Oregon Board of Pharmacy
*REVISED BOARD MEETING AGENDA
August 6-7, 2025

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: 387 689 660#**

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
August 6-7, 2025

Wednesday, August 6, 2025 @ 8:30AM
Thursday, August 7, 2025 @ 8:30AM

- All OBOP meetings, except Executive Sessions, are open to the public. Pursuant to ORS 192.660(1)(2)(f)(L), Executive Sessions are closed to the public, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the board will return to Open Session
- To sign up for Public Comment, email your request to pharmacy.board@bop.oregon.gov by **12:00PM on 8/7/2025**

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

- Kathleen Chinn, APRN, FNP-BC,
- Jennifer Hall, Pharm.D., R.Ph.
- Rich Joyce, CPT, Board President
- Amy Kirkbride, R.Ph., Board Vice President
- Victoria Kroeger, Pharm.D., R.Ph.
- Priyal Patel, Pharm.D., R.Ph.
- Ana Pinedo, CPT
- Bryan Smith, R.Ph.

Agency Staff

- Joe Ball, R.Ph., Chief Compliance Officer
- Brianne Efremoff, Pharm.D., R.Ph., Compliance Director
- Cheryl Fox, R.Ph., Compliance Officer
- Chrisy Hennigan, Licensing Director
- Chehala "K" Klingberg, Compliance Assistant
- Jane Lee, Pharm.D., R.Ph., Compliance Officer
- Danny McComas, Pharm.D., R.Ph., Compliance Officer
- Rachel Melvin, Operations Manager
- Brian Murch, Pharm.D., R.Ph., Compliance Officer
- Tasha Pearson, Compliance Assistant
- Erin Richmond, Pharm.D., M.S., R.Ph., Compliance Officer
- Gary Runyon, Pharm.D., R.Ph., Executive Director
- Angela Hunt, Board Counsel

WEDNESDAY, AUGUST 6, 2025

I. OPEN SESSION, Rich Joyce, CPT, Presiding

***Please note that the board will meet in Executive Session for most of the day and anticipates resuming Open Session @ 4:30PM**

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 than 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 8/7/2025

c. Housekeeping & Meeting Etiquette *the board will break for lunch from 12-1PM
d. Agenda Review and Approval
e. New Board Member Introduction/Installation

f. Recusal Announcements *Action Necessary*

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

a. Legal Advice
b. Consult with counsel concerning the legal rights and duties regarding litigation or litigation likely to be filed
c. Deliberation on Disciplinary Cases and Investigations
d. Contested Case Deliberation *if applicable

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

IV. ADJOURN *Action Necessary*

THURSDAY, AUGUST 7, 2025

I. OPEN SESSION, Rich Joyce, 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 than 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 8/7/2025
c. Housekeeping & Meeting Etiquette - *The board will break for lunch at noon and will resume Open Session @ 1:00PM

II. GENERAL ADMINISTRATION

a. Discussion Items
   i. Rules
      1. Review July 2025 Rulemaking Hearing Report & Comments **#A** *Action Necessary*

   ii. Consider Adoption of Rules
      1. Div 102 – Board Delegated Limited Authority for Vaccine Protocol rules (OAR 855-102-0130) **#B**

         Action Necessary
      2. Div 104/115 – Standard Vaccination Protocols - Prescribing – Formulary, Pursuant to Protocol, Prohibited Practices, Record and Document Retention (OAR 855-104-0055, OAR 855-115-0330, OAR 855-115-0335, OAR 855-115-0340, OAR 855-115-0345 **#B1** *Action Necessary*

a. Vaccination Protocol for Adults 18 Years of Age and Older & Assessment and Treatment Care Pathway **#B1a**
b. Vaccination Protocol for 7 through 17 Years of Age & Assessment and Treatment Care Pathway **#B1b**
c. Vaccination Protocol for 3 through 6 Years of Age & Assessment and Treatment Care Pathway **#B1c**
d. Vaccination Protocol for 6 Months through 2 Years of Age & Assessment and Treatment Care Pathway **#B1d**
e. Vaccination Protocol for Managing Adverse Reactions & Assessment and Treatment Care Pathway **#B1e**

3. Div 115/135 – Standards Adopted by Reference (OAR 855-115-0130, OAR 855-135-0001) **#B2** *Action Necessary*

iii. End of Legislative Session Report **#C**
iv. Board Discussion: Controlled Substances - Pharmacy Prescription Locker (PPL) - DEA Letter **#D**
v. Rules in Development
1. Rulemaking Policy Discussion Items
a. Div 183 – Drug Compounding **#E**

III. *If necessary **EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 192.660(1)(2)(f)(h) and (L), ORS 192.690(1), ORS 676.165, ORS 676.175.**

b. Legal Advice
c. Consult with counsel concerning the legal rights and duties regarding litigation or litigation likely to be filed
d. Deliberation on Disciplinary Cases and Investigations
e. Contested Case Deliberation *if applicable

IV. MOTIONS RELATED TO DISCIPLINARY ACTIONS *Action Necessary*

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

V. GENERAL ADMINISTRATION CONTINUED

a. Discussion Items
i. Rulemaking Policy Discussion Continued – Drug Compounding
ii. Annual Board Best Practices Survey Results **#F**
i. Financial Update **#G**
ii. 2024-2029 Strategic Plan Update
i. Requests – *None*

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

2025 Board Meeting Dates

- October 8-10, 2025 Portland
- November 5, 2025 Portland *Strategic Planning Meeting

- December 10-12, 2025 Portland

2026 Board Meeting Dates

- February 11-12, 2026 Portland
- April 8-9, 2026 Portland
- June 10-11, 2026 Portland
- August 12-13, 2026 Portland
- October 7-8, 2026 Portland
- November 4-5, 2026 TBD *Strategic Planning Meeting
- December 9-10, 2026 Portland

2027 Board Meeting Dates

- February 10-11, 2027 Portland
- April 7-8, 2027 Portland
- June 9-10, 2027 Portland
- August 11-12, 2027 Portland
- October 6-7, 2027 Portland
- November 3, 2027 TBD *Strategic Planning Meeting
- December 8-9, 2027 Portland

2025 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.)

- August 22, 2025
- November 25, 2025

Conferences/Meetings

- 2025 NABP Forum Charging Into the Future, Ensuring Safe Pharmacy for All - October 27-30, 2025, in Rosemont, IL

VI. CONSENT AGENDA* *Action Necessary*

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

a. License/Registration Ratification 5.27.2025-7.21.2025 **# CONSENT-1**
b. Board Meeting Summary June 2025 - **# CONSENT-2**
c. Board Meeting Summary July 16, 2025 - **# CONSENT-3**

VII. PUBLIC COMMENT

VIII. MATTERS TO BE DISCUSSED BY THE BOARD

IX. MATTERS TO BE DISCUSSED BY STAFF

X. 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: July 23, 2025

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

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: July 22, 2025

Hearing Location: Virtual Hearing

Proposed Rules:

- Division 102 - Vaccine Delegated Authority
- Divisions 104/115 - Standard Vaccination Protocols - Prescribing – Formulary, Pursuant to Protocol, Prohibited Practices, Record and Document Retention
  - Vaccination Protocol for Adults 18 years of age and older & Assessment and Treatment Care Pathway
  - Vaccination Protocol for Ages 7 through 17 years & Assessment and Treatment Care Pathway
  - Vaccination Protocol for Ages 3 through 6 years & Assessment and Treatment Care Pathway
  - Vaccination Protocol for Ages 6 months through 2 years & Assessment and Treatment Care Pathway
  - Vaccination Protocol for Managing Adverse Reactions & Assessment and Treatment Care Pathway
- Divisions 115/135 – Standards Adopted by Reference

On June 26, 2025, the July 22, 2025 Rulemaking Hearing public notice was sent out via GovDelivery to 5,556 rulemaking/adopted rules subscribers and to 18,763 licensees/registrants.

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 9:36AM. #4 people joined the public call to listen to the hearing, no participants signed up to provide oral testimony, no oral testimony was provided during the hearing. #4 written comments were received during the open comment period from 4/16/2025 through 4:30PM on 7/22/2025. The hearing was recorded, and the notice of proposed rulemaking filings were available on our website.

Oregon
Tina Kotek, Governor

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

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Division 102 – Board Delegated Authority – Amendment of Vaccine Protocol Rules to Adopt ACIP Recommendations
ADOPT: OAR 855-102-0130

- No oral testimony was provided.

RULES PROPOSED: Divisions 104/115 – Standard Vaccination Protocols

- **Vaccination Protocol for Adults 18 Years of Age and Older**
- **Vaccination Protocol for Adults 18 Years of Age and Older - Assessment and Treatment Care Pathway**
- **Vaccination Protocol for Ages 7 through 17 Years**
- **Vaccination Protocol for Ages 7 through 17 Years - Assessment and Treatment Care Pathway**
- **Vaccination Protocol for Ages 3 through 6 Years**
- **Vaccination Protocol for Ages 3 through 6 Years - Assessment and Treatment Care Pathway**
- **Vaccination Protocol for Ages 6 Months through 2 Years**
- **Vaccination Protocol for Ages 6 Months through 2 Years - Assessment and Treatment Care Pathway**
- **Vaccination Protocol for Managing Adverse Reactions**
- **Vaccination Protocol for Managing Adverse Reactions - Assessment and Treatment Care Pathway**

AMENDS:
OAR 855-104-0055, OAR 855-115-0330, OAR 855-115-0335, OAR 855-115-0340, OAR 855-115-0345

- No oral testimony was provided.

RULES PROPOSED: Divisions 115/135 – Standards Adopted by Reference
AMENDS: OAR 855-115-0130, OAR 855-135-0001

- No oral testimony was provided.

All written comments received by the public comment deadline date of 7/22/2025 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 6/26/2025 Notice of Proposed Rulemaking.

From: bbenbaruch@ashlandhome.net
To: PHARMACY RULEMAKING * BOP
Cc: Sen Golden; Rep Marsh
Subject: Proposed rule changes regarding vaccines
Date: Thursday, June 26, 2025 5:49:13 PM

I am writing regarding the July 22, 2025 Rulemaking Hearing.

Why does the pharmacy board feel it either necessary or proper to change vaccination rules to be “in synch” with ACIP?

I am sure that you are all aware that ACIP’s new rules are no longer based on science or pharmaceutic or medical research. It seems to me that the people of Oregon would be much better served by a pharmacy board that rejects the heavy-handed anti-science polices pf the president and the health secretary and maintains its independence AND INTEGRITY!

I am not a fan of Big Pharma and I am well aware of the fact that much of the implementation of past vaccination policies have led to ginormous profits for Big Pharma. But those profits were not driven by the science of vaccination protocols. They were driven by Congress’s “enthusiastic largesse” in reimbursing the pharmaceutical companies.

Make decisions with integrity based on scientific research and not on the basis of ACIP’s new “junk science”.

Benjamin (Benjy) Ben-Baruch
461 N Mountain Ave
Ashland OR 97520
734-507-0862

Rob Geddes, PharmD, MBA
Executive Director,
Pharmacy Advocacy and Regulatory Affairs

One CVS Drive
Woonsocket, RI 02895

c 208-860-5342

Robert.Geddes@CVSHealth.com

July 17, 2025

Gary Runyon
Executive Director
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Re: Proposed Rule 855-115-0330 and Age Based Vaccination Protocols

Dear Executive Director Runyon,

CVS Health is the largest pharmacy provider in the country with over 9,000 pharmacies in operation. In Oregon we proudly operate 25 pharmacies and will soon add 13 more as we convert several Rite Aid locations into a CVS. Our pharmacists and technicians working in Oregon play a pivotal role in supporting the health of the citizens of the state. CVS pharmacies provide a critical access point for patients in the healthcare ecosystem. I am writing to you in my capacity as Executive Director of Pharmacy Advocacy and Regulatory Affairs for CVS Health as part of our efforts to continue to drive quality in healthcare – including by supporting patient access – through community pharmacy.

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

CVS appreciates the updates being made to this section of regulation. While we support the overall direction taken with these amendments, we have some minor comments to share for this section.

First, in subpart (6) (a) it states that a pharmacist must ensure all training and education requirements have been met prior to engaging in prescribing activities, and a copy of required training and education must be retained. Considering pharmacists graduating from ACPE accredited programs are receiving robust training and education as part of the professional degree program, this may present an undue burden on pharmacists. Under a standard of care approach, a pharmacist would be required to obtain sufficient training, education, and experience to engage in the practice of pharmacy. If the training, education, and experience of the professional training pharmacist undergo during their pharmacy school program does not provide the level necessary to engage in a certain activity, then it would be incumbent upon that pharmacist to obtain additional training, education, or experience to meet the standard of care to practice in the area they are engaging in. We suggest the Board Members consider exempting the requirement to retain a copy of training

and education when the minimum criteria for engaging in a prescribing service is part of the pharmacy school curriculum under ACPE standards.

Second, in subpart (9) we thank the Board Members for acknowledging the value of the ALERT immunization registry. Allowing the primary care provider to be notified of an administered vaccine through reporting to the registry eliminates redundant activities in the pharmacy and we appreciate the Board Members removing this administrative burden. From the perspective of a prescription being issued to a patient, we ask the Board Members to consider patients who are accessing healthcare at a pharmacy who don't have a primary health care provider. We suggest the following minor amendment to the language.

(9) Pharmacists must report the prescription and administration of vaccines to a patient's primary health care provider if identified and to the Oregon Health Authority pursuant to ORS 689.645 (4).

Age Based Vaccination Protocols

We welcome the change being proposed to the vaccination protocols in Oregon. We believe this will be a better approach to allow pharmacists and appropriately trained interns and technicians the ability to operate more effectively, efficiently, and with safety in mind. The following are minor suggestions for the Board Members to consider.

First, the protocols each reference prescribing, dispensing, and administering vaccines in adherence to ACIP recommendations and the respective vaccine list that follows in the protocol. We view the list of vaccines to be redundant to the ACIP recommendations and suggest the removal of the vaccine list in each protocol. This would allow a pharmacist to use the ACIP recommendations and their professional judgment to ensure the patient is receiving the appropriate vaccine for their age and situation. This would also allow for the vaccine list to more nimbly follow the changes that are made by ACIP as they meet regularly, without the Board Members needing to revisit the protocol with each change.

Second, in the protocol for persons 6 months to 2 years old and 3 years to 6 years step 2 in the process requires screening for pregnancy status. We view this as unnecessary due to the age of the patient and question if it could have been included by accident.

Third, the protocol for vaccines administered to patients aged 7 to 17 years old does not include the RSV vaccine. This vaccine is recommended for all pregnant individuals, and the ACIP/CDC recommendations do not limit the age to 18+. We request the Board Members consider adding RSV to this protocol if they continue listing out the vaccines in each protocol. Also the travel vaccine for Chikungunya has been approved and it would be wise to

consider adding it to the 18 years and older protocol to be in alignment with CDC recommendations for travel.

Overall, we thank the Board Members for reacting to feedback and seeking ways to eliminate confusion in the practice of pharmacy and remove the administrative burden. These steps will allow for greater access to pharmacy services.

Thank you for the opportunity to comment on these proposed rules. Please direct any questions to Rob.Geddes@CVSHealth.com or 208-860-5342.

Sincerely,

Rob Geddes, PharmD, MBA
Executive Director,
Pharmacy Advocacy and Regulatory Affairs

From: Eid, Deeb D
To: PHARMACY RULEMAKING * BOP
Cc: Geddes, Rob
Subject: CVS Health Comment Letter
Date: Monday, July 21, 2025 1:37:09 PM
Attachments: Outlook-bgnabkcc.png
CVS Health Comment Letter OR BOP IMZ Protocol 7-21-25.pdf

> You don't often get email from deeb.eid@cvshealth.com. Learn why this is important

Hello Rachel,

I am submitting the attached comment letter on behalf of CVS Health and on behalf of my colleague Rob Geddes who is out on vacation this week in order to meet the deadline of 7/22 for submissions.

If you have any questions, please let us know. Thanks for the opportunity.

Thanks for your time,

DEEB D. EID, PHARMD, RPH, FMPLP
Sr. Manager, Pharmacy Regulatory Affairs & Advocacy
1 CVS Drive, Mail Code 2325, Woonsocket, RI 02895
Located: *Grand Rapids, MI*
Cell: *(W) 616-490-7398* ***| (P) 419-508-1669***
Fax: *401-652-2302*
Email: *Deeb.Eid@CVSHealth.com*

From: Alison Jackson
To: PHARMACY RULEMAKING * BOP
Subject: Proposed vaccine protocol update comment
Date: Friday, July 4, 2025 9:29:28 AM

[You don't often get email from jacksonae75@hotmail.com. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Hello,

I have reviewed the proposed vaccine protocols and have concerns.

The proposed protocols as written rely on CDC recommendations. While I may be misinterpreting, it appears the changes have been made to be able to provide a protocol that does not require the review and update by the Public Health and Pharmacy Formulary Advisory Committee for each individual vaccine. I am inferring that because the protocols no longer have detailed recommendations based on each vaccine and reference the CDC recommendations in protocols that are solely age based.

Our current HHS Secretary, a lawyer who has no scientific or medical education, has significantly changed the CDC approach to public health. He has a strong anti vaccine bias and his actions since taking the post have reflected that. Under his direction, the ACIP committee of 17 nonpartisan advisors was dismissed in order to bring in 8 members with bias. He produced a MAHA report that included studies that have not been published to support his agenda and said it was a "formatting error." He does not take responsibility for his actions resulting in preventable deaths of children. Instead of promoting prevention suggests ineffective and potentially harmful "treatment." He promotes the false idea that vaccines have not been studied for safety and efficacy and intends to conduct unethical "studies" to support his views. Additionally, the CDC has removed significant portions of its available webpages when they do not a support a specific agenda.

The Western States Scientific Safety Review Workgroup was created to address concerns that the CDC may not provide scientifically based recommendations that promote public health and safety. We are in a similar situation where a once mostly unbiased recommendation from the CDC could be referred to with the expectation it was based on sound science.

I am very concerned Oregon Pharmacists that administer vaccines by protocol will not be able to provide vaccines that have a good quality scientific basis that promotes public health if we are directed to vaccinate by CDC recommendations. The CDC recommendations are now subject to a strong anti vaccine bias.

I recognize the current iteration of the proposed protocol relies on specific CDC versions that could reasonably be expected to have been created with the intent to promote public health. There are two problems with that. One is that it means even with new information we will be vaccinating based on old data which may not reflect the best way to promote public health. Good quality science acknowledges new information directs us to change our behavior when necessary. The other is that the CDC has removed information when it does not suit the agenda of the current administration. We would be required to rely on CDC recommendations that may become unavailable.

Thank you for your work in promoting public health and safety.

Sincerely,
Alison Jackson

From: Martha Jones
To: PHARMACY RULEMAKING * BOP
Subject: Immunization rule making
Date: Friday, June 27, 2025 6:32:19 PM

THANK YOU for doing this important work to preserve science based medicine in our state.

The approach of tagging ACIP reccs by date is great, and one that came to my mind when trying to brainstorm how the heck we were going to get through this public health setback. Thank you for doing the work and bringing it forward.

Martha Jones, RPh and very happy to be an Oregonian today.

OFFICE OF THE SECRETARY OF STATE
TOBIAS READ
SECRETARY OF STATE

MICHAEL KAPLAN
DEPUTY SECRETARY OF STATE

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
06/26/2025 9:23 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Board Delegated Limited Authority for Vaccine Protocol rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/22/2025 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: 07/22/2025
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: 429564160
SPECIAL INSTRUCTIONS:
This hearing 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. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on July 22, 2025. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes adding a new rule to allow the board to delegate to the Board President the limited authority to amend the board's vaccine protocols to adopt recommendations by the Advisory Committee on Immunization Practices (ACIP) adopted by the Centers for Disease Control and Prevention (CDC).

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Advisory Committee on Immunization Practices (ACIP) https://www.cdc.gov/acip/index.html

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

The proposed rule is expected to affect racial equity in this state.

FISCAL AND ECONOMIC IMPACT:

No fiscal anticipated. Licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

COST OF COMPLIANCE:

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

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

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

Registrants who identify as a small business and who have signed up to receive notices 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?

No. The resources involved in convening a RAC were not necessary to amend this rule.

ADOPT: 855-102-0130

RULE SUMMARY: Proposes to adopt a new rule that allows the board to delegate to the Board President the limited authority to amend the Board's vaccine protocols to adopt recommendations issued by the Advisory Committee on Immunization Practices (ACIP) adopted by the Centers for Disease Control and Prevention (CDC) and allows the Board President to further delegate that authority to agency staff. The board interprets "advising" for purposes of ORS 689.649 to not include amendments to the board's vaccine protocol rules in OAR 855-115-0345 that are required by recommendations issued by the ACIP adopted by the CDC because those amendments are required by law and the board's only course of action.

CHANGES TO RULE:

855-102-0130
Amendment of Vaccine Protocol Rules to Adopt ACIP Recommendations
Pursuant to ORS 689.645(5), the board delegates to the Board President the limited authority to amend the board's vaccine protocols in OAR 855-115-0345 to adopt recommendations issued by the Advisory Committee on Immunization Practices (ACIP) adopted by the Centers for Disease Control and Prevention (CDC). The Board President may further delegate this authority to board staff. ORS 689.649 does not apply to rule amendments made pursuant to the delegation of authority in this rule because those amendments are required and the board's only course of action.
Statutory/Other Authority: ORS 689.205, ORS 689.645
Statutes/Other Implemented: ORS 689.205, ORS 689.645

OFFICE OF THE SECRETARY OF STATE
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SECRETARY OF STATE

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SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
06/26/2025 9:23 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Standard Vaccination Protocols

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/22/2025 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: 07/22/2025
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: 429564160
SPECIAL INSTRUCTIONS:
This hearing 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. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on July 22, 2025. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes amending current rules by removing “compendia and compendium”, incorporates new streamlined standard vaccination protocols and proposes repealing existing individual vaccine protocols.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

April 9-11, 2025 DRAFT Board Meeting Summary
https://www.oregon.gov/pharmacy/Documents/April_2025_DRAFT_Bd_Meeting_Summary.pdf

April 11, 2025 Teams video part #2 0:20:35 for board discussion https://www.youtube.com/watch?v=FI_Oznvj-9g
PHPFAC Draft 4.23.2025 Meeting Summary
https://www.oregon.gov/pharmacy/Documents/PHPFAC_4.23.2025_DRAFT_Mtg_Summary.pdf
Teams video part #4 1:09:53 for committee discussion https://www.youtube.com/watch?v=pSY7qWs6s_o
Draft Vaccination Protocol for Ages 6 months - 2 yrs
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_6_months_through_2_Years_7.22.2025.pdf
Draft Vaccination Protocol for Ages 6 months - 2 yrs – Assessment Treatment Care Pathway
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_6_months_through_2_Years_Assessment_Treatment_Care_Pathway_7.22.2025.pdf
Draft Vaccination Protocol for Ages 3-6 yrs
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_3_through_6_Years_7.22.2025_DRAFT.pdf
Draft Vaccination Protocol for Ages 3-6 yrs – Assessment Treatment Care Pathway
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_3_through_6_Years_Assessment_Treatment_Care_Pathway_7.22.2025.pdf
Draft Vaccination Protocol for Ages 7-17 yrs
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_7_through_17_Years_7.22.2025.pdf
Draft Vaccination Protocol for Ages 7-17 yrs – Assessment Treatment Care Pathway
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_7_through_17_Years_Assessment_Treatment_Care_Pathway_7.22.2025.pdf
Draft Vaccination Protocol for Adults 18 yrs of age and older
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Adults_18_Years_of_Age_and_Older_7.22.2025.pdf
Draft Vaccination Protocol for Adults 18 yrs of age and older – Assessment Treatment Care Pathway
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Adults_18_Years_of_Age_and_Older_Assessment_Treatment_Care_Pathway_7.22.2025.pdf
Draft Vaccination Protocol for Managing Adverse Reactions
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Managing_Adverse_Reactions_7.22.2025.pdf
Draft Vaccination Protocol for Managing Adverse Reactions - Assessment Treatment Care Pathway
https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Managing_Adverse_Reactions_Assessment_and_Treatment_Care_Pathway_7.22.2025.pdf

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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:

No fiscal anticipated. Licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

COST OF COMPLIANCE:

(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 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 and who have signed up to receive notices 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?

No. Subject Matter Experts (SME) are responsible for drafting proposed amendments or draft protocols and the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) is responsible for recommending proposed or amended protocols to the board for consideration.

RULES PROPOSED:
855-104-0055, 855-115-0330, 855-115-0335, 855-115-0340, 855-115-0345

AMEND: 855-104-0055

RULE SUMMARY: Proposes removing "compendia" and "for 6 years" from (B) to provide clarity to licensees.

CHANGES TO RULE:

855-104-0055
Record and Document Retention
(1) Each licensee and registrant must create documents and retain records required by ORS 475, ORS 689, and OAR 855. Documents and records:¶
(a) May be in written or electronic format; ¶
(b) Must be stored securely;¶
(c) Must be made available to the board upon request; and¶
(d) Must be retained for 3 years except that:¶
(A) Clinical pharmacy records must be retained for 7 years; and¶
(B) Training records for immunization administration and protocol and formulary ~~compendia~~ prescribing, must be retained ~~for 6 years~~ or uploaded into the licensee's electronic licensing record with the board;¶
(2) Records generated by a registrant:¶
(a) Must be stored on-site by the registrant for at least 12 months and must be provided to the board immediately upon request at the time of inspection; ¶
(b) May be stored in a secured off-site location after 12 months of storage at the registrant and must be provided to the board upon request within 3 business days;¶
(3) Records generated in the practice of pharmacy that do not belong to a registrant must be stored by a Pharmacist in a secure manner and provided to the board upon request within 3 business days; and¶
(4) Records must be retained for longer periods of time than required under this rule if:¶
(a) Federal law provides for a longer retention schedule; or¶
(b) Licensee or registrant has received notice of a Board investigation to which the records would be relevant; ¶
(c) Licensee or registrant has received a Board request to retain the records for a longer period of time.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508

AMEND: 855-115-0330

RULE SUMMARY: Proposes removing “compendia” and adds “pursuant to a statewide drug therapy protocol” in (1) to provide clarity to licensees and adds (9) pharmacist requirements related to reporting prescription and administration of vaccines to a patient’s primary healthcare provider and the Oregon Health Authority pursuant to ORS 689.654(4). Proposes differentiating prescribing requirements for protocols and formulary.

CHANGES TO RULE:

855-115-0330
Services: Prescribing - Formulary or Protocol ~~Compendia~~
(1) A Pharmacist located and licensed in Oregon may prescribe and dispense an FDA-approved drug and device included on either the Formulary or ~~Protocol Compendia~~pursuant to a statewide drug therapy protocol (Protocol), set forth in this Division. ¶
(2) A Pharmacist may submit a concept, on a form prescribed by the board to the Public Health and Pharmacy Formulary Advisory Committee for consideration, for the addition of a drug or device to the Formulary ~~Compendia~~ or for the development of a ~~protocol for the Protocol Compendia~~Protocol. A Pharmacist may provide feedback on the Formulary or Protocol ~~Compendia~~s on a board prescribed form ~~and~~ located on the board website.¶
(3) A Pharmacist must only prescribe a drug or device consistent with the parameters of the Formulary ~~and~~or Protocol ~~Compendia~~, and in accordance with federal and state regulations.¶
(4) The Pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.¶
(5) For each drug or device the Pharmacist prescribes via ~~the Formulary or Protocol Compendia~~Protocol, the Pharmacist must:¶
(a) Ensure training and education requirements have been met prior to engaging in prescribing activities. A copy of all required training and education must be retained according to OAR 855-104-0055; ¶
(b) Collect subjective and objective information about the patient's health history and clinical status. If prescribing pursuant to the Formulary ~~Compendia~~ in OAR 855-115-0340, a diagnosis from the patient's health care provider is required. ¶
(c) Assess the information collected in (b). Any physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means.¶
(d) Create an individualized patient-centered care plan that utilizes information obtained in the assessment to evaluate and develop a care plan; ¶
(e) Implement the care plan, to include:¶
(A) Addressing medication and health-related problems and engaging in preventive care strategies;¶
(B) Initiating, modifying, discontinuing, or administering medication therapy as permitted by the Formulary or Protocol ~~Compendia~~;¶
(C) Providing education and self-management training to the patient or caregiver;¶
(D) Contributing to coordination of care, including the referral or transition of the patient to another health care professional; and¶
(E) Scheduling follow-up care as needed to achieve goals of therapy~~.~~; and¶
(f) Monitor and evaluate the effectiveness of the care plan and make modifications to the plan~~; and~~¶
~~(g.~~ ¶
(6) For each drug or device the Pharmacist prescribes via Formulary, the Pharmacist must:¶
(a) Ensure training and education requirements have been met prior to engaging in prescribing activities. A copy of all required training and education must be retained according to OAR 855-104-0055; and¶
(b) Ensure prescribing is pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis.¶
(7) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a Formulary or Protocol ~~Compendia~~ drug or device.¶
(~~6~~8) ~~If consultation is provided through an electronic means, the Oregon licensed~~All records and documents must be retained according to OAR 855-104-0055 and must be made available to the patient and provider upon request.¶
(9) Pharmacists must ~~use~~report the prescription and a~~udiovisual communication system to conduct the consultation.~~¶
~~(7) All~~dministration of vaccines to a patient's primary health care provider and to the Oregon Health Authority pursuant to ORS 689.645(4). The rec~~ords and documents must be retained according to OAR 855-104-0055 and must be made available to the patient and provider upon request~~ting of the prescription and administration of

vaccines to a patient's primary health care provider and to the Oregon Health Authority can be accomplished by reporting to the 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.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-115-0335

RULE SUMMARY: Proposes adding “Formulary or Protocol” to (1)(b) and removes “compendia” to provide clarity to licensees.

CHANGES TO RULE:

855-115-0335
Services: Prescribing - Prohibited Practices
(1) A Pharmacist must not prescribe a drug or device via ~~the~~ Formulary or Protocol ~~Compendia~~:¶
(a) To self; or¶
(b) When the ~~compendia~~Formulary or Protocol requires referral to a non-Pharmacist provider.¶
(2) A Pharmacist must not require, but may allow, a patient to schedule an appointment with the Pharmacist for the prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-115-0340

RULE SUMMARY: Proposes removing “compendium” and adds “Formulary” to provide clarity to licensees.

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, an FDA-approved drug and device listed in the ~~following compendium~~Formulary, 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.~~ ~~D~~Formulary 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 removing "compendium", adds that protocols in their entirety are adopted by the board by specific effective dates referenced can be found on the board website to provide clarity and a path to resources licensees can utilize. Adds "protocol" to (1), (2), (3), (4) and proposes adding new vaccination protocols in (4)(a),(b),(c),(d) and (e) per board and Public Health and Pharmacy Formulary Advisory Committee directives to simplify and streamline vaccine protocols. Proposes repealing (A) through (V) individual existing vaccine protocols which would be relocated and incorporated into the new vaccination protocols in (4) (a) through (e).

CHANGES TO RULE:

855-115-0345
Services: Prescribing Pursuant to - 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~~, pursuant to a Protocol. Protocols in their entirety are adopted by the board by this rule pursuant to the respective effective date referenced and can be found on the board website at https://www.oregon.gov/pharmacy/Pages/PFAC.aspx. ¶
(1) Continuation of therapy Protocol including emergency refills of insulin and early refills of opioid use disorder medications (v. 08/2024)¶
(2) Conditions Protocols:¶
(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) COVID-19 Antigen Self-Test (v. 12/2021);¶
(c) SARS-CoV-2 Antiviral (v. 08/2024)¶
(3) Preventative ~~c~~Care Protocols:¶
(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. 06/2025);¶
(h) Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) (v. 06/2024);¶
(i) Short-acting Opioid Antagonists (v. 06/2024); and¶
(j4) Vaccine Protocols:¶
(~~A~~a) ~~Standard~~Vaccination Protocol for A~~ll Vaccines: Cover Page & Assessment and Treatment Care Pathway~~dults 18 Years of Age and Older (v. 0~~6~~8/2024~~5~~);¶
(~~B~~b) ~~Standard~~Vaccination Protocol for A~~ll Vaccines: Managing Adverse Reactions (v. 06/2024); ¶~~
~~(C) Cholera (v. 02/2024); ¶~~
~~(D) Coronavirus 2019 (v. 06/2025); ¶~~
~~(E) Haemophilus Influenza type b~~ges 7 through 17 Years (v. 0~~6~~8/2024~~5~~);¶
(~~F~~c) ~~Hepatitis A containing vaccines (v. 02/2024); ¶~~
~~(G) Hepatitis B containing vaccines (v. 06/2025); ¶~~
~~(H) Human Papillomavirus (v. 02/2024); ¶~~
~~(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2024-2025~~Vaccination Protocol for Ages 3 through 6 Years (v. ~~12~~08/2024~~5~~); ¶
~~(J) Influenza - Live Attenuated Influenza Vaccine 2024-2025 (v. 12/2024); ¶~~
~~(K) Japanese Encephalitis (v. 06/2024); ¶~~
~~(L) Meningococcal containing vaccines (v. 06/2025); ¶~~
~~(M) Measles Mumps & Rubella containing vaccines (v. 02/2024); ¶~~
~~(N) Pneumococcal~~d) Vaccination Protocol for Ages 6 months through 2 Years (v. 0~~6~~8/2025); and¶
(~~O~~e) ~~Polio (v. 06/2024);¶~~
~~(P) Rabies (v. 02/2024); ¶~~
~~(Q) Respiratory Syncytial Virus (v. 06/2025);¶~~
~~(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~~Vaccination Protocol for Managing Adverse Reactions (v. 0~~2~~8/2024~~5~~).¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 689.205, ORS 689.005
Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689, ORS 689.005

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL FOR PERSONS 18 YEARS OF AGE AND OLDER

PROTOCOL for the OREGON PHARMACIST

Cover Page & Assessment and Treatment Care Pathway

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the Assessment and Treatment Care Pathway for Vaccines **for Persons 18 years of age and older** (pg 2 and 3)
- Utilize the Protocol for Managing Adverse Reactions when applicable

PRESCRIBING PARAMETERS:

- Pharmacists licensed and located in Oregon may prescribe, dispense and administer vaccines in adherence with this protocol and:
  - Centers for Disease Control and Prevention (CDC) Advisory Counsel for Immunization Practices (ACIP) recommendations adopted by reference pursuant to the adoption date referenced next to the respective vaccine listed below;
  - CDC Pink Book: Epidemiology and Prevention of Vaccine Preventable Diseases;
  - CDC Yellow Book: Health Information for International Travel Information;
  - All Oregon Board of Pharmacy laws and rules; and
- An Oregon licensed pharmacist practicing in Oregon may prescribe, dispense and administer the following vaccines to persons **18 years of age and older**:
  - Anthrax (v. 12/13/2019)
  - Cholera (v. 9/30/2022)
  - Coronavirus 19 (v. 12/12/2024)
  - Ebola (v. 2/25/2022)
  - Diphtheria, tetanus and Pertussis containing vaccines (v. 1/24/2020)
  - Haemophilus Influenzae type b (v. 9/12/2024)
  - Hepatitis A containing vaccines (v. 7/03/2020)
  - Hepatitis B containing vaccines (v. 12/05/2024)
  - Human Papillomavirus (v. 8/16/2019)
  - Influenza (v. 8/27/2024)
  - Japanese Encephalitis (v. 7/19/2019)
  - Measles, Mumps & Rubella containing vaccines (v. 5/07/2010)
  - Meningococcal containing vaccines (v. 12/24/2024)
  - Orthopoxviruses (v. 6/03/2022)
  - Pneumococcal (v. 1/8/2025)
  - Polio (v. 12/08/2023)
  - Rabies (v. 5/06/2022)
  - Respiratory Syncytial Virus (v. 8/15/2024)

- Tick-Borne Encephalitis (v. 11/10/2023)
- Typhoid (v. 3/27/2015)
- Varicella containing vaccines (v. 7/19/2013)
- Yellow Fever (v. 7/16/2015)
- Zoster (v. 1/21/2022)

PHARMACIST TRAINING/EDUCATION:

- Prior to any Oregon licensed pharmacist administering a vaccine, in accordance with OAR 855-115-0305, the pharmacist must:
  - Receive practical training on the injection site and administration technique that is utilized;
  - Complete training regarding hands-on injection technique, clinical evaluation of indications and contradictions of vaccines and the recognition and treatment of emergency reactions to vaccines;
  - Hold an active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years; and
  - Ensure any vaccine administered was stored in accordance with the drug storage rules for pharmacies in OAR 855-041-1036
- An Oregon licensed pharmacist practicing in Oregon may allow:
  - An appropriately trained and qualified Intern may perform the same duties as a pharmacist except as prohibited in OAR 855-120-0150.
  - An appropriately trained and qualified Tech may conduct the physical act of administering a vaccine in accordance with OAR 855-125-0305.

RESOURCES

- CDC ACIP: Vaccine Recommendations and Guidelines https://www.cdc.gov/acip-recs/hcp/vaccine-specific/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
- CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases https://www.cdc.gov/pinkbook/hcp/table-of-contents/?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/index.html
- CDC Yellow Book 2026: 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
- CDC Vaccine Information Statements https://www.cdc.gov/vaccines/hcp/current-vis/?CDC_AAref_Val=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

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL FOR PERSONS 18 YEARS OF AGE AND OLDER

PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: DETERMINE VACCINE NEEDED

- In consultation with the patient, collect and assess information to determine what vaccines the patient needs based on age, health conditions, occupation, travel, lifestyle and vaccine history.
- To determine vaccine history, check the ALERT Immunization Information System (IIS), patient health records, and any other sources of records.
- If a patient has no vaccination history or the vaccination history cannot be ascertained, follow current CDC ACIP recommendations.

STEP 2: SCREEN FOR PATIENT PRECAUTIONS AND CONTRAINDICATIONS

- Collect patient information to screen for precautions and contraindications to needed vaccine(s) by utilizing a screening questionnaire.
- The screening questionnaire should include questions that require patient information including current health status, present & past medical history, allergies, medications, immunization history, and pregnancy status.
- Assess information provided in screening questionnaire in combination with review of ALERT ISS, patient health records and any other relevant sources of information to determine any precautions or contraindications to needed vaccine(s).

STEP 3: DISCUSS OPTIONS

- Recommend vaccine(s).
- Advise or counsel on therapeutic values, content, hazards and use of each vaccine.
- Offer to administer vaccine(s) or if requested, refer the patient to another immunizing health care provider.

STEP 4: PRESCRIBE, DISPENSE AND ADMINISTER VACCINE(S)

- Select vaccine(s) to be administered.
- Perform verification of vaccine(s) prior to administration.
- Provide patient or patient's agent with current patient education and Vaccine Information Statements (VIS) and answer any questions prior to administering 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.
- Administer vaccine(s).
- Report vaccination(s) to ALERT Immunization Information System (IIS).

STEP 5: DOCUMENT AND MONITOR PATIENT

- Document vaccination(s) administered to patient and record all required data elements in the patient's permanent health record. Records of administration must include patient identifier, vaccine strength, route and site of administration, date and time of administration and pharmacist identifier.
- Monitor patient per guidelines for signs and symptoms of syncope, localized and/or generalized reactions. If a patient has an Adverse Reporting Event, follow Standard Vaccination Protocol for Managing Adverse Reactions.
- Schedule follow-up for subsequent doses of multidose vaccine series.
- As needed, 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).

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL FOR PERSONS 7 THROUGH 17 YEARS OF AGE

PROTOCOL for the OREGON PHARMACIST

Cover Page & Assessment and Treatment Care Pathway

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the Assessment and Treatment Care Pathway for Vaccines **for Persons 7 through 17 years of age** (pg 2 and 3)
- Utilize the Protocol for Managing Adverse Reactions when applicable

PRESCRIBING PARAMETERS:

- Pharmacists licensed and located in Oregon may prescribe, dispense and administer vaccines in adherence with this protocol and:
  - Centers for Disease Control and Prevention (CDC) Advisory Counsel for Immunization Practices (ACIP) recommendations adopted by reference pursuant to the adoption date referenced next to the respective vaccine listed below;
  - CDC Pink Book: Epidemiology and Prevention of Vaccine Preventable Diseases;
  - CDC Yellow Book: Health Information for International Travel Information;
  - All Oregon Board of Pharmacy laws and rules; and
- An Oregon licensed pharmacist practicing in Oregon may prescribe, dispense and administer the following vaccines to persons **7 through 17 years of age**:
  - Anthrax (v. 12/13/2019)
  - Cholera (v. 9/30/2022)
  - Coronavirus 19 (v. 12/12/2024)
  - Dengue (v. 12/17/2021)
  - Diphtheria, Tetanus and Pertussis containing vaccines (v. 1/24/2020)
  - Haemophilus Influenzae type b (v. 9 /12/2024)
  - Hepatitis A containing vaccines (v. 7/03/2020)
  - Hepatitis B containing vaccines (v. 12/05/2024)
  - Human Papillomavirus (v. 8/16/2019)
  - Influenza (v. 8/27/2024)
  - Japanese Encephalitis (v. 7/19/2019)
  - Measles, Mumps & Rubella containing vaccines (v. 5/07/2010)
  - Meningococcal containing vaccines (v. 12/24/2024)
  - Orthopoxviruses (v. 6/03/2022)
  - Pneumococcal (v. 1/8/2025)
  - Polio (v. 12/08/2023)
  - Rabies (v. 5/06/2022)

- Tick-Borne Encephalitis (v. 11/10/2023)
- Typhoid (v. 3/27/2015)
- Varicella containing vaccines (v. 7/19/2013)
- Yellow Fever (v. 7/19/2015)

PHARMACIST TRAINING/EDUCATION:

- Prior to any Oregon licensed pharmacist administering a vaccine, in accordance with OAR 855-115-0305, the pharmacist must:
  - Receive practical training on the injection site and administration technique that is utilized;
  - Complete training regarding hands-on injection technique, clinical evaluation of indications and contradictions of vaccines and the recognition and treatment of emergency reactions to vaccines;
  - Hold an active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years; and
  - Ensure any vaccine administered was stored in accordance with the drug storage rules for pharmacies in OAR 855-041-1036
- An Oregon licensed pharmacist practicing in Oregon may allow:
  - An appropriately trained and qualified Intern may perform the same duties as a pharmacist except as prohibited in OAR 855-120-0150.
  - An appropriately trained and qualified Tech may conduct the physical act of administering a vaccine in accordance with OAR 855-125-0305.

RESOURCES

- CDC ACIP: Vaccine Recommendations and Guidelines https://www.cdc.gov/acip-recs/hcp/vaccine-specific/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
- CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases https://www.cdc.gov/pinkbook/hcp/table-of-contents/?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/index.html
- CDC Yellow Book 2026: 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 Children and Teens http://www.immunize.org/catg.d/p4060.pdf
- CDC Child and Adolescent immunization Schedule https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
- CDC Vaccine Information Statements https://www.cdc.gov/vaccines/hcp/current-vis/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/vis/current-vis.html

- Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov/index
- National Vaccine Errors Reporting Program (VERP) https://www.ismp.org/form/verp-form

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL FOR PERSONS 7 THROUGH 17 YEARS OF AGE

PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: DETERMINE VACCINE NEEDED

- In consultation with the patient or their representative, collect and assess information to determine what vaccines the patient needs based on age, health conditions, occupation, travel, lifestyle and vaccine history.
- To determine vaccine history, check the ALERT Immunization Information System (IIS), patient health records, and any other sources of records.
- If a patient has no vaccination history or the vaccination history cannot be ascertained, follow current CDC ACIP recommendations.

STEP 2: SCREEN FOR PATIENT PRECAUTIONS AND CONTRAINDICATIONS

- Collect patient information to screen for precautions and contraindications to needed vaccine(s) by utilizing a screening questionnaire.
- The screening questionnaire should include questions that require patient information including current health status, present & past medical history, allergies, medications, immunization history, and pregnancy status.
- Assess information provided in screening questionnaire in combination with review of ALERT ISS, patient health records and any other relevant sources of information to determine any precautions or contraindications to needed vaccine(s).

STEP 3: DISCUSS OPTIONS

- Recommend vaccine(s).
- Advise or counsel on therapeutic values, content, hazards and use of each vaccine.
- Offer to administer vaccine(s) or if requested, refer the patient to another immunizing health care provider.

STEP 4: PRESCRIBE, DISPENSE AND ADMINISTER VACCINE(S)

- Select vaccine(s) to be administered.
- Perform verification of vaccine(s) prior to administration.
- Provide patient or patient's agent with current patient education and Vaccine Information Statements (VIS) and answer any questions prior to administering 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.
- Administer vaccine(s).
- Report vaccination(s) to ALERT Immunization Information System (IIS).

STEP 5: DOCUMENT AND MONITOR PATIENT

- Document vaccination(s) administered to patient and record all required data elements in the patient's permanent health record. Records of administration must include patient identifier, vaccine strength, route and site of administration, date and time of administration and pharmacist identifier.
- Monitor patient per guidelines for signs and symptoms of syncope, localized and/or generalized reactions. If a patient has an Adverse Reporting Event, follow Standard Vaccination Protocol for Managing Adverse Reactions.
- Schedule follow-up for subsequent doses of multidose vaccine series.
- As needed, 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).

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL FOR PERSONS 3 THROUGH 6 YEARS OF AGE

PROTOCOL for the OREGON PHARMACIST

Cover Page & Assessment and Treatment Care Pathway

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the Assessment and Treatment Care Pathway for Vaccines **for Persons 3 through 6 years of age** (pg 2 and 3)
- Utilize the Protocol for Managing Adverse Reactions when applicable

PRESCRIBING PARAMETERS:

- Pharmacists licensed and located in Oregon may prescribe, dispense and administer vaccines in adherence with this protocol and:
  - Centers for Disease Control and Prevention (CDC) Advisory Counsel for Immunization Practices (ACIP) recommendations adopted by reference pursuant to the adoption date referenced next to the respective vaccine listed below;
  - CDC Pink Book: Epidemiology and Prevention of Vaccine Preventable Diseases;
  - CDC Yellow Book: Health Information for International Travel Information;
  - All Oregon Board of Pharmacy laws and rules; and
- An Oregon licensed pharmacist practicing in Oregon may prescribe, dispense and administer the following vaccines to persons **3 through 6 years of age**:
  - Coronavirus 19 (v. 12/12/2024)
    - PREP Act, 12th Amendment
  - Influenza (v. 8/29/2024)
    - ORS 689.645

PHARMACIST TRAINING/EDUCATION:

- Prior to any Oregon licensed pharmacist administering a vaccine, in accordance with OAR 855-115-0305, the pharmacist must:
  - Receive practical training on the injection site and administration technique that is utilized;
  - Complete training regarding hands-on injection technique, clinical evaluation of indications and contradictions of vaccines and the recognition and treatment of emergency reactions to vaccines;
  - Hold an active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider

that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years; and
    - Ensure any vaccine administered was stored in accordance with the drug storage rules for pharmacies in OAR 855-041-1036
- An Oregon licensed pharmacist practicing in Oregon may allow a Pharmacy Intern to perform the following duties related to vaccines:
    - An appropriately trained and qualified Intern may perform the same duties as a pharmacist except as prohibited in OAR 855-120-0150.

RESOURCES

- CDC ACIP: Vaccine Recommendations and Guidelines https://www.cdc.gov/acip-recs/hcp/vaccine-specific/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
- CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases https://www.cdc.gov/pinkbook/hcp/table-of-contents/?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/index.html
- Immunization Action Coalition (IAC) Screening Checklist for Contraindications to Vaccines for Children and Teens http://www.immunize.org/catg.d/p4060.pdf
- 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/current-vis/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/vis/current-vis.html
- Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov/index
- National Vaccine Errors Reporting Program (VERP) https://www.ismp.org/form/verp-form

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL FOR PERSONS 3 THROUGH 6 YEARS OF AGE

PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: DETERMINE VACCINE NEEDED

- In consultation with the patient, collect and assess information to determine what vaccines the patient needs based on age, health conditions, occupation, travel, lifestyle and vaccine history.
- To determine vaccine history, check the ALERT Immunization Information System (IIS), patient health records, and any other sources of records.
- If a patient has no vaccination history or the vaccination history cannot be ascertained, follow current CDC ACIP recommendations.

STEP 2: SCREEN FOR PATIENT PRECAUTIONS AND CONTRAINDICATIONS

- Collect patient information to screen for precautions and contraindications to needed vaccine(s) by utilizing a screening questionnaire.
- The screening questionnaire should include questions that require patient information including current health status, present & past medical history, allergies, medications, immunization history, and pregnancy status.
- Assess information provided in screening questionnaire in combination with review of ALERT ISS, patient health records and any other relevant sources of information to determine any precautions or contraindications to needed vaccine(s).

STEP 3: DISCUSS OPTIONS

- Recommend vaccine(s).
- Advise or counsel on therapeutic values, content, hazards and use of each vaccine.
- Offer to administer vaccine(s) or if requested, refer the patient to another immunizing health care provider.

STEP 4: PRESCRIBE, DISPENSE AND ADMINISTER VACCINE(S)

- Select vaccine(s) to be administered.
- Perform verification of vaccine(s) prior to administration.
- Provide patient or patient's agent with current patient education and Vaccine Information Statements (VIS) and answer any questions prior to administering vaccine(s).
- Verify needle length for injection.
- To avoid injury related to vaccine administration, immunizer must recognize the anatomic landmarks for identifying the muscle at the site of administration (deltoid, or anterolateral thigh) and use proper IM administration technique.
- Administer vaccine(s).
- Report vaccination(s) to ALERT Immunization Information System (IIS).

STEP 5: DOCUMENT AND MONITOR PATIENT

- Document vaccination(s) administered to patient and record all required data elements in the patient's permanent health record. Records of administration must include patient identifier, vaccine strength, route and site of administration, date and time of administration and pharmacist identifier.
- Monitor patient per guidelines for signs and symptoms of syncope, localized and/or generalized reactions. If a patient has an Adverse Reporting Event, follow Standard Vaccination Protocol for Managing Adverse Reactions.
- Schedule follow-up for subsequent doses of multidose vaccine series.
- As needed, 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).

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL FOR PERSONS 3 THROUGH 6 YEARS OF AGE

PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: DETERMINE VACCINE NEEDED

- In consultation with the patient, collect and assess information to determine what vaccines the patient needs based on age, health conditions, occupation, travel, lifestyle and vaccine history.
- To determine vaccine history, check the ALERT Immunization Information System (IIS), patient health records, and any other sources of records.
- If a patient has no vaccination history or the vaccination history cannot be ascertained, follow current CDC ACIP recommendations.

STEP 2: SCREEN FOR PATIENT PRECAUTIONS AND CONTRAINDICATIONS

- Collect patient information to screen for precautions and contraindications to needed vaccine(s) by utilizing a screening questionnaire.
- The screening questionnaire should include questions that require patient information including current health status, present & past medical history, allergies, medications, immunization history, and pregnancy status.
- Assess information provided in screening questionnaire in combination with review of ALERT ISS, patient health records and any other relevant sources of information to determine any precautions or contraindications to needed vaccine(s).

STEP 3: DISCUSS OPTIONS

- Recommend vaccine(s).
- Advise or counsel on therapeutic values, content, hazards and use of each vaccine.
- Offer to administer vaccine(s) or if requested, refer the patient to another immunizing health care provider.

STEP 4: PRESCRIBE, DISPENSE AND ADMINISTER VACCINE(S)

- Select vaccine(s) to be administered.
- Perform verification of vaccine(s) prior to administration.
- Provide patient or patient's agent with current patient education and Vaccine Information Statements (VIS) and answer any questions prior to administering vaccine(s).
- Verify needle length for injection.
- To avoid injury related to vaccine administration, immunizer must recognize the anatomic landmarks for identifying the muscle at the site of administration (deltoid, or anterolateral thigh) and use proper IM administration technique.
- Administer vaccine(s).
- Report vaccination(s) to ALERT Immunization Information System (IIS).

STEP 5: DOCUMENT AND MONITOR PATIENT

- Document vaccination(s) administered to patient and record all required data elements in the patient's permanent health record. Records of administration must include patient identifier, vaccine strength, route and site of administration, date and time of administration and pharmacist identifier.
- Monitor patient per guidelines for signs and symptoms of syncope, localized and/or generalized reactions. If a patient has an Adverse Reporting Event, follow Standard Vaccination Protocol for Managing Adverse Reactions.
- Schedule follow-up for subsequent doses of multidose vaccine series.
- As needed, 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).

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL FOR PERSONS 6 MONTHS THROUGH 2 YEARS OF AGE

PROTOCOL for the OREGON PHARMACIST

Cover Page & Assessment and Treatment Care Pathway

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may prescribe, administer and dispense vaccines pursuant to a statewide drug therapy management protocol

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the Assessment and Treatment Care Pathway for Vaccines **for Persons 6 months through 2 years of age** (pg 2 and 3)
- Utilize the Protocol for Managing Adverse Reactions when applicable

PRESCRIBING PARAMETERS:

- Pharmacists licensed and located in Oregon may prescribe, dispense and administer vaccines in adherence with this protocol and:
  - Centers for Disease Control and Prevention (CDC) Advisory Counsel for Immunization Practices (ACIP) recommendations adopted by reference pursuant to the adoption date referenced next to the respective vaccine listed below;
  - CDC Pink Book: Epidemiology and Prevention of Vaccine Preventable Diseases;
  - CDC Yellow Book: Health Information for International Travel Information;
  - All Oregon Board of Pharmacy laws and rules; and
- An Oregon licensed pharmacist practicing in Oregon may prescribe, dispense and administer the following vaccines to persons **6 months through 2 years of age**:
  - Influenza (v. 8/29/2024)

PHARMACIST TRAINING/EDUCATION:

- Prior to any Oregon licensed pharmacist administering a vaccine, in accordance with OAR 855-115-0305, the pharmacist must:
  - Receive practical training on the injection site and administration technique that is utilized;
  - Complete training regarding hands-on injection technique, clinical evaluation of indications and contradictions of vaccines and the recognition and treatment of emergency reactions to vaccines;
  - Hold an active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years; and
  - Ensure any vaccine administered was stored in accordance with the drug storage rules for pharmacies in OAR 855-041-1036

- An Oregon licensed pharmacist practicing in Oregon may allow a Pharmacy Intern to perform the following duties related to vaccines:
    - An appropriately trained and qualified Intern may perform the same duties as a pharmacist except as prohibited in OAR 855-120-0150.

RESOURCES

- CDC ACIP: Vaccine Recommendations and Guidelines https://www.cdc.gov/acip-recs/hcp/vaccine-specific/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
- CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases https://www.cdc.gov/pinkbook/hcp/table-of-contents/?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/index.html
- Immunization Action Coalition (IAC) Screening Checklist for Contraindications to Vaccines for Children and Teens http://www.immunize.org/catg.d/p4060.pdf
- CDC Child and Adolescent immunization Schedule https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
- CDC Vaccine Information Statements https://www.cdc.gov/vaccines/hcp/current-vis/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/vis/current-vis.html
- Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov/index
- National Vaccine Errors Reporting Program (VERP) https://www.ismp.org/form/verp-form

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL FOR PERSONS 6 MONTHS THROUGH 2 YEARS OF AGE

PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: DETERMINE VACCINE NEEDED

- In consultation with the patient, collect and assess information to determine what vaccines the patient needs based on age, health conditions, occupation, travel, lifestyle and vaccine history.
- To determine vaccine history, check the ALERT Immunization Information System (IIS), patient health records, and any other sources of records.
- If a patient has no vaccination history or the vaccination history cannot be ascertained, follow current CDC ACIP recommendations.

STEP 2: SCREEN FOR PATIENT PRECAUTIONS AND CONTRAINDICATIONS

- Collect patient information to screen for precautions and contraindications to needed vaccine(s) by utilizing a screening questionnaire.
- The screening questionnaire should include questions that require patient information including current health status, present & past medical history, allergies, medications, immunization history, and pregnancy status.
- Assess information provided in screening questionnaire in combination with review of ALERT ISS, patient health records and any other relevant sources of information to determine any precautions or contraindications to needed vaccine(s).

STEP 3: DISCUSS OPTIONS

- Recommend vaccine(s).
- Advise or counsel on therapeutic values, content, hazards and use of each vaccine.
- Offer to administer vaccine(s) or if requested, refer the patient to another immunizing health care provider.

STEP 4: PRESCRIBE, DISPENSE AND ADMINISTER VACCINE(S)

- Select vaccine(s) to be administered.
- Perform verification of vaccine(s) prior to administration.
- Provide patient or patient's agent with current patient education and Vaccine Information Statements (VIS) and answer any questions prior to administering vaccine(s).
- Verify needle length for injection.
- To avoid injury related to vaccine administration, immunizer must recognize the anatomic landmarks for identifying the muscle at the site of administration (deltoid, or anterolateral thigh) and use proper IM administration technique.
- Administer vaccine(s).
- Report vaccination(s) to ALERT Immunization Information System (IIS).

STEP 5: DOCUMENT AND MONITOR PATIENT

- Document vaccination(s) administered to patient and record all required data elements in the patient's permanent health record. Records of administration must include patient identifier, vaccine strength, route and site of administration, date and time of administration and pharmacist identifier.
- Monitor patient per guidelines for signs and symptoms of syncope, localized and/or generalized reactions. If a patient has an Adverse Reporting Event, follow Standard Vaccination Protocol for Managing Adverse Reactions.
- Schedule follow-up for subsequent doses of multidose vaccine series.
- As needed, 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).

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL
MANAGING ADVERSE REACTIONS

PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may prescribe and administer medications for the management of adverse reactions following immunization pursuant to a statewide drug therapy management protocol.

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)

PRESCRIBING PARAMETERS:

- 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.

PHARMACIST TRAINING/EDUCATION:

- Prior to any Oregon licensed pharmacist administering a vaccine, in accordance with OAR 855-115-0305, the pharmacist must:
  - Receive practical training on the injection site and administration technique that is utilized;
  - Complete training regarding hands-on injection technique, clinical evaluation of indications and contradictions of vaccines and the recognition and treatment of emergency reactions to vaccines;
  - Hold an active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years; and
  - Ensure any vaccine administered was stored in accordance with the drug storage rules for pharmacies in OAR 855-041-1036
- An Oregon licensed pharmacist practicing in Oregon may allow a Pharmacy Intern to perform the following duties related to vaccines:
  - An appropriately trained and qualified Intern may perform the same duties as a pharmacist except as prohibited in OAR 855-120-0150.

RESOURCES

- CDC ACIP General Best Practice Guidelines: Preventing and Managing Adverse Reactions- https://www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html
- Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book): Vaccine Administration- https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-6-vaccine-administration.html?CDC_AAref_Val=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
- Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov/index

PREVENTATIVE CARE

STANDARD VACCINATION PROTOCOL
MANAGING ADVERSE REACTIONS

PROTOCOL for the OREGON PHARMACIST

Cover Page & Assessment and Treatment Care Pathway

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)

1. 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:

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]

2. 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]

3. 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.

4. 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.

5. 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)

6. Storage and Handling

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

7. 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/index

B. VAERS Table of Reportable Events Following Vaccination: https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

8. 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.

9. Appendix

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

OFFICE OF THE SECRETARY OF STATE
TOBIAS READ
SECRETARY OF STATE

MICHAEL KAPLAN
DEPUTY SECRETARY OF STATE

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
06/26/2025 9:24 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Updates incorporated standards adopted by reference

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/22/2025 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: 07/22/2025
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: 429564160
SPECIAL INSTRUCTIONS:
This hearing 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. Please indicate which rule(s) you would like to comment on.
You must submit written comments before 4:30PM on July 22, 2025. 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 (OAR 855-102-0045).

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Adopted Standards by Reference:

Part 1301 – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances - 21 CFR (04/01/2024)
Accreditation Council on Pharmaceutical Education (ACPE) Accredited Providers of Continuing Pharmacy Education (05/27/2025)
ACCME List of Recognized State Medical Society Accreditors (05/27/2025)

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:

No fiscal anticipated. Licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

COST OF COMPLIANCE:

(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 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 and who have signed up to receive notices 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?

No. Amendments are required per ORS 183.337 pursuant to ORS 475.035 and ORS 475.055.

RULES PROPOSED:
855-115-0130, 855-135-0001

AMEND: 855-115-0130

RULE SUMMARY: Proposes to revise referenced versions of the Code of Federal Regulations (CFR) in (1)(g)(C)(D).

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~~3~~4); and¶
(D) Listed chemicals per 21 CFR 1310.05 (v. 04/01/202~~3~~4); 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, 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

AMEND: 855-135-0001

RULE SUMMARY: Proposes revising reference versions of ACPE and ACCME in (1)(a)(b).

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:¶
(a) Continuing pharmacy education that is accredited by the Accreditation Council on Pharmaceutical Education (ACPE) (v. 0~~6/01~~5/27/202~~2~~5);¶
(b) Continuing medical education (CME) accredited by the Accreditation Council for Continuing Medical Education (ACCME) or an ACCME-recognized State Medical Society (v. 0~~6~~5/27/202~~2~~5) as an American Medical Association (AMA) Category 1 CME program; or¶
(c) Continuing veterinary medical education (CVME) approved 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

End of Session Report

Report Date: July 23, 2025

Oregon Board of Pharmacy

N/A

Bill #	Status	Effective Date	Last Three Actions
HB 2336 EN	Passed	January 1, 2026	5/14/2025 - Chapter 12, (2025 Laws): Effective date January 1, 2026. 4/23/2025 - Governor signed. 4/15/2025 - President signed.
Modifies the timing of internal audits performed by state agencies and reporting on internal audits by the Oregon Department of Administrative Services.			
HB 2337 EN	Passed		7/17/2025 - Governor signed. 6/26/2025 - President signed. 6/26/2025 - Speaker signed.
Directs the Oregon Department of Administrative Services to establish a small business preferences program for state procurement.			
HB 2385 EN	Passed		6/23/2025 - Chapter 297, (2025 Laws): effective on the 91st day following adjournment sine die. 6/11/2025 - Governor signed. 6/3/2025 - President signed.
Prohibits drug manufacturers from interfering directly or indirectly with a pharmacy or drug outlet acquiring 340B drugs, delivering 340B drugs to certain health care providers or dispensing 340B drugs.			
HB 2387 EN	Passed	May 22, 2025	6/11/2025 - Chapter 147, (2025 Laws): Effective date May 22, 2025. 5/22/2025 - Governor signed. 5/15/2025 - President signed.
Allows licensees of certain health professional regulatory boards to provide psilocybin services as licensed psilocybin service facilitators while providing the health care or behavioral health care services the provider is authorized to provide.			
HB 2461 EN	Passed	January 1, 2026	5/20/2025 - Chapter 23, (2025 Laws): Effective date January 1, 2026. 5/7/2025 - Governor signed. 5/1/2025 - President signed.
Changes notice requirements and requirements related to facilities and technology for motions to allow remote location testimony.			
HB 2464 EN	Passed	January 1, 2026	4/21/2025 - Chapter 2, (2025 Laws): Effective date January 1, 2026. 3/12/2025 - Governor signed. 3/10/2025 - President signed.
Makes nonsubstantive and technical changes in Oregon law.			

End of Session Report

Report Date: July 23, 2025

Oregon Board of Pharmacy

N/A

Bill #	Status	Effective Date	Last Three Actions
HB 2930 EN	Passed	January 1, 2026	7/7/2025 - Chapter 353, (2025 Laws): Effective date January 1, 2026. 6/20/2025 - Governor signed. 6/12/2025 - President signed.
Applies conflict of interest provisions to members of the household of public officials.			
HB 2932 EN	Passed	January 1, 2026	7/7/2025 - Chapter 354, (2025 Laws): Effective date January 1, 2026. 6/20/2025 - Governor signed. 6/12/2025 - President signed.
Provides an exception to the prohibition against a public official using official position or office for financial gain or avoidance of financial detriment.			
HB 2942 EN	Passed		6/11/2025 - Chapter 206, (2025 Laws): effective on the 91st day following adjournment sine die. 5/28/2025 - Governor signed. 5/21/2025 - President signed.
Requires the Oregon Health Authority and coordinated care organizations to reimburse pharmacies and pharmacists in the same manner as other health care providers for certain services related to HIV treatment.			
HB 2944 EN	Passed	January 1, 2026	6/19/2025 - Chapter 270, (2025 Laws): Effective date January 1, 2026. 6/5/2025 - Governor signed. 5/29/2025 - President signed.
Directs the Employment Relations Board to impose civil penalties against a public employer that has a history of failing to comply with certain requirements under the Public Employee Collective Bargaining Act.			
HB 3021 EN	Passed		5/20/2025 - Chapter 43, (2025 Laws): effective on the 91st day following adjournment sine die. 5/8/2025 - Governor signed. 5/1/2025 - President signed.
Makes changes to statutes related to unemployment insurance law and paid family and medical leave insurance law.			
HB 3043 EN	Passed		7/17/2025 - Governor signed. 6/24/2025 - President signed. 6/23/2025 - Speaker signed.
Defines "monitoring agreement" and "workplace monitor" for purposes of the impaired health professional program.			

End of Session Report

Report Date: July 23, 2025

Oregon Board of Pharmacy

N/A

Bill #	Status	Effective Date	Last Three Actions
HB 3044 EN	Passed		6/11/2025 - Chapter 124, (2025 Laws): effective on the 91st day following adjournment sine die. 5/22/2025 - Governor signed. 5/15/2025 - President signed.
Defines "Advanced Practice Registered Nurse," "diagnosing" and "medication aide.			
HB 3045 EN	Passed		6/26/2025 - Governor signed. 6/18/2025 - President signed. 6/18/2025 - Speaker signed.
Authorizes the State Board of Pharmacy to require a person under investigation by the board to undergo a mental, physical, chemical dependency or competency evaluation.			
HB 3134 EN	Passed		6/24/2025 - Governor signed. 6/16/2025 - President signed. 6/13/2025 - Speaker signed.
Requires additional reporting about prior authorization to the Department of Consumer and Business Services from insurers offering a health benefit plan and tells the department to make this data publicly available.			
HB 3187 EN	Passed		6/11/2025 - Chapter 125, (2025 Laws): effective on the 91st day following adjournment sine die. 5/22/2025 - Governor signed. 5/15/2025 - President signed.
Makes it an unlawful employment practice for an employer to require or request disclosure of certain information regarding age and attendance or graduation dates.			
HB 3224 EN	Passed	June 11, 2025	6/23/2025 - Chapter 302, (2025 Laws): Effective date June 11, 2025. 6/11/2025 - Governor signed. 6/4/2025 - President signed.
Requires the Department of Human Services to review the statutes of this state to identify all instances of required background checks under certain statutes and similarities and differences in the different background checks, and report on options to consolidate and reduce the number of different background checks for similar purposes or programs.			
HB 3226 EN	Passed		6/23/2025 - Chapter 303, (2025 Laws): effective on the 91st day following adjournment sine die. 6/11/2025 - Governor signed. 6/4/2025 - President signed.
Includes pharmacy services administrative organizations within the definition of pharmacies for the purpose of ensuring that pharmacy benefit managers are subject			

End of Session Report

Report Date: July 23, 2025

Oregon Board of Pharmacy

N/A

Bill #	Status	Effective Date	Last Three Actions
to laws regulating their activities even if their contracts are with pharmacy services administrative organizations.			
HB 3569 EN	Passed		6/26/2025 - Governor signed. 6/18/2025 - President signed. 6/18/2025 - Speaker signed.
Requires an agency that appoints a rules advisory committee with regard to rules implementing legislation to invite certain legislators to participate on the committee as nonvoting members.			
HB 3588 EN	Passed	May 27, 2025	6/11/2025 - Chapter 158, (2025 Laws): Effective date May 27, 2025. 5/27/2025 - Governor signed. 5/20/2025 - President signed.
Permits the Secretary of State to accept a commercial mail receiving agency as a business entity's principal office, records office address or principal address if the physical street address of the business entity's principal office, records office address or principal address is the same as the physical street address of the commercial mail receiving agency.			
HB 3646 EN	Passed		6/23/2025 - Chapter 304, (2025 Laws): effective on the 91st day following adjournment sine die. 6/11/2025 - Governor signed. 6/3/2025 - President signed.
Adds entities in which employees of the entity own at least 50 percent of the ownership interest in the entity directly or through an employee stock ownership plan to the list of sources to which a contracting agency may give preference in procuring goods or services for public contracts.			
HB 3824 EN	Pending		6/30/2025 - President signed. 6/30/2025 - Speaker signed. 6/27/2025 - House concurred in Senate amendments and repassed bill. Ayes, 39; Nays, 11--Boice, Boshart Davis, Chotzen, Evans, Grayber, Helfrich, Isadore, Marsh, Nelson, Sanchez, Watanabe; Excused, 9--Cate, Harbick, McIntire, Nguyen H, Reschke, Sosa, Wallan, Wright, Yunker; Excused for Business of the House, 1--Osborne.
Allows a physical therapist to perform dry needling.			
HB 3912 EN	Passed		6/26/2025 - Governor signed. 6/20/2025 - President signed. 6/19/2025 - Speaker signed.
Requires an individual who uses the title "doctor" in connection with a health care profession to designate on specified material, including social media and			

End of Session Report

Report Date: July 23, 2025

Oregon Board of Pharmacy

N/A

Bill #	Status	Effective Date	Last Three Actions
professional name badges, the health care profession in which the individual earned a doctoral degree.			
HB 3936 EN	Passed		6/24/2025 - Governor signed. 6/16/2025 - President signed. 6/16/2025 - Speaker signed.
Prohibits any hardware, software or service that uses artificial intelligence from being installed or downloaded onto or used or accessed by state information technology assets if the artificial intelligence is developed or owned by a covered vendor.			
HB 5028 EN	Passed	July 1, 2025	7/7/2025 - Chapter 365, (2025 Laws): Effective date July 1, 2025. 6/20/2025 - Governor signed. 6/12/2025 - President signed.
Limits biennial expenditures from fees, moneys or other revenues, including Miscellaneous Receipts, but excluding lottery funds and federal funds, collected or received by the State Board of Pharmacy.			
HCR 14 EN	Passed		1/23/2025 - Filed with Secretary of State. 1/22/2025 - President signed. 1/22/2025 - Speaker signed.
Adjourns the organizational session of the Senate and the House of Representatives of the Eighty-third Legislative Assembly. Provides that the Eighty-third Legislative Assembly shall convene in regular session on January 21, 2025.			
HCR 15 EN	Passed		1/23/2025 - Filed with Secretary of State. 1/22/2025 - President signed. 1/22/2025 - Speaker signed.
Establishes deadlines for the completion of legislative measures for the 2025 regular session of the Eighty-third Legislative Assembly.			
SB 139 EN	Passed	January 1, 2026	6/11/2025 - Effective date, January 1, 2026. 6/11/2025 - Chapter 257, 2025 Laws. 6/3/2025 - Governor signed.
Permits sharps and waste pharmaceuticals to be consolidated in a single container, subject to certain requirements.			
SB 236 EN	Passed		7/17/2025 - Governor signed. 6/27/2025 - Speaker signed. 6/26/2025 - President signed.

End of Session Report

Report Date: July 23, 2025

Oregon Board of Pharmacy

N/A

Bill #	Status	Effective Date	Last Three Actions
Separates the possession, delivery and manufacture of fentanyl from general controlled substance offense statutes into separate statutes.			
SB 277 EN	Passed	May 14, 2025	5/20/2025 - Effective date, May 14, 2025. 5/20/2025 - Chapter 87, 2025 Laws. 5/14/2025 - Governor signed.
Allows a law enforcement agency or public body to provide information, or enter into an agreement to provide information, as required to effect an international extradition and return of a person charged with or convicted of a crime in this state and for whom a warrant of arrest has been issued.			
SB 289 EN	Passed	January 1, 2026	6/6/2025 - Effective date, January 1, 2026. 6/6/2025 - Chapter 166, 2025 Laws. 5/27/2025 - Governor signed.
Modifies, from quarterly to annually, the timing of the Department of Consumer and Business Services' requirement to report certain information to the Prescription Drug Affordability Board.			
SB 295 EN	Passed	January 1, 2026	6/6/2025 - Effective date, January 1, 2026. 6/6/2025 - Chapter 167, 2025 Laws. 5/27/2025 - Governor signed.
Makes permanent a pharmacist's ability to test for and treat COVID-19.			
SB 476 EN	Pending		6/30/2025 - Speaker signed. 6/30/2025 - President signed. 6/27/2025 - Rules suspended. Senate concurred in House amendments and repassed bill. Ayes, 19; Nays, 10--Bonham, Girod, Hayden, Linthicum, McLane, Nash, Robinson, Smith DB, Starr, Weber; Excused, 1--Thatcher.
Requires professional licensing boards to provide culturally responsive training to specified staff members and publish guidance on pathways to professional authorization for internationally educated individuals.			
SB 598 EN	Passed		7/17/2025 - Governor signed. 6/27/2025 - Speaker signed. 6/27/2025 - President signed.
Requires certain health insurance providers to ensure that coverage for a nonopioid prescription drug is available as an alternative for an opioid prescription drug and to use the same utilization review requirements and cost-sharing provisions for opioid and nonopioid drugs when they are prescribed for the same treatment.			

End of Session Report

Report Date: July 23, 2025

Oregon Board of Pharmacy

N/A

Bill #	Status	Effective Date	Last Three Actions
SB 808 EN	Passed	January 1, 2026	6/6/2025 - Effective date, January 1, 2026. 6/6/2025 - Chapter 137, 2025 Laws. 5/22/2025 - Governor signed.
Provides hiring and promotion preferences in public employment to members and former members of the Oregon National Guard.			
SB 844 EN	Pending		6/30/2025 - Speaker signed. 6/30/2025 - President signed. 6/27/2025 - Rules suspended. Senate concurred in House amendments and repassed bill. Ayes, 20; Nays, 9--Bonham, Hayden, Linthicum, McLane, Nash, Robinson, Smith DB, Starr, Weber; Excused, 1--Thatcher.
Changes the date by which the Oregon Health Authority report on opioid and opiate overdoses is due to the Legislative Assembly.			
SB 907 EN	Passed		6/6/2025 - Effective on the 91st day following adjournment sine die. 6/6/2025 - Chapter 236, 2025 Laws. 5/28/2025 - Governor signed.
Requires an applicant for a license to manufacture psilocybin to submit to the Oregon Health Authority information regarding the ownership and location of the premises to be licensed or for which a license will be renewed.			
SB 968 EN	Pending		6/26/2025 - Speaker signed. 6/25/2025 - President signed. 6/24/2025 - Third reading. Carried by Grayber. Passed. Ayes, 34; Nays, 14--Boice, Boshart Davis, Drazan, Edwards, Elmer, Helfrich, Levy B, Lewis, McIntire, Osborne, Reschke, Scharf, Skarlatos, Wright; Excused, 6--Cate, Diehl, Harbick, Nguyen H, Wallan, Yunker; Excused for Business of the House, 6--Chotzen, Evans, Helm, Owens, Smith G, Walters.
Provides conditions and procedures under which a public employer may deduct amounts of erroneous overpayments from a public employee's wages.			
SB 1005 EN	Pending		6/23/2025 - Speaker signed. 6/23/2025 - President signed. 6/20/2025 - Senate concurred in House amendments and repassed bill. Ayes, 26; Nays, 2--McLane, Robinson; Excused, 2--Hayden, Linthicum.
Provides that when offering a service with age restrictions, a private entity is allowed to swipe a driver license or identification card to verify a person's age, regardless of how old the person looks.			

End of Session Report

Report Date: July 23, 2025

Oregon Board of Pharmacy

N/A

Bill #	Status	Effective Date	Last Three Actions
SB 1090 EN	Passed	June 26, 2025	7/2/2025 - Effective date, June 26, 2025. 7/2/2025 - Chapter 469, 2025 Laws. 6/26/2025 - Governor signed.
Directs the State Chief Information Officer to adopt a policy and procedure for state agencies to follow in requesting funding for information technology budgets and projects.			
SB 1108 EN	Passed	January 1, 2026	6/6/2025 - Effective date, January 1, 2026. 6/6/2025 - Chapter 243, 2025 Laws. 5/28/2025 - Governor signed.
Makes blood donation that is made in connection with a voluntary program that is approved or accredited by the American Association of Blood Banks or the American Red Cross a permissible use of sick time.			
SB 1173 EN	Pending		6/30/2025 - Speaker signed. 6/30/2025 - President signed. 6/27/2025 - Potential conflict(s) of interest declared by Pham H, Tran.
Provides that certain entities providing a product as part of health care services are not a manufacturer, distributor, seller or lessor of the product for purposes of a product liability civil action if the entity was not involved in the design or manufacture of the product.			
SCR 1 EN	Passed		7/1/2025 - Filed With Secretary of State. 6/30/2025 - Speaker signed. 6/30/2025 - President signed.
Adjourns sine die the 2025 regular session of the Eighty-third Legislative Assembly.			

Oregon
Tina Kotek, Governor

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August 01, 2025

DEA Diversion Control Division
Attn: Policy Section
8701 Morrissette Drive
Springfield, VA 22152

Dear DEA Diversion Control Division,

The Oregon Board of Pharmacy adopted rules in April of 2022 to allow Oregon-registered affiliated pharmacies to operate Pharmacy Prescription Lockers (PPLs) for secure storage and pick-up of completed prescriptions. The adopted rules do not permit the storage of Controlled Substance prescriptions in PPLs, as DEA regulations do not currently allow such storage.

Furthermore, during its regular legislative session this year, Oregon passed 2025 SB 236. This legislation permits a retail drug outlet to operate one or more PPLs within the state, which are not required to be at the same physical address as the retail drug outlet. Provided that a PPL operates pursuant to Section 19 of this bill, it is considered part of the retail drug outlet, and a separate license or registration from the State Board of Pharmacy is not required. Notably, SB 236 is silent on the storage of Controlled Substance prescriptions in PPLs.

The Oregon Board of Pharmacy respectfully requests that the DEA reconsider regulations and registration to allow PPLs to securely store prescriptions containing Controlled Substances to increase access for patients in underserved and rural areas of Oregon. We would be happy to work with the DEA to address any concerns related to security and diversion that may arise with the use of PPLs to store Controlled Substances.

We appreciate your consideration of this request and would be happy to provide additional information or answer any questions that may arise.

Sincerely,

Gary Runyon, Pharm.D., R.Ph.
Executive Director

Oregon Board of Pharmacy
800 NE Oregon St, Suite 150
Portland, OR 97232-2142
P: 971-673-0001 | F: 971-673-0002
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cc: Violeta Elizalde, DEA Portland District Office

Enrolled
Senate Bill 236

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 Joint Interim Committee on Addiction and Community Safety Response)

CHAPTER .....

AN ACT

Relating to controlled substances; creating new provisions; amending ORS 137.532, 414.766, 423.478, 475.005, 475.188, 475.245, 475.752, 475.898, 475.900, 475.907, 475.924, 475.934 and 689.005 and sections 2, 7, 8, 35, 36, 52, 54, 76 and 81, chapter 70, Oregon Laws 2024; repealing section 8, chapter 292, Oregon Laws 2025 (Enrolled Senate Bill 610); and declaring an emergency.

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

SEPARATE STATUTES FOR FENTANYL OFFENSES

SECTION 1. Sections 2, 3, 4, 5 and 6 of this 2025 Act are added to and made a part of ORS 475.806 to 475.894.

SECTION 2. (1) It is unlawful for any person knowingly or intentionally to possess fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy, unless the fentanyl or derivative 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 fentanyl is a drug enforcement misdemeanor punishable as described in section 35, chapter 70, Oregon Laws 2024.

(b) Notwithstanding paragraph (a) of this subsection, unlawful possession of fentanyl 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.

(c) Notwithstanding paragraphs (a) and (b) of this subsection, unlawful possession of fentanyl 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 3. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy.

(2) Unlawful delivery of fentanyl is a Class B felony.

(3) Notwithstanding subsection (2) of this section, unlawful delivery of fentanyl is a Class A felony if the delivery is to a person under 18 years of age.

SECTION 4. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy, within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful delivery of fentanyl within 1,000 feet of a school is a Class A felony.

SECTION 5. (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 fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy.

(2) Unlawful manufacture of fentanyl is a Class B felony.

SECTION 6. (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 fentanyl, or any substituted derivative of fentanyl as defined by the rules of the State Board of Pharmacy, within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture of fentanyl within 1,000 feet of a school is a Class A felony.

SECTION 7. ORS 475.752, as amended by sections 28 and 39, chapter 70, Oregon Laws 2024, 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 **and sections 3, 4 and 6 of this 2025 Act**.

(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 drug enforcement misdemeanor punishable as described in section 35, chapter 70, Oregon Laws 2024, 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 drug enforcement misdemeanor punishable as described in section 35, chapter 70, Oregon Laws 2024, except as otherwise provided in ORS 475.814, 475.824, 475.834 or 475.884 **or section 2 of this 2025 Act** or subsection (8) of this section.

(c) A controlled substance in Schedule III, is guilty of a drug enforcement misdemeanor punishable as described in section 35, chapter 70, Oregon Laws 2024.

(d) A controlled substance in Schedule IV, is guilty of a drug enforcement misdemeanor punishable as described in section 35, chapter 70, Oregon Laws 2024.

(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)*] **(a)** The possession is a commercial drug offense under ORS 475.900 (1)(b); or

[*(B)*] **(b)** The person possesses a substantial quantity under ORS 475.900 (3)(b).

SECTION 8. ORS 475.900, as amended by section 25, chapter 70, Oregon Laws 2024, 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 **or section 4 or 6 of this 2025 Act**.

(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.

(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.

(5) Any felony violation of ORS 475.752 or 475.806 to 475.894 not contained in 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.

(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 subsection (1) of this section. The state has the burden of proving each factor beyond a reasonable doubt.

(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.

SECTION 9. ORS 475.907 is amended to read:

475.907. (1) When a person is convicted of the unlawful delivery of cocaine, methamphetamine, heroin**, fentanyl** or ecstasy to a person under 18 years of age, the court shall sentence the person to a term of incarceration ranging from 34 months to 72 months, depending on the person's criminal history.

(2) The sentence described in subsection (1) of this section does not apply to a person who is less than three years older than the person under 18 years of age to whom the controlled substance was delivered, unless the person has a previous conviction for delivery of cocaine, methamphetamine, heroin**, fentanyl** or ecstasy to a person under 18 years of age.

SECTION 10. ORS 475.924 is amended to read:

475.924. As used in ORS [*164.061,*] 475.907, 475.924 and 475.925:

(1) "Controlled substance" means:

(a) Cocaine;

(b) Methamphetamine;

(c) Heroin; [*or*]

(d) Fentanyl; or

[*(d)*] **(e)** Ecstasy.

(2) "Ecstasy" means:

(a) 3,4-methylenedioxymethamphetamine;

(b) 3,4-methylenedioxyamphetamine; or

(c) 3,4-methylenedioxy-N-ethylamphetamine.

(3) "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.

SECTION 11. ORS 475.934 is amended to read:

475.934. (1) When a court sentences a person convicted of a crime listed in subsection (2) of this section, the court may not impose a sentence of optional probation or grant a downward dispositional departure or a downward durational departure under the rules of the Oregon Criminal Justice Commission if the person has a previous conviction for any of the crimes listed in subsection (2) of this section.

(2) The crimes to which subsection (1) of this section applies are:

(a) Manufacture or delivery of a controlled substance under ORS 475.752 (1);

(b) Creation or delivery of a counterfeit substance under ORS 475.752 (2);

(c) Manufacture or delivery of heroin under ORS 475.846, 475.848, 475.850 or 475.852;

(d) Manufacture or delivery of fentanyl under section 3, 4, 5 or 6 of this 2025 Act;

[*(d)*] **(e)** Manufacture or delivery of 3,4-methylenedioxymethamphetamine under ORS 475.866, 475.868, 475.870 or 475.872;

[*(e)*] **(f)** Manufacture or delivery of cocaine under ORS 475.876, 475.878, 475.880 or 475.882;

[*(f)*] **(g)** Manufacture or delivery of methamphetamine under ORS 475.886, 475.888, 475.890 or 475.892;

[*(g)*] **(h)** Manufacture or delivery of a controlled substance within 1,000 feet of a school under ORS 475.904;

[*(h)*] **(i)** Delivery of a controlled substance to a person under 18 years of age under ORS 475.906; and

[*(i)*] **(j)** Possession of a precursor substance with intent to manufacture a controlled substance under ORS 475.967.

(3)(a) For a crime committed on or after November 1, 1989, a conviction is considered to have occurred upon the pronouncement in open court of sentence. However, when sentences are imposed for two or more convictions arising out of the same conduct or criminal episode, none of the convictions is considered to have occurred prior to any of the other convictions arising out of the same conduct or criminal episode.

(b) For a crime committed prior to November 1, 1989, a conviction is considered to have occurred upon the pronouncement in open court of a sentence or upon the pronouncement in open court of the suspended imposition of a sentence.

(4) For purposes of this section, previous convictions must be proven pursuant to ORS 137.079.

(5) As used in this section, "previous conviction" includes convictions entered in any other state or federal court for comparable offenses.

SECTION 12. ORS 475.898 is amended to read:

475.898. (1) A person who contacts emergency medical services or a law enforcement agency to obtain medical assistance for another person who needs medical assistance due to a drug-related overdose is immune from arrest**,** [*or*] prosecution **or the imposition of a civil penalty** for an offense listed in subsection (3) of this section if the evidence of the offense was obtained because the person contacted emergency medical services or a law enforcement agency.

(2) A person who is in need of medical assistance due to a drug-related overdose is immune from arrest**,** [*or*] prosecution **or the imposition of a civil penalty** for an offense listed in subsection (3) of this section if the evidence of the offense was obtained because any person contacted emergency medical services or a law enforcement agency to obtain medical assistance for the person.

(3) The immunity conferred under subsections (1) and (2) of this section applies to arrest**,** [*and*] prosecution **and the imposition of a civil penalty** for:

(a) Frequenting a place where controlled substances are used as described in ORS 167.222;

(b) Possession of a controlled substance as described in ORS 475.752;

(c) Unlawful possession of hydrocodone as described in ORS 475.814;

(d) Unlawful possession of methadone as described in ORS 475.824;

(e) Unlawful possession of oxycodone as described in ORS 475.834;

(f) Unlawful possession of heroin as described in ORS 475.854;

(g) Unlawful possession of fentanyl as described in section 2 of this 2025 Act;

[*(g)*] **(h)** Unlawful possession of 3,4-methylenedioxymethamphetamine as described in ORS 475.874;

[*(h)*] **(i)** Unlawful possession of cocaine as described in ORS 475.884;

[*(i)*] **(j)** Unlawful possession of methamphetamine as described in ORS 475.894;

[*(j)*] **(k)** Unlawfully possessing a prescription drug as described in ORS 689.527 (6); and

[*(k)*] **(L)** Unlawful possession of drug paraphernalia with intent to sell or deliver as described in ORS 475.525.

(4)(a) A person may not be arrested for violating, or found to be in violation of, the conditions of the person's pretrial release, probation, post-prison supervision or parole if the violation involves:

(A) The possession or use of a controlled substance or frequenting a place where controlled substances are used; and

(B) The evidence of the violation was obtained because the person contacted emergency medical services or a law enforcement agency to obtain medical assistance for another person who needed medical assistance due to a drug-related overdose.

(b) A person may not be arrested for violating, or found to be in violation of, the conditions of the person's pretrial release, probation, post-prison supervision or parole if the violation involves:

(A) The possession or use of a controlled substance or frequenting a place where controlled substances are used; and

(B) The evidence of the violation was obtained because the person was in need of medical assistance due to a drug-related overdose and any person contacted emergency medical services or a law enforcement agency to obtain medical assistance for the person.

(5)(a) A person may not be arrested on an outstanding warrant for any of the offenses listed in subsection (3) of this section, or on an outstanding warrant for a violation, other than commission of a new crime, of the conditions of the person's probation, post-prison supervision or parole for conduct that would constitute an offense listed in subsection (3) of this section, if the location of the person was obtained because the person contacted emergency medical services or a law enforcement agency to obtain medical assistance for another person who needed medical assistance due to a drug-related overdose.

(b) A person may not be arrested on an outstanding warrant for any of the offenses listed in subsection (3) of this section, or on an outstanding warrant for a violation, other than commission of a new crime, of the conditions of the person's probation, post-prison supervision or parole for conduct that would constitute an offense listed in subsection (3) of this section, if the location of the person was obtained because the person was in need of medical assistance due to a drug-related overdose and any person contacted emergency medical services or a law enforcement agency to obtain medical assistance for the person.

(c) This subsection does not apply to outstanding federal warrants or outstanding warrants issued from other states.

(6) The immunity from arrest and prosecution described in this section is not grounds for the suppression of evidence relating to a criminal offense other than the offenses listed in subsection (3) of this section.

(7) As used in this section:

(a) "Controlled substance" has the meaning given that term in ORS 475.005.

(b) "Drug-related overdose" means an acute condition, including mania, hysteria, extreme physical illness, coma or death, resulting from the consumption or use of a controlled substance, or another substance with which a controlled substance was combined, that a person would reasonably believe to be a condition that requires medical attention.

SECTION 13. ORS 475.245, as amended by section 53, chapter 70, Oregon Laws 2024, 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**:**

(a) Impose sanctions of up to a total of 30 days of imprisonment[*,*]**;** or

(b) 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) If the court finds that the person has fulfilled the terms and conditions of the probation agreement, discharge the person and dismiss the proceedings against the person as described in subsection (3) of this section;

[*(a)*] **(b)** 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.*]

(c) Resume the criminal proceedings in accordance with the waiver of rights in the probation agreement. If the court proceeds under this paragraph, the person may not contest the sufficiency of the evidence establishing the person's guilt of the offenses in the accusatory instrument.

(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 **or section 2 of this 2025 Act**;

(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.

SECTION 14. ORS 423.478, as amended by section 2, chapter 58, Oregon Laws 2024, and section 47, chapter 70, Oregon Laws 2024, 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, chapter 70, Oregon Laws 2024, 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);

(F) Unlawful possession of fentanyl under [*ORS 475.752 (8)(a)*] **section 2 (2)(a) of this 2025 Act**;

(G) Unlawful possession of fentanyl under section 2 (2)(b) of this 2025 Act;

[*(G)*] **(H)** Unlawful possession of hydrocodone under ORS 475.814 (2)(a);

[*(H)*] **(I)** Unlawful possession of hydrocodone under ORS 475.814 (2)(b);

[*(I)*] **(J)** Unlawful possession of methadone under ORS 475.824 (2)(a);

[*(J)*] **(K)** Unlawful possession of methadone under ORS 475.824 (2)(b);
[*(K)*] **(L)** Unlawful possession of oxycodone under ORS 475.834 (2)(a);
[*(L)*] **(M)** Unlawful possession of oxycodone under ORS 475.834 (2)(b);
[*(M)*] **(N)** Unlawful possession of heroin under ORS 475.854 (2)(a);
[*(N)*] **(O)** Unlawful possession of heroin under ORS 475.854 (2)(b);
[*(O)*] **(P)** Unlawful possession of 3,4-methylenedioxymethamphetamine under ORS 475.874 (2)(a);
[*(P)*] **(Q)** Unlawful possession of 3,4-methylenedioxymethamphetamine under ORS 475.874 (2)(b);
[*(Q)*] **(R)** Unlawful possession of cocaine under ORS 475.884 (2)(a);
[*(R)*] **(S)** Unlawful possession of cocaine under ORS 475.884 (2)(b);
[*(S)*] **(T)** Unlawful possession of methamphetamine under ORS 475.894 (2)(a);
[*(T)*] **(U)** Unlawful possession of methamphetamine under ORS 475.894 (2)(b); or
[*(U)*] **(V)** Interfering with public transportation under ORS 166.116 (1)(e).

(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 15. Section 35, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 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) **or section 2 (2)(a) of this 2025 Act** 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.

SECTION 16. The amendments to ORS 475.907 by section 9 of this 2025 Act apply to conduct occurring on or after the effective date of this 2025 Act.

OPIOID USE DISORDER MEDICATIONS GRANT PROGRAM CHANGES

SECTION 17. Section 81, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 81. As used in sections 81 to 86 [*of this 2024 Act*]**, chapter 70, Oregon Laws 2024**:

(1) "Commission" means the Oregon Criminal Justice Commission.

(2) "Local correctional facility" has the meaning given that term in ORS 169.005 **and also means any facility operated by a county supervisory authority, as defined in ORS 144.087, including facilities for providing corrections supervision services or custodial services**.

(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.

OPIOID USE DISORDER MEDICATION PRESCRIPTION CHANGES

SECTION 18. Section 7, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 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)*] **(1)** A pharmacist may prescribe**,** [*and*] dispense **and administer** 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 this section.*]**:**

(a) A statewide drug therapy management protocol developed, in consultation with a physician with a background in addiction medicine, by the Public Health and Pharmacy Formulary Advisory Committee convened under ORS 689.649 and adopted by State Board of Pharmacy rule pursuant to ORS 689.645; or

(b) A collaborative drug therapy management agreement.

[*(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 Formulary Advisory Committee described in ORS 689.649.*]

(2) A pharmacist may register with the Drug Enforcement Administration of the United States Department of Justice as a mid-level practitioner for the purpose of prescribing, dispensing and administering a controlled substance in Schedule II, III, IV or V that is a medication for the treatment of opioid use disorder.

(3) The board may adopt rules to carry out this section.

SECTION 19. Section 8, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 8. (1) As used in this section, "**pharmacy** 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.*]

(2) A retail drug outlet may operate one or more pharmacy prescription lockers located within this state that need not be at the same physical address as the retail drug outlet. A pharmacy prescription locker operated pursuant to this section is considered part of the retail drug outlet, and a separate license or registration from the State Board of Pharmacy is not required.

[*(4)*] **(3)** The board may adopt rules to carry out this section.

SECTION 20. Section 2, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 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 2024 Act*].

(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 21. ORS 414.766, as amended by section 4, chapter 70, Oregon Laws 2024, 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;

(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 de-*

scribed in] **medications and refills of medications prescribed pursuant to** section 7, chapter 70, Oregon Laws 2024.

(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 21a. ORS 475.005, as amended by section 24, chapter 70, Oregon Laws 2024, and section 98, chapter 73, Oregon Laws 2024, 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, 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)**(a)** "Practitioner" means **a** physician, dentist, veterinarian, scientific investigator, licensed nurse practitioner, physician associate 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*].

(b) "Practitioner" does not include a pharmacist or pharmacy for purposes of the prescription, dispensation or administration of a controlled substance that is not:

(A) Listed in Schedule II, III, IV or V; and

(B) A medication for the treatment of opioid use disorder.

(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" mean a straight line measurement in a radius extending for 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.

SECTION 21b. ORS 475.188 is amended to read:

475.188. (1)**(a)** Prescription drug orders may be transmitted by electronic means from a practitioner authorized to prescribe drugs directly to the dispensing pharmacist.

(b) A prescription drug order for medication for the treatment of opioid use disorder that is issued by a practitioner who is a pharmacist may be electronically transmitted to a dispensing pharmacist in accordance with the requirements of this section if the prescribing pharmacist is not the dispensing pharmacist.

(2) All prescription drug orders communicated by way of electronic transmission [*shall*] **must**:

(a) Be transmitted only by an authorized practitioner;

(b) Be transmitted directly to a pharmacist in a pharmacy of the patient's choice with no intervening person having access to the prescription drug order;

(c) Specify the prescribing practitioner's telephone number for verbal confirmation, the time and date of transmission, the identity of the pharmacy intended to receive the transmission and all other information required for a prescription by federal or state law; and

(d) Be traceable to the prescribing practitioner by an electronic signature or other secure method of validation.

(3) An electronic transmission of a prescription drug order [*shall*] **must** be stored by electronic means or reduced promptly to writing, filed by the pharmacy and retained in conformity with the requirements of ORS 475.165.

(4) The dispensing pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of an electronically transmitted prescription drug order.

(5) All equipment for transmission, storage or receipt of electronically transmitted prescription drug orders [*shall*] **must** be maintained to protect against unauthorized access.

(6) A pharmacist, pharmacy or pharmacy department [*shall*] **may** not enter into an agreement with a practitioner or health care facility concerning the provision of any electronic transmission equipment or apparatus that would adversely affect a patient's freedom to select the pharmacy or pharmacy department of the patient's choice.

(7) A pharmacist, pharmacy or pharmacy department [*shall*] **may** not provide any electronic equipment or apparatus to a practitioner or health care facility for the purpose of providing an incentive to the practitioner or health care facility to refer patients to a particular pharmacy or pharmacy department.

(8) There [*shall be no*] **may not be an** additional charge to the patient because the prescription drug order was electronically transmitted.

(9) Nothing in this section shall be construed as authorizing the electronic transmission of a prescription drug order when a written prescription is required under ORS 127.815, 137.473, 169.750 or 453.025.

SECTION 22. ORS 689.005, as amended by section 5, chapter 17, Oregon Laws 2024, and section 9, chapter 70, Oregon Laws 2024, 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;

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

(p) The prescribing**,** [*and*] dispensing **and administering** of [*early refills of*] medication for the treatment of opioid use disorder pursuant to section 7, chapter 70, Oregon Laws 2024**, or rules adopted under section 7, chapter 70, Oregon Laws 2024**; and

(q) 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, chapter 17, Oregon Laws 2024, and rules adopted by the board pursuant to section 4, chapter 17, Oregon Laws 2024.

(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 23. ORS 689.005, as amended by sections 5 and 6, chapter 17, Oregon Laws 2024, and section 9, chapter 70, Oregon Laws 2024, 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;

(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 **and administering** of [*early refills of*] medication for the treatment of opioid use disorder pursuant to section 7, chapter 70, Oregon Laws 2024**, or rules adopted under section 7, chapter 70, Oregon Laws 2024**.

(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).

OTHER HOUSE BILL 4002 (2024) MODIFICATIONS

SECTION 24. Section 36, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 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*] **chapter 70, Oregon Laws 2024**.

(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 consti-

tuting a drug enforcement misdemeanor under section 35**,** [*of this 2024 Act*] **chapter 70, Oregon Laws 2024**.

(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*] **chapter 70, Oregon Laws 2024**, including but not limited to [*law enforcement agencies, district attorneys and courts*] **a law enforcement agency, the district attorney and, if requested by the court, the circuit court**.

(4) As used in this section, "deflection program" has the meaning given that term in section 37**,** [*of this 2024 Act*] **chapter 70, Oregon Laws 2024**.

SECTION 25. Section 52, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 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) **or section 2 (2)(a) of this 2025 Act** constituting a drug enforcement misdemeanor as described in section 35 [*of this 2024 Act*]**, chapter 70, Oregon Laws 2024**, 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**:**

(a) Impose a sanction**;** or [*may*]

(b) 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) If the court finds that the person has fulfilled the terms and conditions of the probation agreement, discharge the person and dismiss the charge that is the subject of the agreement as described in subsection (4) of this section;

[*(a)*] **(b)** 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.*]

(c) Resume the criminal proceedings in accordance with the waiver of rights in the probation agreement. If the court proceeds under this paragraph, the person may not contest the sufficiency of the evidence establishing the person's guilt of the offenses in the accusatory instrument.

SECTION 26. Section 54, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 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*] **chapter 70, Oregon Laws 2024**, 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 related criminal history records**, 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*] **of an offense** for unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in

section 35**,** [*of this 2024 Act*] **chapter 70, Oregon Laws 2024**, and if no further prosecutorial action on the citation **for the offense** has occurred, within 60 days after the conclusion of the two-year time period **from the date of the offense**, any law enforcement agency or district attorney that possesses records related to the citation, **including related criminal history records,** 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*] **chapter 70, Oregon Laws 2024**, 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 court may enter an order sealing all records related to any other charges that were dismissed or removed from the charging instrument, other than records related to a diversion-related arrest or citation, if no other convictions exist in the case.** 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 **and subsection (4) of this section**, 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*] **chapter 70, Oregon Laws 2024**, 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 court may enter an order sealing all records related to any other charges that were dismissed or removed from the charging instrument, other than records related to a diversion-related arrest or citation, if no other convictions exist in the case.** 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.

(c) Notwithstanding ORS 137.225, when a person is acquitted of unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35, chapter 70, Oregon Laws 2024, the court shall, within 90 days after the acquittal, enter an order sealing all records related to the arrest or citation and the criminal proceedings. The court may enter an order sealing all records related to any other charges that were dismissed or removed from the charging instrument, other than records related to a diversion-related arrest or citation, if no other convictions exist in the case. 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, **and except as provided in paragraph (b) of this subsection,** 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*] **chapter 70, Oregon Laws 2024**, the court shall, within 60 days after the [*three year*] **three-year** period has concluded, enter an order sealing all records related to the arrest or citation, charges and conviction. **The court may enter an order sealing all records related to any other charges that were dismissed or removed from the charging instrument, other than records related to a diversion-related arrest or citation, if no other convictions exist in the case.** 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) If the court issues a warrant on a case with a conviction for unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35, chapter 70, Oregon Laws 2024, the time period between the issuance of the warrant and the date on which the person reappears in court on the case and the warrant is no longer active does not count towards the three-year time period described in paragraph (a) of this subsection.

[*(b)*] **(c)** Notwithstanding ORS 137.225, after three years have passed since the dismissal of [*a*] **an** unlawful possession of a controlled substance **offense** constituting a drug enforcement

misdemeanor as described in section 35**,** [*of this 2024 Act*] **chapter 70, Oregon Laws 2024**, 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*] **three-year** period has concluded, enter an order sealing all records related to the arrest or citation and any criminal proceedings. **The court may enter an order sealing all records related to any other charges that were dismissed or removed from the charging instrument, other than records related to a diversion-related arrest or citation, if no other convictions exist in the case.** 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) If a case involves records related to two or more unlawful possession of a controlled substance offenses constituting a drug enforcement misdemeanor as described in section 35, chapter 70, Oregon Laws 2024, and the records related to each offense are eligible for sealing under this section at different times, the court may not enter an order sealing records related to any drug enforcement misdemeanor in the case until all records related to drug enforcement misdemeanors in the case are eligible to be sealed.

(6) The court may not enter an order under this section sealing records related to unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35, chapter 70, Oregon Laws 2024, while a case has an active warrant.

(7)(a) Notwithstanding subsections (1) to (5) of this section and any other statute authorizing a court to enter an order sealing records related to unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35, chapter 70, Oregon Laws 2024, if a case includes records other than those related to unlawful possession of a controlled substance constituting a drug enforcement misdemeanor, the court may not enter an order sealing records related to unlawful possession of a controlled substance constituting a drug enforcement misdemeanor in the case until the court enters an order setting aside or expunging all other records in the case.

(b) When a court enters an order setting aside or expunging all records in a case other than records pertaining to unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35, chapter 70, Oregon Laws 2024, under any statute authorizing such an order:

(A) If all records related to unlawful possession of a controlled substance constituting a drug enforcement misdemeanor in the case are eligible for sealing under this section, the court may enter an order sealing all records in the case under one order.

(B) Notwithstanding subsections (1) to (5) of this section, if the records related to unlawful possession of a controlled substance constituting a drug enforcement misdemeanor are not eligible for sealing under this section, the court may enter an order sealing the records if the court finds that the sealing would be in the best interests of the person who is the subject of the records and the public.

[*(5)(a)*] **(8)(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*] **is charged with** unlawful possession of a controlled substance constituting a drug enforcement misdemeanor as described in section 35**,** [*of this 2024 Act*] **chapter 70, Oregon Laws 2024**, 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.

(9) As used in this section, "diversion-related arrest or citation" means an arrest or citation for driving while under the influence of intoxicants for a charge that was dismissed as the result of the person's successful completion of a diversion agreement described in ORS 813.200.

SECTION 27. Section 76, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 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*] **chapter 70, Oregon Laws 2024**;

(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*] **by a formula established by the commission**, 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 27a. If Senate Bill 610 becomes law, section 8, chapter 292, Oregon Laws 2025 (Enrolled Senate Bill 610) (amending section 76, chapter 70, Oregon Laws 2024), is repealed.

PRE-PLEA SPECIALTY COURT PROBATION AGREEMENTS

SECTION 28. ORS 137.532 is amended to read:

137.532. (1)(a) Whenever a person is charged with a misdemeanor or a Class C felony, other than driving while under the influence of intoxicants, and has been formally accepted into a specialty court, 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 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) If the court finds that the person has fulfilled the terms and conditions of the probation agreement, discharge the person and dismiss the proceedings against the person as described in subsection (3) of this section;

[*(a)*] **(b)** 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.*]

(c) Resume the criminal proceedings in accordance with the waiver of rights in the probation agreement. If the court proceeds under this paragraph, the person may not contest the sufficiency of the evidence establishing the person's guilt of the offenses in the accusatory instrument.

(5) Nothing in this section is intended to restrict a person's participation in a specialty court or conditional discharge under ORS 475.245.

(6) As used in this section, "specialty court" has the meaning given that term in ORS 137.680.

CAPTIONS

SECTION 29. The unit captions used in this 2025 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 2025 Act.

EMERGENCY CLAUSE

SECTION 30. **This 2025 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2025 Act takes effect on its passage.**

Passed by Senate June 10, 2025

Repassed by Senate June 25, 2025

.....
Obadiah Rutledge, Secretary of Senate

.....
Rob Wagner, President of Senate

Passed by House June 24, 2025

.....
Julie Fahey, Speaker of House

Received by Governor:

.....M.,....., 2025

Approved:

.....M.,....., 2025

.....
Tina Kotek, Governor

Filed in Office of Secretary of State:

.....M.,....., 2025

.....
Tobias Read, Secretary of State

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): Creates new Division 183 for Drug Compounding; Repeals Division 45

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): 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. Proposes to repeal Division 45.

Documents Relied Upon per ORS 183.335(2)(b)(D): *Please note staff will need to amend most of the gray box and will verify correct rule version and standards adopted by reference revisions when applicable.

USP Chapters: USP Compounding Compendium

Designated Person Responsibilities: ASHP List

2024 HB 4010

- 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

Compounding Workgroup Meeting Minutes
(Workgroup consisted of 2 RPH-IP, 2 RPH-RP, 1 CPT-IP, 1 CPT-RP all who were Compounders, 1 public member, & Board members Beaman and Patel)
2.21.2023 Workgroup Mtg Minutes

4.18.2023 Workgroup Mtg Minutes

5.16.2023 Workgroup Mtg Minutes

6.20.2023 Workgroup Mtg Minutes

7.18.2023 Workgroup Mtg Minutes

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:

- **Timeline of Events**
  - The Compounding workgroup held meetings on 2/8/2023, 4/18/2023, 5/16/2023, 6/20/2023, 7/18/2023 – all recordings and meeting summaries are on the board website.

  - **April 2023 bd mtg:** The board adopted Temporary rule OAR 855-045-0205 (mailing #B) "As an alternative to the requirements in OAR 855-045-0200(3)(a) and (3)(b) registrants may comply 45 with any or all standards contained in:
    (a) USP <795> Pharmaceutical Compounding—Non-Sterile Preparations (11/1/2022).

(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (11/1/2022)."

- **June 9, 2023 bd mtg:** The board was unable to review the proposed Compounding rules due to time limits, staff asked the board to consider sending the proposed Compounding rules to the July rulemaking hearing (mailing #C5, page 182) to seek public comment to meet the USP November 2023 deadline. Staff wanted the opportunity to send it out for comment, use the feedback from public comments to amend the draft rules for the board to review during the August board meeting.
  - From the Bd Mtg Minutes "Board staff requested the board consider sending this rule package through rulemaking for the sole purpose of public comment. USP <795> and <797> become effective 11/1/2023 and staff would like to complete the rulemaking process by this date. Board staff indicated that the board would have a full review of this rule package at the August 2023 meeting where the board could send the rule package to a special September rulemaking hearing and motion to adopt at the October 2023 meeting, effective 11/1/2023."
    - Motion carried with Murray, Doyle, Beaman, Chinn, DeBarmore, Hemmings, and Vipperman in favor, Joyce abstained, and Patel opposed

- **July 26, 2023:** Rulemaking hearing was held, 1 person provided oral testimony during the hearing, 20 people/organizations submitted written comments which were provided to the board in their entirety prior to the August 2023 board meeting

- **August 10, 2023 bd mtg:** The board's 1st review of rules (mailing #D1)
  - **The board was provided a mailing with the written comments provided inserted into the margin of the rules for ease of navigation**
  - The board reviewed proposed Compounding rules OAR 855-006-0005 Definitions, 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 (mailing #D1, page 258 on agenda)
  - Board reviewed **Compounding Presentation**
  - The board permanently adopted the Temporary rule from April 2023 for OAR 855-045-0205 related to USP <795> NSP (v. 11/1/20202) and USP <797> SP (v. 11/1/2022) (mailing #D7)

- **September 27, 2023 Rulemaking Hearing**
  - USP <795> and USP <797> OAR 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 (11/1/2022).
    - (2) USP <797> Pharmaceutical Compounding-Sterile Preparations (11/1/2022).

- **December 2023 bd mtg:** The board reviewed OAR 855-183-0050 through the beginning of OAR 855-183-0200

- **February 2024 bd mtg:** The board reviewed a portion of OAR 855-183-0200

- **April 2024 bd mtg:** The board reviewed OAR 855-183-0200 through OAR 855-183-0700

- **May 2, 2025**: New USP version effective date

- **June 2024 bd mtg:** The board reviewed OAR 855-183-0710 and OAR 855-183-0730
  - The board reviewed Compounding Quality Act (specifically slide #10)

- **June 6, 2024:** 2024 HB 4010 effective

Division 183
DRUG COMPOUNDING

855-183-0001
Applicability

(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for 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.

[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

855-183-0005
Definitions

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

(2)"Compounding" means the process of combining, admixing, diluting, pooling, reconstituting, or otherwise altering a drug product or bulk drug substance to create a new preparation.

(a) For non-sterile preparations, compounding does not include reconstituting according to the manufacturers labeling.

(b) For sterile preparations, compounding includes repackaging.

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

855-183-0010
Designation

Each Drug Outlet must maintain an accurate status of compounding services, indicating whether they perform sterile compounding, non-sterile compounding or both, in the board's online registration system.

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

855-183-0050
Personnel

(1) All personnel who prepare and supervise the preparation of a compound must complete appropriate training and demonstrate knowledge and competency as required by the USP standards applicable 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 maintain required skills necessary to perform their assigned tasks and to comply 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) An annual self-inspection is completed using the Compounding Self-Inspection Form provided by the board, by July 1 and within 15 days of appointing a new PIC. The completed self-inspection forms must be signed and dated by the PIC and retained for three years from the date of completion

[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

855-183-0200
Requirements: General

Effective XX/XX/20XX:

(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);

(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);

(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);

(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); and

(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.

(3) 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.

(4) Beginning Month, Day, Year 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.

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

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

(1) For the purposes of this rule, an "automated compounding device" is a device that compounds, measures, and/or packages a specified quantity of individual components in a predetermined sequence for a sterile preparation.

(2) A Drug Outlet Pharmacy, hospital with a drug room, 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

855-183-0400
Labeling: Compounded 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 must prominently and legibly contain the following, at a minimum:

(1) The strength of each active ingredient;

(2) The route of administration;

(3) Indication that the preparation is compounded.

(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

855-183-0410
Labeling: Compounded 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 must prominently and legibly contain the following, at a minimum:

(1) The strength of each active ingredient, to include the identity of the base solution for a sterile parenteral preparation;

(2) The route of administration;

(3) Rate of infusion or titration parameters, for a sterile parenteral preparation;

(4) Indication that the preparation is compounded.

(5) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.

(6) Compounding facility name and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

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

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

Effective XX/XX/20XX:

Each Drug Outlet Pharmacy, DPDO, CF and CHC must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR 855-183-0200 for all aspects of the compounding operation according to the type of compounding performed (e.g., CNSP, CSP Type 1, 2 or 3) and must include written procedures for:

(1) Personnel qualifications, to include training and ongoing competency assessment;

(2) Hand hygiene;

(3) Garbing;

(4) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;

(5) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;

(6) Components, to include selection, receipt, handling, storage and disposal;

(7) Creating master formulation records, with documented approval by a Pharmacist for a Drug Outlet Pharmacy or prescriber with prescribing and dispensing privileges for a DPDO, CF or CHC;

(8) Creating compounding records;

(9) Establishing BUDs;

(10) Labeling;

(11) Continuous quality assurance program and quality controls, to include:

(a) Release testing, end-product evaluation, and quantitative/qualitative testing;

(b) Complaint handling process;

(c) Adverse event and error reporting process; and

(d) Recall procedure; and

(12) Completed compounded preparations, to include handling, packaging, storage and transport.

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

855-183-0550
Records: General Requirements

Effective XX/XX/20XX:

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, competency assessment and qualification records, and corrective actions for any failures. The outlet must maintain a training record for each person, including temporary personnel, who compound preparations or supervise the preparation of compounds.

(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;

(f) Master formulation records for all:

(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.

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

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:

(1) A pharmacist or prescriber with prescribing and dispensing privileges, must perform and document verification that each of the following are correct:

(a) Formula;

(b) Calculations to determine and verify quantities and/or concentrations of components and strength or activity of each API;

(c) Quantities;

(d) Compounding technique; and

(e) Accurate preparation of the CNSP.

(2) Final yield;

(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;

(4) Records of dispensing or transfer of all compounded preparations; 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

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

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:

(1) Pharmacist or prescriber with prescribing and dispensing privileges performance and must perform and documented verification that each of the following are correct:

(a) Formula;

(b) Calculations to determine and verify quantities and/or concentrations of components and strength or activity of each API;

(c) Quantities;

(d) Compounding technique; and

(e) Accurate preparation of the CSP.

(2) Final yield;

(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;

(4) Records of dispensing or transfer of all compounded preparations; 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

855-183-0600
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) Animal 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.

(4) 2024 HB 4010, ORS 689 "The addition of flavoring to a drug intended for dispensation may not be considered compounding if the flavoring:

(a) Is inert, nonallergenic and has no effect other than imparting a flavor to the drug or modifying the flavor of the drug; and

(b) Does not constitute more than five percent of the total volume of the drug"

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205, 2024 HB 4010
Statutes/Other Implemented: ORS 689.155, 2024 HB 4010

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 animals as defined by the FDA 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.

(3) The compounded preparations must not be distributed by an entity other than the Drug Outlet Pharmacy that compounded such veterinary drug preparations.

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

Division 6
DEFINITIONS

855-006-0005 *current version as of 7/2025
Definitions

~~(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.~~

(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.

(a) For non-sterile preparations, compounding does not include reconstituting according to the manufacturers labeling.

(b) For sterile preparations, compounding includes repackaging.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.005, ORS 689.151, ORS 689.155 & ORS 689.703

Division 41
OPERATION OF PHARMACIES

855-041-1018 *current version on our books as of 7/2025
Outlet: General Requirements

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 *current version on our books as of 7/2025
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 (v. 01/01/2024), 16 CFR 1701 (v. 01/01/2024) and 16 CFR 1702 (v. 01/01/2024).

(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) **Unless an exemption applies,** e~~E~~ach 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~~.

(10) The DPDO must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

[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 *Current version on our books as of 7/2025

Correctional Facility **(CF)** - Drug Delivery and Control

(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 within 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 nurses from ~~manufacturer's or Pharmacist's~~ **a** bulk drug containers **as defined in OAR 855-043-0610** must not be administered by **an** unlicensed persons, except under certain emergency and nonroutine situations as described in the facility's policies and procedures.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & 2023 SB 450

855-043-0740 *current version on our books as of 7/2025
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 (v. 01/01/2024), 16 CFR 1701 (v. 01/01/2024) and 16 CFR 1702 (v. 01/01/2024).

(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.

(12~~3~~) **Unless an exemption applies, e**~~E~~ach 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

*If the Board permanently adopts Division 183, the following rules in Div 045 would be repealed

~~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 (01/01/2024); 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 (09/01/2023), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (10/01/2023), 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~~

~~855-045-0205~~
~~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 (11/1/2023).~~

~~(2) USP <797> Pharmaceutical Compounding—Sterile Preparations (11/1/2023).~~

~~[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;~~

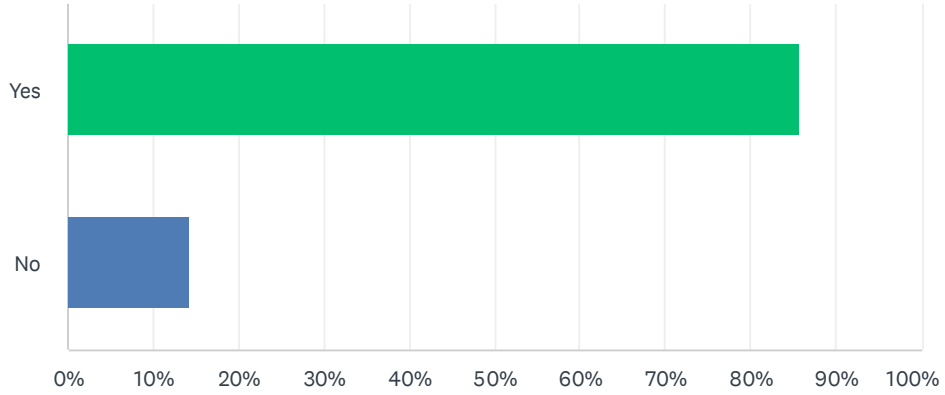
~~(p) Records of dispensing or transfer of all compounded preparations; and~~

~~(q) Any other information required by the pharmacy's policies and procedures.~~

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

Q1 Executive Director's performance expectations are current.

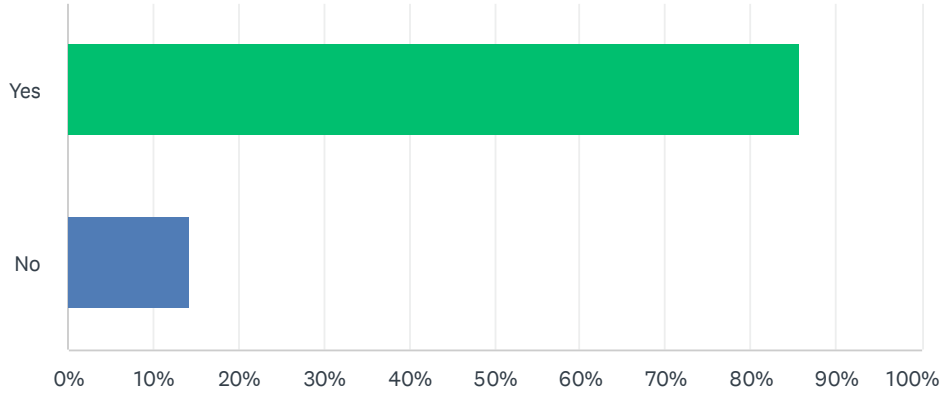
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	6
No	14.29%	1
TOTAL		7

Q2 Executive Director receives annual performance feedback.

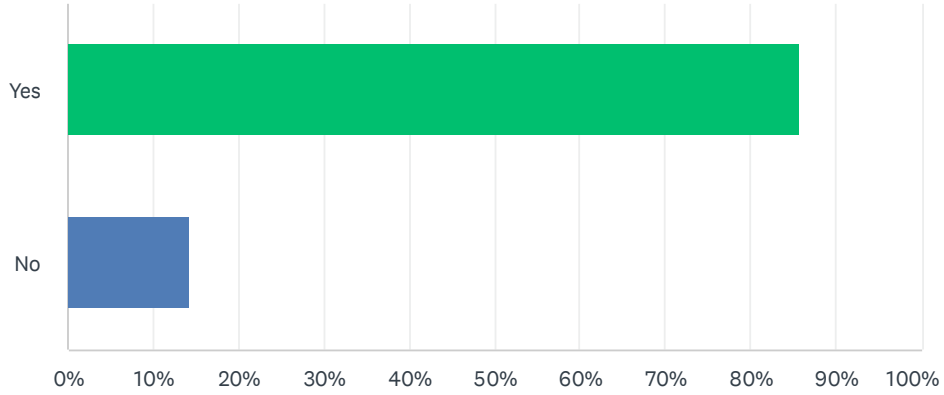
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	6
No	14.29%	1
TOTAL		7

Q3 The agency's mission and high-level goals are current and applicable.

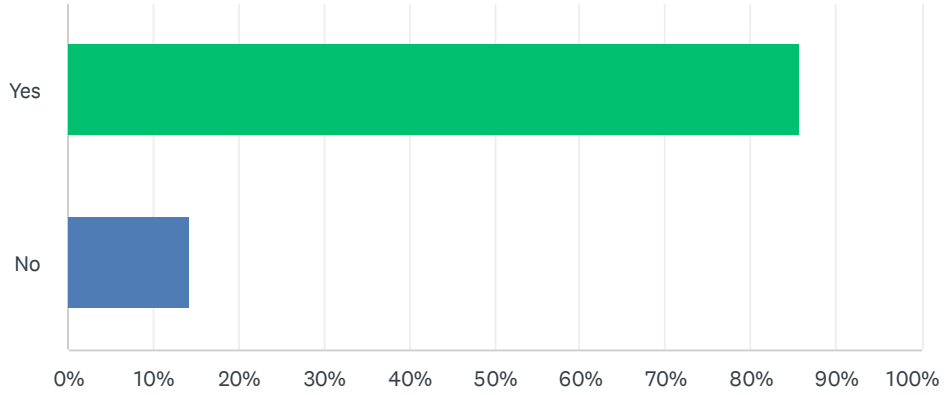
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	6
No	14.29%	1
TOTAL		7

Q4 The board reviews the Annual Performance Progress Report.

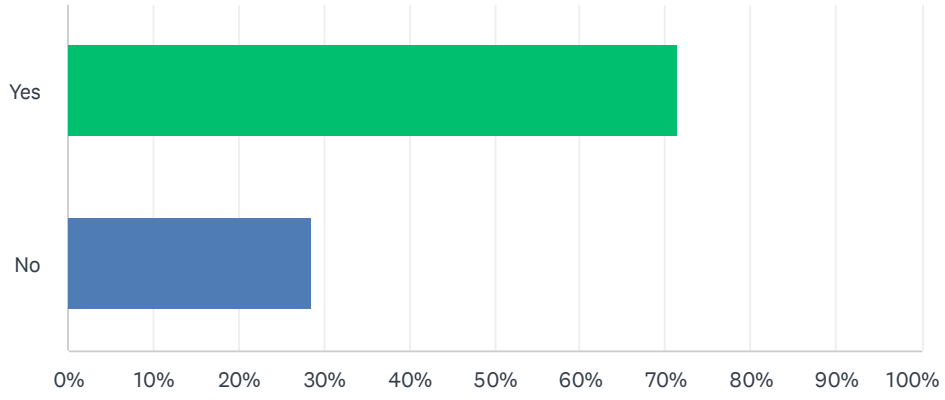
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	6
No	14.29%	1
TOTAL		7

Q5 The board is appropriately involved in review of the agency's key communications.

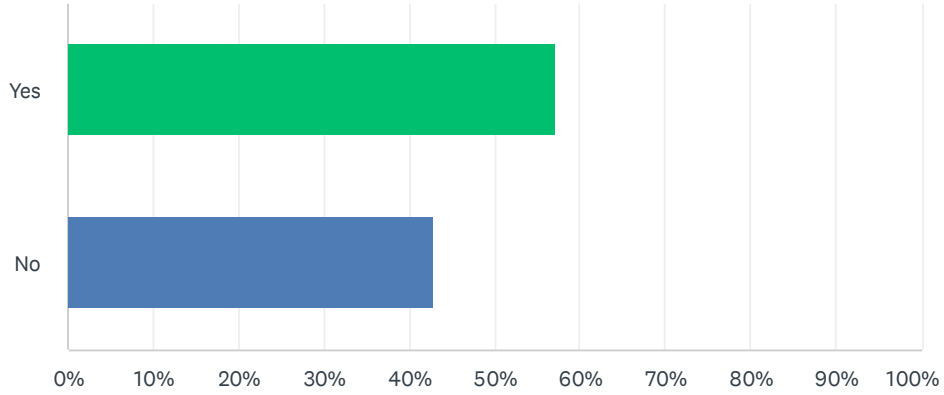
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	71.43%	5
No	28.57%	2
TOTAL		7

Q6 The board is appropriately involved with policy making activities.

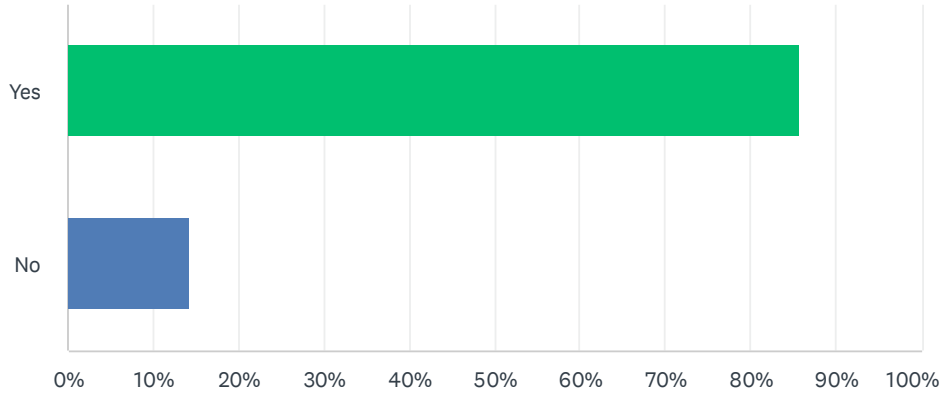
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	57.14%	4
No	42.86%	3
TOTAL		7

Q7 The agency's policy option packages are aligned with their mission and goals.

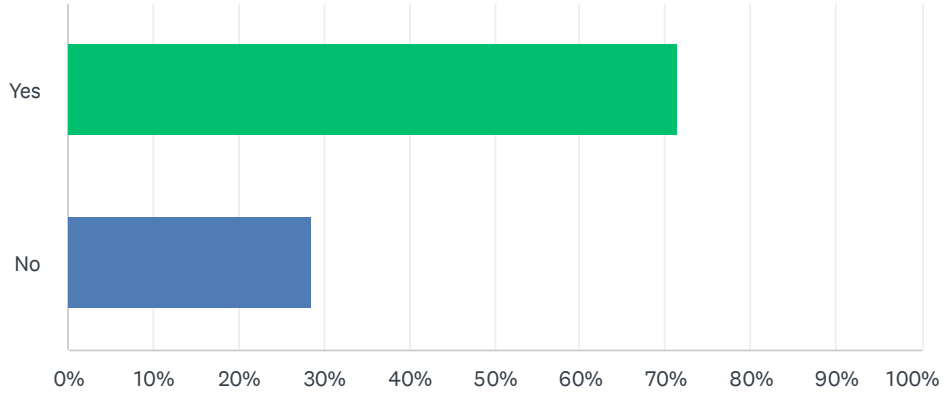
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	6
No	14.29%	1
TOTAL		7

Q8 The board reviews all proposed budgets.

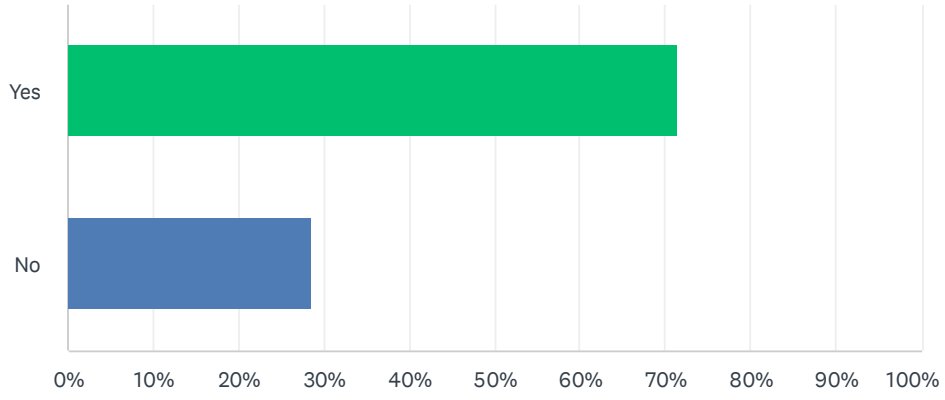
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	71.43%	5
No	28.57%	2
TOTAL		7

Q9 The board periodically reviews key financial information and audit findings.

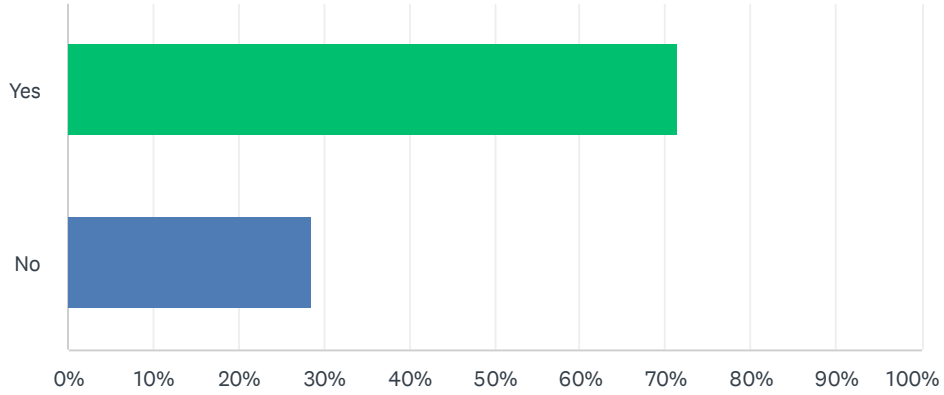
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	71.43%	5
No	28.57%	2
TOTAL		7

Q10 The board is appropriately accounting for resources.

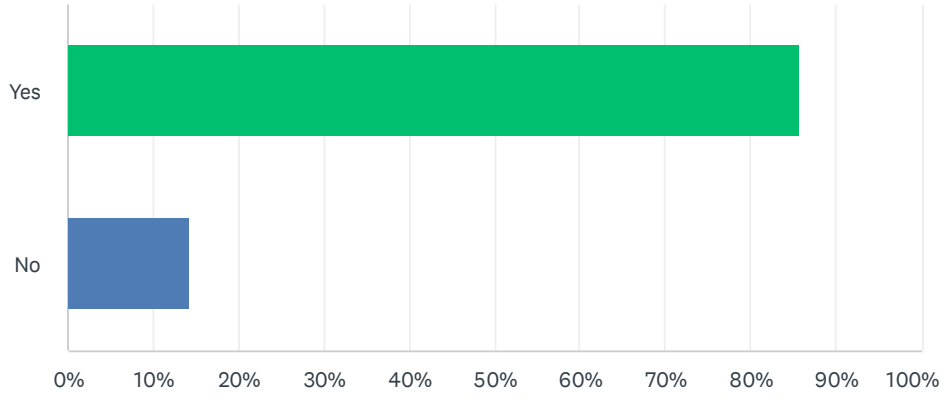
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	71.43%	5
No	28.57%	2
TOTAL		7

Q11 The agency adheres to accounting rules and other relevant financial controls.

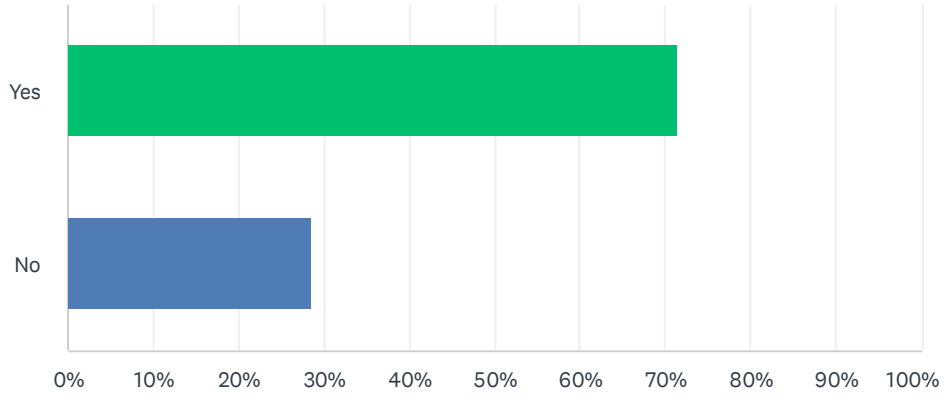
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	6
No	14.29%	1
TOTAL		7

Q12 Board members act in accordance with their roles as public representatives.

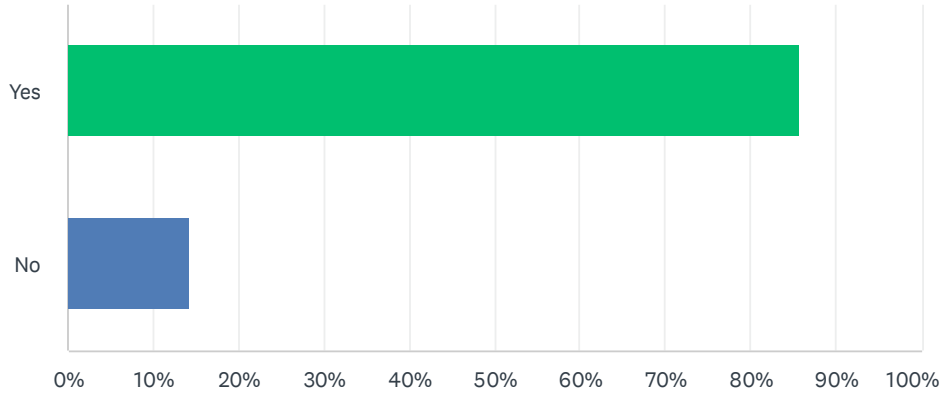
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	71.43%	5
No	28.57%	2
TOTAL		7

Q13 The board coordinates with others where responsibilities and interests overlap.

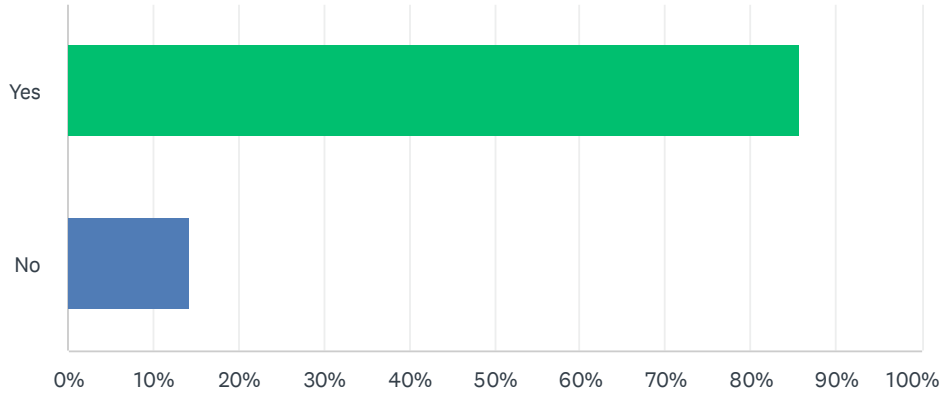
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	6
No	14.29%	1
TOTAL		7

Q13 The board coordinates with others where responsibilities and interests overlap.

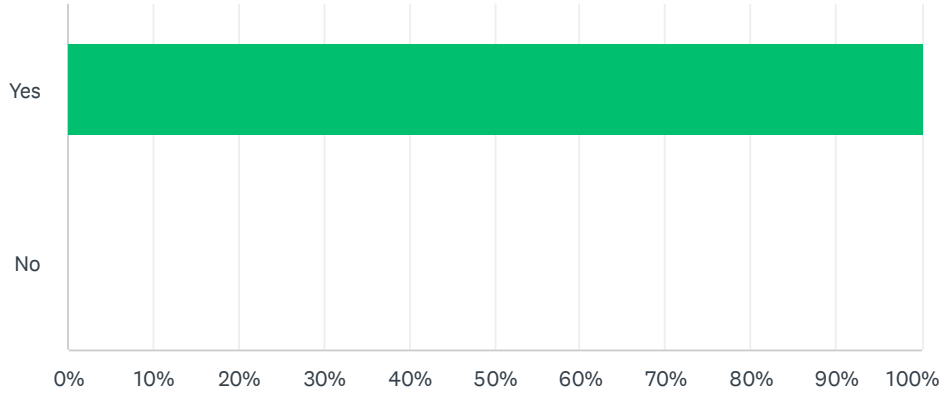
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	6
No	14.29%	1
TOTAL		7

Q14 The board members identify and attend appropriate training sessions.

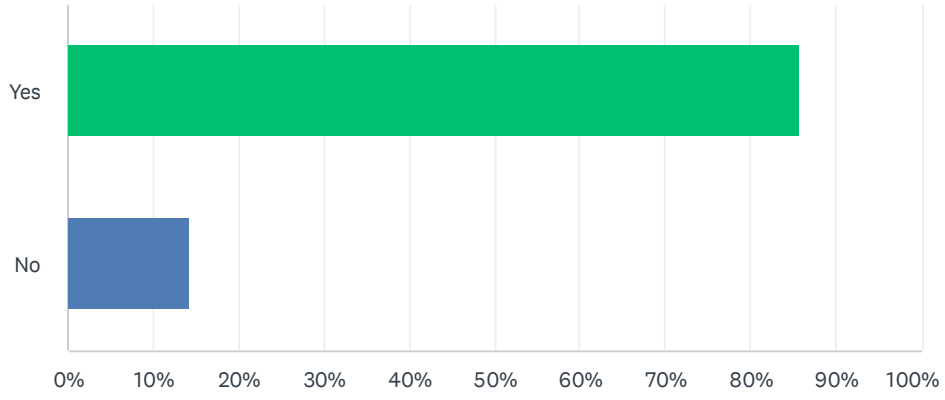
Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	100.00%	7
No	0.00%	0
TOTAL		7

Q15 The board reviews its management practices to ensure best practices are utilized.

Answered: 7 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	6
No	14.29%	1
TOTAL		7

Q16 Please enter your first and last name to validate completion of the Best Practices Self-Assessment survey:

Answered: 7 Skipped: 0

#	RESPONSES	DATE
1	Ana Pinedo	7/22/2025 8:04 AM
2	Priyal Patel	7/21/2025 10:18 AM
3	Rich Joyce	7/14/2025 4:03 PM
4	Victoria Kroeger	7/11/2025 12:58 PM
5	Amy Kirkbride	7/9/2025 1:10 PM
6	Jennifer Hall	7/9/2025 5:00 AM
7	Kathleen Chinn	7/8/2025 6:39 AM

Oregon Board of Pharmacy

Budget Report: May 2025 (FY25 Month 11)

Revenue:

Through May 2025, revenue is $8,996,076 (-4.1%) **under** budget

Expenditures:

Through May 2025, **total expenditures** are $9,598,726 (15.2%) **under** budget

Personal services are $6,866,069 (14.2%) **under** budget

Services and Supplies are $2,732,657 (21.6%) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: ($602,650)

Cash Balance:

Cash balance through May 2025 is $2,737,533 which represents (5.80) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through May 2025. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,228,675, which represents (10.04) months of operating expense*)

Cash balance target is $2,527,814, (6.0 months of operating expense)

*Note: The end of biennium projected cash balance is calculated based on the biennium to date plus the remaining months projections for 2021-23.

Oregon Board of Pharmacy				
Total All Funds - LAB 2023-2025				
Actuals through May 2025				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**3,679,852**	**4,819,712**	
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	9,290,005.00	9,132,736.33	(157,268.67)
210	OTHER NONBUSINESS LICENSES AND FEES	306,570.00	278,252.20	(28,317.80)
505	FINES AND FORFEITS	287,760.00	274,669.66	(13,090.34)
605	INTEREST AND INVESTMENTS	50,000.00	455,819.54	405,819.54
975	OTHER REVENUE	63,975.00	64,851.53	876.53
	TOTAL REVENUE	**9,998,310.00**	**10,206,329.26**	**208,019.26**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	617,120.00	686,112.00	(68,992.00)
	TOTAL TRANSFER OUT	**617,120.00**	**686,112.00**	**(68,992.00)**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	5,186,716.00	4,678,277.83	508,438.17
3115	BOARD MEMBER STIPEND	90,426.00	58,639.00	31,787.00
3160	TEMPORARY APPOINTMENTS	28,453.00	1,747.76	26,705.24
3170	OVERTIME PAYMENTS	-	4,891.88	(4,891.88)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	206,958.00	208,535.22	(1,577.22)
3210	ERB ASSESSMENT	1,254.00	1,174.56	79.44
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	959,821.00	860,142.78	99,678.22
3221	PENSION BOND CONTRIBUTION	245,891.00	224,178.35	21,712.65
3230	SOCIAL SECURITY TAX	397,679.00	363,401.65	34,277.35
3240	UNEMPLOYMENT ASSESSMENT	-	-	-
3241	PAID LEAVE OREGON	19,235.00	18,294.05	940.95
3250	WORKERS' COMPENSATION ASSESSMENT	1,089.00	788.89	300.11
3260	MASS TRANSIT	33,735.00	29,408.28	4,326.72
3270	FLEXIBLE BENEFITS	940,852.00	806,505.80	134,346.20
3435	Personal Services Budget Adj.	(44,046.00)	-	(44,046.00)
	TOTAL PERSONAL SERVICES	**8,068,063.00**	**7,255,986.05**	**812,076.95**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	121,406.00	94,842.61	26,563.39
4125	OUT-OF-STATE TRAVEL	17,739.00	2,585.50	15,153.50
4150	EMPLOYEE TRAINING	26,485.00	59,644.06	(33,159.06)
4175	OFFICE EXPENSES	144,282.00	74,631.08	69,650.92
4200	TELECOMM/TECH SVC AND SUPPLIES	60,655.00	52,985.72	7,669.28
4225	STATE GOVERNMENT SERVICE CHARGES	265,996.00	281,520.30	(15,524.30)
4250	DATA PROCESSING	333,018.00	374,180.03	(41,162.03)
4275	PUBLICITY & PUBLICATIONS	45,627.00	24,759.33	20,867.67
4300	PROFESSIONAL SERVICES	369,608.00	264,808.38	104,799.62
4315	IT PROFESSIONAL SERVICES	169,185.00	3,720.00	165,465.00
4325	ATTORNEY GENERAL LEGAL FEES	687,079.00	573,914.22	113,164.78
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	1,188.00	-	1,188.00
4400	DUES AND SUBSCRIPTIONS	6,124.00	4,733.98	1,390.02
4425	FACILITIES RENT & TAXES	328,585.00	324,159.48	4,425.52
4475	FACILITIES MAINTENANCE	57.00	12.50	44.50
4525	MEDICAL SUPPLIES AND SERVICES	1,252.00	-	1,252.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	260,999.00	210,350.70	50,648.30
4650	OTHER SERVICES AND SUPPLIES	418,953.00	496,494.88	(77,541.88)
4700	EXPENDABLE PROPERTY $250-$5000	17,571.00	-	17,571.00
4715	IT EXPENDABLE PROPERTY	47,128.00	11,925.83	35,202.17
	TOTAL SERVICES & SUPPLIES	**3,322,937.00**	**2,855,268.60**	**467,668.40**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	-	-	-
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**0.00**	**0.00**	**0.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	-	-	-
	Total Special Payments	**0.00**	**0.00**	**0.00**
	TOTAL EXPENDITURES	**11,391,000.00**	**10,111,254.65**	**1,279,745.35**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**1,670,042**	**4,228,675**	
	End of biennium projected cash balance in months		10.04	
	Cash balance target of 6.0 months (working capital)		2,527,814	