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

855-045-0220
Personnel and Responsibilities

(1) All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties.

(2) The Pharmacist-in-Charge (PIC) and the drug outlet must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR 855-045-0200(3) for all aspects of the

~~compounding operation according to the type of compounding performed and must include written procedures for:~~

~~(a) Personnel qualifications, to include training, evaluation and requalification;~~
~~(b) Hand hygiene;~~

~~(c) Garbing;~~

~~(d) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;~~

~~(e) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;~~

~~(f) Components, to include selection, handling, and storage;~~

~~(g) Creating master formulation records, with documented pharmacist approval;~~

~~(h) Creating compounding records;~~

~~(i) Establishing beyond-use dates (BUDs);~~

~~(j) Continuous quality assurance program and quality controls, to include release testing, end-product evaluation, and quantitative/qualitative testing;~~

~~(k) Completed compounded preparations, to include handling, packaging, storage and transport;~~

~~(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug.~~

~~(3) The Pharmacist-in-Charge (PIC) must annually complete a self-inspection using the board's Compounding Self-Inspection Form by July 1 and retain for board inspection.~~

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

~~855-045-0240~~
~~Labeling of Compounded Drugs~~

~~In addition to the labeling requirements specified in OAR 855-041, the label of a compounded drug dispensed or distributed must contain the following, at a minimum:~~

~~(1) The generic or official name of each active ingredient;~~

~~(2) The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation;~~

(3) The dosage form and route of administration;

(4) Rate of infusion, for a sterile parenteral preparation;

(5) The total quantity of the drug product;

(6) A beyond-use date (BUD), compliant with standards required in OAR 855-045-0200(3); and

(7) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.

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

855-045-0270
Records

(1) All records must be maintained in written or electronic format, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if then retrievable within three business days. Required records include, but are not limited to:

(a) Standard operating procedures, including documented annual review;

(b) Personnel training according to the type of compounding performed, including competency assessment, and qualification records, including corrective actions for any failures, including gloved fingertip and thumb sampling test and aseptic manipulation validation. The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations. At a minimum, the record must contain:

(A) Name and signature of the person receiving the training;

(B) Documentation of initial and continuing competency evaluation, to include dates and results of required elements outlined in the outlet's policies and procedures; and

(C) Name and signature of the pharmacist who is designated as responsible for validation of the completion of all training.

(c) Engineering and environmental control records, including equipment, calibration, certification, environmental air and surface monitoring procedures and results, as well as documentation of any corrective actions taken; and

(d) Cleaning and disinfecting of all compounding areas and equipment.

(2) Master formulation records, including as appropriate:

(a) The name, strength and dosage form of the preparation;

~~(b) Physical description of the final preparation;~~

~~(c) Ingredient identities and amounts;~~

~~(d) Complete instructions for preparing the product, including equipment, supplies, and a description of the compounding steps;~~

~~(e) Calculations needed to determine and verify quantities of components and doses of ingredients;~~

~~(f) Compatibility and stability information, including references;~~

~~(g) Beyond-use date (BUD) assignment and storage requirements, including reference source;~~

~~(h) Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration;~~

~~(i) Quality control procedures and expected results; and~~

~~(j) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.~~

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

~~(l) Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used;~~

~~(m) Total quantity compounded;~~

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

~~(o) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;~~

~~(p) Records of dispensing or transfer of all compounded preparations; and~~

~~(q) Any other information required by the pharmacy's policies and procedures.~~

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

Oregon Board of Pharmacy
Board Member
Policy Topic Ranking Survey Results

jJUNE 2024 / #D

6 Board Members Participated

Scale: 1= Top Priority

Survey Dates: 5/23/2024 – 6/9/2024

Policy Topic	Overall Average	Overall Rank
Drug Storage	2.83	1
Clinical Pharmacy Agreements / Collaborative Drug Therapy Management	5.33	2
Applicability of Pharmacist Rules	5.83	3
Safe Pharmacy Practice Conditions	6.33	4
Drug Distribution Agent (DDA/3PL)	6.50	5
Manufacturers	6.83	6
Non-Prescription Drug Outlets (NPDO)	7.00	7
Telework	7.17	8
Outlet Requirements for Pharmacist-in-Charge	7.50	9
Wholesalers	8.67	10
Inspections for Non-Resident Pharmacies	8.83	11
Pharmacies	9.00	12

INSTRUCTIONS: Please review the following policy topics related to pharmacy practice and regulations. For each topic, rank them from highest priority to lowest priority based on your judgment of their importance for board discussion in the next year.

Note: The Drug Supply Chain Security Act (DSCSA) creates a nationwide standard for tracking and tracing prescription drugs throughout the supply chain. This means a shift from potentially varied state regulations to a single federal system. To ensure drug outlets within their jurisdiction are following the DSCSA, the Oregon Board of Pharmacy may need to amend its regulations in a few key ways:
- Incorporating DSCSA Requirements: The board's regulations need to reflect the specific requirements of the DSCSA for outlets (trading partners), such as verification of trading partners, product verification with unique identifiers, and recordkeeping of drug transactions.
- Enforcement Mechanisms: The board may need to establish procedures for investigating and enforcing violations of the DSCSA within outlets. This could involve outlining penalties or disciplinary actions.
- Alignment with Federal Regulations: The board's regulations should be consistent with the U.S. Food and Drug Administration's (FDA) guidance on the DSCSA.
This ensures a smooth implementation and avoids confusion for outlets By amending regulations, the Oregon Board of Pharmacy can ensure outlets within the state are following the DSCSA and contributing to a safer and more secure drug supply chain for

Survey Dates 5/23/2024-6/9/2024, Scale 1= Top Priority

TOPIC	RANK	RANK	RANK	RANK	RANK	RANK	AVERAGE
Applicability of Pharmacist Rules: OAR 855-115-0001 This topic will address when a pharmacist is located outside of Oregon requires licensure to practice for patients in the state. Source: Ongoing discussions 6/2022 to 06/2023, sent to rulemaking 7/2023, decided not to adopt proposed rules and revised rule, sent to rulemaking 9/2023, decided not to adopt proposed rules at 10/2023 meeting and revised rule, sent to rulemaking 11/2023, decided not to adopt proposed rules at 12/2023 meeting and revised rule, sent to rulemaking 1/2024, adopted rule 2/2024 and requested future discussion of rule during 2/2024 board meeting.	4	3	4	11	10	3	**5.83**
Clinical Pharmacy Agreements / Collaborative Drug Therapy Management: ORS 689.005(3) and OAR 855-115-0315 This topic will address the requirements for a pharmacist when participating in a Clinical Pharmacy Agreement and Collaborative Drug Therapy Management.Source: Discussed at 12/2022 board meeting, board requested a workgroup at 2/2023 board meeting, workgroup met 5/2023, board reviewed proposed rules at 10/2023 meeting, sent to rulemaking 11/2023, decided not to adopt proposed rules at 12/2023 meeting and revised rule to match language in 855-019-0260, sent to rulemaking 1/2024, adopted language from 855-019-0260 and requested future discussion of rules during 2/2024 board meeting.	7	2	13	2	7	1	**5.33**
Drug Distribution Agents (DDA): OAR 855-062 This topic will focus on pharmacy regulations related to drug distribution agents (including third-party logistics providers or 3PLs) and incorporate necessary changes as current rules were last revised in 2009 and 2015. Source: Strategic Plan "Update rules for non-pharmacy Registrants: manufacturers, wholesalers, outsourcing facilities, third-party logistics providers, drug distribution agents and non-prescription drug outlets, to address changes in federal regulations.", DSCSA	12	7	7	5	4	4	**6.50**
Drug Storage: OAR 855-041-1036 This topic will focus on regulations for safe and secure storage of medications within Oregon by all registrants. Source: Board requested future discussion during 2/2024 board meeting	1	1	2	3	8	2	**2.83**
Inspections for Non-Resident Pharmacies: This topic will focus on pharmacy regulations that clarify the standards for inspections conducted by third parties (e.g., other boards, NABP, etc) on out-of-state pharmacies. Source: Board requested future discussion during 12/2023 board meeting	6	13	1	13	13	7	**8.83**
Manufacturers: OAR 855-060 This topic will focus on pharmacy regulations related to manufacturers and incorporate necessary changes as current rules were last last revised in 1980, 1994, 2006 and 2015. Source: Strategic Plan "Update rules for non-pharmacy Registrants: manufacturers, wholesalers, outsourcing facilities, third-party logistics providers, drug distribution agents and non-prescription drug outlets, to address changes in federal regulations.", DSCSA	11	8	6	6	2	8	**6.83**
Non-Prescription Drug Outlet (NPDO): OAR 855-035 This topic will focus on pharmacy regulations related to non-prescription drug outlets and incorporate necessary changes as current rules were last revised in 1992, 1996, 2002, and 2008. Currently OAR 855-035 also contains rules for Medical Device, Equipment and Gas outlets. Source: Strategic Plan "Update rules for non-pharmacy Registrants: manufacturers, wholesalers, outsourcing facilities, third-party logistics providers, drug distribution agents and non-prescription drug outlets, to address changes in federal regulations.", DSCSA	9	9	10	4	5	5	**7.00**
Outlet Requirements for Pharmacist-in-Charge: OAR 855-041-1060 and OAR 855-041-1010 This topic will explore current differences in PIC requirements for in-state vs. out-of-state pharmacies including gaps in PIC coverage. Source: Board requested at 2/2022 board meeting, discussed 8/2022, proposed rules 12/2023 not adopted and requested future discussion.	8	4	3	10	11	9	**7.50**
Outsourcing Facilities (503b): OAR 855-060 This topic will focus on pharmacy regulations related to outsourcing facilities and incorporate necessary changes as current rules for 503b's are located in the same division as manufacturers and thus were last revised in 2006, 2009, 2015, 2017, and 2022. Source: Strategic Plan "Update rules for non-pharmacy Registrants: manufacturers, wholesalers, outsourcing facilities, third-party logistics providers, drug distribution agents and non-prescription drug outlets, to address changes in federal regulations.", DSCSA	13	10	8	8	6	10	**9.17**
Pharmacies: OAR 855-041 This topic will focus on all pharmacy outlet regulations and work to separate rules for retail pharmacies (RP) and institutional pharmacies (IP), including clarifying rules for nuclear, charitable pharmacies, home dialysis and long term care pharmacies. Source: Strategic Plan "Amend existing rules for pharmacy Registrants to clarify categories and operating standards, support safe and equitable access, and avoid unnecessary administrative effort.", DSCSA	5	11	11	7	9	11	**9.00**
Safe Pharmacy Practice Conditions: This topic will focus on ensuring safe and effective medication practices within Oregon pharmacies which may include but is not limited to rules related to improving patient safety through ensuring conditions that promote patient care such as staffing, meal breaks, and autonomy in decision-making. Source: Board requested at 12/2023 board meeting, discussed 4/2024 meeting and requested future discussion.	2	5	12	1	12	6	**6.33**
Telework- Supervision: OAR 855-041-3220 This topic will focus on pharmacy regulations related to the % of interactions that must be reviewed by the supervising pharmacist when an Intern, COPT/PT is practicing or assisting in the practice of pharmacy from a location physically located outside of a registered drug outlet. Source: Board requested future discussion during 4/2022 board meeting	3	6	9	12	1	12	**7.17**
Wholesalers: OAR 855-065 This topic will focus on pharmacy regulations related to wholesalers and incorporate necessary changes as current rules were last revised in 2006, 2009, 2015, 2017, and 2022. Source: Strategic Plan "Update rules for non-pharmacy Registrants: manufacturers, wholesalers, outsourcing facilities, third-party logistics providers, drug distribution agents and non-prescription drug outlets, to address changes in federal regulations.", DSCSA	10	12	5	9	3	13	**8.67**
NAME OF RESPONDENT	Jennifer Hall	Kathleen Chinn	Priyal Patel	Ian Doyle	Rachael DeBarmore	Shannon Beaman	

OREGON STATE PHARMACY ASSOCIATION
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April 30, 2024

Dear Executive Director Fox and Members of the Oregon State Board of Pharmacy,

The thoughtful review of rules and engagement with the members of the public, licensees, and registrants is an integral part of the regulatory process. It is with this in mind that OSPA requests the board to review all the rules for Remote Dispensing Site Pharmacies (RDSP) in OAR Chapter 855, Division 139.

As the landscape of community pharmacy continues to rapidly change due to a number of post-pandemic issues, including reimbursement pressures[1] and declining enrollments in schools of pharmacy[2,] the ability to consistently and easily access pharmacy services is becoming more difficult, especially in physically distant or difficult-to-reach locations. Community pharmacies are struggling to remain viable in the wake of these changes, resulting in closures or reduced operating hours. In 2023 at least 36 pharmacies closed in the state of Oregon. As pharmacies close or reduce operating hours, more demand is put on the remaining available pharmacies to serve the patients affected. Telepharmacy technology at an RDSP can help alleviate the pressure on local pharmacies by improving access to pharmaceutical care during the evenings, overnights, and weekends. The use of telepharmacy sites will also increase ready access for patients who may be located in a pharmacy desert. However, at this time, only 1 RDSP license has been issued (License #RDSP0001) in Oregon, and we believe that significant regulatory barriers are limiting broader use and implementation across the state.

OSPA thanks the board for the discussion during the April meeting on the current RDSP rules related to mileage. However, in addition to reviewing the RDSP rules for mileage limitations, OSPA believes the full rules must be reviewed. We also ask the board to review the 2022 Oregon House Bill 4034 (HB 4034), which amends ORS 689.700. HB 4034, Section 19 (2), specifically states that **"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."** OSPA believes that many of the rules, as highlighted below, are overreaching and do not meet the legislative intent of HB 4034. Specifically, the prohibition of interns in an RDSP, the recording and storing of all patient interactions, and the consultation requirements. Of note, the audio recordings and storage requirements are also in possible conflict with state privacy law and pose a significant risk to the protection of patient records and patient's expectation of privacy regarding their health information, particularly as we continue to see cyber threats and attacks on healthcare institutions nationwide.

OSPA formally petitions the board to review all sections of OAR Chapter 855, Division 139, to ensure it meets the legislative intent of HB 4034 and poses no further conflict with current OBOP rules or state statutes. We request that the board engage with the public to ensure that the rules continue to protect patient safety and privacy while also remaining viable and practical to implement.

855-139-0050 Personnel

OSPA is unsure why the board believes a RDSP cannot utilize a licensed pharmacy intern. Appropriately trained intern employees should be allowed to work alongside licensed technicians at an RDSP site. Prohibiting licensed interns from working at an RDSP unnecessarily limits the experiences an intern could gain through different practice sites. It limits their choice for employment while working as an intern. An intern working at an RDSP poses no greater safety concerns than a technician working at the same site, and it is up to the supervising

pharmacist's professional judgment and discretion to determine the role an intern would have at an RDSP. Additionally, if the board wishes to update their rules to allow an intern to work at an RDSP, adjustments are also needed to OAR 855-139-0315, 855-139-0005, 855-139-0010, 855-139-0100, 855-139-0150, 855-139-0200, 855-139-0210 855-139-0220, 855-139-0355, 855-139-0360, 855-139-0455, 855-139-0500, 855-139-0600, 855-139-0602, 855-139-0715, and 855-139-0730.

855-139-0050 - Personnel

(1) The Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy is responsible for all operations at the RDSP including responsibility for the telepharmacy system and enforcing policies and procedures.

(2) ~~A RDSP may not utilize Interns.~~ Unlicensed personnel may not perform any pharmacy services.

855-139-0100 Security

The current rules for pharmacy outlets in Oregon already contain the necessary elements for ensuring no unauthorized access to a pharmacy and sufficient record-keeping requirements for the work performed by pharmacy personnel. We believe maintaining an additional record of the names and license numbers of each person entering the pharmacy is an additional administrative barrier and does not meet the legislative intent of HB 4034. Records maintained such as the schedule of employees, audit trails of work performed, and continuous video recording are sufficient for the security of the pharmacy department, regardless of whether it is at an RDSP or a traditional pharmacy site.

855-139-0100 Security

~~(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.~~

855-139-0200 Outlet: General Requirements

Recently, the National Association of Boards of Pharmacy (NABP) published a report from the task force on Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing, and Telepharmacy. The report from this task force concluded that "mileage requirements dictating the distance between a primary pharmacy and its satellite locations is arbitrary and not helpful."[3] OSPA also believes that the limit of 120 miles is arbitrary and does not help maintain patient safety. This limitation also reduces the likelihood an outlet would utilize telepharmacy sites across the state, especially in remote areas where access to pharmaceutical care is needed most. Additionally, if a supervising pharmacy has policies and procedures to respond to an emergency and ensure that pharmacy operations do not continue without appropriate supervision at the RDSP, the location of the supervising pharmacy should not matter. We recommend consideration of the supervising pharmacy being located in Oregon.

855-139-0200 - Outlet: General Requirements

(1) A RDSP Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.

(2) ~~A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.~~

855-139-0210 Outlet: Supervision

Supervision using a telepharmacy communication system is paramount to ensuring patient safety at an RDSP. However, OSPA contends that the requirement to record, review, and store all patient interactions goes beyond the legislative intent of HB 4034 and does not increase patient safety. No other states have rules that

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require the recording of audio for any components of the telepharmacy systems. The storage of the audio for patient interactions poses a threat to patient privacy and is onerous and costly to implement. When reviewing the impact of the telepharmacy rules, the legislature was clear that it does not want arbitrary and burdensome restrictions that would impede the use of this type of site. A telepharmacy site should not have more restrictions or regulations than a traditional community pharmacy site, and the recording and storage of audio are clearly more restrictive than the rules governing a traditional pharmacy site.

OSPA believes these rules may also conflict with Oregon privacy laws. Communications regarding protected health information in a pharmacy are confidential and subject to a reasonable expectation of privacy; thus, pharmacies cannot require patients to consent to voice recording. Furthermore, video with audio recordings is also often prohibited in healthcare treatment contexts due to the sensitive nature of consultations and services provided. The potential conflicts with ORS 689.700 and ORS 165.540 pose barriers for outlets to explore using telepharmacy to expand patient access. OSPA believes that requiring the storage and review of audio recordings and obtaining patient consent for the recordings would dissuade many patients from using the services of a telepharmacy.

Just like a traditional pharmacy setting maintains video recordings of activity in the pharmacy, diversion can be sufficiently monitored by the perpetual inventory, remote video supervision, and monthly supervision visits as required. Audio recordings do not promote or improve patient safety and are an example of overreaching rules that negatively impact patients.

855-139-0210 Outlet: Supervision

A RDSP and its RDSP Affiliated Pharmacy must:

(1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the **Oregon licensed intern,** Certified Oregon Pharmacy Technician or Pharmacy Technician, and the **audio and visual telepharmacy communication and continuous video** surveillance system is fully operational;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each **Oregon licensed intern,** Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP using an audiovisual communication system. ~~All patient interactions must be recorded, reviewed and stored;~~

(3) The Oregon licensed Pharmacist who is supervising the **Oregon licensed intern,** Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:

~~(a) Using reasonable professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;~~

~~(b) 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;~~

~~(c) Document the following within 24 hours of the review in (3)(b):~~

~~(A) Number of each licensee's patient interactions;~~

~~(B) Number of each licensee's patient interactions Pharmacist is reviewing;~~

~~(C) Date and time of licensee patient interaction Pharmacist is reviewing;~~

~~(D) Date and time of Pharmacist review of licensee's patient interaction; and~~

~~(E) Pharmacist notes of each interaction reviewed; and~~

(a) ~~(d)~~ Report any violation of OAR 855 ~~to the RDSP Affiliated Pharmacy within 24 hours of discovery and~~ to the board within 10 days.

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~~(4) The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.~~
~~(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician or Pharmacy Technician.~~

855-139-0215 Outlet: Pharmacist Utilization

OSPA asks the board to update the RDPS rules to reflect the changes that recently occurred to the patient consultation rules and the role of other licensed personnel in accepting the declination of a consult. While reflecting the changes to the counseling rules, the current rule continues to limit the scope of an intern's role at the RDSP. We ask the board to discuss allowing interns to provide consultations, but only when their work is validated and supervised by a pharmacist.

855-139-0215 Outlet: Pharmacist Utilization
A RDSP and its RDSP Affiliated Pharmacy must:
(1) Utilize an Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy to perform the professional tasks of interpretation, evaluation, DUR, verification, and counseling before the prescription is dispensed; and
(2) Utilize an Oregon licensed Pharmacist and an audiovisual communication system to provide counseling ~~or accept the refusal of counseling from the patient or the patient's agent~~ for each prescription being dispensed when counseling is required under OAR 855-115-0145 and when requested and document the interaction.

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

Sincerely,
Brian Mayo
Executive Director

1. CNN Business. "CVS, Walgreens and Rite Aid are closing thousands of stores. Here's why", *https://www.cnn.com/2023/10/16/business/drug-stores-closing-rite-aid-cvs-walgreens/index.html* (Accessed 30 November 2023)
2. America Associate of Colleges of Pharmacy. "Academic Pharmacy's Vital Statistics" https://www.aacp.org/article/academic-pharmacys-vital-tatistics# Accessed (30 November 2023)
3. *NABP* (2024) *National Association of Boards of Pharmacy*. Available at: https://nabp.pharmacy/wp-content/uploads/2024/02/Report-of-the-Task-Force-on-shared-Pharmacy-Services-Automated-Pharmacy-Systems-Remote-Dispensing-Sites-and-Telepharmacy.pdf (Accessed: 27 March 2024).

05.23.2024

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

Executive Director Fox and Distinguished Members of the Board,

We want to thank the Board for taking the time to review these current rules to ensure Oregon patients are confident they receive high quality and safe care from their local pharmacy without the Board creating unnecessary barriers that do not contribute meaningfully to the Board's mission or goal of the rule.

Today we would like to submit written comments that while the Board consider the current petition to amend rules:

- **OAR 855-139-0050(2)**
- **OAR 855-139-0100(4)**
- **OAR 855-139-0200(2)**
- **OAR 855-139-0210(1)(2)(3)(4)(5), and**
- **OAR 855-139-0215(2)**

the Board should also expand their review to include:

- **OAR 855-041-3220 Telework: Supervision Requirements**

The tasks performed by technicians through a Remote Dispensing Site Pharmacy (RDSP) often overlap with the tasks completed via telework, and in both cases that work is supervised by an Oregon licensed Pharmacist using an audio and visual communication system. We believe that these rules should remain consistent to simplify licensees' ability to comply and meet the intent of these rules. Specifically rule 855-041-3220(2) regarding the audio recording and storage of all patient interactions completed by Interns, Certified Oregon Technicians, and Pharmacy Technicians; as well as rule 855-041-3220(6)(a),(b),(c) related the review and documentation of a minimum of 5% of patient interactions within 48 hours of the interaction.

Recommendations:

If the board decides to amend **OAR 855-139-0210 Outlet: Supervision** as requested due to the potential negative impact on businesses or the unnecessary barriers created, then we believe the same language update will need to be made to **OAR 855-041-3220 Telework: Supervision Requirements** to provide consistency for licensees.

We want to thank the Board and staff for their tireless dedication to continuous improvement and to the Oregonians they serve.

Melissa J. Hansen, PharmD. (she/her)
Specialty Pharmacy Program Director, Ardon Health
office 855.425.4085 **cell** 206.799.1483 | ardonhealth.com

From: Melissa Hansen
To: PHARMACY RULEMAKING * BOP
Cc: Valerie Ott; Heather Chapman
Subject: Invitation for Public Comment - Telepharmacy
Date: Friday, May 24, 2024 3:01:28 PM
Attachments: image002.png
855-041-3220 OR BOP Public Comment.pdf

Please see the attached comments in relation to the petition to amend OAR 855-139-0050 thru OAR 855-139-0215 received by the Oregon Board of Pharmacy on 4/30/2024.

If the Board or staff have any additional questions please don't hesitate to reach out.

I hope you have a wonderful Memorial Day weekend!

Thank you!

Melissa J. Hansen, PharmD. (she/her)
Specialty Pharmacy Program Director, Ardon Health
office 855.425.4085 **cell** 206.799.1483 | ardonhealth.com

Inspiring people and improving lives

05/19/2024

Oregon Board of Pharmacy

800 NE Oregon St

Portland, OR 97232

To Whom It May Concern:

This letter is being submitted in response to the invitation for public comment about the petition for amending rules for Remote Dispensing Site Pharmacies. I am the owner of Irby Pharmacy, Oregon's first and currently only telepharmacy or RDPS. I am a 3rd generation pharmacist and pharmacy owner. The items listed in the notice for invitation for public comment reflect proposed amendment items that I had submitted to the Board within the past couple of years. I will address the items within the recent notice for invitation for public comment individually.

1) OAR 855-139-0050(2)

   Petitioner's proposed amendment:

   (2) ~~A RDSP may not utilize Interns.~~ Unlicensed personnel may not perform any pharmacy services.

   Comment: I feel that forbidding the use of interns at a RDSP is highly unusual. In practice, an intern is a licensee that is under the supervision of the pharmacist much in the same way that a technician is. While we have yet to try to utilize an intern in our practice (in compliance with current rules), we have been brainstorming on ways to utilize an intern in the practice of telepharmacy: having an intern review Rx's remotely through the telepharmacy system, overseeing the surveillance monitoring, and remote counseling. One other function that would be helpful for the intern's training and education is for the intern to assist in the monthly inspection by a pharmacist from the affiliated pharmacy. The way the current rules are written, it could be argued that an intern would not be able to do this since "a RDSP may not utilize interns". I feel that an intern on location at the RDSP would be under the supervision of the pharmacist from the Affiliated Pharmacy the same way a technician at the RDSP is. In my opinion, the current rule is more restrictive than rules for Retail Drug Outlets in Oregon.

2) OAR 855-139-0100(4)

   Petitioner's proposed amendment:

   ~~(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.~~

   Comment: While we at Irby Pharmacy are in compliance with this rule, we have felt from the beginning that this is a redundancy that is unnecessary. There already exist tools and processes that record a licensee's presence and functions performed within the restricted area of the pharmacy. Almost all of said tools are automated due to the nature of the existing technological

requirements. The nature of the required procedures record other functions performed that are not recorded by the technology. In my opinion, the current rule is more restrictive that rules for Retail Drug Outlets in Oregon.

3) OAR 855-139-0200(2)

Petitioner's proposed amendment:

~~(2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.~~

Comment: I have mixed feelings regarding the rule restricting the distance between a RDSP and the Affiliated Pharmacy. I do feel it would be helpful to not restrict the distance between the two pharmacies if both pharmacies are located within the state of Oregon. It is my opinion that there should be a distance restriction between the two pharmacies should the Affiliated Pharmacy be located outside the state of Oregon. I do not feel that it would be appropriate for a pharmacy located in Florida to be supervising a pharmacy in Oregon.

4) OAR 855-139-0210(1)(2)(3)(4)(5)

Petitioner's proposed amendments:

(1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the **Oregon licensed intern**, Certified Oregon Pharmacy Technician or Pharmacy Technician, and the **audio and visual telepharmacy communication and continuous video** surveillance system is fully operational;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each **Oregon licensed intern**, Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP using an audiovisual communication system. ~~All patient interactions must be recorded, reviewed and stored~~;

(3) The Oregon licensed Pharmacist who is supervising the **Oregon licensed intern**, Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:

~~(a) Using reasonable professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;~~

~~(b) 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;~~

~~(c) Document the following within 24 hours of the review in (3)(b):~~

~~(A) Number of each licensee's patient interactions;~~

~~(B) Number of each licensee's patient interactions Pharmacist is reviewing;~~

~~(C) Date and time of licensee patient interaction Pharmacist is reviewing;~~

~~(D) Date and time of Pharmacist review of licensee's patient interaction; and~~

~~(E) Pharmacist notes of each interaction reviewed; and~~

(a) ~~(d)~~ Report any violation of OAR 855 ~~to the RDSP Affiliated Pharmacy within 24 hours of discovery and~~ to the board within 10 days.

~~(4) The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.~~

~~(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician or Pharmacy Technician.~~

Comment: I find that the recording, storing, and reviewing of all patient interactions a burdensome and unrealistic requirement. Nothing close to this is required of Retail Drug Outlets in Oregon. The functions of licensees are already supervised in real time by the pharmacist from the Affiliated Pharmacy in the same manner that licensees at a Retail Drug Outlet are supervised. Even though a pharmacist in a Retail Drug Outlet setting is not privy to every single patient interaction in its entirety, should a problem or question arise, the pharmacist is made aware of it by a licensee, a patient or caregiver, or another healthcare professional (such as a representative from a prescriber's office). I have found the same process occurring in the setting/coworking relationship of a RDSP and the pharmacist from the Affiliated Pharmacy.

None of the 5 closest states to Oregon even require continuous surveillance in a telepharmacy setting. In addition, I have found that none of the 27 states in the union that have rules for the practice of telepharmacy require retention of data recordings for 6 months other than Oregon. More than half of these states have no requirement of retaining data. The ones that do seem to require an average of 30-60 days. Idaho, which has a history of rules governing the practice telepharmacy since at least 2016 actually reduced their requirement of retaining data from 90 days to 30 days a couple of years ago. This board recognized that the longer retention was not needed as it was costly for licensees to implement and maintain, and it did not directly impact safety or security standards.

I have not found a requirement for retaining data at all for Retail Drug Outlets in Oregon. In my opinion, the current rule is more restrictive than rules for Retail Drug Outlets in Oregon.

5) OAR 855-139-0215(2)

Petitioner's proposed amendment:

(2) Utilize an Oregon licensed Pharmacist and an audiovisual communication system to provide counseling ~~or accept the refusal of counseling from the patient or the patient's agent~~ for each prescription being dispensed when counseling is required under OAR 855-115-0145 and when requested and document the interaction.

Comment: I feel this amendment is appropriate considering the new rules for licensees allowing them to accept a declination of counseling. The current rule is more restrictive than rules for Retail Drug Outlets in Oregon.

When Irby Pharmacy was being licensed, a comment was made by Board of Pharmacy staff that an entity that was very interested in the Board creating rules for telepharmacy never applied for a license

once the rules were in place. Its possible that the existing rules may be perceived as being too prohibitive for most parties to apply for licensure for a RDSP. I do feel that if the proposed amendments are seriously considered, Oregon could possibly and realistically have pharmacy services provided to ever expanding underserved areas of the state.

Thank you for your attention and the opportunity to comment on the matter,

Wade Irby, RPh, PIC

Irby Pharmacy

Beaverton Pharmacy

From:	PAT Hubbell
To:	PHARMACY RULEMAKING * BOP
Subject:	Public comment from Brooklyn Pharmacy
Date:	Monday, May 20, 2024 7:06:30 AM
Attachments:	Outlook-pzbtecyf.png

Proposed Amendments

OAR 855-139-0050(2)

Petitioner's proposed amendment:

(2) ~~A RDSP may not utilize Interns.~~ Unlicensed personnel may not perform any pharmacy services. **Agreed**

OAR 855-139-0100(4)

Petitioner's proposed amendment:

~~(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.~~ **AGREED**

OAR 855-139-0200(2)

Petitioner's proposed amendment:

~~(2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.~~ **AGREED**

OAR 855-139-0210(1)(2)(3)(4)(5)

Petitioner's proposed amendments:

(1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the **Oregon licensed intern**, Certified Oregon Pharmacy Technician or Pharmacy Technician, and the **audio and visual telepharmacy communication and continuous video** surveillance system is fully operational;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each **Oregon licensed intern**, Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP using an audiovisual communication system. ~~All patient interactions must be recorded, reviewed and stored~~;"**DIRECTS AND CONTROLS "IS TOO RESTRICTIVE. SUPERVISES**

IS SUFFICIENT AND APPROPRIATE

(3) The Oregon licensed Pharmacist who is supervising the **Oregon licensed intern**, Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:

~~(a) Using reasonable professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;~~

~~(b) 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;~~

~~(c) Document the following within 24 hours of the review in (3)(b):~~

~~(A) Number of each licensee's patient interactions;~~

~~(B) Number of each licensee's patient interactions Pharmacist is reviewing;~~

~~(C) Date and time of licensee patient interaction Pharmacist is reviewing;~~

~~(D) Date and time of Pharmacist review of licensee's patient interaction; and~~

~~(E) Pharmacist notes of each interaction reviewed; and~~

(a) ~~(d)~~ Report any violation of OAR 855 ~~to the RDSP Affiliated Pharmacy within 24 hours of discovery and~~ to the board within 10 days. **DUPLICATIVE FOR ANY RETAIL SETTING**

~~(4) The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.~~

~~(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician or Pharmacy Technician.~~

OAR 855-139-0215(2)

Petitioner's proposed amendment:

(2) Utilize an Oregon licensed Pharmacist and an audiovisual communication system to provide counseling ~~or accept the refusal of counseling from the patient or the patient's agent~~ for ***each prescription*** being dispensed when counseling is required under OAR 855-115-0145 and when requested and document the interaction.

FOR EACH "NEW "PRESCRIPTION, REFILLS SHOULD NOT REQUIRE COUNSELING

PATIENT ALWAYS HAS THE RIGHT TO REFUSE COUNSELING

If you have any questions, please reach out to the Agency Rules Coordinator, Rachel Melvin at pharmacy.rulemaking@bop.oregon.gov

Pat Hubbell, RPh/Owner
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Portland, OR 97202
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NPI 1114968815
NCPDP 3803409

BROOKLYN
PHARMACY

CVSHealth

Mark Johnston, R.Ph
Executive Director, Pharmacy Advocacy and Regulatory Affairs
One CVS Drive
Woonsocket, RI 02895
401-601-1968
Mark.Johnston@cvshealth.com

5/24/24

Oregon Board of Pharmacy,

CVS Health is in support of the Oregon State Pharmacy Association's (OSPA) Petition to Promulgate, Amend, or Repeal Rule, dated 4/30/24. Although the Oregon State Board of Pharmacy's (Board) Notice for Invitation of Public Comment only lists OAR 855-139-0050(2), OAR 855-139-0100(4), OAR 855-139-0200(2), OAR 855-139-0210(1)(2)(3)(4)(5), and OAR 855-139-0215(2), CVS notes that OSPA's Petition also includes OAR 855-139-0315, 855-139-0005, 855-139-0010, 855-139-0100, 855-139-0150, 855-139-0200, 855-139-0210 855-139-0220, 855-139-0355, 855-139-0360, 855-139-0455, 855-139-0500, 855-139-0600, 855- 139-0602, 855-139-0715, and 855-139-0730. Therefore, we suggest that the entire Division 139 be opened for potential promulgation that amends or repeals.

As OSPA's Petition and CVS Health's 5/22/24 comment letter notes: HB 4034, Section 19 (2), specifically states: 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. As a result of the Board's decision to promulgate 48 separate rules, some of which are arguably not in harmony with HB 4034, it is our understanding that only one Remote Dispensing Site Pharmacy (RDSP) has opened within the State of Oregon, as opposed to the many telepharmacies that are successfully servicing patients in your boarder states of Idaho and Washington, who each regulate the practice of telepharmacy via one short rule.

If the Board chooses to approve OSPA's petition, CVS Health requests that the Board revise Division 139 to specifically allow for a licensed pharmacy to act as a RDSP at certain times, such as nights, weekends, holidays and emergency situations such as those experienced during the pandemic. Other Boards of Pharmacy, including AZ, ID, IL, and WA, have realized that such an allowance may retain or even expand the hours that patients in certain communities may access pharmaceutical care. This could be especially impactful, as pharmacy school enrollment and graduation rates plummet, as OSPA points out in their petition and as we heard during a presentation at our 2023 National Association of Boards of Pharmacy District VII meeting. Current Division 139 does not appear to contemplate this concept.

In summary, there is a need for a parsed down version of Division 139, so that telepharmacies may service Oregon residents, but current Division 139 is much too complex. Current Division 139 conflicts with much shorter and successful telepharmacy rules in neighboring states, whose rules arguably achieve Division 139 and HB 4034's substantive goals while reducing the negative economic impact on businesses, while current Division 139 establishes barriers to entry. Therefore, CVS Health supports OSPA's petition and requests the opening for of the entire Division 139 for potential promulgation.

Sincerely,

CVSHealth

Mark Johnston, R.Ph

Senior Director

Pharmacy Regulatory Affairs

From: jason melander
To: PHARMACY RULEMAKING * BOP
Subject: Proposed telepharmacy rules
Date: Tuesday, May 21, 2024 9:23:02 AM

To who it may concern,

I have serious concerns about the proposed telepharmacy rules to allow more remote dispensing and less supervision of technicians.

I'm unclear how giving more responsibility and less supervision to technicians promotes patient safety. Loosening the rules to allow more techs to not require onsite supervision when dispensing drugs is only to save corporations money. This is not intended to help patients. Pharmacy school enrollment and staffing is more challenging because people can't work under the current conditions in retail pharmacies.

We can barely keep qualified technicians hired in adequate numbers to meet demand and they do not have the knowledge or expertise to dispense medication. They leave for better positions as soon as they are available. Only a pharmacist sees working in a pharmacy as a career. I have had to correct many errors and caution techs not to exceed their license scope many times. I'm not clear how that could be done remotely when the rph is monitoring from afar. Pharmacies should have a pharmacist on site period. Someone there should know what the medication does. A technician can't help a patient trouble shoot how to set up an inhaler or insulin pen. Some patients need this in person help because they don't have the physical dexterity to do these taks. This is necessary for safety.

Interns should be learning from a preceptor. Having an intern in the pharmacy with no pharmacist is just corporate pharmacy trying to have someone consult with no pharmacist present. How can an intern learn to be a pharmacist when their preceptor can't monitor and teach? This cannot be done adequately remotely. Interns deserve a good education!

There are plenty of pharmacists in Oregon who want to work. They won't work in understaffed and unsafe pharmacies. Do not loosen the rules to allow more remote dispensing. These proposed rule changes are simply to save corporations money. Not increase patient access.

-Jason Melander

(Also one of the links in your email sends this response to the department of education)

From: Eli Dailey
To: PHARMACY RULEMAKING * BOP
Subject: Public Comment Re: RDSP Mileage Limitation OAR 855-139-0200(2)
Date: Sunday, May 26, 2024 9:24:49 AM

Dear members of the Oregon Board of Pharmacy,

Managed Healthcare Pharmacy (Eugene) and our recently opened second pharmacy, MHP Medford, appreciate and support the board's discussion from the 4/12/2024 Board Meeting open-session regarding either increasing the mileage limitations between a Remote Dispensing Site Pharmacy (RDSP) and an RDSP-affiliated pharmacy, or eliminating OAR 855-139-0200(2) altogether.

MHP Medford (RP-0003955-CS) is a long-term care pharmacy which primarily bubble packs medications for delivery to long-term care facilities in the southern Oregon area. Our mission is to provide the right medication, to the right patient, at the right time. MHP Medford operates Monday through Friday from 10:00AM-6:30PM.

The greater-Medford / southern Oregon area has an immediate need for increased patient access to pharmacy services between the hours of 7:00PM through 9:00AM on weekdays and throughout the weekends. Examples of what our LTC patient population struggles with after-hours and weekends include: hospital discharges with new/changed med orders, late urgent care antibiotic orders, caregivers at facilities calling *after* they have discovered that they've completely ran out of a behavioral-health or anti-seizure medication, rapidly declining hospice patients running out of comfort medications due to an increase in dose or frequency, etc. In our brief time operating in the Medford area, we have found staffing a pharmacy to be difficult.

We strongly feel that the solution to increasing LTC patient pharmacy access and care in this area is for MHP Medford to be able to operate as a Remote Dispensing Site Pharmacy after-hours and on weekends, seeing that we have the technology and the pharmacist staff available at our Eugene location to provide supervision, direction, and control of a pharmacy technician remotely. Managed Healthcare Pharmacy and MHP Medford support the repeal of OAR 855-139-0200(2) *or* a rewrite with the intent of specifying the maximum limitations of an entity's *pharmacist's* proximity to the RDSP, as opposed to the current language specifying the max limitation of the *affiliated pharmacy's* proximity.

Thank you for your consideration. We look forward to hearing the outcome upon further discussion at the June 2024 Board Meeting.

Sincerely,

Eli Dailey, PharmD
PIC | Managed Healthcare Pharmacy
1750 Willow Creek Circle, Eugene, OR 97402
Ph: 541-744-1641 | F: 541-744-1052

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

May 23, 2024

Oregon State Board of Pharmacy
Attention: Jamal Fox, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232

Via Email: jamal.t.fox@bop.oregon.gov

RE: RDSP Petition

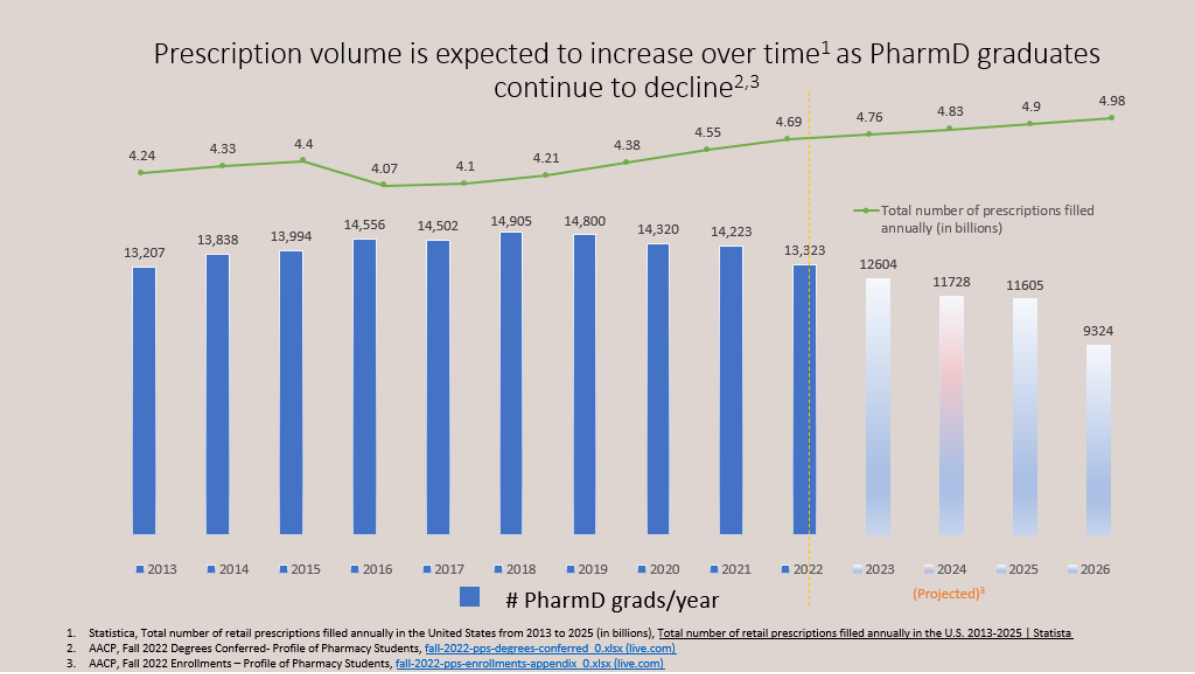
Dear Director Fox and Board Members,

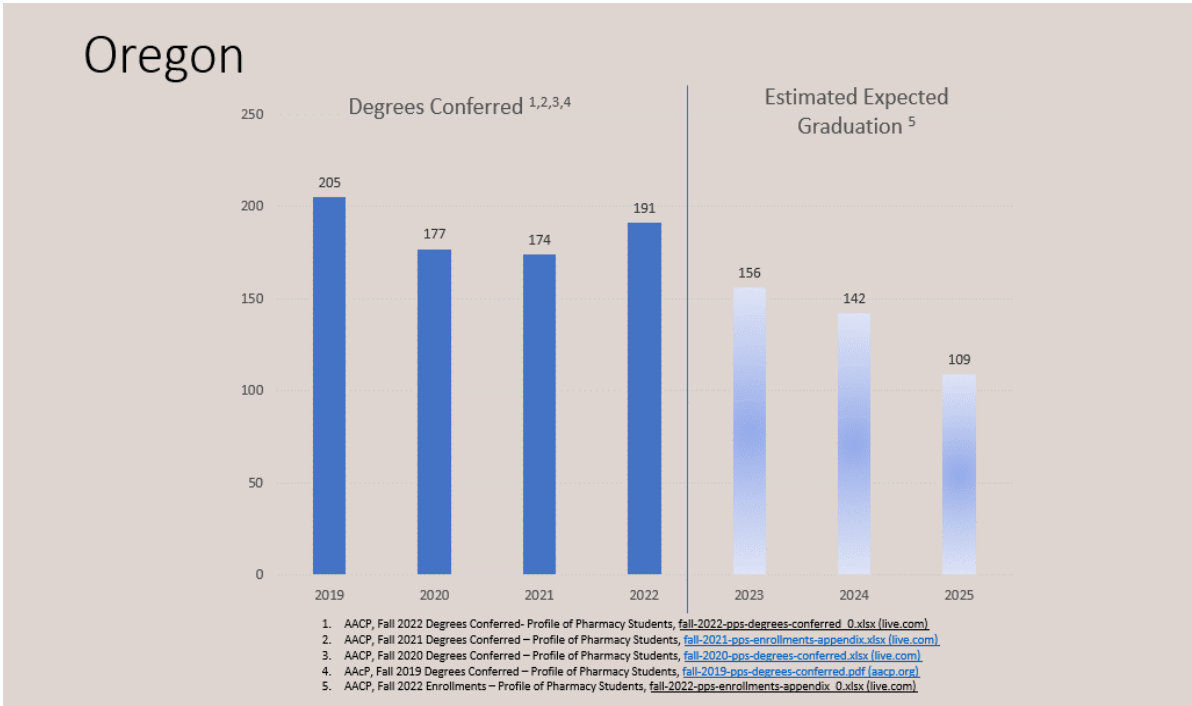
On behalf of Walgreen Co. and its Oregon-licensed pharmacies, we extend our heartfelt gratitude to the Oregon State Pharmacy Association and the Board of Pharmacy for bringing this important topic to light. We deeply value this opportunity to contribute our comments to the discussion on such a crucial matter.

Walgreens fully supports all the proposed changes listed in the Oregon State Pharmacy Association's petition. The ability for pharmacies to use technology to maintain or increase access to pharmacy services is critical to the public health, safety, and wellness of the citizens of Oregon. All healthcare professions are struggling with the reduction of providers and an increased burden of patient need for services as the population ages. Over the past two decades, we have seen tremendous growth in the adoption and acceptance of telemedicine, to the point that it has become a standard of care across the United States. A 2023 publication of MHealth states, "In just 20 years, since the private sector recognized the need, and the public enthusiastically understood the advantages, the use of telehealth in the United States increased 154% increase during early stages of the pandemic and stabilized at levels 38 times higher than levels in 2019."[1] Further, this same publication addressed patient satisfaction with telemedicine, where it was concluded that there was no significant difference in patient ratings of telehealth visits and in-person clinic visits, except in medicine specialties, which rated higher for in-person visits.[1] The Oregon Board of Medicine has taken action to issue a "Statement of Philosophy on Telemedicine" which supports the expansion of telemedicine as a tool to deliver care in the state. A specific statement of interest is from the Oregon Board of Medicine's statement: "The Oregon Medical Board supports a consistent standard of care and scope of practice for licensees, regardless of the delivery tool or business method enabling provider-patient communication. Telemedicine is an important tool in the delivery of health care. The Oregon Medical Board supports a consistent standard of care and scope of practice for physicians, physician assistants, and acupuncturists, regardless of the delivery tool or business method enabling provider-patient communication. Telemedicine is not a separate form of medicine, but rather a delivery tool. It is the practice of medicine, podiatry, or acupuncture through means of electronic communication, information technology, or other means of interaction between a provider at one location and a patient in another location."[2] Coming on the heels of this trend, the practice of telepharmacy is growing to address the challenges with staffing, reimbursement and access to care for patients in communities both rural and urban in nature.

OSPA mentions in their petition the concerns regarding decreased enrollments in pharmacy schools. A recent article published in Pharmacy Times noted that pharmacy school applications have decreased by more than 60% nationally in the last decade.[3] This comes at a time when prescription volume is growing exponentially (figure 1).[3,4,5] Further, a review of the AACP enrollment data specific to Oregon indicates that the state of Oregon will outpace the national average in the decline of graduates (34% national vs. 50% in Oregon) by 2026 when compared to 2021 based on the current enrollment numbers (figure 2).[3,4,5] Pharmacies of all sizes are impacted

by the reimbursement and enrollment pressures outlined in the petition from OSPA. OSPA notes that in 2023, at least 36 pharmacies closed. So far this calendar year, Walgreen Co. has closed 3 pharmacies in the State of Oregon based on the inability to find pharmacists in several more remote geographies. With the declining enrollment rates nationally and in Oregon, one would expect that more and more patients will be impacted by pharmacy closures and reduced operating hours, especially in those more physically distant locations.





In a review of the specific amendments submitted by OSPA, Walgreens provides the following comments by proposed amendment:

855-139-0050 Personnel

Walgreens supports these proposed amendments. The restriction on using interns is arbitrary and not generally contemplated in any other state. Pharmacy interns' ability to gain experience in various practice settings, including remote dispensing site pharmacies, is critical to the growth and development of their future professional practice. The supervision tools required in RDSP pharmacies will still ensure appropriate safety and security standards for pharmacy interns, just like they do for pharmacy technicians.

855-139-0100 Security

Walgreens is in support of these proposed amendments. The current rules for outlet security and the other surveillance measures addressed throughout Division 139 should more than address the concerns of ensuring that only authorized personnel may enter a pharmacy. The arbitrary requirement to document name and license numbers for every person entering the pharmacy can add additional unnecessary costs and/or administrative burdens to implement remote dispensing.

855-139-0200 Outlet: General Requirements

Walgreens is in support of these proposed amendments. As noted in the OSPA petition, the mileage requirement between the supervising and remote pharmacies is arbitrary. What makes it unsafe for the supervising pharmacy to be 121 miles from the remote pharmacy vs 120 miles? With Portland being the center of population for the state of Oregon, it is possible for a pharmacy to employ an extra pharmacist within the metro area to serve some of the more remote communities in Oregon that are struggling with hiring pharmacists. However, with the current mileage requirements, that would often be impossible.

855-139-0210 Outlet: Supervision

Walgreens is in support of these proposed amendments. The requirement to record and review audio of interactions in the supervision language is extremely burdensome, costly, and of concern from a privacy standpoint. From a standard of care perspective in a traditional retail drug outlet, it is not commonplace, nor is it an expectation for a pharmacist to overhear or review conversations conducted by pharmacy technicians by telephone or in their entirety in pharmacy. No other state has any regulations that are similar in nature that permit remote dispensing/telepharmacies. The current requirements are a regulatory overreach that limits the potential utilization of remote pharmacy services.

855-139-0215 Outlet: Pharmacist Utilization

Walgreens is in support of these proposed amendments. With the recent change in the consultation rules these requirements are confusing and not consistent with other facility types.

In addition to the recommendations posed by OSPA, I urge you to thoroughly review the NABP Task Force Report on Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing Sites, and Telepharmacy from October 2023 (enclosed). As a member of this Task Force, I am very familiar with the recommendations; you will note the report reveals numerous recommendations for NABP to update their Model Rules for the Practice of Pharmacy, thereby expanding the scope for implementing these technologies to ensure patient access given the current marketplace environment. I strongly encourage Oregon to take a similar approach to your rules for the benefit of the citizens of Oregon.

We encourage the Board to consider the changes proposed in the OSPA petition and swiftly begin rulemaking. Thank you for your time and consideration on this important patient access issue.

Sincerely,

Lorri Walmsley

Lorri Walmsley, RPh, FAzPA

References:

1. Andino, Juan J, et al. "Overview of Telehealth in the United States since the COVID-19 Public Health Emergency: A Narrative Review." MHealth, vol. 9, no. 26, 1 July 2023, pp. 26–26, https://doi.org/10.21037/mhealth-23-15.
2. *Oregon Medical Board : Telemedicine : Topics of interest : State of Oregon*. (n.d.). Telemedicine : Oregon Medical Board. https://www.oregon.gov/omb/topics-of-interest/pages/telemedicine.aspx
3. Aislinn Antrim, Assistant Managing Editor & Aislinn Antrim, Assistant Managing Editor; (2023, April 10). Despite rapid growth of institutions, pharmacy school applications decline. *Pharmacy Times*. https://www.pharmacytimes.com/view/despite-rapid-growth-of-institutions-pharmacy-school-applications-decline
4. Statistica, Total number of retail prescriptions filled annually in the United States from 2013 to 2025 (in billions), Total number of retail prescriptions filled annually in the U.S. 2013-2025 | Statista
5. AACP, Fall 2022 Degrees Conferred- Profile of Pharmacy Students, fall-2022-pps-degrees-conferred_0.xlsx (live.com)
6. AACP, Fall 2022 Enrollments – Profile of Pharmacy Students, fall-2022-pps-enrollments-appendix_0.xlsx (live.com)

NABP
National Association of Boards of Pharmacy

Report of the Task Force on

SHARED PHARMACY SERVICES, AUTOMATED PHARMACY SYSTEMS, REMOTE DISPENSING SITES, AND TELEPHARMACY

Report of the Task Force on Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing Sites, and Telepharmacy

Members Present

John Colaizzi, Jr. (NJ), *chair*; Erick Axcell (KS); Ronda M. Chakolis (MN); Michelle Chan (MA); Debbie Chisolm (CT); Caroline Juran (VA); Yeh "Ling" Yuan Lee (VA); Jerry Moore (AL); Eileen Ortega (PR); Richard "Rich" Palombo (NJ); Carrie Phillips (VT); Genine Pitts (MT); Andy Truong (KS); Lorri Walmsley (AZ); Maria Young (MI).

Others Present

Shane Wendel, *Executive Committee liaison;* Lemrey "Al" Carter, Melissa Becker, Eileen Lewalski, Andrew Funk, Gertrude "Gg" Levine, Maureen Schanck, Cameron Orr, *NABP staff*.

Introduction

The task force met on October 17 and 18, 2023, at NABP Headquarters in Mount Prospect, IL. This task force was established pursuant to a recommendation of the Committee on Law Enforcement/Legislation, which met in February 2023, to review the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act*) sections pertaining to shared services, automated pharmacy systems, remote dispensing sites, and telepharmacy.

Review of the Task Force Charge

Charge of the task force:

1. Review *Model Act* sections pertaining to Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing Sites, and Telepharmacy;
2. Amend, if necessary, the *Model Act* accordingly.

Background and Discussion

Discussion began with a review of the task force charge and the recognition that the task force was established pursuant to a recommendation of the Committee on Law Enforcement/Legislation, which met in February 2023. They also recognized the history of the charge stemming from the *Model Act* Review Committee in May 2022 and agreed that these subjects needed additional attention and review.

The task force then studied trends that are putting pressure on the practice of pharmacy to do more with less. The trends that the members discussed included a decline in applications to schools and colleges of pharmacy, a projected increase in prescription volume over time as the number of PharmD graduates continues to decline, and steady growth in pharmacy school graduates taking post-doctoral residency positions rather than entering traditional pharmacy practice. Members also observed a growing number of individuals retiring from pharmacy practice, as well as community pharmacies permanently closing an increasing number of stores.

The task force acknowledged that these trends may pose a public health risk if, in the future, pharmacists are in short supply and patients cannot access a pharmacy to get their medications or immunizations. Members noted that many patients will not get immunizations if they are unable to get them at a pharmacy. Given the risks, the task force recognized that these trends require pharmacies – particularly community pharmacies – to change their practice model to ensure their viability to continue safe dispensing of prescription medications in the years to come. Additionally, they recognized the duty of the boards of pharmacy to ensure that pharmacies have the latitude to implement necessary changes.

The task force identified issues in pharmacy practice that may need to be changed to raise the practice to its full potential. For instance, they observed discordant trends in pharmacy education versus pharmacy practice today. With the advent of the PharmD requirement for pharmacists entering the practice, pharmacy school curricula started moving toward high-level cognitive services. Members observed that the community pharmacy practice model, meanwhile, has yet to evolve to allow the provision of those services. They said this is partially because of a lack of reimbursement for clinical services, as well as the fact that patients remain unaware of all the clinical skills today's pharmacy graduates have. They expressed a need to educate patients and other health care providers on the range of services that pharmacists can provide. Members further noted that the practice model needs to change to allow more time for pharmacists to provide the advanced clinical services in which they have been trained.

Members acknowledged that community pharmacists must often contend with circumstances that may distract from pharmacy practice, such as aspects of retail business that do not factor into other health care practices. The fact that they provide counseling by phone at no charge was recognized by the task force as another significant difference between community pharmacists and other professionals, such as attorneys and physicians, many of whom charge fees to answer calls or emails.

Members observed that health-system pharmacy practice has, in some ways, evolved beyond community pharmacy practice. For instance, they noted that health-system pharmacies often have equipment and systems in place that optimize efficiency, such as centralized fulfillment by robotics and machinery, allowing pharmacists to focus on clinical services, whereas the community pharmacy model has not undergone the same degree of transformation. Members also mentioned that technicians in community pharmacies tend to be paid less than those in hospital settings, and

that hospital pharmacies have an easier time getting reimbursed by benefits management companies than community pharmacies do.

In regard to modernizing the practice of pharmacy, the subject of a hybrid work environment, in which personnel work some days in the pharmacy and some days remotely, was also discussed. The task force recognized that few states currently allow this model but that personnel have come to expect it, especially since the COVID-19 pandemic. Some members stated that they know of no reason not to allow it, and boards of pharmacy in some states, including Kansas, are considering it. Members mentioned that pharmacists could, for example, verify prescription orders from home before sending them to a fulfillment center; meanwhile, a pharmacist in the community could focus on counseling patients.

Overall, the task force agreed on the need to enhance efficiency and productivity through practice models such as shared pharmacy services, automated pharmacy systems, remote dispensing sites, and telepharmacy. Members also acknowledged a need to expand the reach of pharmacy practice to locales that may be physically distant or otherwise difficult to access. Members noted that there are not enough pharmacists available to physically staff 24-hour pharmacies and that these evolving practice models make expanded service hours possible.

Noting that practice models such as telepharmacy are routinely used in hospital pharmacies, members stated that satellite pharmacies operated by a pharmacy technician who is overseen by a pharmacist in another location could be used to extend the resources of community pharmacies. The task force noted that such practice models were instrumental in responding quickly during the COVID-19 pandemic. Members raised concerns, however, that if pharmacists are already busy at the primary pharmacy, they may not have time to supervise another location, and that businesses may be capitalizing on this model to the detriment of pharmacy personnel and patients.

There are multiple factors to consider before pharmacies can implement a shared services or telepharmacy model if the board of pharmacy explicitly allows for it or does not have laws and/or rules preventing it. Others mentioned that there are nuances within those allowances that may create unintended barriers and prevent pharmacies from being able to implement these innovative practice models. The task force considered how to encourage more states to allow it and, within those states that do allow it, how to make it more accessible. In North Dakota, for example, the board allows pharmacies to decide how many telepharmacies, or satellite locations, a pharmacist can safely oversee, noting that it depends partly on the pharmacy's prescription volume.

Turning their attention to the *Model Act,* the members first considered the defined terms and then referred to the relevant section of the act to review it in detail.

The first definition they considered was for "automated pharmacy systems," which led to questions about the types of systems it should encompass. One such question was whether artificial intelligence would be encompassed by this definition. Another question pertained to the use of

technology that can identify active pharmaceutical ingredients in medications to determine whether they are authentic or counterfeit. Members opted to strike the word “mechanical” from the definition, agreeing that the definition should encompass all systems that are automated, including the examples discussed and future advancements.

In Section 9. Automated Pharmacy Systems, the task force considered whether any provisions were missing or too prescriptive. Regarding the locations in which automated pharmacy systems can be used, members discussed whether the term “shared pharmacy services pharmacies,” as used in Paragraph (1), was redundant and confusing and recommended removing this wording. They agreed to supplement “and other locations approved by the board” with the phrase “in accordance with all state and federal laws and rules” to cover all compliant locations.

Members considered whether it is necessary to require a pharmacist to be available at the site of the automated pharmacy system, noting that the necessity may depend on the setting (eg, day surgery center, outpatient center, kiosk). They further discussed requirements for supervision, seeking to keep the language as broad and unrestrictive as possible, allowing boards of pharmacy leeway for interpretation. They agreed to remove the requirement that the system be “supervised electronically,” and replaced that wording with “appropriately secured and monitored.” The rationale was that the word “monitored” is less restrictive than “supervised,” and, noting that monitoring differs depending on the system, they agreed on “appropriately.”

Regarding documentation, as described in Section 9 Subparagraph (1)(a), members recommended revisions to modernize, clarify, and broaden the language and eliminate redundancies. For example, they recommended changing “serial numbers” to “facility-specific unique identifiers.”

Members recommended striking from Subparagraph (1)(b) “[a] pharmacist shall be accessible to respond to inquiries or requests pertaining to drugs dispensed from the automated pharmacy system” and replacing it with the language that was contained in a footnote: “[i]n order to facilitate communication between the pharmacy and the site where the automated pharmacy system is located, a pharmacy should provide a telephone number so that the pharmacist is accessible at all times the automated pharmacy system is operational.” Within this statement, they removed the requirement for the phone number to be “toll-free.” Several additional items within Paragraph (1) were changed or combined for brevity and to eliminate redundancies. Paragraph (2) and its subsections were removed, as they were deemed duplicative.

Moving on to the definition for “practice of telepharmacy,” the task force agreed to strike “registered,” noting it is assumed that the pharmacist is registered or licensed. Members also struck “located within US jurisdictions” and “at distances that are located within US jurisdictions.” The latter strikeouts were made to avoid addressing jurisdiction in a definition, as jurisdiction is already addressed in the statutory sections pertaining to licensing. Recognizing that the practice of

telepharmacy may include technicians providing immunization and test-and-treat services, the task force recommended adding a footnote to this effect.

The meaning of “telepharmacy” and whether it involves dispensing was a matter of some deliberation. Members stated that, traditionally, the term refers to a brick-and-mortar pharmacy remotely supervised by a pharmacist. In some jurisdictions the term encompasses dispensing sites, whereas in Vermont, it encompasses only the tasks that precede dispensing.

Members raised concerns that the terms “telepharmacy,” “remote dispensing site,” and “shared pharmacy services” could be confused. They considered eliminating the term telepharmacy but decided against it because the term is commonly used. Members also expressed the need for pharmacy stakeholders to move away from terms such as “retail” and “store” because it commoditizes the practice of pharmacy and noted that reserving the term “clinical pharmacist” for non-retail pharmacists overlooks the fact that pharmacists in all practice settings must have clinical skills.

In discussing Section 14. Telepharmacy, members agreed that a mileage requirement dictating the distance between a primary pharmacy and its satellite locations is arbitrary and not helpful. Members mentioned that areas in addition to rural communities can experience limited accessibility to a pharmacy, such as in the case of urban “pharmacy deserts,” wherein a community pharmacy may not be available within several city blocks. With this in mind, the members recommended adding a footnote to Subsection (2) Remote Dispensing Site Requirements, stating that “[t]o allow for emerging practice models, states should not impose volume restrictions, mileage restrictions, or unnecessary limitations that would limit patient access to remote dispensing sites.”

The task force recommended striking Subparagraph (2)(d) and making it a somewhat less prescriptive footnote: “[t]he pharmacist-in-charge shall oversee inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.” An additional footnote was added indicating that “[s]tates may allow pharmacy interns to perform the functions of a certified pharmacy technician at a remote dispensing site.” The task force agreed that a remote dispensing site must maintain contact with “a pharmacist” but not necessarily “at the supervising pharmacy.”

Regarding the communication system, the task force recommended striking “provide an adequate number of views of the entire site” and moving up the language of Subparagraph (n) to bring common subjects together: “[t]he remote dispensing site must use telepharmacy technology that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and prescription drug order.” They agreed to strike Subparagraph (j) and the items beneath it that required the remote dispensing site to retain a recording of facility surveillance. Regarding Subparagraph (m) requiring a remote dispensing site to display a sign, the task force struck the requirements for it to say “this is a remote site” and provide the location of the supervising

pharmacy, requiring it to say only that a pharmacist "is available to counsel" the patient using audio and video communication systems.

Turning to the definition of "shared pharmacy services," the task force agreed to strike "pursuant to a request from another participating pharmacist or pharmacy." Regarding the types of services, they recommended adding, "or provide pharmacist care services" and "product verification, counseling," and removing "reviewing therapeutic interventions."

In Section 8. Shared Pharmacy Services, the task force recommended striking subsections they considered to be too prescriptive and moving some subsections to improve continuity. Members agreed to strike Subsection (3) Drug Storage and Security, as these provisions are addressed in Subsection (2) Operations. In Subsection (4), members qualified "policies and procedures for shared pharmacy services" by adding "that outline the responsibilities of each pharmacy and describe policies reflecting operation requirements," and recommended striking the rest of the section, which they considered to be overly detailed and redundant.

The last definition that the task force considered was for "remote dispensing site." The members recommended keeping the definition as it is and adding a footnote: "[s]tates may interpret 'remote supervision of a pharmacist' to allow certified pharmacy technicians to provide immunizations and 'test and treat' services at a remote dispensing site."

After careful review and deliberation, the task force recommended that NABP amend the *Model Act* as follows. The amendments recommended by the task force are denoted by underlines and ~~strikethroughs~~.

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

August 2023

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Section 105. Definitions.

…

"Automated pharmacy systems" include, but are not limited to, ~~mechanical~~ systems that perform operations or activities, compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs, and which collect, control, and maintain all transaction information.

"Practice of telepharmacy[1]" means the practice of pharmacy by ~~registered~~ pharmacists ~~located within US jurisdictions~~ through the use of telepharmacy technologies between a licensee and patients or their agents ~~at distances that are located within US jurisdictions~~.

"Remote dispensing site" means a location, other than where a pharmacist is located, where drugs are maintained and prescriptions are filled by a certified pharmacy technician and dispensed under the ~~direct,~~ remote supervision of a pharmacist[2].

"Shared pharmacy services" means a system that allows a participating pharmacist or pharmacy ~~pursuant to a request from another participating pharmacist or pharmacy~~ to process or fill a prescription drug order or provide pharmacist care services, which may include preparing, packaging, labeling, compounding for specific patients, dispensing, product verification, counseling, performing drug utilization reviews, conducting claims adjudication, obtaining refill authorizations, ~~reviewing therapeutic interventions~~, and/or reviewing institutional facility orders.

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Model Rules for the Practice of Pharmacy

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Section 8. Shared Pharmacy Services.

(1) General Requirements[3, 4]

(a) The pharmacy must possess a resident or nonresident permit issued by the board prior to engaging in shared pharmacy services.[5]

(b) A pharmacy may provide or utilize shared pharmacy services only if the pharmacies involved:

(i) have the same owner; or

[1] States may interpret the definition of the practice of telepharmacy to allow certified pharmacy technicians to provide immunizations and "test and treat" services.

[2] States may interpret "remote supervision of a pharmacist" to allow certified pharmacy technicians to provide immunizations and "test and treat" services at a remote dispensing site.

[3] The Board may want to consider the extent to which this General Requirements Section is applicable to institutional-based shared pharmacy services pharmacies, as such application may be subject to interpretation of existing state and federal law governing institutional facilities.

[4] In order to ensure accountability, the pharmacist-in-charge of a pharmacy engaging in shared pharmacy services must possess a license to practice pharmacy in all jurisdictions that they are engaging in such series until such a time in which provisions for multistate practice exist.

[5] Often the terms "licensure," "registration," and "permit" are used interchangeably throughout the *Model Act*. In the case of shared pharmacy services pharmacies that utilize automated pharmacy systems, boards may determine that it is appropriate to issue a permit for the automated pharmacy system but not for the physical site where the automated pharmacy system is located.

(ii) have a written contract or agreement that outlines the services provided and the shared responsibilities of each pharmacy in complying with federal and state pharmacy laws and rules; and

(iii) share a common electronic file or technology that allows access to information necessary or required to perform shared pharmacy services in conformance with the pharmacy act and the board's rules.

(c) A pharmacy engaged in shared pharmacy services shall comply with appropriate federal and state controlled substance registrations for each pharmacy if controlled substances are maintained.

(2) Operations

(a) Pharmacies engaging in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services shall:

(i) maintain records identifying, individually, for each prescription drug order processed, the name of each pharmacist or pharmacy intern who took part in the drug utilization review, refill authorization, or therapeutic intervention functions performed at that pharmacy and the name of any certified pharmacy technician or certified pharmacy technician candidate if they assisted in any of those functions;

~~(ii) maintain records identifying individually, for each prescription drug order filled or dispensed, the name of each pharmacist or pharmacy intern who took part in the filling, dispensing, and patient counseling functions performed at that pharmacy and the name of any certified pharmacy technician or certified pharmacy technician candidate if they assisted in any of those functions;~~

~~(iii) report to the board as soon as practical the results of any disciplinary action taken by another state's board of pharmacy involving shared pharmacy services;~~

(iv) maintain a mechanism for tracking the prescription drug order during each step of the processing and filling procedures performed at the pharmacy;

(v) maintain a mechanism for the patient, upon request, to identify all pharmacies involved in filling the prescription drug order; and

(vi) be able to obtain for inspection any required record or information ~~within 72 hours~~ of any request by the board or its designee.

(vii) operate a continuous quality improvement program for shared pharmacy services.

~~(3) Drug Storage and Security~~

~~(a) Drugs shall be stored in compliance with state and federal laws and in accordance with these Rules, including those addressing temperature, proper containers, and the handling of outdated drugs.~~

~~(b) Access to the area where drugs are stored at the shared pharmacy services pharmacy must be limited to:~~

~~(i) pharmacists, certified pharmacy technicians, certified pharmacy technician candidates, or pharmacy interns who are employed by the shared pharmacy services pharmacy; or~~

~~(ii) personnel employed at the institutional facility or clinic where the shared pharmacy services pharmacy is located who:~~

~~(A) are licensed health care providers;~~

~~(B) are documented by the pharmacist-in-charge or the person responsible for the supervision and on-site operation of the facility where the shared services pharmacy is located; and~~

~~(C) have completed documented training concerning their duties associated with the shared pharmacy services Pharmacy.~~

~~(d) Shared pharmacy services pharmacies shall have adequate security to:~~

~~(i) comply with federal and state laws and regulations; and~~

~~(ii) protect the confidentiality and integrity of protected health information.~~

(4) Policies and Procedures

~~(a)~~ Each pharmacy in shared pharmacy services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for shared pharmacy services that outline the responsibilities of each pharmacy and describe policies reflecting operation requirements. ~~Each pharmacy is required to maintain the portion of the joint policies and procedures that relate to that pharmacy's operations. The policies and procedures shall:~~

~~(i) outline the responsibilities of each pharmacy;~~

~~(ii) include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in shared pharmacy services; and~~

~~(iii) include processes for:~~

~~(A) notifying patients that their prescription drug orders may be processed or filled by another pharmacy and providing the name of the pharmacy;~~

~~(B) protecting the confidentiality and integrity of protected health information;~~

~~(C) dispensing prescription drug orders when the filled prescription drug order is not received or the patient comes in before the prescription drug order is received:~~

~~(D) maintaining required manual or electronic records to identify the name, initials or identification code and specific activity or activities of each pharmacist, certified pharmacy technician, certified pharmacy technician candidate, or pharmacy intern who performed any shared pharmacy services;~~

~~(E) complying with federal and state laws; and~~

(F) ~~operating a continuous quality improvement program for shared pharmacy services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems~~.

(5) Individual Practice

(a) Nothing in this Section shall prohibit an individual pharmacist licensed in the state, who is an employee of or under contract with a pharmacy, or a licensed certified pharmacy technician, certified pharmacy technician candidate, or pharmacy intern, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the prescription drug order processing functions permitted by the Pharmacy Act, if both of the following conditions are met:

(i) the pharmacy establishes controls to protect the confidentiality and integrity of protected health information; and

(ii) no part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

Section 9. Automated Pharmacy Systems.

(1) Automated pharmacy systems can be utilized in licensed pharmacies~~, shared pharmacy services pharmacies,~~ and other locations approved by the board in accordance with all state and federal laws and rules. A pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is appropriately secured and monitored ~~supervised electronically by a pharmacist~~. Automated pharmacy systems shall comply with the following provisions.

(a) Documentation as to type of equipment, ~~serial numbers,~~ facility-specific unique identifiers, and ~~content,~~ policies and procedures~~, and shared pharmacy services pharmacy location shall be maintained in the pharmacy for review~~. Such documentation shall include, but is not limited to:

(i) name and address of the pharmacy and the ~~shared pharmacy services pharmacy~~ name and address of the location where the automated pharmacy system is being used;

(ii) manufacturer's name and model, if applicable;

(iii) description of how the automated pharmacy system is used;

(iv) continuous quality assurance procedures ~~to determine continued appropriate use of the automated pharmacy system~~;

(v) ~~documentation evidencing that the automated pharmacy system has been tested prior to initial use and on a periodic basis at each location to ensure that the automated pharmacy system is operating properly~~.

(b) ~~A pharmacist shall be accessible to respond to inquiries or requests pertaining to drugs dispensed from the automated pharmacy system.~~[6] In order to facilitate communication between the pharmacy and the site where the automated pharmacy system is located, a pharmacy should provide a telephone number so that the pharmacist is accessible at all times the automated pharmacy system is operational.

[6] ~~In order to facilitate communication between the pharmacy and the site where the automated pharmacy system is located, a pharmacy should provide a toll-free telephone number so that the pharmacist is accessible at all times the automated pharmacy system is operational.~~

(c) ~~Any pharmacy that maintains an automated pharmacy system for the purposes of remote dispensing to outpatients shall maintain an interactive communication system to provide for effective communication between the patient and the pharmacist; the~~ For remote dispensing to outpatients[7], a ~~the~~ video/auditory communication system shall allow for the appropriate exchange of oral and written communication and patient counseling; if the video/auditory communication system malfunctions, then all operations of the automated pharmacy system shall cease until the system is fully functional.

(d) Automated pharmacy systems shall have adequate security systems to:
- (i) prevent unauthorized access;
- (ii) comply with federal and state regulations; and
- (iii) prevent the illegal use or disclosure of protected health information.

(e) Records and/or electronic data kept by automated pharmacy systems shall meet the following requirements.
- ~~(i) All events involving the contents of the automated pharmacy system must be recorded electronically.~~
- (ii) Records must be maintained by the pharmacy and must be readily available to the board. Such records shall include:
  - (A) identity of system accessed;
  - (B) identification of the individual accessing the system;
  - (C) type of transaction;
  - (D) name, strength, dosage form, and quantity of the drug accessed;
  - (E) name of the patient for whom the drug was ordered; and
  - (F) such additional information as the pharmacist-in-charge may deem necessary.

(f) Access to and limits on access (eg, security levels) to the automated pharmacy system shall be defined.[8]

(g) The pharmacist-in-charge shall have the responsibility to:
- (i) assign, discontinue, or change access to the system;
- (ii) ensure that access to the drugs complies with state and federal regulations;
- ~~(iii) ensure that the automated pharmacy system is filled/stocked accurately.~~

(h) The filling/stocking of all drugs in the automated pharmacy system shall be accomplished by qualified personnel under the supervision of a licensed pharmacist. A record of drugs filled/stocked into an automated pharmacy system shall be

[7] Although an "outpatient" generally refers to a person who receives drugs for use outside of an institutional facility, the definition of "outpatient" must be defined by each state. For example, although the *Model Act* classifies penal institutions as a type of institutional facility and therefore its inmates as inpatients, the pharmacist is exempt from providing patient counseling. However, some states may consider inmates of penal institutions as outpatients and therefore should decide if a video/audio communication system is required in such facilities so that the pharmacist is able to provide patient counseling.

[8] This Section anticipates that decisions regarding which health care professionals may access the automated pharmacy system and the level of access allowed (eg, access to drugs, access to patient profiles for viewing only, access to patient profiles for modification) will be left up to the individual(s) responsible for the automated pharmacy system; however, states may decide to take on this responsibility and define those who may have access to the system and the levels of access allowed.

maintained and shall include identification of the persons filling/stocking and checking for accuracy.[9]

~~(i) A record of drugs filled/stocked into an automated pharmacy system shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.~~

(j) All ~~containers of drugs stored in the automated pharmacy system shall be packaged and labeled~~ prescription fulfillment activities shall take place in accordance with federal and state laws and regulations.

~~(k) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.~~

~~(l) The automated pharmacy system shall provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the automated pharmacy system, all in accordance with existing state and federal law.[10]~~

(m) The automated pharmacy system shall provide a mechanism for securing and accounting for wasted or discarded drugs in accordance with existing state and federal law.

~~(2) Policies and Procedures~~

~~(a) The pharmacist-in-charge is responsible for developing or adopting, implementing, and maintaining automated pharmacy systems policies and procedures that address the following:~~

~~(i) system operation, safety, stocking accuracy, patient confidentiality, access and limits to access, environmental controls, and malfunction;~~

~~(ii) provision of pharmacist care;~~

~~(iii) security, including:~~

~~(A) preventing unauthorized access;~~

~~(A) prevention of the illegal use or disclosure of protected health information.~~

~~(b) All policies and procedures shall be maintained in the pharmacy responsible for the automated pharmacy system and, if the automated pharmacy system is being used at a different location, at that location as well.~~

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Section 14. Telepharmacy

(1) General Requirements

(a) The pharmacy shall:

(i) obtain a resident or nonresident permit issued by the board prior to engaging in the practice of telepharmacy;

[9] This Section anticipates that states will allow non-pharmacist personnel to fill/stock automated pharmacy systems under a pharmacist's supervision; however, the state may decide to only allow a pharmacist to perform this function. Should the state allow non-pharmacist personnel to perform this function, it should define the level of pharmacist supervision necessary (eg, immediate, direct, or general).

[10] The state may require that each licensed pharmacy or facility have in place written policies and procedures to address situations in which drugs removed from the system remain unused and must be secured and accounted for.

(ii) comply with appropriate federal and state controlled substance laws and rules for each pharmacy if controlled substances are maintained;
(iii) maintain additional policies and procedures specific to telepharmacy.

(2) Remote Dispensing Site Requirements[11]

(a) The pharmacy shall submit an application to the board.

(b) The pharmacist-in-charge of the supervising pharmacy shall be responsible for all operations[12].

(c) The pharmacy shall have a written contract or agreement that outlines the services provided and the responsibilities of each party in complying with federal and state pharmacy laws and rules.

~~(d) The pharmacist-in-charge shall oversee monthly inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.~~

~~(e) A pharmacist must be designated to be available within (_) hours, in case of emergency.~~

(f) Unless staffed by a pharmacist, a remote dispensing site must be staffed by at least one (1) certified pharmacy technician[13]. All certified pharmacy technicians and certified pharmacy technician candidates shall be under the supervision of a pharmacist ~~at the supervising pharmacy~~ at all times that the remote site is operational. The pharmacist shall supervise telepharmacy operations electronically ~~from the supervising pharmacy~~.

(g) The remote dispensing site and the supervising pharmacy must utilize a common electronic record-keeping system that must be capable of the following:
(i) Electronic records must be available to, and accessible from, both the supervising pharmacy and the remote dispensing site at all times of operations; and
(ii) Prescriptions dispensed at the remote dispensing site must be distinguishable from those dispensed from the supervising pharmacy.

(h) Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, state and federal law.

(i) A supervising pharmacy of a remote dispensing site must maintain a video and audio communication system that provides for effective communication between a pharmacist ~~the supervising pharmacy~~ and the remote dispensing site personnel and patients or caregivers. The system must ~~provide an adequate number of views of the entire site,~~ facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and

[11] To allow for emerging practice models, states should not impose volume restrictions, milage restrictions, or unnecessary limitations that would limit patient access to remote dispensing sites.

[12] The pharmacist-in-charge shall oversee inspections, maintenance, and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.

[13] States may allow pharmacy interns to perform the functions of a certified pharmacy technician at a remote dispensing site.

other matters involved in the lawful transaction or delivery of drugs. The remote dispensing site must use telepharmacy technology that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and prescription drug order.

(j) ~~The remote dispensing site must retain a recording of facility surveillance, excluding patient communications, for a minimum of (_) days.~~

~~(i) Adequate supervision by the pharmacist in this setting is maintaining uninterrupted visual supervision and auditory communication with the site and full supervisory control of the automated system, if applicable, and must not be delegated to another person.~~

~~(ii) Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing site must be, or remain, closed to the public if any component of the communication system is malfunctioning, until system corrections or repairs are completed.~~

~~(iii) The video and audio communication system used to counsel and interact with each patient or patient's caregiver must be secure and compliant with state and federal confidentiality requirements.~~

(k) Unless a pharmacist is present at the remote site, that ~~a remote dispensing~~ site must not be open or its employees allowed access to it during times ~~the~~ a supervising pharmacist ~~pharmacy~~ is unavailable. ~~closed.~~ The security system must allow for tracking of entries into the remote dispensing site, and the pharmacist-in-charge must periodically review the provision of access and record of entries.

(l) ~~If drugs are maintained or dispensed from the remote dispensing site, drug transfers to the remote dispensing site must comply with applicable state and federal requirements.~~

(m) A remote dispensing site must display a sign, easily visible to the public, which informs patients~~:~~

~~(i) this is a remote site~~

~~(ii) location of supervising pharmacy; and~~

(iii) that a pharmacist is available to ~~will~~ counsel the patient using audio and video communication systems each time a new drug is dispensed and at the time it is refilled, if necessary, at a remote dispensing site.

~~(n) The remote dispensing site must use telepharmacy technology that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and prescription drug order.~~

From: Cyndi V <oboptech1@gmail.com>
Sent: Monday, May 27, 2024 9:08 AM
To: ODE.RuleTestimony@state.or.us
Subject: Invitation of Public Comment

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

Dear Board Members,

I am writing to respond to the invitation for comment on the OAR 855-139-0210(1)(2)(3)(4)(5)
The proposed amendments are:
(1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Oregon licensed intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, and the audio and visual telepharmacy communication and continuous video surveillance system is fully operational;
(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Oregon licensed intern, Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP using an audiovisual communication system. All patient interactions must be recorded, reviewed and stored;
(3) The Oregon licensed Pharmacist who is supervising the Oregon licensed intern, Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:
(a) Using reasonable professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;
(b) 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;
(c) Document the following within 24 hours of the review in (3)(b):
(A) Number of each licensee's patient interactions;
(B) Number of each licensee's patient interactions Pharmacist is reviewing;
(C) Date and time of licensee patient interaction Pharmacist is reviewing;
(D) Date and time of Pharmacist review of licensee's patient interaction; and
(E) Pharmacist notes of each interaction reviewed; and
(a) (d) Report any violation of OAR 855 to the RDSP Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.
(4) The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.

(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician or Pharmacy Technician.

I am a 27-year licensed CPhT within the State of Oregon. I currently work in a hospital setting but have worked in community retail pharmacy for 21 of the 27 years. I have trained numerous pharmacy technicians in those 27 years. I am also a former Board Member.
I want to focus my remarks on my opposition the proposed amendments OAR 855-139-0210 on 3 (a) and (b)4 and 5.

Without proper oversight, there's a risk of pharmacy technicians making medication errors or providing information that is out of their scope. Pharmacists play a critical role in ensuring accurate dispensing, drug interactions, and patient safety. Regular review of technicians' work helps identify and correct any mistakes.
In an in-pharmacy, a technician is monitored when a pharmacist is present, as is their responsibility. But taking out the overview of the transactions at the RDSP the Oregon Board of Pharmacy is taking away the public safety feature that may help minimize patient error or overreach of a technician.
Finding the right balance between autonomy and oversight for pharmacy technicians is essential. While allowing them more independence can improve efficiency, patient safety remains paramount. Regular review and ongoing training are crucial to maintaining high standards of care.
In a National Observational Study there are 4 errors per day in a pharmacy that fills 250 prescriptions daily. And the errors got up with more prescripts that are filled. There is an estimated of 51.5 million errors filling 3 billion prescriptions annually nationwide.

How are we going to ensure that Remote Technicians will be monitored if the current 10% requirement is removed?
The consequences of pharmacy technician errors can be quite serious and range from minor discomfort to severe health complications, and in some cases, even death. Here are some potential outcomes of such errors:

- Wrong Prescription: If a technician hands out the wrong prescription, it could mean the patient takes the wrong set of medicines, which could lead to adverse drug reactions or lack of treatment for their actual condition.

- Incorrect Drug Dispensing: Dispensing the wrong drug due to negligence or misreading a prescription can have serious consequences, especially if the patient is allergic to the new drug or if it worsens their symptoms.

- Drug Substitution Without Approval: Substituting one drug for another without consulting the prescribing doctor could lead to complications, as the pharmacist might not be qualified to make such a switch.

- Expired Medications: Giving out drugs that are past their expiration dates can either cause harm or be ineffective, as they may not work as intended past a certain date.

- Misinterpretation of Handwriting: Misinterpreting a doctor's handwriting and filling a prescription with the wrong medication can have dire consequences.

As the Board Members of the Oregon Board of Pharmacy, you are tasked with keeping the public safe. Please, remember that per Oregon Rules 855-125-0105 3 (b) Pharmacy Technicians only assist in the practice of pharmacy under the supervision, direction, and control of a Pharmacist, and that includes RDSP outlets. It is not more restrictive than standards for the delivery of in-person pharmacy services, including standards regarding prescription and dispensation of drugs when we ask for 10% to be monitored and not the 100% that is monitored at an in-person pharmacy. As stated previously, even under the guidance and supervision of an in-person pharmacy there are errors, and if interactions are not monitored, will put the public at risk.
I also believe that many pharmacy technicians may not fully understand the rules of the Oregon Board of Pharmacy and they may be in jeopardy of unknown consequence if they are not supervised and coached when they are doing the wrong act and then continue without any intervention.

As a nationally certified pharmacy technician and former board member, I believe that every pharmacy technician should be educated through a national or state certification program so that the pharmacy technician knows what the rules are and how they are implied, to perform the duties within the scope of their position in their preferred language. A pharmacist has 5 or more years of education and training behind them, it should not be too much of an ask to protect the public by having technicians know what the rules of the state board are.
I trust that the Board will consider this matter with the seriousness it deserves. I believe the rules should stay intact with the RDSP, and there should be accountability by someone listening/watching at least 10% of the interaction between a pharmacy technician and the public to make sure all rules are followed.
Thank you for your time and attention to this matter.
Sincerely,
Cyndi Vipperman CPhT
Bend, Oregon

1 SBAR: Petition to Amend OAR 855-139

S

Situation:

- The Oregon State Pharmacy Association has submitted a petition to amend OAR 855-139-0050(2), OAR 855-139-0100(4), OAR 855-139-0200(2), OAR 855-139-0210(1)(2)(3)(4)(5), and OAR 855-139-0215(2), as authorized under OAR 137-001-0070 Petition to Promulgate, Amend, or Repeal Rule
  - OSPA believes the current Remote Dispensing Site Pharmacy rules are overly restrictive and conflict with 2022 HB 4034.
  - OSPA purposes that limited access to pharmacies in rural areas necessitates wider RDSP use.
  - OSPA believes that current rules create unnecessary burdens and discourage the wider adoption of RDSPs
- 2021 SB 629 and 2022 HB 4034 (Sections 17/18/19) -> ORS 689.700 permit telepharmacy services with some limitations

B

Background:

- In 2021, SB 629 required the board to write rules to permit telepharmacy.
  - 08/2021- Board conducted first review of proposed rules for RDSPs
  - 10/2021- Board conducted a second review of proposed rules and motioned to send to rulemaking
  - 11/2021- Rulemaking hearing
  - 12/2021- Board adopted rules
- In 2022, HB 4034 amended ORS 689.700 by prohibiting the board from establishing standards for telepharmacy that are stricter than standards for in-person delivery of pharmacy services.
  - 04/2022- Board conducted first review of proposed revisions to RDSP rules, adopted temporary rules to address the requirements of 2022 HB 4034, and motioned to send permanent rules to rulemaking
    - Amendments updated certain personnel and ratio requirements
  - 05/2022- Rulemaking hearing
  - 06/2022- Board adopted permanent rules and board adopted temporary rule to amend OAR 855-139-0600 Prohibited Practices
    - Amendment allows a Retail Drug Outlet RDSP to deliver a prescription
  - 10/2022- Board motioned to send to rulemaking
  - 11/2022- Rulemaking hearing
  - 12/2022- Board adopted permanent rule

- Per ORS 689.700, "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.
- Per OAR 855-139-0005(2), "Remote Dispensing Site Pharmacy" or "RDSP" means an Oregon location registered as a Retail Drug Outlet Remote Dispensing Site Pharmacy staffed by a Certified Oregon Pharmacy Technician or Pharmacy Technician under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.

- OSPA requests review of multiple RDSP rules including:
  - Allowing interns to work at RDSPs.
  - Removing the requirement to record each person entering the pharmacy area.
  - Removing the 120-mile limit for supervising pharmacy location.

	○ Removing the requirement to record all patient interactions. ○ Removing requirement for Pharmacist to accept refusal of counseling • OSPA proposes these changes would: ○ Increase opportunities for pharmacy interns. ○ Align with the legislative intent of 2022 HB 4034 ○ Improve access to pharmacy services, especially in remote areas. Related Statutes and Rules (full text at end of document): • OAR 137-001-0070 Petition to Promulgate, Amend, or Repeal Rule • ORS 689.700 Telepharmacy; requirements; rules. • OAR 855-006-0005(3) "Audiovisual Communication System" and (53) "Surveillance System • OAR 855-139-0005(4) "Telepharmacy System" • OAR 855-139-0050(2) Personnel • OAR 855-139-0100(4) Security • OAR 855-139-0200(2) Outlet: General Requirements • OAR 855-139-0210(1)(2)(3)(4)(5) Outlet: Supervision • ORS 689.486 When license required; qualifications for licensure; renewal; temporary license; supervision required. • ORS 689.455 Duty to report suspected violations and prohibited conduct; liability for reporting; confidentiality of report. • OAR 855-104-0010 Responsibilities: Duty to Report • ORS 165.540 Obtaining contents of communications. • OAR 855-139-0215(2) Outlet: Pharmacist Utilization • OAR 855-115-0145 Counseling
A	Assessment: • See individual assessments per rule
R	Recommendation: • To comply with the provisions of OAR 137-001-0070: 1. The board invited public comment on this request, including whether options exist for achieving the rule's substantive goals in a way that reduces the negative economic impact on businesses and provided those comments to the board. 2. The board must, within 90 days of the request received on 4/30/2024, review public comments and either deny the request in writing or initiate rulemaking.

Inquiry Date: 04/30/2024
Board Review Date: 06/13/2024

OAR 137-001-0070
Petition to Promulgate, Amend, or Repeal Rule

OAR 137-001-0070 was adopted by the Attorney General as required by ORS 183.390. Agencies must apply this rule without further adoption or amendment.

(1) An interested person may petition an agency to adopt, amend, or repeal a rule. The petition shall state the name and address of the petitioner and any other person known to the petitioner to be interested in the rule. The petition shall be legible, signed by or on behalf of the petitioner, and shall contain a detailed statement of:

(a) The rule petitioner requests the agency to adopt, amend, or repeal. When a new rule is proposed, the petition shall set forth the proposed language in full. When an amendment of an existing rule is proposed, the rule shall be set forth in the petition in full with matter proposed to be deleted and proposed additions shown by a method that clearly indicates proposed deletions and additions;

(b) Facts or arguments in sufficient detail to show the reasons for and effects of adoption, amendment, or repeal of the rule;

(c) All propositions of law to be asserted by petitioner.

(2) If the petitioner requests the amendment or repeal of an existing rule, the petition must also contain comments on:

(a) Options for achieving the existing rule's substantive goals while reducing the negative economic impact on businesses;

(b) The continued need for the existing rule;

(c) The complexity of the existing rule;

(d) The extent to which the existing rule overlaps, duplicates, or conflicts with other state or federal rules and with local government regulations; an

(e) The degree to which technology, economic conditions, or other factors have changed in the subject area affected by the existing rule, since the agency adopted the rule.

(3) If a petition requests the amendment or repeal of a rule, before denying a petition, the agency must invite public comment upon the rule, including whether options exist for achieving the rule's substantive goals in a way that reduces the negative economic impact on businesses.

(4) The agency

(a) May provide a copy of the petition, together with a copy of the applicable rules of practice, to all persons named in the petition;

(b) May schedule oral presentations;

(c) Shall, in writing, within 90 days after receipt of the petition, either deny the petition or initiate rulemaking proceedings.

ORS 689.700

Telepharmacy; requirements; rules.

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

(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. [2021 c.340 §2; 2022 c.45 §19]

OAR 855-006-0005
Definitions

(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.

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

OAR 855-139-0005
Definitions

The following words and terms, when used in OAR 855-139, 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) “RDSP Affiliated Pharmacy” means a Retail Drug Outlet Pharmacy registered in Oregon where an Oregon licensed Pharmacist provides pharmacy services through a telepharmacy system.

(2) “Remote Dispensing Site Pharmacy” or “RDSP” means an Oregon location registered as a Retail Drug Outlet Remote Dispensing Site Pharmacy staffed by a Certified Oregon Pharmacy Technician or Pharmacy Technician under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.

(3) “Telepharmacy” means the delivery of pharmacy services by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician or Pharmacy Technician.

(4) “Telepharmacy system” means a system of telecommunications technologies that enables monitoring, documenting, and recording of the delivery of pharmacy services at a remote location by an electronic method which must include the use of audio and video, still image capture, and store and forward.

Statutory/Other Authority: ORS 689.205, ORS 689.522, ORS 689.700 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.522, ORS 689.564, ORS 689.700 & 2022 HB 4034

OAR 855-139-0050
Personnel

(1) The Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy is responsible for all operations at the RDSP including responsibility for the telepharmacy system and enforcing policies and procedures.

(2) A RDSP may not utilize Interns. Unlicensed personnel may not perform any pharmacy services.

Petitioner’s proposed amendment:
(2) ~~A RDSP may not utilize Interns.~~ Unlicensed personnel may not perform any pharmacy services.

(3) The Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy who is supervising a RDSP must determine how many licensed individuals the Pharmacist is capable of supervising, directing and controlling based on the services being provided.

(4) The RDSP Affiliated Pharmacy and the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy are required to comply with the Pharmacist’s determination in (3) and retain records.

(5) The RDSP and RDSP Affiliated Pharmacy must ensure adequate staffing at both the RDSP and RDSP Affiliated Pharmacy.

(6) Prior to working at a RDSP, the RDSP Affiliated Pharmacy, and the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy are responsible for ensuring the Certified Oregon Pharmacy Technician or Pharmacy Technician and the Oregon licensed Pharmacist supervising the RDSP are adequately trained to perform their duties and have completed a training program on the proper use of the telepharmacy system.

(7) A RDSP Affiliated Pharmacy that terminates or allows a board licensee to resign in lieu of termination must report the termination or resignation to the board within 10 working days.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305 & 2022 HB 4034
History:
BP 36-2022, amend filed 06/15/2022, effective 06/16/2022

BP 26-2022, temporary amend filed 04/22/2022, effective 04/22/2022 through 10/18/2022
BP 43-2021, adopt filed 12/16/2021, effective 01/01/2022

OAR 855-139-0100
Security

(1) The area in a registered RDSP where legend and/or controlled substances are stored, possessed, prepared, compounded or repackaged must be restricted in access by utilizing physical barriers to include floor to ceiling walls and a locked separate entrance to ensure the security of those drugs.

(2) The RDSP Affiliated Pharmacy, the RDSP, Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the RDSP is responsible for the security of the prescription area including provisions for adequate safeguards against loss, theft or diversion of prescription drugs, and records for such drugs.

(3) The RDSP must be locked and the alarm system armed to prevent, deter and detect entry when:

(a) There is no Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy actively supervising the RDSP; or

(b) There is no Certified Oregon Pharmacy Technician or Pharmacy Technician present in the RDSP; or

(c) Any component of the surveillance system is not functioning.

(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.

Petitioner's proposed amendment:
~~(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.~~

(5) No one may be in the prescription area of a RDSP unless authorized in real-time by an Oregon licensed Pharmacist who is supervising the RDSP and from the RDSP Affiliated Pharmacy.

(6) Minimum security methods must include a properly functioning:

(a) Alarm system at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy if unauthorized access occurs;

(b) Electronic entry system that is controlled by an Oregon licensed Pharmacist and records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the RDSP;

(B) Identification of the Certified Oregon Pharmacy Technician or Pharmacy Technician accessing and securing the RDSP; and

(C) Date and time of each activity.

(c) Surveillance system that utilizes continuously accessible and recorded video between the RDSP Affiliated Pharmacy and the RDSP. The system must provide a clear view of:

(A) Dispensing site entrances;

(B) Preparation areas;

(C) Drug storage areas;

(D) Pick up areas;

(E) Office areas; and

(F) Publicly accessible areas.

Statutory/Other Authority: ORS 475.035, ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.155 & 2022 HB 4034
History:
BP 36-2022, amend filed 06/15/2022, effective 06/16/2022
BP 26-2022, temporary amend filed 04/22/2022, effective 04/22/2022 through 10/18/2022
BP 17-2022, amend filed 04/20/2022, effective 04/20/2022
BP 43-2021, adopt filed 12/16/2021, effective 01/01/2022

OAR 855-139-0200
Outlet: General Requirements

(1) A RDSP Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.

(2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.

Petitioner's proposed amendment:
~~(2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.~~

(3) A RDSP and its RDSP 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 each prescription is dispensed in compliance with OAR 855-115, OAR 855-125 and OAR 855-139;

(d) Comply with all applicable federal and state laws and rules;

(e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians authorized to access the RDSP and operate the telepharmacy system;

(f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system and RDSP;

(g) Develop, implement and enforce a continuous quality improvement program for dispensing services from a RDSP 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;

(h) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy; and

(i) Develop, implement and enforce a process for an in person physical inspection of the RDSP by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy. The inspection must utilize the RDSP self-inspection form, be documented, and records retained.

Statutory/Other Authority: ORS 689.205 & 2021 SB 629
Statutes/Other Implemented: 2021 SB 629 & ORS 689.155
History:
BP 32-2024, minor correction filed 04/10/2024, effective 04/10/2024
BP 36-2022, amend filed 06/15/2022, effective 06/16/2022
BP 26-2022, temporary amend filed 04/22/2022, effective 04/22/2022 through 10/18/2022
BP 7-2022, minor correction filed 01/05/2022, effective 01/05/2022
BP 43-2021, adopt filed 12/16/2021, effective 01/01/2022

OAR 855-139-0210
Outlet: Supervision

A RDSP and its RDSP Affiliated Pharmacy must:

(1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician, and the surveillance system is fully operational;

Petitioner's proposed amendments:

(1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Oregon licensed intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, and the audio and visual telepharmacy communication and continuous video surveillance system is fully operational;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP using an audiovisual communication system. All patient interactions must be recorded, reviewed and stored;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Oregon licensed intern, Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP using an audiovisual communication system. ~~All patient interactions must be recorded, reviewed and stored~~;

(3) The Oregon licensed Pharmacist who is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:

(a) Using reasonable professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;

(b) 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;

(c) Document the following within 24 hours of the review in (3)(b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions Pharmacist is reviewing;

(C) Date and time of licensee patient interaction Pharmacist is reviewing;

(D) Date and time of Pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

Petitioner's proposed amendments:

(3) The Oregon licensed Pharmacist who is supervising the Oregon licensed intern, Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:

~~(a) Using reasonable professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;~~

~~(b) 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;~~

~~(c) Document the following within 24 hours of the review in (3)(b):~~

~~(A) Number of each licensee's patient interactions;~~

~~(B) Number of each licensee's patient interactions Pharmacist is reviewing;~~

~~(C) Date and time of licensee patient interaction Pharmacist is reviewing;~~

~~(D) Date and time of Pharmacist review of licensee's patient interaction; and~~

~~(E) Pharmacist notes of each interaction reviewed; and~~

(d) Report any violation of OAR 855 to the RDSP Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.

Petitioner's proposed amendments:
(a) ~~(d)~~ Report any violation of OAR 855 ~~to the RDSP Affiliated Pharmacy within 24 hours of discovery and~~ to the board within 10 days.

(4) The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.

Petitioner's proposed amendments:
~~(4) The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.~~

(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician or Pharmacy Technician.

Petitioner's proposed amendments:
~~(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician or Pharmacy Technician.~~

(6) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP.

Statutory/Other Authority: ORS 689.205, ORS 689.225 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305 & 2022 HB 4034
History:
BP 36-2022, amend filed 06/15/2022, effective 06/16/2022
BP 26-2022, temporary amend filed 04/22/2022, effective 04/22/2022 through 10/18/2022
BP 17-2022, amend filed 04/20/2022, effective 04/20/2022
BP 43-2021, adopt filed 12/16/2021, effective 01/01/2022

ORS 689.486

When license required; qualifications for licensure; renewal; temporary license; supervision required.

(1) It is unlawful for any person to perform the duties of a pharmacy technician or use the title of pharmacy technician unless licensed to perform the duties of a pharmacy technician.

(2) To be licensed to perform the duties of a pharmacy technician, a person shall:

(a) Submit a license application in the manner prescribed by the State Board of Pharmacy; and

(b) Pay the license fee established by the board.

(3) The license application prescribed by the board shall include, but not be limited to:

(a) The name and address of the applicant;

(b) The educational qualifications of the applicant;

(c) The work history of the applicant; and

(d) The applicant's criminal offender record of any conviction or of any arrest less than one year old on which there has been no acquittal or dismissal.

(4) A license under this section expires annually. To renew a license to perform the duties of a pharmacy technician, a person shall:

(a) Submit the application for renewal of a license in the form prescribed by the board;

(b) Pay the license renewal fee established by the board;

(c) Pay the fee for late license renewal, if applicable;

(d) Provide updated information regarding educational qualifications, work history and criminal arrest and conviction history; and

(e) Comply with all other requirements for license renewal established by the board.

(5) The board may adopt rules to issue a temporary license to perform the duties of a pharmacy technician to a qualified applicant. A temporary license issued under this subsection may be renewed once.

(6) A person may not employ an individual to perform the duties of a pharmacy technician unless the individual is licensed to perform the duties of a pharmacy technician under this chapter.

(7) A person licensed to perform the duties of a pharmacy technician may perform the duties of a pharmacy technician only under the supervision, direction and control of a pharmacist. [1997 c.729 §6; 2001 c.595 §2; 2005 c.313 §7; 2013 c.514 §9; 2023 c.90 §1]

ORS 689.455

Duty to report suspected violations and prohibited conduct; liability for reporting; confidentiality of report.

(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, a pharmacist or pharmacy technician shall report:

(a) Any suspected violations of this chapter or of ORS 475.005 to 475.285 and 475.752 to 475.980 to the State Board of Pharmacy; and

(b) Any prohibited conduct as defined in ORS 676.150 in the manner provided in ORS 676.150.

(2) Any pharmacist or pharmacy technician who reports to the board as required by subsection (1) of this section in good faith shall not be subject to an action for civil damages as a result thereof.

(3) Any information that the board obtains pursuant to ORS 689.405 or 689.445 or this section is confidential as provided under ORS 676.175.

OAR 855-104-0010

Responsibilities: Duty to Report

(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each licensee must report to the board without undue delay, but within

(a) 10 days if they:

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

(B) Are arrested for a felony; or

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

(b) 10 working days if they have reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct to that licensee's board; or

(c) 15 days, if any change in:

(A) Legal name;

(B) For Pharmacists and Interns, name used when engaging in the practice of pharmacy and for Certified Oregon Pharmacy Technicians and Pharmacy Technicians, name used when assisting in the practice of pharmacy.

(C) Preferred email address;

(D) Personal phone number;

(E) Personal physical address;

(F) Personal mailing address; and

(G) Employer.

(2) A licensee who reports to a board in good faith as required by ORS 676.150 is immune from civil liability for making the report.

(3) A Pharmacist, Certified Oregon Pharmacy Technician or Pharmacy Technician who reports to a board in good faith as required by ORS 689.455 is not subject to an action for civil damages as a result thereof.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.150, ORS 689.155, ORS 689.455 & ORS 689.486
History:
BP 15-2023, adopt filed 08/15/2023, effective 03/01/2024

ORS 165.540
Obtaining contents of communications.

(1) Except as otherwise provided in ORS 133.724 or 133.726 or subsections (2) to (8) of this section, a person may not:

(a) Obtain or attempt to obtain the whole or any part of a telecommunication or a radio communication to which the person is not a participant, by means of any device, contrivance, machine or apparatus, whether electrical, mechanical, manual or otherwise, unless consent is given by at least one participant.

(b) Tamper with the wires, connections, boxes, fuses, circuits, lines or any other equipment or facilities of a telecommunication or radio communication company over which messages are transmitted, with the intent to obtain unlawfully the contents of a telecommunication or radio communication to which the person is not a participant.

(c) Obtain or attempt to obtain the whole or any part of a conversation by means of any device, contrivance, machine or apparatus, whether electrical, mechanical, manual or otherwise, if not all participants in the conversation are specifically informed that their conversation is being obtained.

(d) Obtain the whole or any part of a conversation, telecommunication or radio communication from any person, while knowing or having good reason to believe that the conversation, telecommunication or radio communication was initially obtained in a manner prohibited by this section.

(e) Use or attempt to use, or divulge to others, any conversation, telecommunication or radio communication obtained by any means prohibited by this section.

(2)(a) The prohibitions in subsection (1)(a), (b) and (c) of this section do not apply to:

(A) Officers, employees or agents of a telecommunication or radio communication company who perform the acts prohibited by subsection (1)(a), (b) and (c) of this section for the purpose of construction, maintenance or conducting of their telecommunication or radio communication service, facilities or equipment.

(B) Public officials in charge of and at jails, police premises, sheriffs' offices, Department of Corrections institutions and other penal or correctional institutions, except as to communications or conversations between an attorney and the client of the attorney.

(b) Officers, employees or agents of a telecommunication or radio communication company who obtain information under paragraph (a) of this subsection may not use or attempt to use, or divulge to others, the information except for the purpose of construction, maintenance, or conducting of their telecommunication or radio communication service, facilities or equipment.

(3) The prohibitions in subsection (1)(a), (b) or (c) of this section do not apply to subscribers or members of their family who perform the acts prohibited in subsection (1) of this section in their homes.

(4) The prohibitions in subsection (1)(a) of this section do not apply to the receiving or obtaining of the contents of any radio or television broadcast transmitted for the use of the general public.

(5) The prohibitions in subsection (1)(c) of this section do not apply to:

(a) A person who records a conversation during a felony that endangers human life;

(b) A person who records a conversation in which a law enforcement officer is a participant, if:

(A) The recording is made while the officer is performing official duties;

(B) The recording is made openly and in plain view of the participants in the conversation;

(C) The conversation being recorded is audible to the person by normal unaided hearing; and

(D) The person is in a place where the person lawfully may be;

(c)(A) A person who, pursuant to ORS 133.400, records an interview conducted by a peace officer in a law enforcement facility; or

(B) A person who, pursuant to ORS 133.402, records a custodial interview, as defined ORS 133.402;

(d) A law enforcement officer who is in uniform and displaying a badge and who is operating:

(A) A vehicle-mounted video camera that records the scene in front of, within or surrounding a police vehicle, unless the officer has reasonable opportunity to inform participants in the conversation that the conversation is being obtained; or

(B) A video camera worn upon the officer's person that records the officer's interactions with members of the public while the officer is on duty, unless:

(i) The officer has an opportunity to announce at the beginning of the interaction that the conversation is being obtained; and

(ii) The announcement can be accomplished without causing jeopardy to the officer or any other person and without unreasonably impairing a criminal investigation; or

(e) A law enforcement officer who, acting in the officer's official capacity, deploys an Electro-Muscular Disruption Technology device that contains a built-in monitoring system capable of recording audio or video, for the duration of that deployment.

(6)(a) The prohibitions in subsection (1)(c) of this section do not apply to persons who intercept or attempt to intercept oral communications that are part of any of the following proceedings, if the person uses an unconcealed recording device or if the communications occur through a video conferencing program:

(A) Public or semipublic meetings such as hearings before governmental or quasi-governmental bodies, trials, press conferences, public speeches, rallies and sporting or other events;

(B) Regularly scheduled classes or similar educational activities in public or private institutions; or

(C) Private meetings or conferences if all others involved knew or reasonably should have known that the recording was being made.

(b) The prohibitions in subsection (1)(c) of this section do not apply to a person who, with the intent to capture alleged unlawful activity, obtains or attempts to obtain a conversation occurring through a video conferencing program if the person is a participant in the conversation, or at least one participant in the conversation consents to the recording, and:

(A) The person is a law enforcement officer or is acting in coordination with a law enforcement officer;

(B) The person is acting in coordination with an attorney or an enforcement or regulatory entity; or

(C) The person reasonably believes that the recording may be used as evidence in a judicial or administrative proceeding.

(7) The prohibitions in subsection (1)(a), (c), (d) and (e) of this section do not apply to any:

(a) Radio communication that is transmitted by a station operating on an authorized frequency within the amateur or citizens bands; or

(b) Person who intercepts a radio communication that is transmitted by any governmental, law enforcement, civil defense or public safety communications system, including police and fire, readily accessible to the general public provided that the interception is not for purposes of illegal activity.

(8) The prohibitions in subsection (1)(d) and (e) of this section do not apply to a person who did not participate in initially obtaining the conversation, telecommunication or radio communication if the conversation, telecommunication or radio communication is regarding a matter of public concern.

(9) Violation of subsection (1) or (2)(b) of this section is a Class A misdemeanor.

(10) The exception described in subsection (5)(b) of this section does not authorize the person recording the law enforcement officer to engage in criminal trespass as described in ORS 164.243, 164.245, 164.255, 164.265 or 164.278 or to interfere with a peace officer as described in ORS 162.247.

(11) As used in this section:

(a) "Electro-Muscular Disruption Technology device" means a device that uses a high-voltage, low power charge of electricity to induce involuntary muscle contractions intended to cause temporary incapacitation. "Electro-Muscular Disruption Technology device" includes devices commonly known as tasers.

(b) "Law enforcement officer" has the meaning given that term in ORS 133.726.

[1955 c.675 §§2,7; 1959 c.681 §2; 1961 c.460 §1; 1979 c.744 §9; 1983 c.693 §1; 1983 c.740 §35; 1983 c.824 §1; 1987 c.320 §87; 1989 c.983 §14a; 1989 c.1078 §1; 2001 c.104 §54; 2001 c.385 §4; 2003 c.14 §62; 2007 c.879 §1; 2009 c.488 §2; 2015 c.550 §2; 2015 c.553 §1; 2019 c.216 §3; 2021 c.357 §2; 2023 c.234 §1]

OAR 855-139-0215
Outlet: Pharmacist Utilization

A RDSP and its RDSP Affiliated Pharmacy must:

(1) Utilize an Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy to perform the professional tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is dispensed; and

(2) Utilize an Oregon licensed Pharmacist and an audiovisual communication system to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-115-0145 and when requested and document the interaction.

Petitioner's proposed amendment:
(2) Utilize an Oregon licensed Pharmacist and an audiovisual communication system to provide counseling ~~or accept the refusal of counseling from the patient or the patient's agent~~ for each prescription being dispensed when counseling is required under OAR 855-115-0145 and when requested and document the interaction.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
History:
BP 33-2024, minor correction filed 04/10/2024, effective 04/10/2024
BP 17-2022, amend filed 04/20/2022, effective 04/20/2022
BP 43-2021, adopt filed 12/16/2021, effective 01/01/2022

OAR 855-115-0145
Counseling

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

(2) Counseling must be provided or offered to be provided to the patient or patient's agent on the use of a drug or device:

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

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

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

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

(3) An offer for the pharmacist to counsel under (1) and (2) must be made by a licensee.

(4) The pharmacist must counsel the patient or patient's agent on the use of a drug or device upon request.

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

(6) For a prescription where counseling has only been provided in writing, the pharmacist must provide drug information in a format accessible by the patient, including information on when the pharmacist is available and how the patient or patient's agent may contact the pharmacist.

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

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

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

(8) Counseling must be provided under conditions that maintain patient privacy and confidentiality.

(9) Counseling, offers to counsel or declinations of counseling regarding prescriptions must be documented with the licensee's identity.

(10) 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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 689.155
History:
BP 31-2023, adopt filed 12/19/2023, effective 03/01/2024

SBAR: Petition to Amend OAR 855-139-0050(2)

<table>
<tr><td rowspan="2">B</td><td>Background:
Current rule: OAR 855-139-0050
• (2) A RDSP may not utilize Interns. Unlicensed personnel may not perform any pharmacy services.</td><td>Petitioner's proposed amendment:
• (2) ~~A RDSP may not utilize Interns.~~ Unlicensed personnel may not perform any pharmacy services.</td></tr>
<tr><td colspan="2">Previous Board Discussion:
• 8/2021 Board Meeting Mailing #A4
o Policy Discussion: Interns and unlicensed personnel are not contemplated in the bill and thus there is not statutory authority to permit interns or unlicensed personnel in the Remote Dispensing Site Pharmacy.
• 12/2021 Board Meeting Mailing #B4
o 12/2021 Board Meeting Minutes (pg. 11-12)
▪ Board motioned to adopt rule, 6 in favor, 1 absent- motion carried

Related Statutes and Rules (full text on primary SBAR):
• ORS 689.700 Telepharmacy; requirements; rules.
• OAR 855-139-0050(2) Personnel</td></tr>
<tr><td>A</td><td colspan="2">Assessment:
• ORS 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.
o ORS 689.700 only permits a pharmacy technician to staff a telepharmacy.

For Board Discussion:
• Would the Board like to see a legislative change to permit an RDSP to be staffed by an Intern?</td></tr>
</table>

Inquiry Date: 04/30/2024
Board Review Date: 06/13/2024

SBAR: Petition to Amend OAR 855-139-0100(4)

<table>
<tr><td rowspan="2">B</td><td>Background:
Current rule: OAR 855-139-0100
(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.</td><td>Petitioner's proposed amendment:
~~(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.~~</td></tr>
<tr><td colspan="2">Previous Board Discussion:
• 8/2021 Board Meeting Mailing #A4
• 10/2021 Board Meeting Mailing #A6/A6a
o 10/2021 Board Meeting Minutes (pg. 21-22)
▪ "The Board inquired if an electronic entry system can record the identity of the specific licensee entering the facility"
• "Board staff clarified that pharmacies are already using technology that allows for this."
• 12/2021 Board Meeting Mailing #B4
o 12/2021 Board Meeting Minutes (pg. 11-12)
▪ Board motioned to adopt rule, 6 in favor, 1 absent- motion carried

Related Statutes and Rules (full text on primary SBAR):
• ORS 689.700 Telepharmacy; requirements; rules.
• OAR 855-139-0100(4) Security</td></tr>
<tr><td>A</td><td colspan="2">Assessment:
• OAR 855-139-0100(5) No one may be in the prescription area of a RDSP unless authorized in real-time by an Oregon licensed Pharmacist who is supervising the RDSP and from the RDSP Affiliated Pharmacy.

For Board Discussion:
• NA to discuss if this rule is sufficient to meet the board's intent for ensuring security and supervision, direction, and control of the pharmacy.</td></tr>
</table>

Inquiry Date: 04/30/2024
Board Review Date: 06/13/2024

SBAR: Petition to Amend OAR 855-139-0210(1)

B

Background:	Petitioner's proposed amendment:
Current rule: OAR 855-139-0210 A RDSP and its RDSP Affiliated Pharmacy must: (1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician, and the surveillance system is fully operational;	A RDSP and its RDSP Affiliated Pharmacy must: (1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Oregon licensed intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, and the audio and visual telepharmacy communication and continuous video surveillance system is fully operational;

Previous Board Discussion:

- 12/2021 Board Meeting Mailing #B4
  - Policy Discussion:
    - Rule was noticed for the November 2021 rulemaking hearing as "… and the telepharmacy system is fully operational."
    - A telepharmacy system does not do surveillance. Surveillance replicates the in-person supervision of a technician- audio and video allows for you to be remote, but still be able to supervise at the same level as in person. The technician could be in the pharmacy and do inventory tasks, etc. if the telepharmacy system was not working, but they could not be in the pharmacy if the surveillance system was not working.
    - Based on this information, it was suggested to change the rule from "telepharmacy system" to "surveillance system."
    - This was a substantive change that would require new rulemaking
  - Minutes (pg. 11)
    - "The Board discussed the need to update line 367 to state "surveillance" instead of "telepharmacy" and how to make this change without violating the rulemaking process."
      - "The Board discussed the risk of removing line 367 completely with the intent of adding the updated version of the line back into the rule during the rulemaking process in early 2022."
      - "Board staff advised that it is unlikely that there will be a remote dispensing pharmacy operating before the rule can be amended during the rulemaking process in early 2022."
      - "Board staff and the Board discussed how the requirement of a functioning system is included in other areas of the rule."
      - "The Board voiced support for removing 855-139-0100(3)(c) and adding it back in at a later date."
    - Board motioned to adopt subsection (1) of the proposed rule OAR 855-139-0100, 5 in favor, 1 opposed, 1 absent- motion carried
- 2/2022 Board Meeting Mailing #B8
  - Minutes (pg. 8)

SBAR: Petition to Amend OAR 855-139-0210(1)

	▪ "At the December 2021 board meeting, it was identified that in a few cases the incorrect system was utilized in a rule and to changes to the rule to utilize the correct term would have been considered substantive and thus would need to go back through rulemaking. As a result, board staff have analyzed the use of these terms and related terms (e.g., "security system") throughout OAR 855 and determined where amendments are necessary to ensure clarity and transparency." ▪ "The revisions add definitions for surveillance system, communication system, alarm system and entry system; Removes references to a security system. Amends use of these terms in promulgated rules to ensure clarity to registrants as to when each system is required." ▪ "Staff suggested that the board consider sending the proposed rules to March 2022 rulemaking hearing with the potential of permanent adoption in April 2022 and to be effective upon filing." • 6/2022 Board Meeting Mailing #B10 o Minutes (pg. 8) ▪ Board motioned to adopt proposed amendments to OAR 855-139-0210. 6 in favor, 2 absent- motion carried Related Statutes and Rules (full text on primary SBAR): • ORS 689.700 Telepharmacy; requirements; rules. • OAR 855-139-0100 Security • OAR 855-139-0210(1) Supervision • OAR 855-139-0500 Prohibited Practices • OAR 855-006-0005(3) "Audiovisual Communication System" and (53) "Surveillance System • OAR 855-139-0005(4) "Telepharmacy System"
A	Assessment: • Adding "Oregon licensed intern" o See SBAR for OAR 855-139-0050(2) Personnel • Adding "audio and visual telepharmacy communication and continuous video" o See OAR 855-006-0005 ▪ (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) "Telepharmacy system" means a system of telecommunications technologies that enables monitoring, documenting, and recording of the delivery of pharmacy services at a remote location by an electronic method which must include the use of audio and video, still image capture, and store and forward. ▪ (53) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance. o To ensure consistency with Board adopted definitions, this amendment would read:

SBAR: Petition to Amend OAR 855-139-0210(1)

	RDSP and its RDSP Affiliated Pharmacy must: (1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician, audiovisual communication system, telepharmacy system and surveillance system is fully operational; • It appears the proposed amendment is adding additional requirements that the board did not determine were needed at the time the rule was adopted. ▪ "At the December 2021 board meeting, it was identified that in a few cases the incorrect system was utilized in a rule and to changes to the rule to utilize the correct term would have been considered substantive and thus would need to go back through rulemaking. As a result, board staff have analyzed the use of these terms and related terms (e.g., "security system") throughout OAR 855 and determined where amendments are necessary to ensure clarity and transparency." ▪ "The revisions add definitions for surveillance system, communication system, alarm system and entry system; Removes references to a security system. Amends use of these terms in promulgated rules to ensure clarity to registrants as to when each system is required." ▪ "Staff suggested that the board consider sending the proposed rules to March 2022 rulemaking hearing with the potential of permanent adoption in April 2022 and to be effective upon filing." • 6/2022 Board Meeting Mailing #B10 o Meeting Minutes (pg. 8) ▪ Board motioned to adopt proposed amendments to OAR 855-139-0210. 6 in favor, 2 absent- motion carried For Board Discussion: • How can a Pharmacist at a RDSP Affiliated Pharmacy supervise, direct, and control a technician located at a RDSP as required by ORS 689.486? o What systems need to be operational to facilitate this requirement? Audiovisual, Telepharmacy, Surveillance systems

Inquiry Date: 04/30/2024
Board Review Date: 06/13/2024

SBAR: Petition to Amend OAR 855-139-0200(2)

B

Background:
Current rule: OAR 855-139-0200

- (2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.

Petitioner's proposed amendment:

- ~~(2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.~~

Previous Board Discussion:

- 8/2021 Board Meeting Mailing #A4
  - Policy Discussion: From a patient safety perspective, if there is an issue or problem, a RPH needs to quickly assess and be on-site. The majority of testimony for SB 629 focused on providing prescription access to rural areas. Multiple states with telepharmacy laws have minimum and/or maximum distance limits.
  - 8/2021 Board Meeting Minutes (pg. 4-7)
    - "The Board voiced support for the distance parameters as drafted with only a maximum distance outlined."
- 12/2021 Board Meeting Mailing #B4
  - Policy Discussion: There is potential for the closest pharmacy to a RDSP to be greater than 120 miles. Unknown if this scenario exists, but it is possible. Reiterated policy discussion from August 2021 board meeting.
  - 12/2021 Board Meeting Minutes (pg. 11-12)
    - "The Board discussed the maximum distance allowance of 120 miles between the RDSP and affiliated pharmacy as required by OAR 855-139-0200(2)."
    - Board motioned to adopt rule, 6 in favor, 1 absent- motion carried

Related Statutes and Rules (full text on primary SBAR):

- ORS 689.700 Telepharmacy; requirements; rules.
- OAR 855-006-0005(3) "Audiovisual Communication System" and (53) "Surveillance System
- OAR 855-139-0005(4) "Telepharmacy System"
- OAR 855-139-0100(3)(6) Security
- OAR 855-139-0200(2) Outlet: General Requirements
- OAR 855-139-0210(1) Outlet: Supervision
- OAR 855-139-0500(2) Policies and Procedures

A

Assessment:

- The current 120-mile distance was adopted in rule per the board direction above.

For Board Discussion:

- Is the 120-mile limit necessary?
  - Modify the current limit?
    - If so, what is the most appropriate revised distance?
  - Eliminate the distance limit entirely?
    - If so, are there alternative parameters to ensure patient safety and access to care?
- Should RDSP Affiliated Pharmacies be limited to only Oregon resident pharmacies?

Inquiry Date: 04/30/2024
Board Review Date: 06/13/2024

SBAR: Petition to Amend OAR 855-139-0210(2)(3)(4)(5)

B	Background: Current rule: OAR 855-139-0210	Petitioner's proposed amendment:
	(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP using an audiovisual communication system. All patient interactions must be recorded, reviewed and stored;	(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Oregon licensed intern, Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP using an audiovisual communication system. ~~All patient interactions must be recorded, reviewed and stored~~;
	(3) The Oregon licensed Pharmacist who is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:	(3) The Oregon licensed Pharmacist who is supervising the Oregon licensed intern, Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:
	(a) Using reasonable professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;	~~(a) Using reasonable professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;~~
	(b) 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;	~~(b) 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;~~
	(c) Document the following within 24 hours of the review in (3)(b): (A) Number of each licensee's patient interactions; (B) Number of each licensee's patient interactions Pharmacist is reviewing; (C) Date and time of licensee patient interaction Pharmacist is reviewing; (D) Date and time of Pharmacist review of licensee's patient interaction; and (E) Pharmacist notes of each interaction reviewed; and	~~(c) Document the following within 24 hours of the review in (3)(b):~~ ~~(A) Number of each licensee's patient interactions;~~ ~~(B) Number of each licensee's patient interactions Pharmacist is reviewing;~~ ~~(C) Date and time of licensee patient interaction Pharmacist is reviewing;~~ ~~(D) Date and time of Pharmacist review of licensee's patient interaction; and~~ ~~(E) Pharmacist notes of each interaction reviewed; and~~
	(d) Report any violation of OAR 855 to the RDSP Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.	(a) ~~(d)~~ Report any violation of OAR 855 ~~to the RDSP Affiliated Pharmacy within 24 hours of discovery and~~ to the board within 10 days.
	(4) The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.	~~(4) The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.~~
	(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician or Pharmacy Technician.	~~(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician or Pharmacy Technician.~~

SBAR: Petition to Amend OAR 855-139-0210(2)(3)(4)(5)

Previous Board Discussion:

- 10/2021 Board Meeting Mailing #A6/A6a
  - Policy Discussion:
    - In a traditional pharmacy, the pharmacist would be able to overhear most of the conversations that are occurring and be able to intervene in real-time as necessary. At an RDSP the pharmacist is not present and would likely not be able to intervene in real-time.
  - Minutes (pg. 23)
    - "Board staff requested input on the requirement for a supervising pharmacist to review COPT/patient interaction and to report the discovery of a violation within 24 hours if its occurrence.
      - The Board discussed how this time limit could be restrictive and possibly unreasonable.
      - The Board discussed how it could be more reasonable to require the supervising pharmacist to report within 24 hours of the discovery of a violation rather than within 24 hours from the actual occurrence. The Board also discussed changing the language to 1 business day to account for locations being closed on weekends."
    - "The Board discussed the challenges of reviewing a minimum of 25% of COPT/patient interactions within 24 hours.
      - Board staff explained that this expectation was crafted with patient safety in mind.
      - The Board discussed using a different metric. Such as requiring pharmacists to review a certain number of interactions rather than a percentage as calculating a percentage could be challenging.
      - The Board discussed if review is necessary with the technology that is available for real time supervision.
      - The Board discussed lowering the percentage requirement to 10%.
      - Board members discussed that the 25% requirement could be in the best interest for protecting patient safety despite the workload it could create."
    - "The Board came to a consensus to voice support for changing the requirement to review COPT/patient interactions within 48 hours."
    - "The Board inquired about how the pharmacist is expected to determine what 25% of COPT/patient interactions is.
      - Board staff clarified that upon a visit to a remote pharmacy and a review of their software it became clear that the software can generate the metrics needed for the pharmacist to review."
    - "The Board voiced support for requiring the supervising pharmacist to report any violation to the affiliated pharmacy within 24 hours of discovery rather than within 24 hours of the incident."
    - "The Board inquired on why Board staff included the minimum of 25% of patient interactions to be reviewed.

	• Board staff explained that that a pharmacist supervising in person would be able to supervise close to 100% of interactions and that this percentage was determined based on comments from the technician Rules Advisory Committee in September. • The Board came to a consensus to voice support for keeping the requirement at 25%." • 12/2021 Board Meeting Mailing #B4 o Minutes (pg. 11) ▪ "Pertaining to OAR 855-139-0210(3), the Board discussed how CPT/patient interactions are measured, how a percentage of interactions is calculated, and if the requirement for the minimum percentage of retrospective review will deter pharmacies from utilizing the model. • Board staff clarified that, as the rule is currently written, the review is not required to be retrospective and could be real time surveillance throughout the day. • The Board discussed the risks and benefits of removing a percentage requirement. • The Board discussed adjusting the language to state that a specific percentage of CPT/patient interactions must be reviewed or observed to add clarity that retrospective review isn't the only option to fulfill the minimum requirement. • The Board voiced support for drafting a motion changing the percentage to 10% and adding the word "observed." ▪ Board motioned to adopt subsection (2) of the proposed rule OAR 855-139-0210, 6 in favor, 1 absent- motion carried ▪ Board motioned to adopt subsection (3) of the proposed rule OAR 855-139-0210, 4 in favor, 2 opposed, 1 absent- motion carried ▪ Board motioned to adopt subsection (4) of the proposed rule OAR 855-139-0210, 6 in favor, 1 absent- motion carried ▪ Board motioned to adopt subsection (5) of the proposed rule OAR 855-139-0210, 6 in favor, 1 absent- motion carried Related Statutes and Rules (full text on primary SBAR): • ORS 689.700 Telepharmacy; requirements; rules. • OAR 855-139-0210(2)(3)(4)(5) Outlet: Supervision • OAR 855-139-0050(2) Personnel • ORS 689.486 When license required; qualifications for licensure; renewal; temporary license; supervision required. • ORS 689.455 Duty to report suspected violations and prohibited conduct; liability for reporting; confidentiality of report. • OAR 855-104-0010 Responsibilities: Duty to Report
A	Assessment: • (2) o Adding "Oregon licensed intern"

- See SBAR for OAR 855-139-0050(2) Personnel
- Removing "all patient interactions must be recorded, reviewed and stored," see assessment below for (3)

- (3)
  - Adding "Oregon licensed intern"
    - See SBAR for OAR 855-139-0050(2) Personnel
  - Removing (3)(a)(b) and (c) which require supervising pharmacist at RDSP to review at least 10% of technician interactions within 48 hours and document the review within 24 hours.
    - Per ORS 689.486, Pharmacists are required to supervise, direct and control pharmacy technicians at all times.
  - Amending (d) by removing to "to the RDSP Affiliated Pharmacy within 24 hours of discovery."
    - Per ORS 689.455 a pharmacist or pharmacy technician to report any suspected violation to the board.
    - OAR 855-104-0010 requires a licensee to report a suspected violation to the board within 10 days.
- (4)
  - Removing (4) "The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records."
    - If (3)(a)(b) are deleted, (4) would no longer be necessary.
    - If (3)(a)(b) are retained, to be consistent with other rules related to Safe Pharmacy Practice Conditions (OAR 855-041-1018(7)), (4) should also be retained.
- (5)
  - Removing (5) "Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician or Pharmacy Technician."
    - If (2), (3)(a)(b) are deleted, (5) would no longer be necessary.
    - If (2), (3)(a)(b) are amended, (5) may also need to be amended.
  - Related to the privacy concerns, ORS 165.540 requires consent to be given by at least one participant.
    - RDSPs can mitigate concerns about recordings by using signs and greetings that clearly state that conversations are being recorded.
    - Some pharmacies record phone conversations (e.g., mail-order, specialty)

For Board Discussion:

- In the RDSP setting, how does a pharmacist provide supervision, direction and control of a pharmacy technician as required by ORS 689.486 at all times?
  - Through surveillance, audiovisual, and/or telepharmacy systems?
  - Is documentation needed?
- In the RDSP setting, how does the supervising pharmacist ensure there is timely communication with the outlet?
  - There is not a requirement in ORS 689 or OAR 855 that requires a pharmacist in a traditional pharmacy to report a potential violation to the outlet.

	o Licensees and registrants are required to report a potential violation to the board per: ▪ ORS 689.455 Duty to report suspected violations and prohibited conduct; liability for reporting; confidentiality of report. ▪ OAR 855-104-0010 Responsibilities: Duty to Report

Inquiry Date: 04/30/2024
Board Review Date: 06/13/2024

Petition to Amend OAR 855-139-0215(2)

B

Background:
Current rule: OAR 855-139-0215

(2) Utilize an Oregon licensed Pharmacist and an audiovisual communication system to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-115-0145 and when requested and document the interaction.

Petitioner's proposed amendment:

(2) Utilize an Oregon licensed Pharmacist and an audiovisual communication system to provide counseling ~~or accept the refusal of counseling from the patient or the patient's agent~~ for each prescription being dispensed when counseling is required under OAR 855-115-0145 and when requested and document the interaction.

Previous Board Discussion:

- 8/2021 Board Meeting Mailing #A4
  - Minutes (pg. 5)
    - "The Board discussed the counseling requirement and voiced support for retaining the same requirements for counseling as outlined in OAR 855-019-0230 prior to dispensing prescriptions from a Remote Dispensing Site Pharmacy."
- 12/2021 Board Meeting Mailing #B4
  - Minutes (pg. 11-12)
    - Board motioned to adopt rule, 6 in favor, 1 absent- motion carried

Related Statutes and Rules (full text on primary SBAR):

- ORS 689.700 Telepharmacy; requirements; rules.
- OAR 855-139-0215(2) Outlet: Pharmacist Utilization
- OAR 855-115-0145 Counseling

A

Assessment:

- Agency staff have internally identified rules (like this rule) that will require amending due to other recent rule changes.
- Revising this language as proposed would reconcile this rule with OAR 855-115-0145(3) and (7).

  (3) An offer for the pharmacist to counsel under (1) and (2) must be made by a licensee.
  (7) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused:
  (a) Only a licensee can accept a patient's or patient's agent's request not to be counseled, when counseling is required.
  (b) The pharmacist may choose not to release the prescription until counseling has been completed.

For Board Discussion:

- Assess the priority of this amendment while considering other board priorities.
  - One RDSP currently registered and in operation.

Inquiry Date: 04/30/2024
Board Review Date: 06/13/2024

Boards and Commissions
Best Practices Measure

1. What's this about?
Department of Administrative Services (DAS) and the Legislative Fiscal Office (LFO) were given a joint budget note for 2005-07 asking them to develop best management practices performance measures to be applied to governance boards and commissions. A recommendation was submitted to and approved by JLAC in July, 2006. In 2007-09 the Legislature added it to all governing Boards and Commissions.

2. What's the measure?
The approved measure is "percent of total best practices met by the board." The measure is calculated as the percent of "yes" responses provided in a self-assessment of best practices. The Self-assessment Guidance that lists 15 best practices is provided in the recommendation. Applicable boards/commissions will need to conduct annual self-evaluations to gather information to report on the measure.

3. Who is impacted?
The requirement is being applied to boards and commissions that meet the following criteria:

- The board/commission has an independent state budget or is included in another state agency's budget.
- The board/commission hires the agency or board's executive director.

These criteria focus on governing boards/commissions. A complete list of applicable boards/commissions is provided in the recommendation.

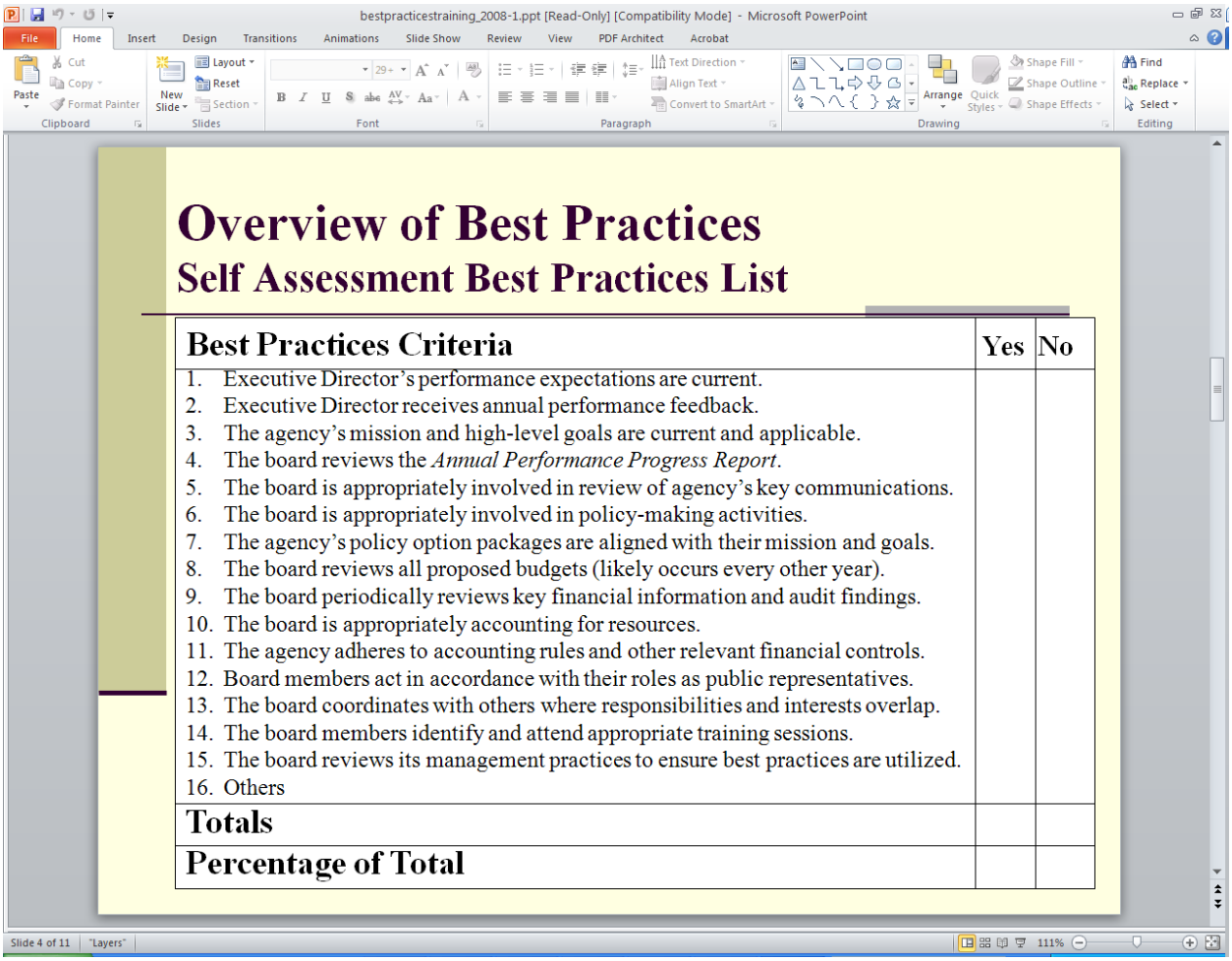
4. How often do we report on this measure?
Yearly

Standard Measure – Percent of best practices met by the Board and/or Commission

Self-Assessment/Best Practices Criteria

1. Executive Director's performance expectations are current.
2. Executive Director receives annual performance feedback.
3. The agency's mission and high-level goals are current and applicable.
4. The board reviews the *Annual Performance Progress Report*.
5. The board is appropriately involved in review of agency's key communications.
6. The board is appropriately involved in policy-making activities.
7. The agency's policy option packages are aligned with their mission and goals.
8. The board reviews all proposed budgets (likely occurs every other year).
9. The board periodically reviews key financial information and audit findings.
10. The board is appropriately accounting for resources.
11. The agency adheres to accounting rules and other relevant financial controls.
12. Board members act in accordance with their roles as public representatives.
13. The board coordinates with others where responsibilities and interests overlap.
14. The board members identify and attend appropriate training sessions.
15. The board reviews its management practices to ensure best practices are utilized.
16. Others

Totals
Percentage of Total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Clipboard
New Slide
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Reset
Section
Slides
Font
Text Direction
Align Text
Convert to SmartArt
Paragraph
Arrange
Quick Styles
Shape Fill
Shape Outline
Shape Effects
Drawing
Find
Replace
Select
Editing
Overview of Best Practices
Self Assessment Best Practices List
Best Practices Criteria
Yes
No
1. Executive Director's performance expectations are current.
2. Executive Director receives annual performance feedback.
3. The agency's mission and high-level goals are current and applicable.
4. The board reviews the Annual Performance Progress Report.
5. The board is appropriately involved in review of agency's key communications.
6. The board is appropriately involved in policy-making activities.
7. The agency's policy option packages are aligned with their mission and goals.
8. The board reviews all proposed budgets (likely occurs every other year).
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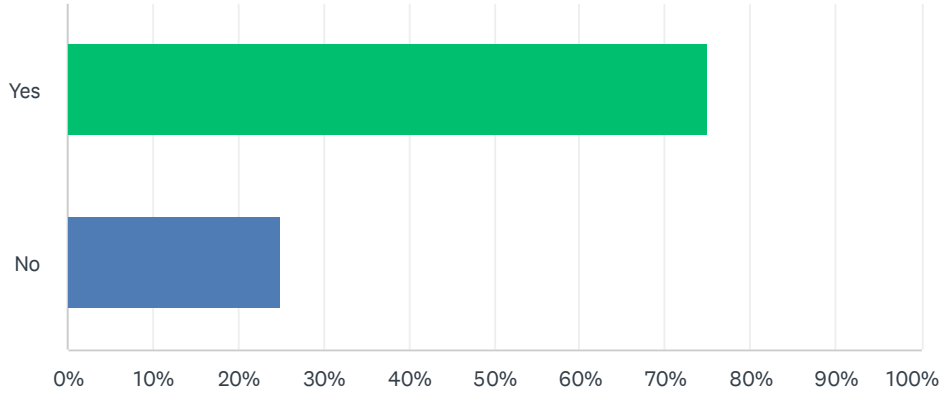
10. The board is appropriately accounting for resources.
11. The agency adheres to accounting rules and other relevant financial controls.
12. Board members act in accordance with their roles as public representatives.
13. The board coordinates with others where responsibilities and interests overlap.
14. The board members identify and attend appropriate training sessions.
15. The board reviews its management practices to ensure best practices are utilized.
16. Others
Totals
Percentage of Total
Slide 4 of 11
"Layers"
111%

Q1 Executive Director's performance expectations are current.

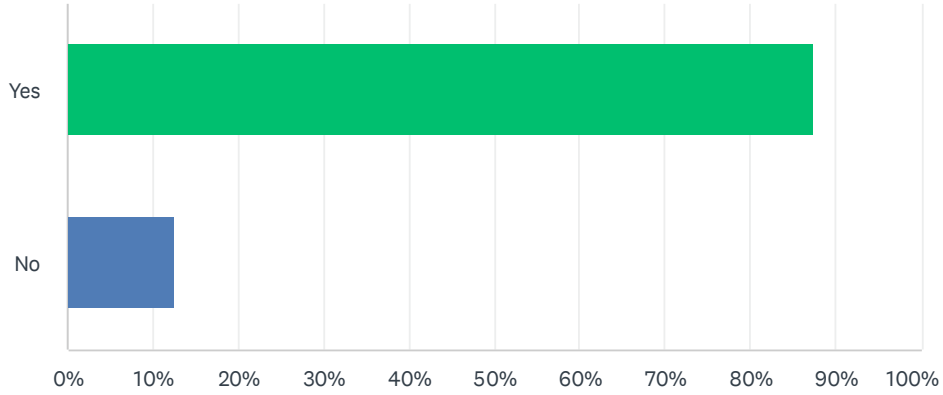
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

Q2 Executive Director receives annual performance feedback.

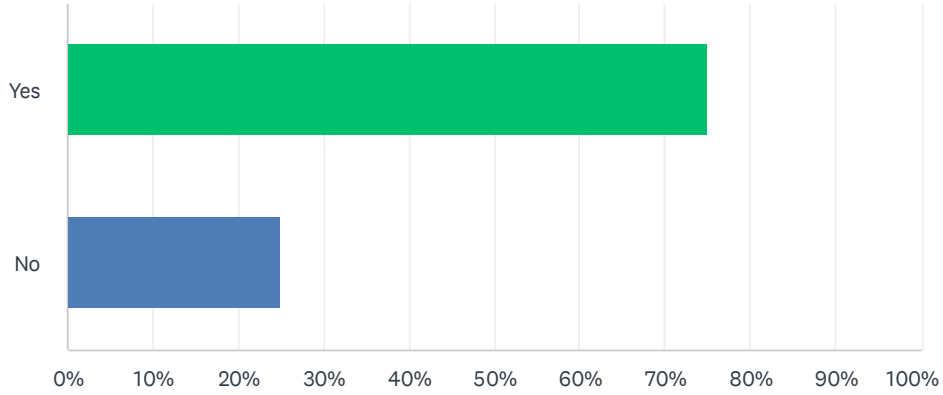
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	87.50%	7
No	12.50%	1
TOTAL		8

Q3 The agency's mission and high-level goals are current and applicable.

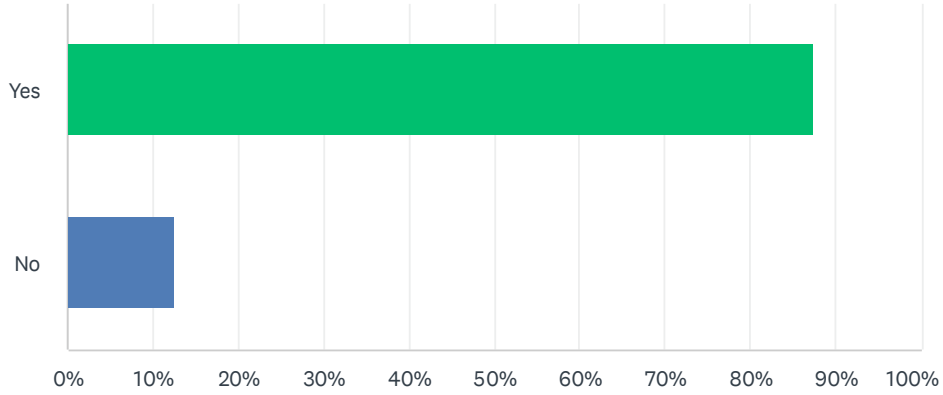
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

Q4 The board reviews the Annual Performance Progress Report.

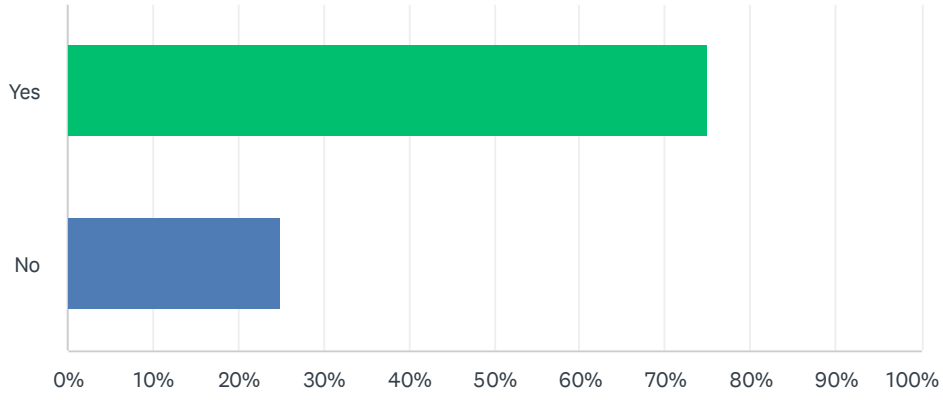
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	87.50%	7
No	12.50%	1
TOTAL		8

Q5 The board is appropriately involved in review of the agency's key communications.

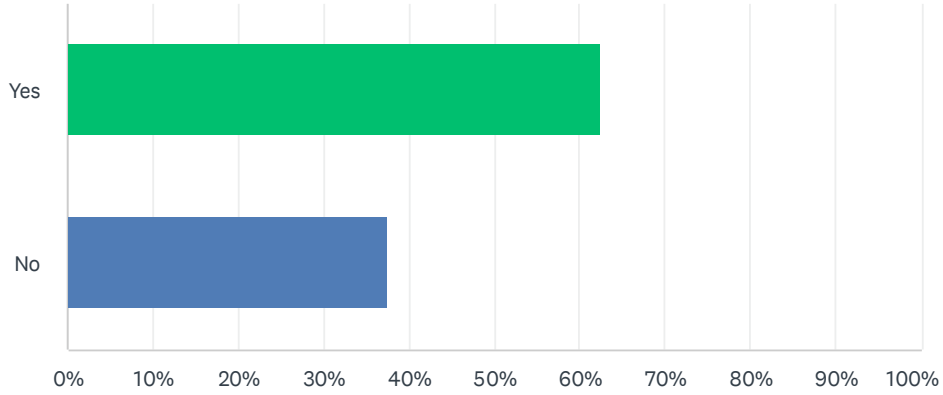
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

Q6 The board is appropriately involved with policy making activities.

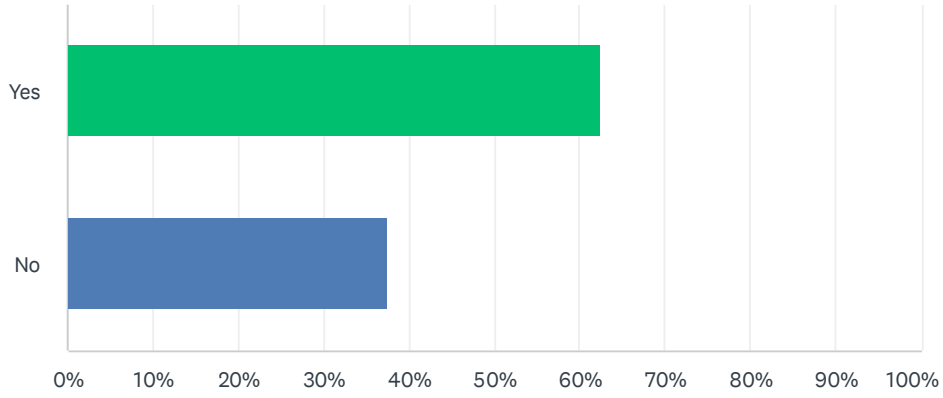
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	62.50%	5
No	37.50%	3
TOTAL		8

Q7 The agency's policy option packages are aligned with their mission and goals.

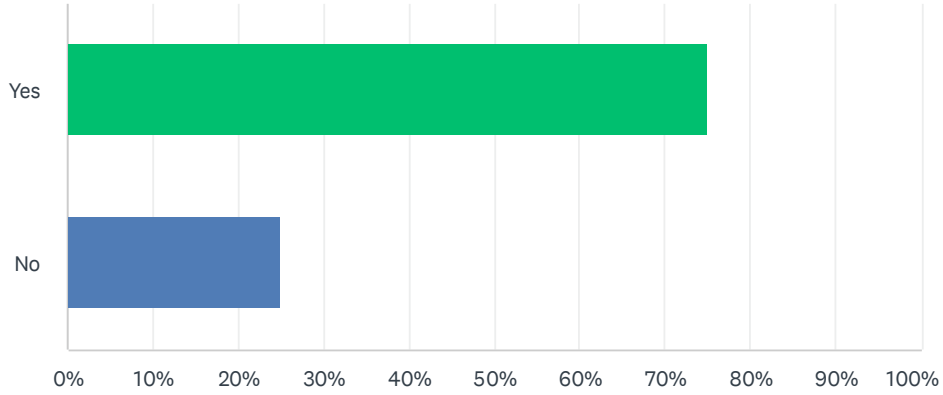
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	62.50%	5
No	37.50%	3
TOTAL		8

Q8 The board reviews all proposed budgets.

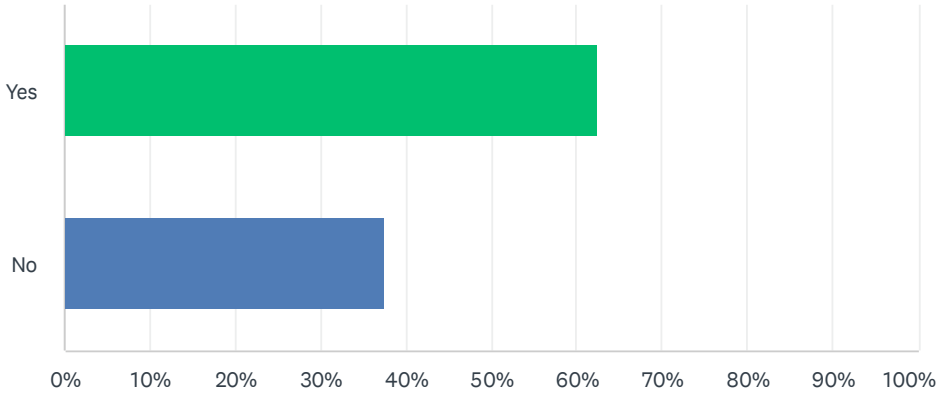
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

Q9 The board periodically reviews key financial information and audit findings.

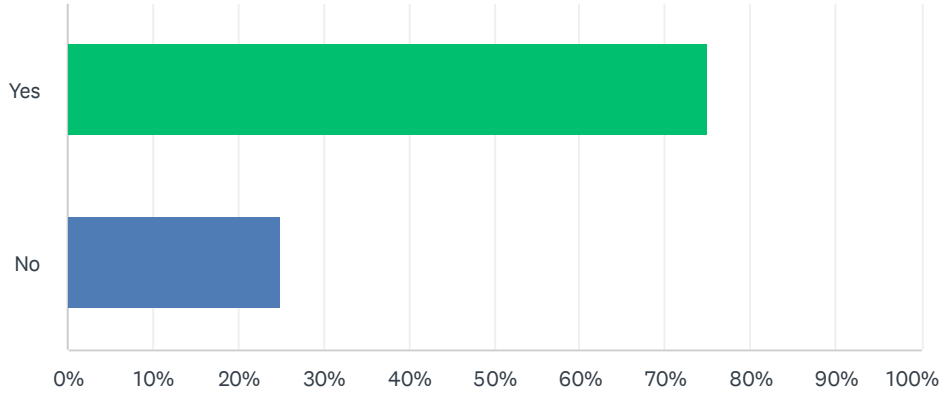
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	62.50%	5
No	37.50%	3
TOTAL		8

Q10 The board is appropriately accounting for resources.

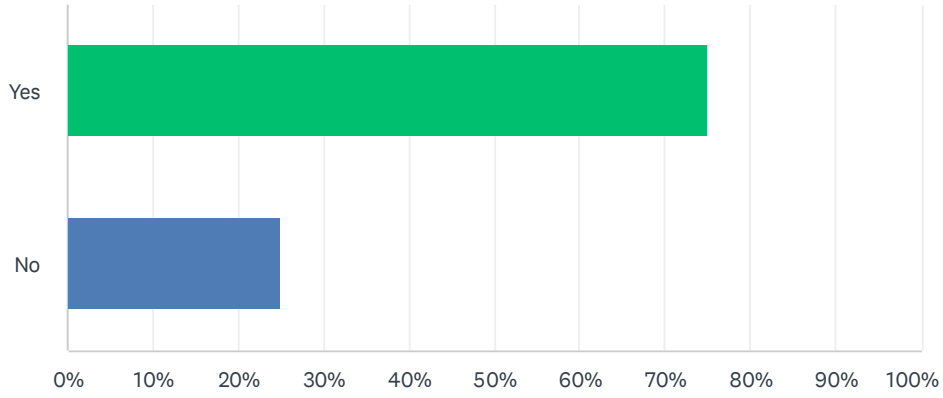
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

Q11 The agency adheres to accounting rules and other relevant financial controls.

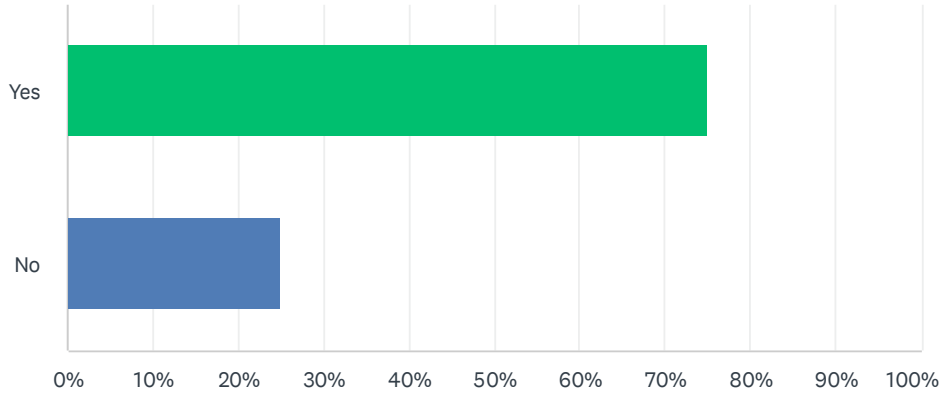
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

Q12 Board members act in accordance with their roles as public representatives.

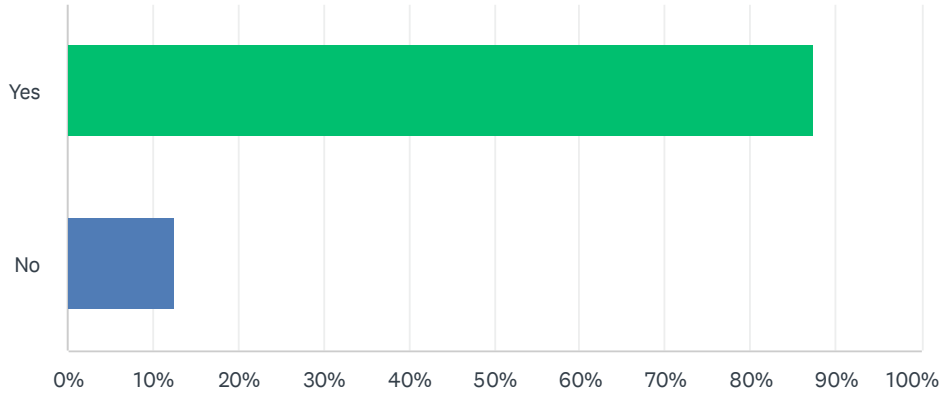
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

Q13 The board coordinates with others where responsibilities and interests overlap.

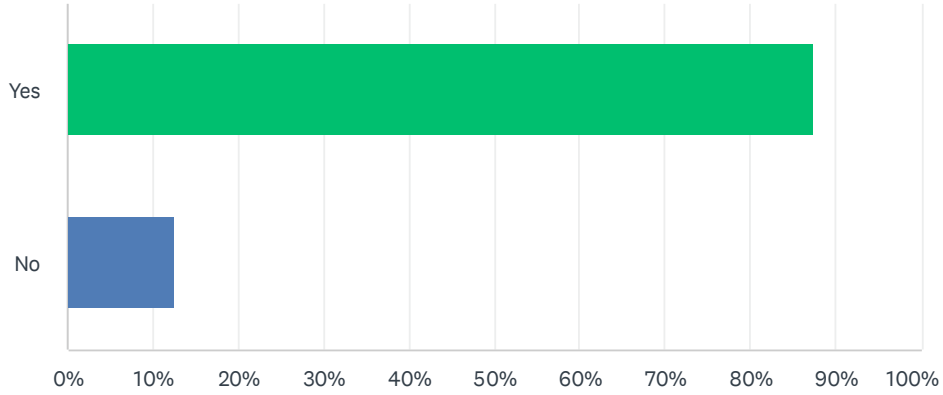
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	87.50%	7
No	12.50%	1
TOTAL		8

Q14 The board members identify and attend appropriate training sessions.

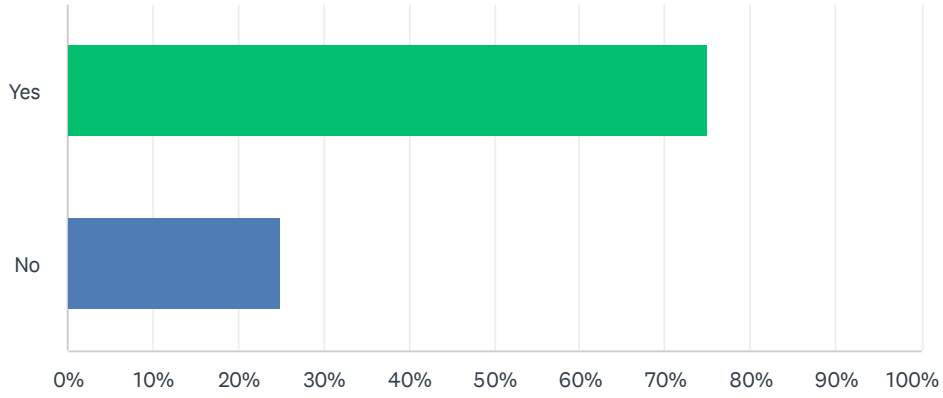
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	87.50%	7
No	12.50%	1
TOTAL		8

Q15 The board reviews its management practices to ensure best practices are utilized.

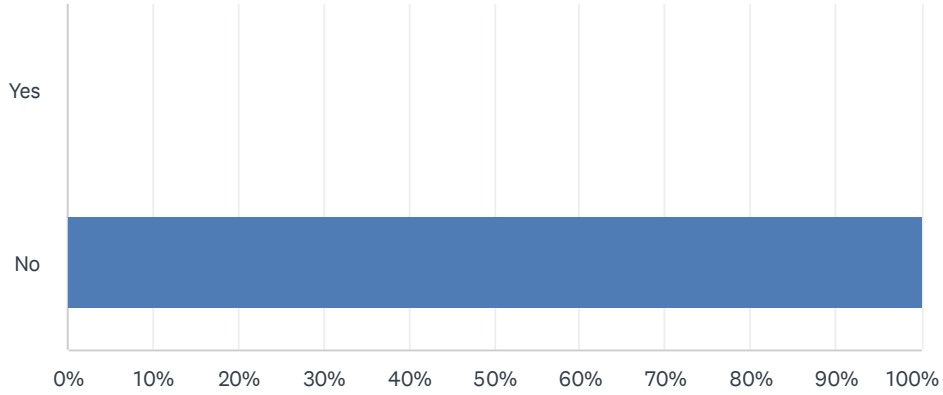
Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	75.00%	6
No	25.00%	2
TOTAL		8

Q16 The on-boarding process for new board members works well.

Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	0.00%	0
No	100.00%	8
TOTAL		8

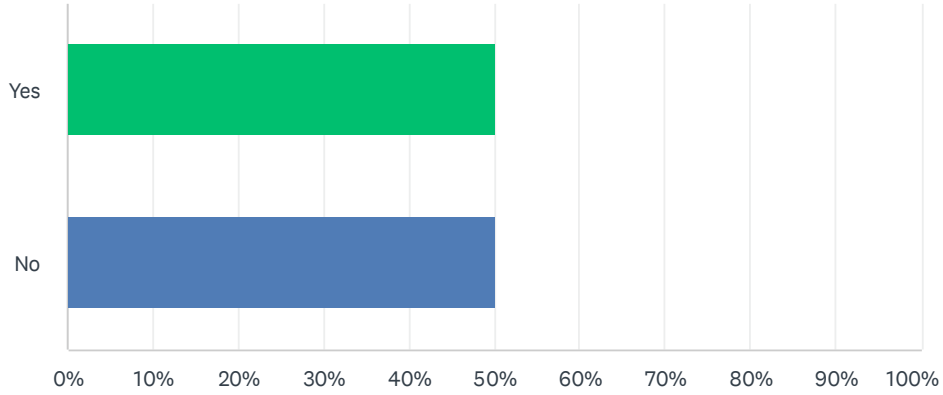
Q17 Thinking about the workload for each board meeting, how many hours do you spend reviewing materials and preparing for a board meeting?

Answered: 8 Skipped: 0

#	RESPONSES	DATE
1	I dedicate approximately 40 hours to reviewing and preparing for each board meeting. However, a significant portion of my time is spent reviewing drafted rules both before and after the meeting, as they often fail to align with statutes and legislative intent. The fact that we receive public comments of up to 60 pages during rule-making meetings indicates that there is ample room for improvement.	5/10/2024 4:49 PM
2	Varies based on case load and rules packages	5/8/2024 2:37 PM
3	20-30 hours	5/2/2024 7:55 AM
4	20	4/30/2024 10:43 AM
5	16-24 hours depending on the amount and complexity of the materials to be reviewed and acted upon.	4/29/2024 11:28 PM
6	20	4/29/2024 2:39 PM
7	16-24	4/26/2024 11:27 PM
8	Too many	4/26/2024 2:55 PM

Q18 The workload of each board meeting is manageable.

Answered: 8 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	50.00%	4
No	50.00%	4
TOTAL		8

Q19 Do you have suggestions to reduce workload?

Answered: 8 Skipped: 0

#	RESPONSES	DATE
1	We need to shift our focus away from imposing burdensome regulations and proof of compliance onto pharmacists, and instead prioritize reducing administrative burdens so they can focus on providing optimal patient care without unnecessary license concerns. While statutes allow the board to establish rules regulating pharmacy practice, they don't imply a constant need for rule changes at every meeting. Rule adjustments should not be made hastily unless prompted by legislation or precedent, and the responsibility lies with board members and staff to justify any proposed changes. Rather than creating rules based on hypothetical safety concerns and assuming minimal compliance from licensees, we should establish minimum standards for operating a drug outlet. These standards should be broad and flexible, encouraging innovation without the need for explicit permission. Only when specific deficiencies arise should additional rules be introduced to address them.	5/10/2024 4:49 PM
2	No	5/8/2024 2:37 PM
3	Understanding the drivers of investigatory case load. Have we created the growing number of cases with the specificity of our rules, the detail of the inspection process and how in depth each investigation goes.	5/2/2024 7:55 AM
4	Assure that materials are delivered for board member review at least 2 weekends in advance of meeting. Weekends are when I have been able to prepare mostly (eg 4 hours each of the 4 Sat and Sundays preceding Wed meeting start)… or at least 50% of material for weekend #1 and remaining 50% for weekend #2	4/30/2024 10:43 AM
5	For all case review summaries, list at least one maybe two proposals for board considerations based on similar cases to help guide discussion for each case number. It seems the vast majority of cases have very similar prior Incidents and there should be fewer that are “open for discussion”. Too often, even though I have a full understanding of a case, I still struggle to measure the amount of discipline because my memory can only draw from my previous experience as a board member and not the thousands of cases the board has reviewed. We really need to implement more ideas that would fall under staff delegated authority! For example violations with measurable parameters like temperature excursions and violations that can be quantified like “no PIC for X days”, similar to what we do for licencees with CE failures.	4/29/2024 11:28 PM
6	Give all the materials once without adding or changing anything. Help new board members with how to best prepare and manage.	4/29/2024 2:39 PM
7	Not currently	4/26/2024 11:27 PM
8	Condense and simplify content provided	4/26/2024 2:55 PM

Q20 Please validate the Best Practices Self-Assessment Score Card by entering your first and last name.

Answered: 8 Skipped: 0

#	RESPONSES	DATE
1	Priyal Patel	5/10/2024 4:49 PM
2	Shannon Beaman	5/8/2024 2:37 PM
3	Rachael DeBarmore	5/2/2024 7:55 AM
4	Ian Doyle	4/30/2024 10:43 AM
5	Richard Joyce	4/29/2024 11:28 PM
6	Jennifer Hall- why is this not anonymous? Some questions I am not sure yet of the answers	4/29/2024 2:39 PM
7	Kathleen Chinn	4/26/2024 11:27 PM
8	Rosemarie Hemmings	4/26/2024 2:55 PM

Board of Pharmacy

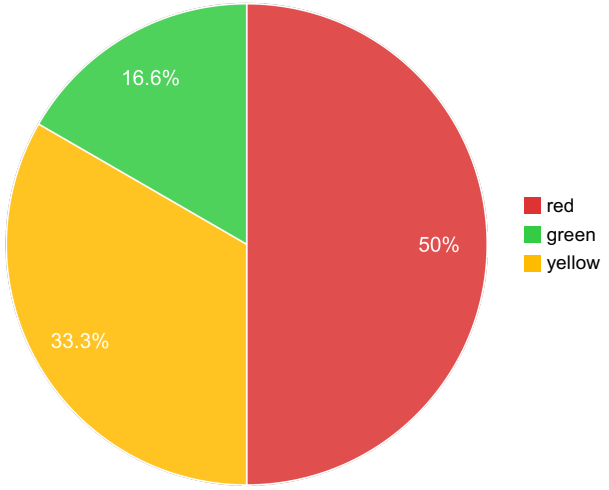
Annual Performance Progress Report

Reporting Year 2023

Published: 12/22/2023 4:19:53 PM

Please note, for Measures #1 and #3, the accurate data collection period reflects 2/1/22 through 6/30/23 (17 months)

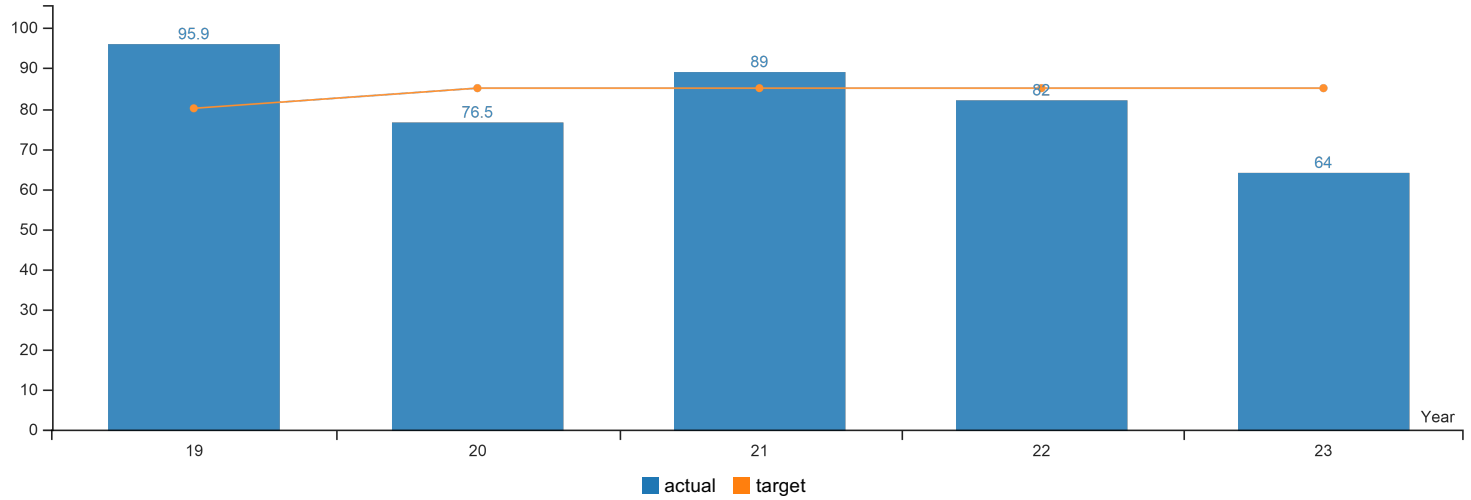
KPM #	Approved Key Performance Measures (KPMs)
1	Percent of inspected pharmacies that are in compliance annually. -
2	Percentage of individual and facility licenses that are issued within 30 days. -
3	Percent of pharmacies inspected every two years. -
4	Average number of days to complete an investigation 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:	16.67%	33.33%	50%

KPM #1	Percent of inspected pharmacies that are in compliance annually. -
	Data Collection Period: Feb 01 - Jun 30

** Upward Trend = positive result*



Report Year	2019	2020	2021	2022	2023
Percentage of Pharmacies that are in compliance annually.					
Actual	95.90%	76.50%	89%	82%	64%
Target	80%	85%	85%	85%	85%

How Are We Doing

This report reflects 17 months.

From February 1, 2022 - June 30, 2023 board Compliance Officers completed 678 Retail and Institutional pharmacy inspections of which 437 were in compliance. Of the 678 completed inspections, 139 passed inspection, 298 passed with notes for improvement, 73 received deficiency notifications and 170 notifications of non compliance were issued; note all notifications are reviewed by the board to determine if disciplinary action is warranted.

Additional inspctions completed: 1 Charitable Pharmacy, 1 Consulting / Drugless Pharmacy, 14 Dispensing Practitioner Drug Outlet, 4 Wholesalers - 2 outlets - 64% of outlets inspected in 2022/23 were in compliance.

Note, the board shifted its reporting for this measure to correspond to with rule changes.

Factors Affecting Results

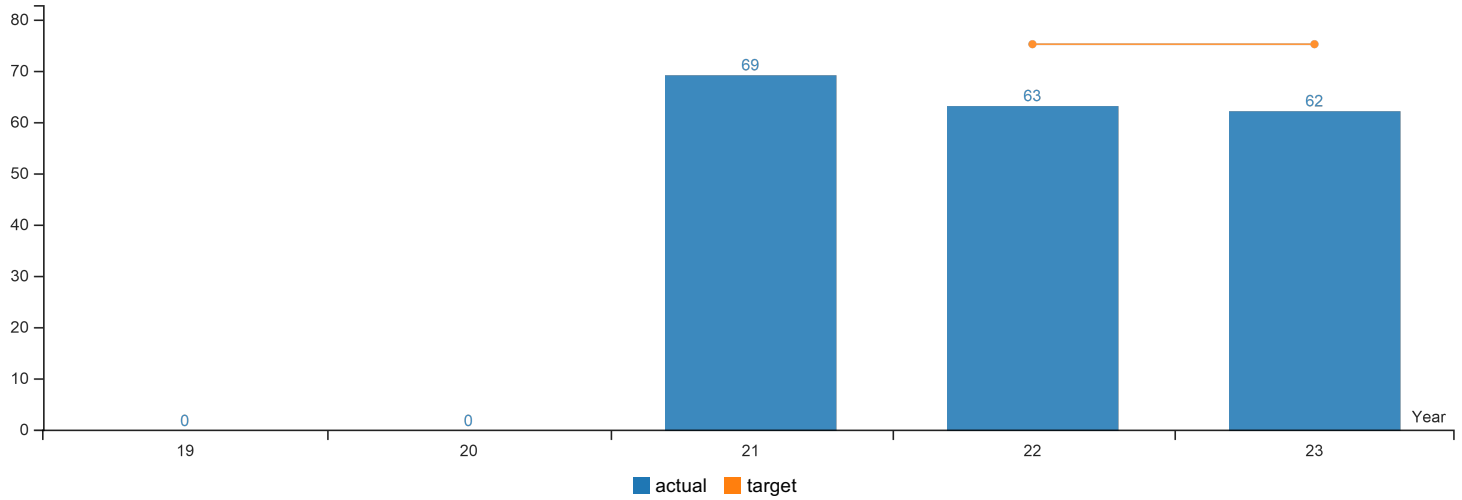
The COVID-19 public health emergency continued into May 2023, virtual and in person inspections were conducted with a focus on locations assessed to be places of concern related to patient safety. Virtual inspections take more time than in person inspections due to the time to get information from outlets 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 this inspection cycle. 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	2019	2020	2021	2022	2023
Percentage of individual and facility licenses that are issued within 30 days.					
Actual			69%	63%	62%
Target				75%	75%

How Are We Doing

In 2022, the percentage of licenses that were issued within 30 days was 62%. This is down 1% from 2021. There were a total of 2948 licenses issued. In 2022 average number of days to issue a license was 38 days for facilities and 35 days for individuals. While the overall percentage was down 1%, we saw improvement in the average number of days to issue a license. In 2021, the average number of days to issue a license was 48 days for facilities and 54 days for individuals.

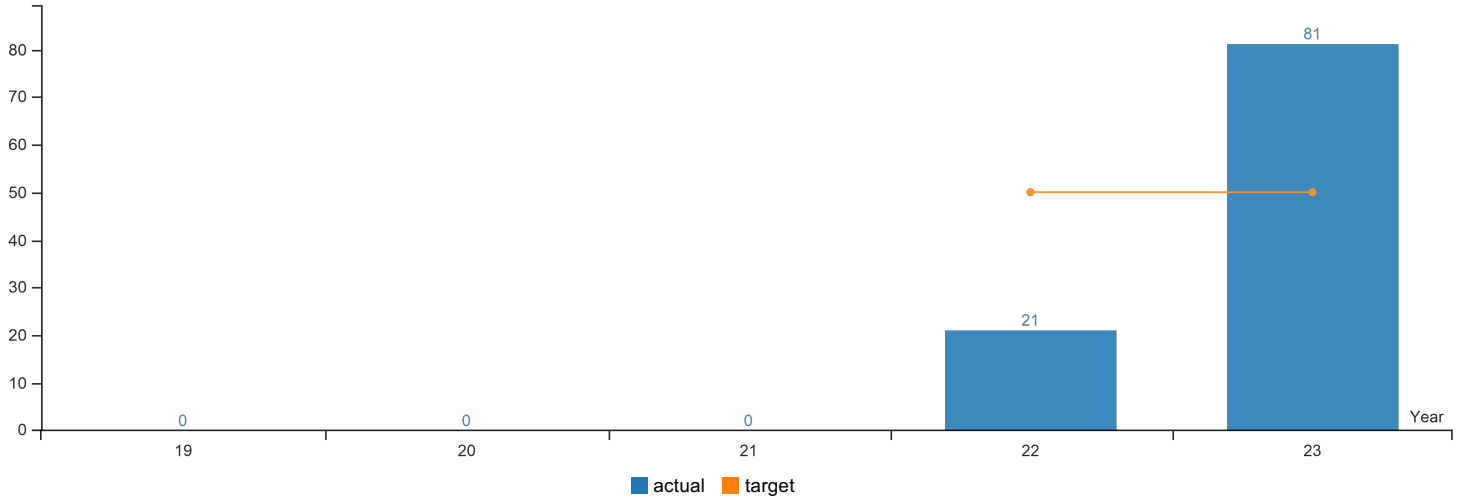
Factors Affecting Results

In 2022, two long term employees issued their overlapping resignations from state service. This was a 33% reduction in staffing in the first and second quarters of 2022 which greatly affected application processing times. The second quarter of each year is typically the board's busiest time of the year for incoming applications and renewals.

Board staff is focusing on continued improved communication with applicants, as well as creating efficient workflow processes within the agency. In 2022, board staff worked closely with Board Counsel to review all aspects of the license applications to update and clarify general application instructions and reporting requirements in plain language. On January 1, 2023, the Board launched the new and improved applications with the goal of streamlining the application process for individuals. The focus for 2023 is to do the same for facility registration applications.

KPM #3	Percent of pharmacies inspected every two years. -
	Data Collection Period: Feb 01 - Jun 30

** Upward Trend = positive result*



Report Year	2019	2020	2021	2022	2023
Percent of pharmacies inspected every 2 years.					
Actual				21%	81%
Target				50%	50%

How Are We Doing

This measure reflects 17 months of data.

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. 2023 is the first year reporting with data from 2-1-2022 through 6-30-2023 data.

684 inspections were completed in a transion cycle of 17 months equaling 81% of the pharmacies.

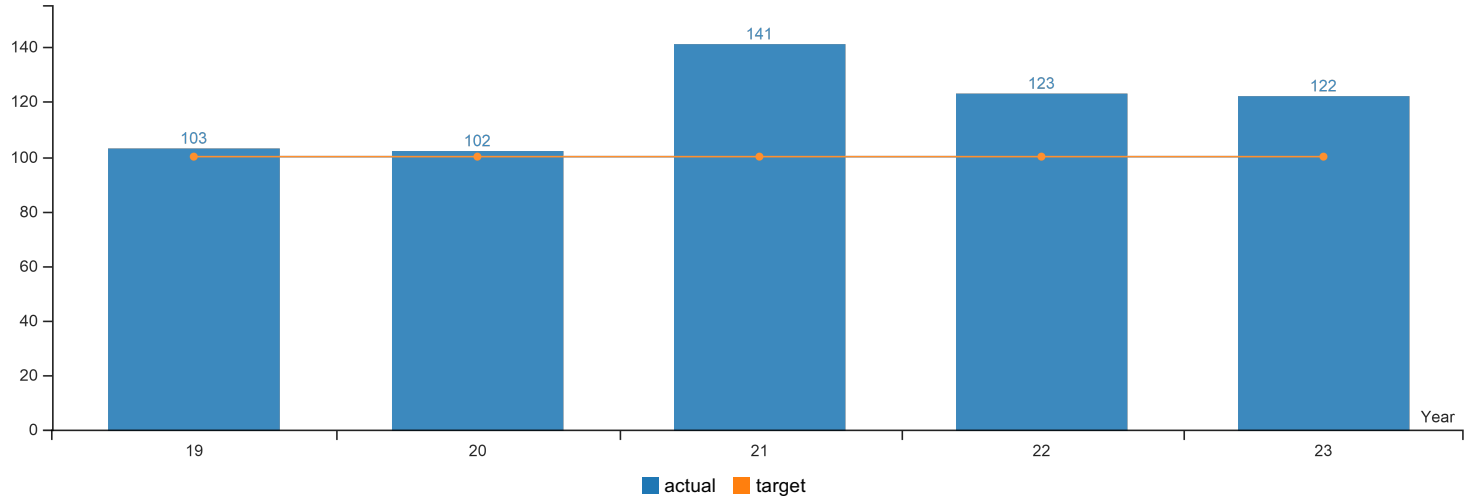
At present, in a two year cycle, there are 847 retail and institutional pharmacies located in Oregon. The board seeks to also complete inspections of other drug outlet registration on a rotating basis.

Factors Affecting Results

This was the first cycle of going from annual to biennial inspections and unfortunately due to COVID, high case volumn and limited staff resources we were unable to complete all inspections.

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	2019	2020	2021	2022	2023
Number of days to process complete investigation from complaint to Board presentation.					
Actual	103	102	141	123	122
Target	100	100	100	100	100

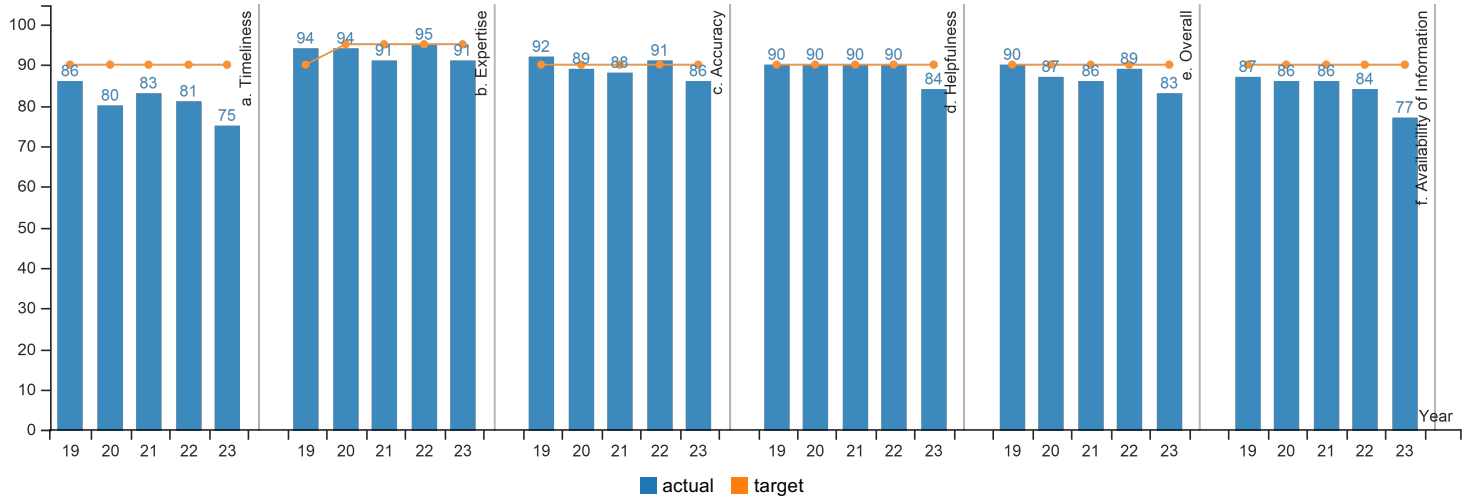
How Are We Doing

The total number of investigatory cases from January 1, 2022 - December 31, 2022 was 1061, which is a increase of 220 from 2021. 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 121.81 or (122 rounded up) days. This is a decrease of 1 days from 2021 and 2 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 2022, which helped see improvement for this measure. An additional Compliance Officer position was approved in the 2023-25 Legislatively Adopted 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	2019	2020	2021	2022	2023
a. Timeliness					
Actual	86%	80%	83%	81%	75%
Target	90%	90%	90%	90%	90%
b. Expertise					
Actual	94%	94%	91%	95%	91%
Target	90%	95%	95%	95%	95%
c. Accuracy					
Actual	92%	89%	88%	91%	86%
Target	90%	90%	90%	90%	90%
d. Helpfulness					
Actual	90%	90%	90%	90%	84%
Target	90%	90%	90%	90%	90%
e. Overall					
Actual	90%	87%	86%	89%	83%
Target	90%	90%	90%	90%	90%
f. Availability of Information					
Actual	87%	86%	86%	84%	77%
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, 2022 and December 31, 2022. We utilized the tools in Survey Monkey to directly email the survey link to 2889 new licensees. 234 individuals either fully completed or partially completed the survey. This represents an overall response rate of 8.1%. This is a 2.7% decrease from the 2021 overall response rate of 10.1%. The Board continues to see a decline in responses from licensees.
2162 of the 2889 licensees opened the email and of those 10.8% responded to the survey.

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 customer satisfaction average of 83%

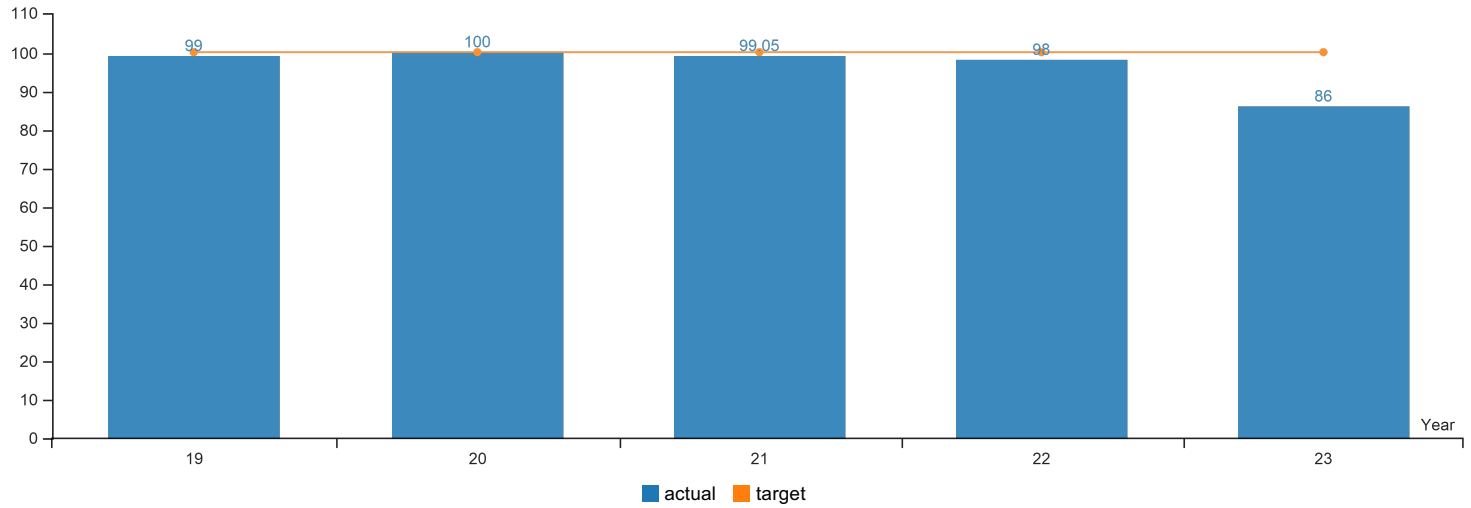
Factors Affecting Results

Factors that contributed to the results:

- 33% reduction in licensing staff due to overlapping resignations (1 failed recruitment – increased hiring timeframes)
- Staff resources at a minimum during peak workload times
- Staff category reassignments & additional training times on additional licensure categories
- Training time for new employees

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	2019	2020	2021	2022	2023
Is the Board following Best Practices?					
Actual	99%	100%	99.05%	98%	86%
Target	100%	100%	100%	100%	100%

How Are We Doing

The full Board participated in the response this year. A score of 86% of the 15 questions received a yes response, 14% received a no response with comments and questions from one or two people.

The Board regularly works to follow best practices. The Executive Director provides weekly communications to the Board and meets with the President as needed in between meetings.

Factors Affecting Results

This year, nine out of nine members participated in providing feedback for this measure. Two of the members responded for the first time this year, that may be the reason for the no responses with comments and questions. Staff will be spending more time during orientation to ensure members understand the Best Practices questions and answer their questions up front moving forward.

Lincoln County Public Health and Human Services (CHC- 0000087) Exemption Request – Drug Security

S	**Situation: Request** • Lincoln County Public Health and Human Services (CHC-0000087) is a small, rural public health department located in Newport, Oregon is seeking review and approval of a waiver request to Community Health Center (CHC) security rules.
B	**Background:** • Lincoln County Public Health and Human Services has a single Registered Nurse (RN) with access to the medication room, responsible for dispensing medications. • To ensure adequate staffing and patient care, it requires an additional Licensed Practical Nurse (LPN) to have access to the medication room. **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. Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.305 History: BP 24-2020, minor correction filed 08/06/2020, effective 08/06/2020 BP 2-2016, f. 6-30-16, cert. ef. 7-1-16
A	**Assessment:** • Restricting access only to the RN creates a potential bottleneck in service delivery, impacting patient care. • Granting access to a qualified LPN would improve efficiency and ensure continued service in case of the RN's absence. • Agency staff to provide site specific information at the time of the board meeting.
R	**Recommendation:** *For Board Discussion:* • Would approving a waiver of OAR 855-043-0720(2) to allow a LPN to access the medicine room further public health or safety or the health and safety of a patient? ○ If approved, time frame for approval? Examples: 3 years, 5 years? • Would the board like agency staff to begin drafting a rule amendment to modify the existing rule to permit LPN access?

Lincoln County Public Health and Human Services (CHC- 0000087) Exemption Request – Drug Security

	○ Discuss if amendment should modify language to be similar to OAR 855-043-0525(1) related to Dispensing Practitioner Drug Outlets- 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. ○ If yes, what is the priority? Should this be amended as part of strategic plan to update all outlet rules when CHC rules are amended? Or sooner?

Monroe Health Center (CHC 0000080) Exemption Request – Drug Security

S	Situation: Request Monroe Health Center (CHC 0000080) is a rural, school-based health center located in Monroe, Oregon is seeking review and approval of a waiver to Community Health Center (CHC) security rules.
B	Background: • The center is obligated to provide family planning services as mandated by School Based Health Center requirements. • Alex Shaffer, PA-C, serves as the primary provider at this location and is qualified to offer these services. • Current OAR regulations restrict a Physician Assistant/Associate, from accessing the drug cabinet/room (and dispensing family planning products) hindering the center's ability to deliver these essential services. 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. Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.305 History: BP 24-2020, minor correction filed 08/06/2020, effective 08/06/2020 BP 2-2016, f. 6-30-16, cert. ef. 7-1-16
A	Assessment: • Restricting access only to a Physician creates a potential bottleneck in service delivery, impacting patient care. • Granting access to a qualified PA would improve efficiency and ensure continued service in case of the Physician's absence. • Agency staff to provide site specific information at the time of the board meeting.
R	Recommendation: <u>For Board Discussion:</u> • Would approving a waiver of OAR 855-043-0720(2) to allow a PA to access the medicine room further public health or safety or the health and safety of a patient?

	○ If approved, time frame for approval? Examples: 3 years, 5 years? • Would the board like agency staff to begin drafting a rule amendment to modify the existing rule to permit a PA access? ○ Discuss if amendment should modify language to be similar to OAR 855-043-0525(1) related to Dispensing Practitioner Drug Outlets- 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. ○ If yes, priority? Should this be amended as part of strategic plan to update all outlet rules when CHC rules are amended? Or Sooner?

Prairie City School Based Community Clinic (CHC-000162) Exemption Request – Drug Security

S	Situation: Request • Prairie City School Based Community Clinic (CHC-000162) is a rural, school-based health center in Prairie City, Oregon and is seeking review and approval of a waiver request to Community Health Center (CHC) security rules.
B	Background: • Prairie City School Based Community Clinic has a single Nurse Practitioner (NP) with access to the medication room, responsible for dispensing medications. • To ensure adequate staffing and patient care, it requires an additional Medical Assistant (MA) to have access to the medication room. • In the clinic, the MA has access the storage room that has supplies (swabs, bandages, etc…), which is also the same room that medications are stored in. • MA's are not licensed in Oregon, the Oregon Medical Board only provides guidance to licensees when utilizing medical assistants in a Statement of Philosophy. 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. Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.305 History: BP 24-2020, minor correction filed 08/06/2020, effective 08/06/2020 BP 2-2016, f. 6-30-16, cert. ef. 7-1-16
A	Assessment: • Restricting access only to the NP creates a potential bottleneck in service delivery, impacting patient care. • Granting access to a qualified MA would improve efficiency and ensure continued service in case of the NP's absence. • An existing waiver is approved for the clinics affiliated site, Grant County Health Department (CHC-0000025), which permits MAs to access the medication room. • Agency staff to provide site specific information at the time of the board meeting

Prairie City School Based Community Clinic (CHC-000162) Exemption Request – Drug Security

R	Recommendation: <u>For Board Discussion:</u> • Would approving waiver of OAR 855-043-0720(2) to allow a MA to access the medicine room further public health or safety or the health and safety of a patient. o If approved, time frame for approval? Examples: 3 years, 5 years? • Would the board like agency staff to begin drafting a rule amendment to modify the existing rule to permit a MA access? o Discuss if amendment should modify language to be similar to OAR 855-043-0525(1) related to Dispensing Practitioner Drug Outlets- 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. o If yes, what is the priority? Should this be amended as part of strategic plan to update all outlet rules when CHC rules are amended? Or sooner?

SBAR: Oregon Veterinary Medical Examining Board (OVMEB) Dispensing Practitioner Drug Outlet (DPDO) Registration Exemption Extension Request

S	Situation: • OVMEB is requesting an Extension to DPDO Registration Exemption.
B	Background: • OAR 855-043-0510(11) The Board may grant a time-limited waiver exempting DPDO registration when a practitioner licensing board submits a request to the Board with a plan to annually inspect the dispensing facility to the standards of the Board. • Initial request received in 2018 and board approved waiver for 3 years; 2021 request approved for 3 years. This is the board's third review of this waiver request. June 2018 Board Meeting: • OVMEB members Dr. Emilio DeBess, Dr. Allison Lamb, and Executive Director Lori Makinen appeared. • The OVMEB members discussed their request to have dispensing veterinarians exempt from OBOP DPDO registration. • OVMEB stated they have new facility registration and inspection regulations for veterinary compliance. • The OVMEB has two employees for these new processes, 1 inspector and 1 investigator allotted. • They have approximately 700 registered facilities and their plan is to inspect as often as feasible, but not less than once every three years and probably closer to once every 1.5 years. • OVMEB stated they have 68 clinics that have American Animal Hospital Association (AHHA) accreditation which are currently excluded from proactive inspections, because they have to meet a series of standards and have strict guidelines they have to follow in the areas of dispensing, controlled substances, etc.; these locations will be inspected pursuant to a complaint. • They also discussed the ability for OVMEB inspections to clearly address drug acquisition, storage, labeling and recordkeeping and be willing to use the OBOP DPDO self-inspection form as a foundation for those aspects. • The members of each board discussed additional similarities and differences in OBOP and OVMEB facility oversight rules. • The Board motioned to accept the OVMEB proposal to exclude veterinary dispensing locations from DPDO registration via exemption for 3 years of OAR 855-043-0510(2) and was unanimously carried. June 2021 Board Meeting: • OVMEB member and chair Dr. Emilio Debess and Interim Executive Director Cass McLeod-Skinner appeared. • OVMEB requested an extension to their exemption to OAR 855-0430-0510(12). • The Board was provided with OVMEB's written request. • Rules in alignment with BOP DPDO rules were adopted in 2020 – see OAR 875-0015-0040

SBAR: Oregon Veterinary Medical Examining Board (OVMEB) Dispensing Practitioner Drug Outlet (DPDO) Registration Exemption Extension Request

	• OVMEB created a self-inspection for veterinary clinics to ensure compliance with the BOP and OVMEB rules during COVID-19. OVMEB received a positive response to this self-inspection and had a 100% reply rate. • As COVID-19 subsides, OVMEB will begin in person inspections once again. June 2024 Board Meeting: • OVMEB submitted a written extension request
A	Assessment: • There are 701 OVMEB licensed facilities in Oregon. If this waiver is not granted the Board would be required to register and inspect all OVMEB licensed facilities that meet the DPDO registration requirements. • In 2024, agency staff requested OVMEB provide the Board a written request to extend DPDO registration exemption that includes: o How OVMEB meets BOP requirements for Inspections ▪ Provide any changes to the process from what was previously presented in 2021. o Provide information related to the following questions based on the past 3 years: ▪ What types of registrations does the OVMEB have? ▪ How many locations are registered with OVMEB? ▪ What is the cycle or frequency at which each registered location is inspected? • Did OVMEB inspect all outlets within this cycle? ▪ How many locations were inspected? ▪ What types of outlets were inspected? • To confirm, are all AHHA facilities also being inspected? ▪ What timeframe were these outlets inspected in? o How OVMEB rules align with BOP DPDO rules (OAR 855-043-0700 to 0750)? ▪ Drug Security ▪ Drug Acquisition ▪ Drug Storage ▪ Drug Dispensing and Delivery ▪ Labeling ▪ Drug Disposal ▪ Record keeping • Have any updates been made to these rules since 1/1/2020? o Provide a copy of the current Inspection Form used for inspections. ▪ What were the results of the inspections? ▪ How many outlets were in compliance? ▪ What actions were taken if an outlet was not in compliance? • OVMEB Response and Request to Board- See separate letter

SBAR: Oregon Veterinary Medical Examining Board (OVMEB) Dispensing Practitioner Drug Outlet (DPDO) Registration Exemption Extension Request

R	Recommendation: • Accept OVMEB's request for DPDO registration exemption for veterinary dispensing locations via OAR 855-043-0510(12) for 3 years. For Board Discussion: • How would approving a waiver of OAR 855-043-0510(12) to allow the OVMEB to inspect veterinary DPDO locations further public health or safety or the health and safety of a patient? • If approved, time frame for approval? Examples: 3 years, 5 years?

Oregon
Tina Kotek, Governor

Oregon Veterinary Medical Examining Board
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Portland, OR 97232
Phone: 971-673-0224
Fax: 971-673-0226
OVMEB.info@oregon.gov
www.oregon.gov/ovmeb

June 11, 2024

Oregon Board of Pharmacy
Jamal Fox, Executive Director
Brianne Efremoff, Compliance Director *Via email: Brianne.efremoff@obob.oregon.gov*

RE: OVEMB Request to Continue Extension of DPDO Registration Exemption

Dear Members of the Board, Director Fox, and Ms. Efremoff,

The Oregon Veterinary Medical Examining Board (OVMEB) originally approached you in June 2018 to request its first Dispensing Practitioner Drug Outlet (DPDO) registration exemption, which was granted for a three-year period, expiring in June 2021. In May 2021, OVMEB requested an extension of that exemption. Today, we request further continuation of this arrangement and provide the following information in support of that request.

Overview of Compliance Efforts

On May of 2021, the OVMEB adopted OAR 875-015-0040, Minimum Standards for Veterinary Medical Facilities and Veterinary Practice, which mandates compliance with DPDO requirements regarding drug security, acquisition, storage, dispensing, delivery, labeling, disposal, and record-keeping. OAR 875-015-0040, attached, was modeled after and corresponds with the Board of Pharmacy DPDO requirements. These rules apply to all facilities.

All licensed facilities must submit a completed pharmacy self-inspection checklist annually. Following this submission, the OVMEB conducts an on-site pharmacy inspection to review any self-reported non-compliance issues with the managing veterinarian. The inspector provides a follow-up report indicating any non-compliance issues noted during the inspection. The managing veterinarian must then correct these issues, explain how they were addressed, and provide the date of correction.

Annual Pharmacy Self-Inspections

All facilities / Managing Veterinarians must complete the pharmacy self-inspection checklist annually and must return the completed checklist with all new facility registrations and all facility renewals. The pharmacy self-inspection checklist has been provided.

NOTE: Some facilities do not administer or dispense any prescription medications. These facilities submit this information on the annual self-inspection checklist. Each year these facilities we verify that they do not administer or dispense medications and give a full explanation on the self-inspection checklist. These facilities do not require on-site pharmacy inspections as they don't have any pharmacy to inspect. However, they must verify this annually with the Inspector so that OVMEB can say with 100% certainty that the OVMEB has performed an onsite inspection of every facility each year or has verified that no pharmacy inspection is required of that particular facility, verified in writing each year.

Inspection Factors

1. **OAR 875-015-0150 Compliance:** All facilities are subject to OAR 875-015-0150.
2. **AAHA Accredited Facilities:** These facilities are included in the pharmacy inspection requirements and must submit the annual pharmacy self-inspection checklist and submit to on-site inspections by OVMEB.
3. **Donation and Dispensing of Expired Medications:** OVMEB rules allow the donation, administration, and dispensing of expired, non-controlled substance medications by licensed facilities, provided the client is informed, and there is no charge for the medication. This rule also supports shelters and low-income clients by providing access to affordable veterinary care and treatment.
4. **Prescription-Only Pet Foods:** OVMEB does not consider pet foods marketed as "prescription only" as prescription medications unless they contain medication that requires a prescription.
5. **Inspecting Veterinary Facilities:**
    - Adopted OAR 875-015-0040, requiring compliance with DPDO and DEA requirements.
    - Mandated the submission of pharmacy self-inspection checklists by all licensed facilities.
    - Conducted initial reviews of submitted checklists and documented non-compliance issues.
    - Conducting annual on-site facility inspections to ensure compliance with OAR 875-015-0040.

2022-2024 Inspections

There are currently 701 licensed facilities in Oregon. By rule, routine full facility onsite inspections are due once every 3 years. Our agreement stipulates we will conduct inspections every two years.

Yearly Self inspection, 2023

Complete: 645 (92%)	Incomplete: 56 (8%)

Individual facilities that did not respond were contacted by OVMEB staff and we now have 100 % compliance.

On-Site Inspections

Year	Number (percent)
2022	413 (58.9%)
2023	142 (20.2%)
Total	**79.2%**

79.2 % of the facilities were inspected between 2022-2023. On-site inspections in this period were impacted by Covid restrictions. With a newly hired, trained and active inspector, we are currently on track to return to pre-pandemic levels for our on-site inspection completion rate.

The OVMEB performs yearly self-inspections, both the routine inspection and the pharmacy inspection, at all facilities biennially. Between July 1, 2022, and June 2024 we have completed 540 inspections. Our long established and experienced inspector conducted the majority of those. She retired in July 2023. In

October 2023, we hired a new inspector. The two were able to train together on the inspections process. Inspections continue on pace currently.

Conclusion

Based on the above progress and actions taken by the board, we respectfully request to continue this exemption of the DPDO registration exemption.

Thank you for your consideration.

Sincerely,

Peter J. Burns
Executive Director

Oregon Veterinary Medical Examining Board
800 NE Oregon Street Suite 407, Portland, OR 97232
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VETERINARY INSPECTION

Facility Name:_____ Date _____

Managing Veterinarian:_____

Facility Address:_____

Facility phone:_____

Type of Inspection: ☐ **Initial** ☒ **Routine** ☐ **Re-Inspection** ☐ **Complaint**

For questions contact OVMEB Inspector at: 503-995-3121 / ovmeb.inspector@ovmeb.oregon.gov

C = Compliant NC = Not Compliant
NA = Not Applicable or Not reviewed

	#	Law/Regulation	Rule Language and Guidance
			Licenses and Permits
	1	OAR 875-015-0020(10)	Licenses of every veterinarian or veterinary technician practicing in the veterinary medical facility shall be displayed in a place conspicuous to the public. Relief or temporary licensees may post legible photocopies of licenses. Mobile practice licensees shall have their license or a legible copy available for verification upon client request.
	2	OAR 875-015-0020(11)	Prescriptions: If requested, a written prescription shall be provided to a client for medications prescribed by the veterinarian under a valid VCPR. The facility shall post in a place conspicuous to the public a notice indicating availability of written prescriptions. The facility shall use, or replicate the specifications of, a notice template provided by the Board.
			Managing Veterinarian (MV)
	3	OAR 875-010-0031	Every veterinary facility shall have a designated Managing Veterinarian (MV) who is registered with the Board.
			Minimum Standards for Biologicals, Drugs and Facility Pharmacy
	4	OAR 875-015-0040(2)(a)	Does the facility have written policies and procedures for drug security, acquisition, storage, labeling, disposal and record keeping?

	5	OAR 875-015-0030(7)(a)	All biological substances shall be stored, maintained, administered, dispensed and prescribed in compliance with federal and state laws and manufacturers' recommendations;
	6	OAR 875-015-0030(7)(c)	No biological or drug shall be administered or dispensed after the expiration date, for a fee.
	7	OAR 875-015-0040(3)(a)	Does the outlet keep all drugs in a locked drug cabinet or secure drug storage area that denies access to unauthorized persons?
	8	OAR 875-015-0040(3)(b)	Are controlled substances listed in schedules I, II, III, IV, and V kept in a locked cabinet with access limited to persons authorized by the Managing Veterinarian?
	9	OAR 875-015-0040(9)	Does the outlet only acquire drugs from a supplier registered with the Oregon Board of Pharmacy?
	10	OAR 875-015-0040(8)(c)	Are invoices readily retrievable and kept for a minimum of 3 years?
	11	OAR 875-015-0040(7)	Are all outdated, damaged, deteriorated, misbranded, or adulterated drugs properly quarantined and physically separated until destroyed or returned to the supplier?
	12	OAR 875-015-0040(4)	Are all drugs stored in appropriate conditions including temperature, light, humidity, sanitation, ventilation, and space? How does the outlet ensure proper temperature are maintained?_____
	13	OAR 875-015-0040(5)(a-i)	Are all prescriptions properly labeled? • Name of patient; • Name or initials of prescriber; • Name, address and phone number of the clinic; • Date of dispensing; • Name and strength of the drug; • Quantity dispensed; • Directions for use; • Manufacturers expiration date, or an earlier date if preferable, after which the drug should not be used; • Cautionary Information: In accordance with 21 CFR &290.5, the label of any controlled substance must include the statement “Caution Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."
	14	OAR 875-015-0040(1)(b)	Are Controlled substances and legend drugs dispensed, ordered or prescribed based on a VCPR?
	15	OAR 875-015-0040(1)(b)	Does the veterinarian or their representative orally counsel the client concerning all new drugs prescribed unless circumstances would render oral counseling ineffective?
	16	OAR 875-015-0040(6)(d)	Are prescription drugs dispensed in a suitable container appropriately labeled for subsequent veterinary patient administration, to a client or other individual entitled to receive the prescription drug?

	17	OAR 875-015-0040(8)(a)	For all drugs Is a unique dispensing record maintained separately from the patient chart? Are records kept for a minimum of 3 years?
	18	OAR 875-015-0040(8)(a)(A-E)	Does the dispensing record contain? • Name of patient • Dose, dosage form, quantity dispensed • Directions for use • Date of dispensing; and • Name of person dispensing the prescription
	19	OAR 875-015-0040(6)(c)	Are Rabies vaccines administered only by an Oregon-licensed veterinarian, a Certified Veterinary Technician under direct supervision of an Oregon-licensed veterinarian, or a person authorized by the Oregon Public Health Veterinarian pursuant to OAR 333-019-0017?
			Minimum Facility Standards
	20	OAR 875-015-0020(1)	Air Quality: Adequate heating and cooling must be provided for the comfort and well-being of the animals, and the facility must have sufficient ventilation in all areas to prevent mildew and condensation, and to exhaust toxic and/or nauseous fumes and/or odors.
	21	OAR 875-015-0020(2)	Lighting in all areas must be sufficient for the safety of personnel and the intended use of this area.
	22	OAR 875-015-0020(3)	Water: Potable water must be available.
	23	OAR 875-015-0020(4)	Waste Disposal: Waste disposal equipment shall be so operated as to minimize insect or other vermin infestation, and to prevent odor and disease hazards or other nuisance conditions. The veterinary medical facility shall have sanitary and aesthetic disposal of dead animals and other wastes which complies with all applicable federal, state, county and municipal laws, rules, ordinances and regulations.
	24	OAR 875-015-0020(5)	Storage: All supplies, including food and bedding, shall be stored in a manner that adequately protects such supplies against infestation, contamination or deterioration. Adequate refrigeration shall be provided for all supplies that are of a perishable nature, including foods, drugs and biologicals.
	25	OAR 875-015-0020(6)	Examination Area: Examination and surgery tables shall have impervious surfaces.
	26	OAR 875-015-0020(7)	Laboratory: May be either in the veterinary medical facility or through consultative services, adequate to render diagnostic information. An in-house laboratory shall meet the following minimum standards:

			(a) The laboratory shall be clean and orderly with provision for ample storage; (b) Adequate refrigeration shall be provided; (c) Any tests performed shall be properly conducted by currently recognized methods to assure reasonable accuracy and reliability of results. (d) Laboratory equipment must provide results of diagnostic quality. Protocols must be in place and followed regularly to assure the quality and reproducibility of the diagnostic information produced.
	27	OAR 875-015-0020(8)	Radiology: Equipment for diagnostic radiography must be available either on or off the veterinary medical facility. Such equipment must be on the premises if orthopedic or open thoracic procedures are performed. The equipment must meet federal and state protective requirements and be capable of producing, reading and labeling good quality diagnostic radiographs, including imaging diagnosis and findings. Diagnostic oral radiography must be available whenever surgical dental services are offered.
	28	OAR 875-015-0020-(9)	Animal Housing Areas: Each veterinary medical facility confining animals must have individual cages, pens, exercise areas or stalls to confine said animals in a comfortable, sanitary and safe manner. Animals that are hospitalized for treatment of contagious diseases must be isolated physically and procedurally so as to prevent the spread of disease.
	29	OAR 875-015-0030(3) (a)	Aseptic surgery shall be performed in a room or area designated for that purpose and isolated from other activities during the procedure.
	30	OAR 875-015-0030(3) (b)	The surgery room or area shall be clean, orderly, well-lighted and maintained in a sanitary condition;
	31	OAR 875-015-0030(3) (c)	All appropriate equipment shall be sterilized: (a) Chemical disinfection ("cold sterilization") shall be used only for field conditions or antiseptic surgical procedures; (b) Provisions for sterilization shall include a steam pressure sterilizer (autoclave) or gas sterilizer (e.g., ethylene oxide) or equivalent.
	32	OAR 875-015-0030(3)	(d) For each aseptic surgical procedure, a separate sterile surgical pack shall be used for each animal. Surgeons and surgical assistants shall use aseptic technique throughout the entire surgical procedure; (e) Minor surgical procedures shall be performed at least under antiseptic surgical techniques;
	33	OAR 875-015-0030(1)	Each Managing Veterinarian should review this rule and ensure facility recordkeeping protocols meet its standards.
	34	OAR 875-015-0030(5)	Library: Appropriate and current veterinary journals and textbooks or internet resources shall be available for ready reference.

Immediate correction is expected for any noncompliant conditions that may constitute threats to public or animal health and safety. The Board may issue an emergency suspension of the facility license for failure to promptly correct such noncompliant conditions. Scheduled correction will be permitted for other noncompliance identified on this inspection report.

This inspection report will be reviewed by the Board. If any identified noncompliant conditions warrant further Board action, the Managing Veterinarian will be notified of required action(s) and/or re-inspection(s).

Inspector Comments:

Signature of Managing Veterinarian _____ Date _____

Printed Name of Managing Veterinarian _____