Oregon Board of Pharmacy
***REVISED 6/6/2023**
BOARD MEETING AGENDA
June 7-9, 2023

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: 779 863 495#**

The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

Wednesday, June 7, 2023 @ 8:00AM
Thursday, June 8, 2023 @ 8:00AM
Friday, June 9, 2023 @ 8:00AM

- All OBOP meetings, except Executive Sessions, are open to the public. Pursuant to ORS 192.660(1)(2)(f)(L), Executive Sessions are closed to the public, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the board will return to Open Session
- To sign up for Public Comment, email your request to pharmacy.board@bop.oregon.gov by **12:00PM on 6/9/2023**

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

WEDNESDAY, JUNE 7, 2023

I. OPEN SESSION, Michelle Murray RPh, Presiding
***Please note that the board will meet in Executive Session for most of the day and anticipates resuming Open Session between 4:30-4:45PM.**

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

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

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

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

Adjourn *Action Necessary*

THURSDAY, JUNE 8, 2023

I. OPEN SESSION, Michelle Murray RPh, Presiding
***Please note that the board will meet in Executive Session after the Executive Director Recruitment Discussion and anticipates resuming Open Session at 1:00PM**

a. Roll Call
b. Executive Director Recruitment Discussion

Oregon Board of Pharmacy
***REVISED 6/6/2023**
BOARD MEETING AGENDA
June 7-9, 2023

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

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

IV. GENERAL ADMINISTRATION

a. Rules
   i. Review Rulemaking Hearing Report & Comments – *Melvin* **#A** *Action Necessary*
   ii. Consider Adoption of Temporary Rules – *None*
   iii. Consider Adoption of Rules –
      1. **Div 006/041/043/045/080/139/141-** Standards Adopted by Reference- **#B** *Action Necessary*
      2. **Div 019/020-** Pharmacist Prescriptive Authority – COVID-19 Monoclonal Antibody, COVID-19 Antiviral, Continuation of Therapy including emergency refills of insulin, Contraception, PEP, PrEP, Travel Medications Protocols- **#B1, B1a, B1b, B1c, B1d, B1e**
      3. **Div 019/041/080/139/141/143-** Self-Inspection Form Completion Date- **#B2** *Action Necessary*
   iv. Rules in Development - *Davis*
   v. Rulemaking Policy Discussion Items – *Davis*
      1. **Div 104-** Universal Rules **#C** *Action Necessary*
      3. **Div 102-** Board Administration **#C1** *Action Necessary*
      4. **Div 115-** Pharmacists - Procedural Rule Review **#C2** *Action Necessary*
      5. **Div 120-** Interns - Procedural Rule Review **#C3** *Action Necessary*
      6. **Div 125-** Pharmacy Technicians - Procedural Rule Review **#C4** *Action Necessary*
      7. **Div 041/043/183-** Drug Compounding **#C5** *Action Necessary*
      8. **Div 006-** Definitions – Unprofessional Conduct Defined **#C6** *Action Necessary*
      9. **Div 080-** Schedule 1 – Xylazine **#C7** *Action Necessary*

Adjourn *Action Necessary*

FRIDAY, JUNE 9, 2023

I. OPEN SESSION, Michelle Murray RPh, Presiding

a. Roll Call

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

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

III. ANNUAL BOARD BUSINESS MEETING

a. Update on Board & PHPFAC appointments – *Schnabel*
b. Election of New Officers – *Murray/Schnabel* *Action Necessary*

c. Approval of ACPE Accredited Schools & Colleges of Pharmacy & ACPE Accredited Providers of Continuing Pharmacy Education – *Davis* **#D,Da** *Action Necessary*
d. Recognition of outgoing Board Member Murray – *Schnabel*

IV. GENERAL ADMINISTRATION

a. Resume Rulemaking Policy Discussions Items – *Davis*
b. Discussion Items
   i. Board Action Report – *Efremoff* **#F**
   ii. Public Health and Pharmacy Formulary Advisory Committee Update – *Davis*
   iii. Workgroup Update - *Davis*
   iv. Strategic Plan Update - *Schnabel*
   v. Legislative Update – *Schnabel* **#G**
   vi. Financial/Budget Report – *MacLean* **#H**

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

2023 Board Meeting Dates

- August 9-11, 2023 Portland
- October 11-13, 2023 Portland
- November 8-9, 2023 Newport, OR (Strategic Planning)
- December 13-15, 2023 Portland

2024 Board Meeting Dates

- February 7-9, 2024 Portland
- April 10-12, 2024 Portland
- June 12-14, 2024 Portland
- August 7-9, 2024 Portland
- October 9-11, 2024 Portland
- November 7, 2024 Portland (Strategic Planning)
- December 11-13, 2024 Portland

Rulemaking Hearing Dates

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

- July 26, 2023
- November 21, 2023

Conferences/Meetings

- NABP Districts 6, 7, 8 Meeting – October 22-25, 2023 Jackson Hole, WY

VI. APPROVE CONSENT AGENDA* *Action Necessary*

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

a. License/Registration Ratification 3.28.2023-5.22.2023 - **# CONSENT-1**
b. Board Meeting Minutes – April 2023 - **# CONSENT-2**

VII. PUBLIC COMMENT

Adjourn *Action Necessary*

Oregon
Tina Kotek, Governor

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

Date: May 24, 2023
To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: May 23, 2023

Hearing Location: Virtual Hearing via Teams

Proposed Rules:

- Divisions 006/041/043/045/080/139/141/143 related to Standards Adopted by Reference
- Divisions 019/020 related to Pharmacist Prescriptive Authority
- Divisions 019/041/043/045/080/139/141/143 related to Self-Inspection Form Completion Date

On April 19, 2023, the May 23, 2023 Rulemaking Hearing public notice was sent out via GovDelivery to 3,672 rulemaking/adopted rules subscribers and 19,016 licensees/registrants (22,688 total).

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

The rulemaking hearing convened at 9:30AM and adjourned at 9:37AM. #10 people joined the public call to listen to the hearing. We didn't have anyone sign up to provide oral testimony, therefore there were no comments provided during the hearing. #2 written comments were received during the open comment period from 4/19/2023 through 4:30PM on 5/23/2023. The hearing was recorded, and the notice of proposed rulemaking filings were available on our website.

The following board and staff members participated virtually:

Board Member Beaman
Board Member DeBarmore
Staff Member Efremoff
Staff Member Melvin

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

SUMMARY OF ORAL TESTIMONY:

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

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Pharmacist Prescriptive Authority and Protocols *Repeal of COVID-19 Monoclonal Antibody, *Repeal of COVID-19 Antiviral, Continuation of therapy including refills of insulin v. 06/2023, Travel Medications v. 06/2023, PEP v. 06/2023, PrEP v. 06/2023, and Contraception v. 06/2023.

AMEND: OAR 855-020-0030
REPEAL: OAR 855-019-0470

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Self-Inspection Form Completion Date
AMEND: OAR 855-019-0300, OAR 855-041-1060, OAR 855-043-0560, OAR 855-045-0220, OAR 855-080-0100, OAR 855-139-0030, OAR 855-141-0030, and OAR 855-143-0030.

- No oral testimony was provided.

All written comments received by the public comment deadline date of 5/23/2023 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 4/19/2023 Notice of Proposed Rulemaking.

OREGON VETERINARY
medical association

March 15, 2023

Honorable Governor Tina Kotek
Office of the Governor
900 Court Street, Suite 254
Salem, OR 97301-4047

Re: Importance of Xylazine in Veterinary Medicine

Dear Governor Kotek:

Veterinarians in Oregon recognize the threat of illicit xylazine and its increasing role in the drug epidemic, and we strongly support the recent actions of the FDA, DEA and Congress in the fight against the importation and use of illicit xylazine. We also applaud your efforts to help combat the opioid addiction crisis in Oregon through Senate Bill 1043.

We are reaching out to you because the chemical xylazine that has been found mixed with illicitly manufactured fentanyl and other narcotics in all 50 states **is not** the same essential medication used in veterinary medicine. This is an important distinction, as any executive order making xylazine a scheduled controlled substance would dramatically change the way veterinarians are able to care for their patients and would be an animal welfare and human safety issue.

Xylazine, which has been approved in the United States for veterinary use since 1972, is an important medication in large animal species, particularly horses and cattle, as well as some wildlife and laboratory animal species. In these species it is a very safe, effective, and relatively short-acting non-opioid drug that provides sedation and analgesia needed to perform certain medical evaluations, treatments, and procedures. This also helps make veterinary practice safer for veterinarians, technicians, producers, and animal owners when working with animals that can easily injure people (or themselves) during procedures, because of their size and typical behavior.

No form other than the injectable (liquid) xylazine is used in veterinary medicine. In contrast, the xylazine used to adulterate illicit drugs is a bulk powder (active pharmaceutical ingredient – API), and the source of this API (street name "Tranq") is from illegal importation by sellers operating on the internet. [1] Injectable veterinary xylazine is a liquid, making it difficult to use as an adulterant. For example, the Illinois Department of Health stated in 2022 that there is no evidence that xylazine was being diverted from veterinary practice for use in illegal drug manufacture. [2]

In February 2023, the FDA took action to restrict the unlawful entry of illegally imported xylazine API to combat the "Tranq" supply chain. [3] The FDA recognizes that the xylazine being trafficked in communities across the United States comes from imported bulk ingredients, often from Chinese suppliers selling online, and is **not diverted from veterinary clinics.** This FDA action, strongly supported by the OVMA, places xylazine on the Import Alert "Red List." Such placement now challenges the FDA to verify that imported xylazine is properly labeled, not adulterated, and is intended for legitimate use.

1880 Lancaster Drive NE, Suite 118 | Salem, OR 97305
800/235-3502 | 503/399-0311 | 503/363-4218 fax
oregonvma.org | contact@oregonvma.org

Additionally, the OVMA supports the "Combatting Illicit Xylazine Act H.R. 1839 / S. 993" introduced March 28, 2023, in the 118th Congress. [4] This bill, along with the FDA's efforts, targets the supply chain of "Tranq," while giving regulatory flexibility to FDA-approved veterinary xylazine. The federal legislation also contains harsher penalties for diversion than what currently exists in the Controlled Substances Act. The American Veterinary Medical Association also supports this legislation.

We believe that illicit drugs are a major public health threat and support efforts to eliminate illegal "Tranq." However, placing additional burdens or restrictions on the legitimate veterinary use of xylazine will have minimal, if any, effect on this public health crisis; it would almost certainly eliminate a critical medication for our veterinary patients in Oregon.

There are currently only two manufacturers of xylazine for veterinary use in the United States. If it is scheduled as a controlled substance, there is a very real risk that it will cease to be available in Oregon because of the increased regulatory burden and costs for the manufacturers and distributors. Our understanding is that one of the manufacturers has already ceased making the product until there is more clarity and that one of the major distributors has stopped distributing it to states that have scheduled xylazine. This leaves one manufacturer currently providing product to the entire U.S. market.

It is our hope that you will support the thoughtfully conceived policies on the federal level and ensure that veterinarians in Oregon continue to have access to this important drug. Our concern is that restricting access to xylazine would have unintended consequences affecting veterinary practice, animal welfare, and human safety, without reducing drug overdoses and deaths in people.

Thank you, Governor Kotek, for your time and consideration. Please do not hesitate to contact us, if we can answer questions and concerns you might have.

Sincerely,

Jill E. Parker

Jill E. Parker, VMD, DACVS
President, Oregon Veterinary Medical Association

cc. Joe Schnabel, R.Ph. Oregon Board of Pharmacy
Emilio DeBess, DVM, MPH, Oregon Veterinary Medical Examining Board

1. The growing threat of xylazine and its mixture with illicit drugs. Accessed May 10, 2023. https://www.dea.gov/documents/2022/2022-12/2022-12-21/growing-threat-xylazine-and-its-mixture-illicit-drugs
2. Patchwork effort to curb illicit use of xylazine raises concerns - News - VIN. Accessed May 10, 2023. https://news.vin.com/default.aspx?pid=210&Id=11464312&useobjecttypeid=10&fromVINNEWSASPX=1&f5=1
3. FDA takes action to restrict unlawful import of xylazine: Agency aims to maintain availability for legitimate use in animals wile preventing importation for illicit purposes. FDA News Release February 28, 2023. Accessed May 10, 2023. https://www.fda.gov/news-events/press-announcements/fda-takes-action-restrict-unlawful-import-xylazine
4. Combating Illicit Xylazine Act. H.R.1839 and S.993 118th Congress (2023-2024): Published March 28, 2023. Accessed May 10, 2023. https://www.congress.gov/bill/118th-congress/house-bill/1839/text and https://www.congress.gov/bill/118th-congress/senate-bill/993?s=1&r=18

From:	PHARMACY BOARD * BOP
To:	PHARMACY RULEMAKING * BOP
Subject:	FW: Importance of Xylazine in Veterinary Medicine
Date:	Monday, May 15, 2023 12:48:39 PM
Attachments:	Xylazine Letter Governor Kotek 1.pdf

From: Glenn Kolb <glenn.kolb@oregonvma.org>
Sent: Monday, May 15, 2023 12:43 PM
To: DEBESS Emilio E <Emilio.E.DEBESS@oha.oregon.gov>; PHARMACY BOARD * BOP <pharmacy.board@bop.oregon.gov>
Subject: Importance of Xylazine in Veterinary Medicine

Dear Dr. DeBess and Dr. Schnabel,

Attached is a letter we sent to Gov. Tina Kotek in which we address the use of xylazine in veterinary medicine, as compared to the illicit manufacturing and illegal use/access of this drug. The distinction is important to us, as some governors and legislators in other states have sought to schedule the non-opioid medication as a controlled substance. Our concern is that if this were to happen in Oregon, it would dramatically change the way veterinarians are able to care for their patients and would present an animal welfare and a human safety issue.

Thank you for your time.

Sincerely,

Glenn

Glenn M. Kolb, Executive Director

Oregon Veterinary Medical Association
1880 Lancaster Dr. NE, #118
Salem, OR 97305
800-235-3502
www.oregonvma.org / glenn.kolb@oregonvma.org

May 22, 2023

To: Oregon Board of Pharmacy

Re: Rulemaking comment on a proposed change to all protocols related to Pharmacist Prescriptive Authority

Prescryptive Health appreciates the work of the PHPFAC and the Board of Pharmacy to provide expanding pharmacist prescribing and treatment opportunities for communities across Oregon. What is equally exciting is that technology to support these activities is also advancing. Available today from multiple companies, is an electronic medical record with a patient facing smartphone application (note: Prescryptive is not claiming all these capabilities, but they are available in the market). These applications allow for the patient to make an appointment for a clinical service at a pharmacy, answer required screening questions, receive results of the appointment/tests, and receive after visit summaries and referrals if needed. **For pharmacists, the treatment algorithms can be custom programed to meet any state requirements, prompting for required data inputs, and presenting the treatment options allowed by the protocol.** The software can also generate referrals, reporting, and provider notification. The software operates with smooth user interfaces which are easy to use and account for health literacy. In addition, multiple languages are being developed. Because the software is a medical record, it remembers demographic and health data so fewer questions are needed on subsequent visits.

The problem is that many of these applications cannot be used in Oregon as there are rules requiring use of specific forms. Whereas these forms can be turned into fillable PDFs, these are incompatible with many user interface programs and the forms remove the efficiencies and benefits of the software. **The information contained in protocol forms is excellent, but technology companies need the ability to selectively display the exact requirements electronically in varying formats.** Similarly, we request that referral, after visit summaries, and notification forms be allowed to vary in format while including required information. This will allow nationally standardized forms to be used. In addition, we suggest allowing for use of existing patient information so duplicate questions can be eliminated.

For example, the PEP protocol requires the use of a specific patient intake form. The top of the form is information commonly already known and required in an electronic medical record. Wouldn't it be a much better patient experience if they were only prompted for missing information?

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

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

Legal Name_____ Name _____

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

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

Street Address _____

Phone ( ) _____ Email Address _____

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

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

Any allergies to medications? Yes / No If yes, please list _____

There was a comment in a Board of Pharmacy meeting that the exact forms must be used for protocols like Tobacco Cessation as the complex treatment algorithm refers to specific questions on the form. **This level of complexity is exactly what software can help with- provide just the questions needed for the circumstance and then display just the treatment options which are appropriate for the data collected.** Protocols are very clear, and this would be easy to program if allowed.

Enabling technology for ease of use and efficiency is essential for achieving our healthcare goals. People are quick to use services which are easy to access and understand. People avoid complex interactions which are frustrating. The same is true of pharmacists and pharmacies. If services are quick and easy to provide, then more pharmacies will adopt them. **Allowing use of technology will increase public access to and utilization of pharmacist clinical services.**

We suggest that a line be added to bottom of the Standardized Patient Assessment Process Elements section of all protocols to read:

> **"A pharmacist may collect, display, and send information electronically, in varied formats, to meet the exact requirements of the protocol."**

About us: Prescryptive Health is a healthcare technology company that builds solutions for the healthcare industry. We are working to deliver better healthcare through patient engagement. Core strategies include improving patient access to needed medications and connecting patients to pharmacists who can provide value added clinical services. We have a community pharmacy in Redmond, Oregon which is piloting and demonstrating our technology.

Thank you for your consideration.

Sincerely,

Kevin Russell RPh, MBA, BCACP
Director of Pharmacy | Clinical Operations
Prescryptive Health
2127 S HWY 97 STE 150
Redmond, OR 97756
Office: (206) 413-9475
Mobile: (541) 609-0306
kevinr@prescryptive.com
www.prescryptive.com

From: Kevin Russell
To: PHARMACY RULEMAKING * BOP
Subject: Written comments for May 23rd rulemaking hearing
Date: Monday, May 22, 2023 4:44:14 PM
Attachments: image002.png
Prescryptive rulemaking comments 5-23-2023.docx

Prescryptive Health would like to submit the attached comment for all 5 of the pharmacist prescriptive protocols being considered in the rulemaking hearing. Thank you.

Kevin Russell RPh, MBA, BCACP
Director of Pharmacy | Clinical Operations
Prescryptive Pharmacy & Patient Services, Inc.
2127 S HWY 97 STE 150
Redmond, OR 97756
Pharmacy: 541-526-3565
Mobile: (541) 609-0306
Prescryptivepharmacy.com

Division 006/041/043/045/080/139/141: Adopted Standards by Reference in Definitions/Drug Disposal/Closures/Containers/Dispensing/Compounding/Controlled Substance Schedules/RDSP/Kiosk and Scheduling Xylazine as CIII

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Updates incorporated standards adopted by reference; Amends Schedule III

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments incorporate updated standards adopted by reference as required by the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019). Amends Schedule III rule by adding scheduling xylazine as a Schedule III.

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

Adopted Standards by Reference- 16 CFR (1/1/2022), 21 CFR (4/1/2022), 21 USC 352 (12/28/2022), 21 USC 353 (12/28/2022) 21 USC 351 (3/20/2023), 21 USC 811 (3/20/2023), 21 USC 812 (3/20/2023), 21 USC 822 (3/20/2023), 21 USC 822a (3/20/2023), 21 USC 827 (3/20/2023), 21 USC 828 (3/20/2023), 42 USC 262 (12/28/2022), United States Pharmacopeia <USP> and National Formulary <NF> (USP NF 2023, Issue 1 38 v. 2023), Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2023), USP 1229.5 (08/01/2022), and DEA Table of Exempted Prescription Products (08/22/2022).

Scheduling Xylazine-
Federal Bill: Combating Illicit Xylazine Act – Discussion Draft
DEA Public Safety Alert 3/21/2023
National Institute on Drug Abuse- Xylazine
OAR 875-015-0040 Minimum Standards for Veterinary Drugs

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated related to adoption of standards by reference. Regarding scheduling xylazine as a Schedule III, all veterinary facilities are required to have a controlled substance safe, or securely locked cabinet for storage of controlled substances; thus, it is not anticipated that there will be a fiscal impact on veterinary facilities.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Amendments are required per ORS 183.337 pursuant to ORS 475.035 and ORS 475.055.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments include revised reference versions of 16 CFR (1/1/2022), 21 CFR (4/1/2022), 21 USC 352 (12/28/2022), 21 USC 353 (12/28/2022) 21 USC 351 (3/20/2023), 21 USC 811 (3/20/2023), 21 USC 812 (3/20/2023), 21 USC 822 (3/20/2023), 21 USC 822a (3/20/2023), 21 USC 827 (3/20/2023), 21 USC 828 (3/20/2023), 42 USC 262 (12/28/2022), United States Pharmacopeia <USP> and National Formulary <NF> (USP NF 2023, Issue 1 38 v. 2023), Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2023), USP 1229.5 (08/01/2022), and DEA Table of Exempted Prescription Products (08/22/2022). Amendments are required per ORS 183.337 and pursuant to ORS 475.035 and ORS 475.055.

Amends OAR 855-080-0023 by adding "and products containing xylazine including it's salts, isomers, and salts of isomers of xylazine as an active ingredient" to Schedule III. Proposed amendments are necessary due to federal legislation that requires veterinarians to treat xylazine as a Controlled Substance.

DIVISION 006
DEFINITIONS

855-006-0005
Definitions

As used in OAR Chapter 855:

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. 3/15/2023).

(2) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.

(3) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.

(4) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

(5) "Biosimilar" product means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (v. 12/28/2022).

(6) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(7) "Certified health care interpreter" has the meaning given that term in ORS 413.550.

(8) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the Pharmacist are not considered Certified Oregon Pharmacy Technicians or Pharmacy Technicians.

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

(10) "Collaborative Drug Therapy Management" means the participation by a Pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration, and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one Pharmacist and one practitioner; or

(b) Is agreed to by one or more Pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic, or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.

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

(a) As the result of a practitioner’s prescription drug order, or initiative based on the relationship between the practitioner, the Pharmacist and the patient, in the course of professional practice; or

(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or

(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(12) "Confidential Information" means any patient information obtained by a Pharmacist or pharmacy.

(13) "Consulting Pharmacist" means a Pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.

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

(15) “Custodian of pharmacy records” means a board licensee or registrant who is responsible for the maintenance, care or keeping of pharmacy records based on the services provided by the pharmacy, regardless of whether the records are in that person's actual physical custody and control.

(16) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(17) "Drug Regimen Review" or "DRR" means the process conducted by a Pharmacist who is consulting for a long-term-care facility or other institution, either prior to dispensing or at a later time, with the goal of ensuring that optimal patient outcomes are achieved from the drug therapy.

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

(19) "Final verification" means after prescription information is entered into a pharmacy's electronic system and reviewed by a Pharmacist for accuracy, a physical verification that the drug and drug dosage, device or product selected from a pharmacy's inventory pursuant to the electronic system entry is the prescribed drug and drug dosage, device, or product.

(20) "Good standing" means a license or registration that is not suspended, revoked, or otherwise restricted from the practice of pharmacy or subject to a current disciplinary order.

(21) "Health care interpreter" has the meaning given that term in ORS 413.550.

(22) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.

(23) "Individual with limited English proficiency" means a person who, by reason of place of birth or culture, communicates in a language other than English and does not communicate in English with adequate ability to communicate effectively with a health care provider.

(24) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 USC 262(k)(4) (v. 12/28/2022).

(25) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.

(26) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.

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

(28) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.

(29) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.

(30) "Nationally Certified Exam" means an exam that is approved by the board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible, and valid.

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

(32) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:

(a) The creation and retention of accurate and complete patient records;

(b) Assuming authority and responsibility for product selection of drugs and devices;

(c) Developing and maintaining a safe practice setting for the Pharmacist, for pharmacy staff and for the general public;

(d) Maintaining confidentiality of patient information.

(33) “Official compendium” means the official United States Pharmacopeia <USP>, official National Formulary <NF> (v. USP NF 2023, Issue 1), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2023), or any supplement to any of these.

(34) "Oral Counseling" means an oral communication process between a Pharmacist and a patient or a patient’s agent in which the Pharmacist obtains information from the patient (or agent) and the patient's pharmacy records, assesses that information, and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.

(35) Participation in Drug Selection and Drug Utilization Review:

(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.

(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the Pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review include, but are not limited to:

(A) Over-utilization or under-utilization;

(B) Therapeutic duplication;

(C) Drug-disease contraindications;

(D) Drug-drug interactions;

(E) Incorrect drug dosage;

(F) Incorrect duration of treatment;

(G) Drug-allergy interactions; and

(H) Clinical drug abuse or misuse.

(36) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:

(a) Cure of a disease;

(b) Elimination or reduction of a patient's symptomatology;

(c) Arrest or slowing of a disease process; or

(d) Prevention of a disease or symptomatology.

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

(38) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board but has not completed the specialized education program pursuant to OAR 855-025-0012.

(39) “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.

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

(41) “Prescription drug” or “legend drug” is as defined in ORS 689.005 and:

(a) Required by federal law, prior to being dispensed or delivered, to be labeled with “Rx only”; or

(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

(42) "Prescription released by the Pharmacist" means, a prescription which has been reviewed by the Pharmacist that does not require further Pharmacist intervention such as reconstitution or counseling.

(43) "Prohibited conduct" means conduct by a licensee that:

(a) Constitutes a criminal act against a patient or client; or

(b) Constitutes a criminal act that creates a risk of harm to a patient or client.

(44) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:

(a) Assure retention of their purity and potency;

(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;

(c) Assure security and minimize the risk of their loss through accident or theft;

(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;

(e) Protect the health, safety and welfare of the Pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.

(45) "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.

(46) "Reasonable professional judgment" means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities, qualifications, and competencies, after careful review, analysis and consideration of the relevant subject matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion, or conclusion.

(47) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (v. 12/28/2022) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

(48) "Repackage" means the act of taking a drug from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug.

(49) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication,

the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.

(50) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as Certified Oregon Pharmacy Technicians or Pharmacy Technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or

(b) A structured program approved by the board and designed to educate Certified Oregon Pharmacy Technicians or Pharmacy Technicians in one or more specific issues of patient health and safety that is offered by:

(A) An organization recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians;

(B) An employer recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians; or

(C) A trade association recognized by the board as representing pharmacies.

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

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

(53) "Supervision by a Pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician being supervised, coupled with the ability to control and be responsible for the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician's action.

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

(55) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.

(56) "Verification" means the confirmation by the Pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an Intern, a Certified Oregon Pharmacy Technician, or a Pharmacy Technician.

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

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

DIVISION 041
OPERATION OF PHARMACIES

855-041-1046
Secure and Responsible Drug Disposal

(1) A pharmacy that operates a drug take back collection program or that participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered with the DEA as an authorized collector to collect controlled and non-controlled drugs for destruction.

(2) A pharmacy that operates as a Drug Enforcement Agency (DEA) authorized collector must notify the board within 30 days of initiating or terminating the program and must establish and enforce policies and procedures, including but not limited to:

(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is accessible to the public, within view of the pharmacy counter and must not be located behind the pharmacy counter; and

(b) Provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation, and key accountability; and

(c) Personnel training and accountability.

(3) A pharmacy must inform consumers to directly deposit drugs into the collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected.

(4) A pharmacy must not dispose of drugs from pharmacy stock in a collection receptacle.

(5) The liner must be inserted and removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel.

(6) Liners that have been removed from a collection receptacle and immediately sealed must be directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution agent (such as registered UPS, FedEx, or USPS) or a reverse wholesaler registered with the DEA and the board.

(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to the board in writing within one day of discovery.

(8) A pharmacy must maintain all drug disposal records for a minimum of 3 years.

(9) Authorized collectors are required to comply with the following federal and state laws:

(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236, ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;

(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370, and OAR 340-098-0390;

(c) 21 CFR 1317.30 (04/01/2022), 21 CFR 1317.35 (04/01/2022), 21 CFR 1317.40 (04/01/2022), 21 CFR 1317.55 (04/01/2022), 21 CFR 1317.60 (04/01/2022), 21 CFR 1317.65 (04/01/2022), 21 CFR 1317.70 (04/01/2022), 21 CFR 1317.75 (04/01/2022), 21 CFR 1317.80 (04/01/2022), and 21 CFR 1317.85 (04/01/2022); and

(d) 21 USC 822 (03/20/2023), 21 USC 822a (03/20/2023).

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218

855-041-1092
Retail Drug Outlet Pharmacy Closures: Temporary, Permanent or Emergency

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a Retail Drug Outlet pharmacy is temporarily closed to the public the pharmacy must:

(a) Post notification of closure on each pharmacy entrance as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the pharmacy is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

(d) Federal and state holidays are exempt from the requirements of (1).

(2) Permanent Closing. If a Retail Drug Outlet pharmacy is permanently closing to the public, the pharmacy must:

(a) Prior to closing, the pharmacy must comply with the following:

(A) Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:

(i) The last day the pharmacy will be open;

(ii) Name, address and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(B) The notification must be made via:

(i) Distribution by direct mail or written notice with each prescription dispensed;

(ii) Public notice in a newspaper of general circulation, if available, in the area served by the pharmacy; and

(iii) Posting a closing notice on each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).

(iv) In addition to (i), (ii) and (iii), the pharmacy may also provide notification via email or text.

(C) Provide any new patients filling prescriptions during the 15 calendar day period prior to the pharmacy closing with written notification that includes:

(i) The last day the pharmacy will be open;

(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records;

(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/2022).

(b) On the date of closing or up to 24 hours after the permanent closure begins, the Pharmacist-in-charge must comply with the following:

(A) Complete and document an inventory of all controlled substances.

(B) If the pharmacy dispenses prescriptions:

(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed Pharmacist who will serve as the custodian of records;

(ii) Update the pharmacy operating status with each electronic prescribing vendor; and

(iii) Remove all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications).

(c) After closing. Within 30 calendar days after the closing of the pharmacy, the Pharmacist-in-charge must:

(A) Complete and document an inventory of all non-controlled drugs and devices.

(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the pharmacy by one or a combination of the following methods:

(i) Return to manufacturer or supplier (credit or disposal);

(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or

(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (04/1/2022), 21 CFR 1304.22 (04/1/2022), 21 CFR 1317.05 (04/1/2022), 21 CFR 1317.90 (04/1/2022) and 21 CFR 1317.95 (04/1/2022).

(C) Provide the board a written notice of the closing on a board prescribed form which includes the following information:

(i) Date of closing to the public and discontinuance of the business;

(ii) Date and time the inventory of all prescription drugs and devices was conducted;

(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the pharmacy were transferred or disposed;

(iv) If drugs were destroyed, name and license numbers of individuals that who witnessed the destruction;

(v) If the pharmacy is registered to possess controlled substances, confirmation that the pharmacy complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2022) for discontinuing operation as a pharmacy that dispenses controlled substances.

(vi) The name, address and phone number of the pharmacy that took possession of the pharmacy records or the Oregon licensed Pharmacist who is serve as the custodian of pharmacy records which must be maintained according to OAR 855-041-1160;

(vii) Confirmation all pharmacy labels and blank prescriptions were destroyed;

(viii) Confirmation all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and

(ix) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.

(D) Once the pharmacy has notified the board that the pharmacy is permanently closed, the license may not be renewed. The pharmacy may apply for a new license as specified in OAR 855-041-1080.

(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.

(3) Emergency closing. If a Retail Drug Outlet pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, or other emergency circumstances and the Pharmacist-in-charge cannot provide notification as required in (1), the Pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

(4) Non-resident Retail Drug Outlet pharmacies are exempt from (1)-(3) and must follow laws and rules in the pharmacy's state of residence pertaining to temporary, permanent and emergency closures. The non-resident pharmacy must provide the board a written notice of the closing within 30 calendar days on a form prescribed by the board which includes the following information:

(a) Date of closing to the public and discontinuance of the business;

(b) If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or Oregon licensed Pharmacist who will serve as the custodian of records for Oregon patients to which the prescriptions, including refill information, and patient medication records were transferred; and

(c) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.

(5) The board may conduct an inspection to verify all requirements in subsection (1), (2), (3) and (4) of this section have been completed.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205, ORS 475.035
Statutes/Other Implemented: ORS 689.205

855-041-1145
New Containers

Each pharmacy must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022), and 16 CFR 1702 (01/01/2022).

[Publications: Publications referenced are available for review at the agency.]

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

855-041-7050
Definitions- Long Term Care Pharmacy

As used in OAR 855-041-7000 through 855-041-7080:

(1) "Long term care facility" means a facility with permanent facilities that include inpatient beds, providing medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the director, to provide treatment for two or more unrelated patients. "Long Term Care facility" includes skilled nursing facilities and intermediate care facilities but may not be construed to include facilities licensed and operated pursuant to ORS 443.400 to 443.455.

(2) For the purposes of Schedule II prescriptions in 21 CFR 1306.11 (04/01/2022), 21 CFR 1306.12 (04/01/2022), 21 CFR 1306.13 (04/01/2022), 21 CFR 1306.14 (04/01/2022), and 21 CFR 1306.15 (04/01/2022), the DEA definition of "long term care facility" as defined in 21 CFR 1300.01 (04/01/2022) includes "community-based care facilities."

(3) "Community Based Care Facility" means a home, facility or supervised living environment licensed or certified or otherwise recognized by an agency of the state of Oregon which provides 24-hour care, supervision, and assistance with medication administration. These include but are not limited to Adult Foster Homes, Residential Care Facilities (RCF), Assisted Living Facilities (ALF), Group Homes for the Developmentally Disabled and Mentally Retarded and Inpatient Hospice.

(4) "Pharmaceutical Care" means the responsible provision of any or all of the following services by the pharmacist:

(a) Develop and maintain policies and procedures for pharmaceutical services;

(b) Provide direction and oversight regarding all aspects of the acquisition, disposition, handling, storage, and administration of drugs including but not limited to the following:

(A) Receipt and interpretation of physician's orders;

(B) Ordering and receiving of medications;

(C) Handling of emergency drugs and supplies;

(D) Labeling of all drugs;

(E) Selection of drug delivery systems;

(F) Development of systems to provide timely delivery of drugs and supplies;

(G) Monitoring of drug storage conditions and expiration dates;

(H) Monitoring accuracy and efficiency of medication administration and compliance with physician's orders;

(I) Establishing and monitoring of appropriate record keeping;

(J) Accountability of controlled substances;

(K) Return, release, and/or destruction of discontinued or outdated drugs; and

(L) Compliance with state and federal laws and regulations related to pharmaceutical services and medication management.

(c) Provide training and in-service education to facility staff;

(d) Perform drug regimen review for each resident on a regularly scheduled basis for the purpose of promoting therapeutic appropriateness and achieving the desired drug therapy outcomes by identifying issues such as:

(A) Over-utilization or underutilization;

(B) Therapeutic duplication;

(C) Drug-disease contraindications;

(D) Drug-drug interactions;

(E) Incorrect drug, drug dosage or duration of drug treatment;

(F) Drug-allergy interaction;

(G) Clinical abuse/misuse;

(H) Untreated indication;

(I) Monitoring and assessing of drug therapy outcomes;

(e) Communicate effectively with residents' physicians and facility staff; and

(f) Participate in resident care planning.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

DIVISION 043
PRACTITIONER DISPENSING

855-043-0545
Dispensing Practitioner Drug Outlets- Dispensing and Drug Delivery

(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by the practitioner's licensing board.

(2) Drugs dispensed from the DPDO must be dispensed in compliance with the requirements of the practitioner's licensing board.

(3) A DPDO must comply with all requirements of State or federal law.

(4) A DPDO must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

(5) Dispensed drugs must be packaged by the DPDO, a pharmacy, or a manufacturer registered with the board.

(6) A DPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(7) A DPDO may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(8) The DPDO must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(9) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

855-043-0740
Community Health Clinic (CHC) – Dispensing and Drug Delivery

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.

(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.

(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.

(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.

(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

(7) Dispensed drugs must be packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the board.

(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(9) A CHC must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

(10) A CHC may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The CHC offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(11) The CHC must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(12) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient’s agent when the product is dispensed, unless an exemption applies.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

DIVISION 045
DRUG COMPOUNDING

855-045-0200
Application

(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for use or distribution in Oregon must register with the board as a drug outlet and comply with board regulations.

(2) These rules apply to sterile and non-sterile compounding of a drug.

(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:

(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (05/01/2020 v. 2014);

(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (05/01/2020 v. 2008);

(c) USP <800> Hazardous Drugs—Handling in Healthcare Settings (07/01/2020 v. 2020);

(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging (12/01/2020 v. 2020); and

(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2022), 1231 (12/01/2021), and 1821 (05/01/2017).

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

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

DIVISION 080
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0020
Schedules

Pursuant to ORS 475.005(6) those drugs and their immediate precursors classified in Schedules I through V under the Federal Controlled Substances Act, 21 USC 811 (03/20/2023), 21 USC 812 (03/20/2023) and as amended by the board pursuant to ORS 475.035 are the controlled substances for purposes of regulation and control under the Act. Those schedules are set out in OAR 855-080-0021 through 855-080-0026.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

855-080-0021
Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.11 (04/01/2022), and unless specifically exempt or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;

(b) Gamma-butyrolactone

(c) Methamphetamine, except as listed in OAR 855-080-0022;

(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)

(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.

(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,

(A) Methylmethcathinone (Mephedrone);

(B) Methylenedioxypyrovalerone (MDPV);

(C) Methylenedioxymethylcathinone (Methylone);

(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);

(E) Fluoromethcathinone (Flephedrone);

(F) 4-Methoxymethcathinone (Methedrone).

(2) Schedule I also includes any compounds in the following structural classes (2a–2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:
(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);

(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;

(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and

(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) is not an FDA approved drug or is exempted from the definition of controlled substance in ORS 475.005(6)(b)(A)-(E).

(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.

(5) Schedule I also includes any compounds in the following structural classes (a – b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Benzodiazepine class: A fused 1,4-diazepine and benzene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Clonazolam, Flualprazolam

(b) Thienodiazepine class: A fused 1,4-diazepine and thiophene ring structure with a phenyl connected to the 1,-4-diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Etizolam

(6) Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;

(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;

(c) The following substances per ORS 475.005(6)(b):

(A) The plant Cannabis family Cannabaceae;

(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;

(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;

(D) The seeds of the plant Cannabis family Cannabaceae; or

(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055 & ORS 475.065

855-080-0022
Schedule II

Schedule II consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.12 (04/01/2022) and any quantity of methamphetamine, when in the form of a FDA approved product containing methamphetamine, its salts, isomers, and salts of its isomers as an active ingredient for the purposes of currently accepted medical use.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055 & ORS 475.065

855-080-0023
Schedule III

Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.13 (04/01/2022); and products containing xylazine including its salts, isomers, and salts of isomers of xylazine as an active ingredient.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205 & ORS 475.973
Statutes/Other Implemented: ORS 475.035

855-080-0024
Schedule IV

Schedule IV consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.14 (04/01/2022), unless specifically excepted or listed in another schedule.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

855-080-0026
Schedule V

Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.15 (04/01/2022); and

(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.

(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.

(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active ingredient.

(4) In order to provide non-prescription pseudoephedrine or ephedrine to a purchaser, a pharmacy must:

(a) Store all pseudoephedrine and ephedrine behind the pharmacy counter in an area that is inaccessible to the public;

(b) Utilize an electronic system meeting the requirements under ORS 475.230;

(c) Train individuals who are responsible for providing pseudoephedrine or ephedrine to purchasers on the requirements of the Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177), the Combat Methamphetamine Enhancement Act of 2010, P.L. 111-268, and use of the electronic system as described in ORS 475.230;

(d) Ensure that only a Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician provides pseudoephedrine or ephedrine to the purchaser after:

(A) Verifying that the purchaser is 18 years of age or older;

(B) Verifying the identity of the purchaser with valid government-issued photo identification; and

(C) Confirming the purchase is allowed via the electronic system; and

(e) Maintain an electronic log for at least three years from the date of the transaction that documents the following elements:

(A) Date and time of the purchase;

(B) Name, address and date of birth of the purchaser;

(C) Form of government-issued photo identification and the identification number used to verify the identity of the purchaser;

(D) Name of the government agency that issued the photo identification in (C);

(E) Name of product purchased;

(F) Quantity in grams of product purchased;

(G) Name or initials of Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician who provides the drug; and

(H) Signature of the purchaser. The signature of the purchaser may be recorded on a written log that also contains the transaction ID generated by the electronic system.

(5) All sales of pseudoephedrine or ephedrine are subject to the following quantity limits and restrictions:

(a) No more than 3.6 grams in a 24-hour period, no more than 9 grams in a 30-day period without regard to the number of transactions; and

(b) For non-liquids, product packaging is limited to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches.

(6) Sections (4) and (5) do not apply to a pseudoephedrine or ephedrine when the drug is dispensed pursuant to a prescription.

(7) Each pharmacy, Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/2022), 21 CFR 1314.02 (04/01/2022), 21 CFR 1314.03 (04/01/2022), 21 CFR 1314.05 (04/01/2022), 21 CFR 1314.10 (04/01/2022), 21 CFR 1314.15 (04/01/2022), 21 CFR 1314.20 (04/01/2022), 21 CFR 1314.25, (04/01/2022); 21 CFR 1314.30 (04/01/2022), 21 CFR 1314.35 (04/01/2022), 21 CFR 1314.40 (04/01/2022), 21 CFR 1314.42 (04/01/2022), 21 CFR 1314.45 (04/01/2022); and 21 CFR 1314.50 (04/01/2022).

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205, ORS 475.230 & 2022 HB 4034
Statutes/Other Implemented: ORS 475.035, ORS 475.230 & 2022 HB 4034

855-080-0028
Excluded or Exempted Substances

(1) The board adopts the excluded substances list found in 21 CFR 1308.22 (04/01/2022).

(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/2022).

(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (08/22/2022) pursuant to 21 CFR 1308.32 (04/01/2022).
[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205 & ORS 475.035
Statutes/Other Implemented: ORS 689.155 & ORS 475.035

855-080-0031
Registration Requirements

(1) Every person who manufactures, delivers, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, delivery or dispensing of any controlled substance within this state must obtain a controlled substance registration annually issued by the State Board of Pharmacy.

(2) The board adopts the exceptions to registration for distribution by dispenser to another practitioner pursuant to 21 CFR 1307.11 (04/01/2022).

(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/2022).

[Publications: Publications referenced are available for review at the agency.]

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

855-080-0065
Security

(1) All applicants and registrants as applicable to the registration classification must comply with the security requirements of 21 CFR 1301.01 (04/01/2022), 21 CFR 1301.02 (04/01/2022), 21 CFR 1301.71 (04/01/2022), 21 CFR 1301.72 (04/01/2022), 21 CFR 1301.73 (04/01/2022), 21 CFR 1301.74 (04/01/2022), 21 CFR 1301.75 (04/01/2022), 21 CFR 1301.76 (04/01/2022), 21 CFR 1301.77 (04/01/2022), 21 CFR 1301.90 (04/01/2022), 21 CFR 1301.91 (04/01/2022), 21 CFR 1301.92 (04/01/2022), and 21 CFR 1301.93 (04/01/2022).

(2) The security requirements of (1) of this rule apply to all controlled substances, as defined in these rules, including ephedrine, pseudoephedrine, and phenylpropanolamine.

(3) Applicants and registrants must guard against theft and diversion of ephedrine, pseudoephedrine, and phenylpropanolamine.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.135 & ORS 475.125

855-080-0070
Records and Inventory

(1) All registrants must, as applicable to the registration classification, keep records and maintain inventories in compliance with 21 USC 827 (03/15/2022); 21 CFR 1304.01 (04/01/2021), 21 CFR 1304.02 (04/01/2022), 21 CFR 1304.03 (04/01/2022), 21 CFR 1304.04 (04/01/2022), 21 CFR 1304.05 (04/01/2022), 21 CFR 1304.06 (04/01/2022); 21 CFR 1304.11 (04/01/2022); 21 CFR 1304.21 (04/01/2022), 21 CFR 1304.22 (04/01/2022), 21 CFR 1304.23 (04/01/2022), 21 CFR 1304.24 (04/01/2022), 21 CFR 1304.25 (04/01/2022), 21 CFR 1304.26 (04/01/2022); 21 CFR 1304.31 (04/01/2022), 21 CFR 1304.32 (04/01/2022), 21 CFR 1304.33 (04/01/2022).

(2) A written inventory of all controlled substances must be taken by registrants annually within 367 days of the last written inventory.

(3) All such records must be maintained for a period of three years.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 475.035 & ORS 689.205
Statutes/Other Implemented: ORS 475.165

855-080-0075
Orders for Schedule I and II Controlled Substances

Controlled substances in Schedules I and II must be distributed by a registrant to another registrant only pursuant to an order form or electronic order in compliance with 21 USC 828 (03/20/2023) and 21 CFR 1305.01 (04/01/2022), 21 CFR 1305. 02 (04/01/20212, 21 CFR 1305.03 (04/01/2022), 21 CFR 1305.04 (04/01/2022), 21 CFR 1305.05 (04/01/2022), 21 CFR 1305.06 (04/01/2022), 21 CFR 1305.07 (04/01/2022); 21 CFR 1305.11 (04/01/2022), 21 CFR 1305.12 (04/01/2022), 21 CFR 1305.13 (04/01/2022), 21 CFR 1305.14 (04/01/2022), 21 CFR 1305.15 (04/01/2022), 21 CFR 1305.16 (04/01/2022), 21 CFR 1305.17 (04/01/2022), 21 CFR 1305.18 (04/01/2022), 21 CFR 1305.19 (04/01/2022), 21 CFR 1305.20 (04/01/2022); 21 CFR 1305.21 (04/01/2022), 21 CFR 1305.22 (04/01/2022), 21 CFR 1305.23 (04/01/2022), 21 CFR 1305.24 (04/01/2022), 21 CFR 1305.25 (04/01/2022), 21 CFR 1305.26 (04/01/2022), 21 CFR 1305.27 (04/01/2022), 21 CFR 1305.28 (04/01/2022), and 21 CFR 1305.29 (04/01/2022).

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.175

855-080-0085
Prescription Requirements

(1) Registrants, practitioners and Pharmacists as specified therein in the issuance, preparation, labeling, dispensing, recordkeeping and filing of prescriptions for controlled substances must comply with the provisions of 21 CFR 1306.01 (04/01/2022), 21 CFR 1306.02 (04/01/2022), 21 CFR 1306.03 (04/01/2022), 21 CFR 1306.04 (04/01/2022), 21 CFR 1306.05 (04/01/2022), 21 CFR 1306.06 (04/01/2022), 21 CFR 1306.07 (04/01/2022), 21 CFR 1306.08 (04/01/2022), 21 CFR 1306.09 (04/01/2022); 21 CFR 1306.11 (04/01/2022), 21 CFR 1306.12 (04/01/2022), 21 CFR 1306.13 (04/01/2022), 21 CFR 1306.14 (04/01/2022), 21 CFR 1306.15 (04/01/2022); 21 CFR 1306.21 (04/01/2022), 21 CFR 1306.22 (04/01/2022); 21 CFR 1306.23 (04/01/2022), 21 CFR 1306.24 (04/01/2022), 21 CFR 1306.25 (04/01/2022), 21 CFR 1306.27 (04/01/2022); and 21 CFR 1304.03(d) (04/01/2022).

(2) Controlled substances listed in 21 CFR 1308.15 (04/01/2022) as schedule V are prescription drugs.

(3) Pseudoephedrine and ephedrine may be:

(a) Provided to a patient without a prescription under ORS 475.230.

(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/2022), 21 CFR 1306.22 (04/01/2022); 21 CFR 1306.23 (04/01/2022), 21 CFR 1306.24 (04/01/2022), 21 CFR 1306.25 (04/01/2022), and 21 CFR 1306.27 (04/01/2022).

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.185 & ORS 475.188

DIVISION 139
REMOTE DISPENSING SITE PHARMACY

855-139-0145
Outlet: Closure- Temporary, Permanent and Emergency

(1) Temporary Closing. Unless subject to an exemption in OAR 855-139-0145(3), when a RDSP is temporarily closed to the public the RDSP must:

(a) Post notification of closure on each RDSP entrance as soon as the need to deviate from the posted hours is known by the RDSP, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the RDSP is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

(d) Federal and state holidays are exempt from the requirements of (1).

(2) Permanent Closing. If a RDSP is permanently closing to the public, the RDSP must:

(a) Prior to closing, the RDSP must comply with the following:

(A) Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:

(i) The last day the RDSP will be open;

(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(B) The notification must be made via:

(i) Distribution by direct mail or written notification with each prescription dispensed;

(ii) Public notice in a newspaper of general circulation, if available, in the area served by the RDSP; and

(iii) Posting a closing notice at each building and each RDSP entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).

(iv) In addition to (i), (ii) and (iii), the RDSP may also provide notification via email or text.

(C) Provide any new patients filling prescriptions during the 15-calendar day period prior to the RDSP closing with written notification that includes:

(i) The last day the RDSP will be open;

(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/2022).

(b) On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:

(A) Complete and document an inventory of all controlled substances.

(B) If the RDSP dispenses prescriptions:

(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed Pharmacist who will serve as the custodian of records;

(ii) Update the RDSP operating status with each electronic prescribing vendor; and

(iii) Remove all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications).

(c) After closing. Within 30 calendar days after the closing of the RDSP, the pharmacist-in-charge must:

(A) Complete and document an inventory of all non-controlled drugs and devices.

(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the RDSP by one or a combination of the following methods:

(i) Return to manufacturer or supplier (credit or disposal);

(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or

(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (4/1/2022), 21 1304.22 (4/1/2022), 21 CFR 1317.05 (4/1/2022), 21 CFR 1317.90 (4/1/2022) and 21 CFR 1317.95 (4/1/2022).

(C) Provide the board a written notice of the closing on a board prescribed form which includes the following information:

(i) Date of closing to the public and discontinuance of the business;

(ii) Date and time the inventory of all prescription drugs and devices was conducted;

(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the RDSP were transferred or disposed;

(iv) If drugs were destroyed, name and license numbers of individuals who witnessed the destruction;

(v) If the RDSP is registered to possess controlled substances, confirmation that the RDSP complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2022) for discontinuing operation as a RDSP that dispenses controlled substances.

(vi) If the RDSP dispenses prescriptions, the name, address and phone number of the RDSP or Oregon licensed Pharmacist who will serve as the custodian of records to which the prescriptions, including refill information, and patient medication records were transferred;

(vii) Confirmation all RDSP labels and blank prescriptions were destroyed;

(viii) Confirmation all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and

(ix) Confirmation that each registration certificate issued to the RDSP by the board has been mailed to the board office.

(D) Once the RDSP has notified the board that the RDSP is permanently closed, the license may not be renewed. The RDSP may apply for a new license as specified in OAR 855-139-0015.

(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.

(3) Emergency closing. If the RDSP is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the Pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

(4) The board may conduct an inspection to verify all requirements in subsection (1), (2), and (3) of this section have been completed.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.700
Statutes/Other Implemented: ORS 689.155, ORS 689.700

855-139-0350
Dispensing: Containers

Each pharmacy must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022), and 16 CFR 1702 (01/01/2022).
[Publications: Publications referenced are available for review at the agency.]

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

855-139-0460
Drugs and Devices: Take-back Program

(1) A RDSP that operates a drug take-back collection program or that participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered with the DEA as an authorized collector to collect controlled and non-controlled drugs for destruction.

(2) A RDSP that operates as a Drug Enforcement Agency (DEA) authorized collector must notify the board within 30 days of initiating or terminating the program and must establish and enforce policies and procedures, including but not limited to:

(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is accessible to the public, within view of the pharmacy counter and must not be located behind the pharmacy counter; and

(b) Provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation, and key accountability; and

(c) Personnel training and accountability.

(3) A RDSP must inform consumers to directly deposit drugs into the collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected.

(4) A RDSP must not dispose of drugs from pharmacy stock in a collection receptacle.

(5) The liner must be inserted and removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel.

(6) Liners that have been removed from a collection receptacle and immediately sealed must be directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution agent (such as registered UPS, FedEx, or USPS) or a reverse wholesaler registered with the DEA and the board.

(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to the board in writing within one day of discovery.

(8) A RDSP must maintain all drug disposal records for a minimum of 3 years.

(9) Authorized collectors are required to comply with the following federal and state laws:
(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236, ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;

(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370, and OAR 340-098-0390;

(c) 21 CFR 1317.30 (04/01/2022), 21 CFR 1317.35 (04/01/2022), 21 CFR 1317.40 (04/01/2022), 21 CFR 1317.55 (04/01/2022), 21 CFR 1317.60 (04/01/2022), 21 CFR 1317.65 (04/01/2022), 21 CFR 1317.70 (04/01/2022), 21 CFR 1317.75 (04/01/2022), 21 CFR 1317.80 (04/01/2022), and 21 CFR 1317.85 (04/01/2022); and

(d) 21 USC 822 (03/20/2023), 21 USC 822a (03/20/2023).

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218

DIVISION 141
PHARMACY PRESCRIPTION KIOSK

855-141-0350
Dispensing: Containers

Each PPK must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022), and 16 CFR 1702 (01/01/2022).

[Publications: Publications referenced are available for review at the agency.]

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

Divisions 019/020: Emergency Insulin; Pharmacist Prescriptive Authority (COVID-19 Monoclonal Antibody, COVID-19 Antiviral Protocols; Amends Protocol Compendium)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals COVID-19 Monoclonal Antibody & Antiviral protocols; Repeals Emergency Insulin rule and amends Protocol Compendium

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals statewide drug therapy management protocols for COVID-19 Monoclonal Antibody and COVID-19 Antiviral. Repeals OAR 855-019-0470 related to emergency insulin. Amends the Protocol Compendium with revisions to Continuation of Therapy now including emergency refills of insulin, Contraception, PEP, PrEP and Travel Medications as recommended by the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC).

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

COVID-19

● Determination of Public Health Emergency https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency

● Emergency Use Authorization of Medical Products and Related Authorities- https://www.fda.gov/media/97321/download

COVID-19 Monoclonal Antibody:

● REGEN-COV EUA- https://www.fda.gov/media/145610/download; https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs

COVID-19 Antiviral:

● Paxlovid EUA- https://www.fda.gov/media/155050/download

● Frequently Asked Questions on the Emergency Use Authorization for Paxlovid for Treatment of COVID-19- https://www.fda.gov/media/155052/download

References for Pharmacist Prescriptive Authority ORS 689.645, ORS 689.649, ORS 689.689

References for each protocol are included in the protocol.

Proposed Statewide Drug Therapy Management Protocol – Continuation of Therapy v. 06/2023

Proposed Statewide Drug Therapy Management Protocol – Contraception v. 06/2023

Proposed Statewide Drug Therapy Management Protocol – HIV Post-Exposure Prophylaxis (PEP) v. 06/2023

Proposed Statewide Drug Therapy Management Protocol – HIV Pre-Exposure Prophylaxis (PrEP) v. 06/2023

Proposed Statewide Drug Therapy Management Protocol – Travel Medications v. 06/2023

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 impact is unknown on how or who the removal of COVID-19 Monoclonal and COVID-19 Antiviral protocols may impact. By making treatment for continuation of therapy including emergency refills of insulin, contraception, PEP, PrEP and travel medications easily accessible to patients at their local pharmacy, it may improve access for patients who are not able to otherwise access these services.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public), Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government, or small businesses. Pharmacy stakeholders and the public may be impacted by these rules if utilized. Provision of formulary and protocol compendia prescribing services by a pharmacist/pharmacy is voluntary. The professional time to offer these services and comply with record keeping requirements may increase costs to the outlet, which may possibly be passed on to the public for prescribing services. Outlets will be required to establish and enforce policies and procedures and pharmacists must comply with the rules if they offer the services.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of the proposed rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The FDA Emergency Use Authorizations for COVID-19 Monoclonal Antibody and COVID-19 Antiviral changed, making them no longer appropriate for prescribing by Oregon pharmacists under OAR 855-020 . The statutorily mandated PHPFAC informed the content of the proposed draft protocols and proposed amendments to existing protocols.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Permanently repeals statewide drug therapy protocols for COVID-19 Monoclonal Antibody and COVID-19 Antiviral. COVID-19 Monoclonal Antibody- REGENCOV: REGEN-COV (casirivimab and imdevimab) is not currently authorized in any U.S. region. COVID-19 Antiviral- Paxlovid: Under Oregon state laws, pharmacists cannot diagnose. The current Paxlovid EUA requires a diagnosis to prescribe Paxlovid, which is not required in the Board's Paxlovid protocol (based on the EUA dated 10/27/2022) and appears to be preempted by federal law.

Repeals OAR 855-019-0470 related to Emergency Insulin which will now be located within the Continuation of Therapy statewide drug therapy management protocol.

Proposed amendments include revised protocol versions of Continuation of Therapy now including emergency refills of insulin, Contraception, PEP, PrEP, and Travel Medications as recommended by the PHPFAC.

DIVISION 19
PHARMACISTS

~~855-019-0470~~
~~Emergency Insulin~~

~~Emergency Insulin. A pharmacist who has completed a Board approved ACPE accredited training program may prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies, not including insulin pump devices, to a person who has evidence of a previous prescription from a licensed health care provider; in such cases, a pharmacist shall prescribe the lesser of a 30-day supply or the smallest available package size, and not more than three emergency refills and supplies in a calendar year.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: 2019 OL Ch. 95~~

DIVISION 20
PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0300
Protocol Compendium

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

(1) Continuation of therapy including emergency refills of insulin (v. 06/2023)

(2) Conditions

(a) Cough and cold symptom management

(A) Pseudoephedrine (v. 06/2021);

(B) Benzonatate (v. 06/2021);

(C) Short-acting beta agonists (v. 06/2021);

(D) Intranasal corticosteroids (v. 06/2021);

(b) Vulvovaginal candidiasis (VVC) (v. 06/2021);

(c) COVID-19 Antigen Self-Test (v. 12/2021);

(3) Preventative care

(a) Emergency Contraception (v. 06/2021);

(b) Male and female condoms (v. 06/2021);

(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT (v. 06/2022);

(d) Travel Medications (v. 06/2023);

(e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);

(f) HIV Pre-exposure Prophylaxis (PrEP) (v. 06/2023); and

(g) Contraception (v. 06/2023).

[Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689 & ORS 689.696

CONTINUATION OF THERAPY

Including Emergency Refills of Insulin

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Per ORS 689.696, a pharmacist may prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies to a person who has evidence of a previous prescription from a licensed health care provider.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe any non-controlled medication to a person who has evidence of a previous prescription from a licensed health care provider in order to:
  - Replace a damaged prescription therapy within the original duration of therapy; or
  - Extend a patient's current prescription therapy (same drug, dose and directions) to avoid interruption of treatment.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

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

PRESCRIBING PARAMETERS

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

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

PHARMACIST TRAINING/EDUCATION: None required.

Continuation of Therapy: Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

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

Background Information:

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

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

To Be Completed by a Pharmacist:

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

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

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

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

RPH Signature_____Date_____

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

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

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

RECOMMENDED REGIMEN:

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

COUNSELING POINTS:

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

Continuation of Therapy Prescription

Optional-May be used by pharmacy if desired

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

☐ Verified DOB with valid photo ID

Rx

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

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

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

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

Written Date: _____

Prescriber Name:_____Prescriber Signature: _____

Pharmacy Address:_____Pharmacy Phone: _____

Optional-May be used by pharmacy if desired

Patient Information
Continuation of Therapy

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

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

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

Follow-up and Next Steps

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

Provider Notification
Continuation of Therapy

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

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

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

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

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

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

_____
_____
_____
_____
_____

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

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

RPH Signature_____ RPH Name (Print)_____ Date: _____

Please contact us if you have any questions about the care provided to our mutual patient or if you would like to obtain additional information please contact the pharmacy. The prescription(s) was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-020-0300.

PREVENTIVE CARE

CONTRACEPTION – Oral, Transdermal Patch, Vaginal Ring and Injectable

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.689, a pharmacist may prescribe and administer injectable hormonal contraceptives and prescribe and dispense self-administered hormonal contraceptives.
- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe oral, vaginal ring, transdermal patch or injectable hormonal contraceptives for the prevention of pregnancy.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Contraception Patient Intake Form (pg. 2-3)
- Utilize the standardized Contraception Assessment and Treatment Care Pathway Form (pg. 4-8)
- Utilize the standardized Contraception Prescription Template *optional* (pg. 9)
- Utilize the standardized Contraception Provider Notification Form (pg. 10)
- Utilize the standardized Contraception Patient Visit Summary Form (pg. 11)

PHARMACIST TRAINING/EDUCATION:

- Completed a Board-approved and Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist.

REFERENCES:

- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2016). US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016. Retrieved from https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf
- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2020). Summary Chart of US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2020. Retrieved from https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf
- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2016). US Selected Practice Recommendations (US SPR) for Contraceptive Use, 2016. Retrieved from https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf

RESOURCES:

- CDC US MEC & US SPR App
- National Family Planning and Reproductive Health Association. (2020). Self-Administration of Injectable Contraception Retrieved from https://www.nationalfamilyplanning.org/file/documents---service-delivery-tools/NFPRHA---Depo-SQ-Resource-guide---FINAL-FOR-DISTRIBUTION.pdf

Contraception Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

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

Background Information:

1.	Have you previously had a contraceptive prescribed to you by a pharmacist? If yes, when was the last time a pharmacist prescribed a contraceptive to you?	□ Yes □ No ___/___/___
2.	What was the date of your last reproductive or sexual health clinical visit with a non-pharmacist?	___/___/___

Contraception History:

3.	Have you ever been told by a healthcare professional not to take hormones? -If yes, what was the reason? _____	□ Yes □ No
4.	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection?	□ Yes □ No
5.	Did you ever experience a bad reaction to using hormonal birth control? - If yes, what kind of reaction occurred? _____	□ Yes □ No
6.	Are you currently using any method of birth control including pills, patch, ring or shot/injection? - If yes, which one do you use? _____	□ Yes □ No
7.	Do you have a preferred method of birth control that you would like to use? - If yes, please check one: □ Oral pill □ Skin patch □ Vaginal ring □ Injection □ Other (IUD, implant)	□ Yes □ No

Pregnancy Screen:

8.	Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have you had no menstrual period since the delivery?	□ Yes □ No
9.	Have you had a baby in the last 4 weeks?	□ Yes □ No
10.	Did you have a miscarriage or abortion in the last 7 days?	□ Yes □ No
11.	Did your last menstrual period start within the past 7 days?	□ Yes □ No
12.	Have you abstained from sexual intercourse since your last menstrual period or delivery?	□ Yes □ No
13.	Have you been using a reliable contraceptive method consistently and correctly?	□ Yes □ No

Medical Health & History:

14.	What was the first day of your last menstrual period?	___/___/___
15.	Have you had a recent change in vaginal bleeding that worries you?	□ Yes □ No
16.	Have you given birth within the past 21 days? If yes, how long ago? _____	□ Yes □ No
17.	Are you currently breastfeeding?	□ Yes □ No
18.	Do you smoke cigarettes?	□ Yes □ No
19.	Do you have diabetes?	□ Yes □ No
20.	Do you get migraine headaches? If yes, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	□ Yes □ No □ Yes □ No □ N/A
21.	Are you being treated for inflammatory bowel disease?	□ Yes □ No
22	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	□ Yes □ No
23.	Have you ever had a heart attack or stroke, or been told you had any heart disease?	□ Yes □ No

Contraception Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

24.	Have you ever had a blood clot?	□ Yes □ No
25.	Have you ever been told by a healthcare professional that you are at risk of developing a blood clot?	□ Yes □ No
26.	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	□ Yes □ No
27	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	□ Yes □ No
28.	Have you had bariatric surgery or stomach reduction surgery?	□ Yes □ No
29.	Do you have or have you ever had breast cancer?	□ Yes □ No
30.	Have you had an organ transplant?	□ Yes □ No
31.	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	□ Yes □ No
32.	Do you have lupus, rheumatoid arthritis, or any blood disorders?	□ Yes □ No
33.	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)? - If yes, list them here: _____	□ Yes □ No
34.	Do you have any other medical problems or take any medications, including herbs or supplements? - If yes, list them here: _____ _____ _____	□ Yes □ No

Patient Signature_____Date_____

To Be Completed by a Pharmacist:

1. Blood Pressure Reading _____/_____ mmHg

2a. If contraception was prescribed/dispensed, please complete the following:

Drug: _____

Directions: _____

Quantity: _____

Refills:_____

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

2b. If contraception was administered, please complete the following:

Drug: _____

Directions: _____

Quantity: _____

Product/Lot: _____ Expiration: ___/___/_____

Injection Sites:

□ Depo-Provera CI - IM □ R deltoid or □ L deltoid

□ Depo-SubQ Provera- SQ in □ R anterior thigh or □ L anterior thigh or □ abdomen

Administration Time: ____:_____ AM/PM

3. Healthcare Provider (if known) contacted/notified of therapy Date _____/_____/_____

If contraception was not prescribed/dispensed/administered, please indicate reason(s) for referral:

_____

_____

_____

RPH Signature_____Date_____

Standardized Assessment and Treatment Care Pathway - Contraception

Algorithm A: Oral, Vaginal and Transdermal Contraception with Combined Hormonal Contraceptives (CHC) and Progestin Only Pills (POP). RPH must utilize Summary US MEC (v. 2020) & Full US MEC (v. 2016) to make determinations below. In Full US MEC, Appendix D contains classifications for CHCs and Appendix C contains classifications for POPs.

1) Background Information – Review Patient Intake Form Questions #1-2. Each patient must complete a new Patient Intake Form a minimum of every twelve months.

-Never prescribed contraception by RPH **-or-**
-Previously prescribed contraception by RPH **-and-**
had clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years

→ No Exclusion Criteria

-Never prescribed contraception by RPH **-or-**
-Previously prescribed contraception by RPH **-and-**
has not had clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years

→ Any Exclusion Criteria → Refer

2) Pregnancy Screen- Review Patient Intake Form #8-13

- If YES to AT LEAST ONE and is free of pregnancy symptoms → Patient is not pregnant

- If NO to ALL of these questions, pregnancy can NOT be ruled out → Patient is possibly pregnant → Refer

3) Medical and Medication History - Review Patient Intake Form #14-34 (and med list in pharmacy record). Evaluate medical health & history utilizing the US MEC. Evaluate medications utilizing the US MEC and any current references for drug-drug interactions with contraceptives.

- If ALL boxes are labeled 1 or 2 (green) on the US MEC for the type of contraception that RPH plans to prescribe (e.g., CHC, POP) → No Contraindicated Condition(s) or Medication(s)

-If ANY boxes are labeled 3 or 4 (pink/red) on the US MEC or a significant drug-drug or drug-disease interaction exists for the type of contraception that RPH plans to prescribe (e.g., CHC, POP) → Any Contraindicated Condition(s) or Medication(s) → Refer

4) Blood Pressure Screen:
Assess the patient's self-reported blood pressure or document the pharmacist's measurement of the patient's current blood pressure. Note: RPH may choose to take a second reading if initial report or measurement is **≥** 140/90

- CHC + BP < 140/90 **-or-** POP + Any BP
- CHC + BP **≥** 140/90 → Refer or consider POP or DMPA

5) Evaluate patient contraception history, preference, and current therapy for selection of treatment.

- Not currently on birth control

6a) Choose Contraception

- ***Initiate*** contraception based on patient preferences, adherence, and history for new therapy

- Currently on birth control

6b) Choose Contraception

- ***Continue*** current form of pills, ring or patch, if no change is necessary **-or-**
- ***Alter*** therapy based on patient concerns, such as side effects patient may be experiencing; or refer, if appropriate

- ***Prescribe and dispense*** up to 12 months of desired contraception product. This must be done as soon as practicable after the pharmacist issues the prescription and must include any relevant educational materials.
  ORS 743A.066 requires prescription drug benefit programs to reimburse for 3 months for the first dispensing and 12 months for subsequent dispensing of the same contraceptive.

7) Provide Counseling

- Address any unexplained vaginal bleeding that worries patient (Patient Intake Form #15) – Refer for further evaluation
- Address any high blood pressure - Refer for further evaluation
- Discuss the management and expectations of side effects (bleeding irregularities, etc.)
- Discuss initiation strategy for initial treatment/change in treatment (as applicable). For quick start - instruct patient they can begin contraceptive today; use backup method for 7 days
- Discuss adherence and opportunities for follow-up visits
- Encourage routine health screenings and STI prevention

8) Discuss and provide visit summary to patient and advise the patient to consult with a primary care practitioner or women's health care practitioner per ORS 689.689(2)(b)(D).

Standardized Assessment and Treatment Care Pathway - Contraception

Algorithm B: Injectable Contraception- Depot Medroxyprogesterone (DMPA). RPH must utilize Summary US MEC (v. 2020) & Full US MEC (v. 2016) to make determinations below. In Full US MEC, Appendix C contains classifications for DMPA.

1) Background Information – Review Patient Intake Form (Questionnaire) #1-2. Each patient must complete a new Patient Intake Form a minimum of every twelve months.

-Never prescribed contraception by RPH **-or-**
-Previously prescribed contraception by RPH **-and-**
had clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years

→ No Exclusion Criteria

-Never prescribed contraception by RPH **-or-**
-Previously prescribed contraception by RPH **-and-**
has not had clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years

→ Any Exclusion Criteria → Refer

2) Pregnancy Screen- Review questionnaire #8-13

- If YES to AT LEAST ONE and is free of pregnancy symptoms → Patient is not pregnant
- If NO to ALL of these questions, pregnancy can NOT be ruled out → Patient is possibly pregnant → Refer

3) Medical and Medication History - Review Patient Intake Form #14-34 (and med list in pharmacy record). Evaluate medical health & history utilizing the US MEC. Any unexplained vaginal bleeding that worries patient (Patient Intake Form #15) – requires a referral. Evaluate medications utilizing the US MEC and any current references for drug-drug interactions with contraceptives.

- If ALL boxes are labeled 1 or 2 (green) on the US MEC for the type of contraception that RPH plans to prescribe (e.g., CHC, POP) → No Contraindicated Condition(s) or Medication(s)
- If ANY boxes are labeled 3 or 4 (pink/red) on the US MEC or a significant drug-drug or drug-disease interaction exists for the type of contraception that RPH plans to prescribe (e.g., CHC, POP) → Any Contraindicated Condition(s) or Medication(s) → Refer

4) Blood Pressure Screen: Assess the patient's self-reported blood pressure or document the pharmacist's measurement of the patient's current blood pressure. Note: RPH may choose to take a second reading if initial report or measurement is **≥** 160/100.

- BP < 160/100
- BP **≥** 160/100 → Refer or consider POP

5) Discuss DMPA therapy and provide counseling

- Discuss the management and expectations of side effects (bleeding irregularities, etc.)
- Discuss plans for follow-up visits, particularly for every 3-month administration of DMPA.
  - Stress importance of returning for next injection within 11-13 weeks of previous injection.
  - Provide patient with specific calendar date range for next injection.
- Caution with use of DMPA > 2 years (due to loss of bone mineral density). For therapy > 2 years, consultation with healthcare provider is indicated.
- Encourage routine health screenings and STI prevention

- Initial dose of DMPA IM or SQ
- Follow-up (every) 3-month dose of DMPA IM or SQ

6a) *Prescribe* and *administer (IM or SQ) or dispense (SQ)* DMPA to the patient.

- Instruct patient that if this injection is not within 7 days of start of their period, then abstain or use backup method for 7 days.
- If *administering* DMPA IM or SQ, observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device. **-or-**
- If *dispensing* DMPA SQ for self-administration, the first self-administration must be observed by RPH or by appropriately trained and authorized HCP after providing the patient with educational materials that include step-by-step instructions for self-injection, as well as guidance on the proper disposal of needles. The patient may complete self-administration at home after the initial observation. **SEE NEXT PAGE ->**

6b) *Continue* current form of contraception, DMPA, if no change is necessary.

- Confirm that date of last injection or dispensing was within 11-15 weeks.
  - If > 15 weeks ago, then pharmacist must rule out pregnancy (repeat Step 2, and document), and instruct patient to abstain or use backup method for 7 days.
  - If between 11-15 weeks ago, administer or dispense the medication.
  - Do not administer or dispense if < 11 weeks ago.

-or-

***Alter* therapy based on patient concerns (see Algorithm A), such as side effects patient may be experiencing; or refer, if appropriate.**

SEE NEXT PAGE ->

Prescribe and administer up to 3 months ***or dispense*** up to 12 months of desired contraception product. This must be done as soon as practicable after the pharmacist issues the prescription and must include any relevant educational materials.
ORS 743A.066 requires prescription drug benefit programs to reimburse for 3 months for the first dispensing and 12 months for subsequent dispensing of the same contraceptive.

7) *Discuss* and *provide* visit summary to patient and *refer* the patient to the patient's primary care practitioner or women's health care practitioner per ORS 689.689(2)(b)(C).

Standardized Assessment and Treatment Care Pathway - Contraception

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

This summary sheet only contains a subset of the recommendations from the USMEC. It is color coded in the left column to match the corresponding question of the Contraception Patient Intake Form
For complete guidance, see: Summary US MEC (v. 2020) & Full US MEC (v. 2016)
Note: Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condom reduces the risk of STDs and HIV

Key:

1	No restriction (method can be used)	
2	Advantages generally outweigh theoretical or proven risks	
3	Theoretical or proven risks usually outweigh the advantages	
4	Unacceptable health risk (method not to be used)	

Corresponding to the Contraception Patient Intake Form:

Condition	Sub-condition	Combined pill, patch (CHC)		Progestin-only Pill (POP)		DMPA (Inj)		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	Initiating	Continuing	
a. Age		Menarche to <40=1		Menarche to <18=1		Menarche to <18=2		Yes
		≥40=2		18-45=1		18-45=1		Yes
				>45=1		>45=2		Yes
b. Smoking	a) Age < 35	2		1		1		Yes
	b) Age ≥ 35, < 15 cigarettes/day	3		1		1		Yes
	c) Age ≥ 35, ≥15 cigarettes/day	4		1		1		Yes
c. Pregnancy	(Not Eligible for contraception)	NA*		NA*		NA		NA*
d. Vaginal Bleeding	Unexplained or worrisome vaginal bleeding	2		2		3		Yes
e. Postpartum (see also Breastfeeding)	a) < 21 days	4		1		1		Yes
	b) 21 days to 42 days:							
	(i) with other risk factors for VTE	3*		1		1		Yes
	(ii) without other risk factors for VTE	2		1		1		Yes
	c) > 42 days	1		1		1		Yes
f. Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3/4*		2*		2*		Yes
	b) 30 days to 42 days							
	(i) with other risk factors for VTE	3*		2*		2*		Yes
	(ii) without other risk factors for VTE	2*		1*		1*		Yes
	c)> 42 days postpartum	2*		1*		1*		Yes
g. Diabetes mellitus (DM)	a) History of gestational DM only	1		1		1		Yes
	b) Non-vascular disease							
	(i) non-insulin dependent	2		2		2		Yes
	(ii) insulin dependent‡	2		2		2		Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		3		Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		3		Yes
h. Headaches	a) Non-migrainous	1*		1		1		Yes
	b) Migraine:							
	i) without aura (includes menstrual migraines)	2*		1		1		Yes
	iii) with aura	4*		1		1		Yes
i. Inflammatory Bowel Disease	a) Mild; no risk factors	2		2		2		
	b) IBD with increased risk for VTE	3						
j. Hypertension	a) Adequately controlled hypertension	3*		1*		2*		Yes
	b) Elevated blood pressure levels (properly taken measurements):							
	(i) systolic 140-159 or diastolic 90-99	3*		1*		2*		Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4*		2*		3*		Yes
	c) Vascular disease	4*		2*		3*		Yes
k. History of high blood pressure during pregnancy		2		1		1		Yes
l. Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function:							
	(i) < 6 months	4		1		1		Yes
	(ii) ≥ 6 months	3		1		1		Yes
	b) Moderately or severely impaired cardiac function	4		2		2		Yes
m. Multiple risk factors for arterial CVD	(such as older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	3/4*		2*		3*		Yes
n. Ischemic heart disease‡	Current and history of	4		2	3	3		Yes
o. Valvular heart disease	a) Uncomplicated	2		1		1		Yes
	b) Complicated‡	4		1		1		Yes
p. Stroke‡	History of cerebrovascular accident	4		2	3	3		Yes
q. Known Thrombogenic mutations‡		4*		2*		2*		Yes

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable
* Please see the complete guidance for a clarification to this classification: Full US MEC (v. 2016)
‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

CONTINUES NEXT PAGE →

Standardized Assessment and Treatment Care Pathway - Contraception

Condition	Sub-condition	Combined pill, patch (CHC)		Progestin-only Pill (POP)		DMPA (Inj)		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	Initiating	Continuing	
r. Deep venous thrombosis (DVT) & Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoag therapy							
	i) higher risk for recurrent DVT/PE	4		2		2		Yes
	ii) lower risk for recurrent DVT/PE	3		2		2		Yes
	b) Acute DVT/PE	4		2		2		Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months							
	i) higher risk for recurrent DVT/PE	4*		2		2		Yes
	ii) lower risk for recurrent DVT/PE	3*		2		2		Yes
	d) Family history (first-degree relatives)	2		1		1		Yes
	e) Major surgery							
	(i) with prolonged immobilization	4		2		2		Yes
	(ii) without prolonged immobilization	2		1		1		Yes
	f) Minor surgery without immobilization	1		1		1		Yes
s. Superficial venous disorders	a) Varicose veins	1		1		1		
	b) Superficial venous thrombosis (acute or history)	3*		1		1		
ll. Multiple Sclerosis	a) With prolonged immobility	3		1		2		Yes
	b)Without prolonged immobility	1		1		2		Yes
t. History of bariatric surgery‡	a) Restrictive procedures	1		1		1		Yes
	b) Malabsorptive procedures	COCs: 3	P/R: 1	3		1		Yes
u. Breast Disease & Breast Cancer	a) Undiagnosed mass	2*		2*		2*		Yes
	b) Benign breast disease	1		1		1		Yes
	c) Family history of cancer	1		1		1		Yes
	d) Breast cancer:‡							
	i) current	4		4		4		Yes
	ii) past/no evidence current disease x 5yr	3		3		3		Yes
v. Solid Organ Transplant	a) Complicated – graft failure, rejection, etc.	4		2		2		Yes
	b) Uncomplicated	2*		2		2		Yes
w. Viral hepatitis	a) Acute or flare	3/4*	2 C	1		1		Yes
	b) Carrier/Chronic	1	1	1		1		Yes
x. Cirrhosis	a) Mild (compensated)	1		1		1		Yes
	b) Severe‡ (decompensated)	4		3		3		Yes
y. Liver tumors	a) Benign:							
	i) Focal nodular hyperplasia	2		2		2		Yes
	ii) Hepatocellular adenoma‡	4		3		3		Yes
	b) Malignant‡ (hepatoma)	4		3		3		Yes
z. Gallbladder disease	a) Symptomatic:							
	(i) treated by cholecystectomy	2		2		2		Yes
	(ii) medically treated	3		2		2		Yes
	(iii) current	3		2		2		Yes
	b) Asymptomatic	2		2		2		Yes
aa. History of Cholestasis	a) Pregnancy-related	2		1		1		Yes
	b) Past COC-related	3		2		2		Yes
bb. Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4*		3*		3*	3*	Yes
	b) Severe thrombocytopenia	2*		2*		3*	2*	Yes
	c) Immunosuppressive treatment	2*		2*		2*	2*	Yes
	d) None of the above	2*		2*		2*	2*	Yes
cc. Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		2*		Yes
	(i) Long-term corticosteroid therapy					3		Yes
	b) Not on immunosuppressive therapy	2		1		2		Yes
dd. Blood Conditions & Anemias	a) Thalassemia	1		1		1		Yes
	b) Sickle Cell Disease‡	2		1		1		Yes
	c) Iron-deficiency anemia	1		1		1		Yes
ee. Epilepsy‡	(see also Drug Interactions)	1*		1*		1*		Yes
ff. Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*		1*		1*		Yes
	b) Pelvic	1*		1*		1*		Yes
gg. HIV	a) High risk for HIV	1		1		1*		Yes
	b) HIV infection	1*		1*		1*		Yes
	(i) On ARV therapy	If on treatment, see Drug Interactions						Yes
hh. Antiretroviral therapy (All other ARVs are a 1 or 2)	a) Fosamprenavir (FPV)	3		2		2		Yes
	(i) Fosamprenavir + Ritonavir (FPV/r)	2		2		1		Yes
ii. Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		1*		Yes
	b) Lamotrigine	3*		1		1		Yes
jj. Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		Yes
	b) Antifungals	1		1		1		Yes
	c) Antiparasitics	1		1		1		Yes
	d) Rifampin or rifabutin therapy	3*		3*		1*		Yes
kk. Supplements	a) St. John's Wort	2		2		1		Yes

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable

* Please see the complete guidance for a clarification to this classification: Full US MEC (v. 2016)

‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

Contraception Prescription

Optional-May be used by pharmacy if desired

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

Rx

☐ **Drug:** _____

- Directions: _____
- Quantity: _____
- Refills:_____

Written Date: _____

Prescriber Name:_____Prescriber Signature: _____

Pharmacy Address:_____Pharmacy Phone: _____

Provider Notification
Contraception

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

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

Your patient _____(name) _____/_____/_____ (DOB) was:

☐ **Prescribed and dispensed** contraception at our Pharmacy on ____/_____/_____ noted above. The prescription issued and dispensed consisted of:

- Drug: _____
  - Directions: _____
  - Quantity: _____
  - Refills:_____

☐ **Prescribed and administered** contraception at our Pharmacy on ____/_____/_____ noted above. The prescription issued and administered consisted of:

- Drug: _____
  - Directions: _____
  - Quantity: _____
  - Refills:_____

☐ **NOT prescribed, dispensed or administered** contraception at our Pharmacy noted above, because:

□ Pregnancy cannot be ruled out.

Notes: _____

□ The patient indicated they have a health condition than requires further evaluation.

Notes: _____

□ The patient indicated they take medication(s) or supplements that may interfere with contraception.

Notes: _____

□ Their blood pressure reading was _____/_____ :

□ ≥140/90 mmHg and I am unable to prescribe any combined hormonal contraceptive (estrogen + progesterone) pill, patch, or ring

□ ≥160/100 mmHg and I am unable to prescribe any injectable (progesterone only)

□ The patient did not have a clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years.

The prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-020-0300.

- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2016). US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016. Retrieved from https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf
- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2020). Summary Chart of US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2020. Retrieved from https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf
- Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. (2016). US Selected Practice Recommendations (US SPR) for Contraceptive Use, 2016. Retrieved from https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf

Pharmacist Referral and Visit Summary

CONTRACEPTION – Oral, Transdermal Patch, Vaginal Ring or Injectable

Pharmacy Name:_____ Pharmacist Name:_____

Pharmacy Address:_____

Pharmacy Phone: _____ Pharmacy Fax: _____

□ Today you were prescribed (and □ administered) the following hormonal contraception:

_____

Notes: _____

If you have a question, my name is _____.

Please review this information with your healthcare provider.

-- or --

□ I am not able to prescribe hormonal contraception to you today, because:

□ Pregnancy cannot be ruled out.

Notes: _____

□ You have a health condition than requires further evaluation.

Notes: _____

□ You take medication(s) or supplements that may interfere with contraception.

Notes: _____

□ Your blood pressure reading is _____/_____ :

□ ≥140/90 mmHg and I am unable to prescribe any combined hormonal contraceptive (estrogen + progesterone) pill, patch, or ring

□ ≥160/100 mmHg and I am unable to prescribe any injectable (progesterone only)

Each checked box requires additional evaluation by another healthcare provider. Please share this information with your provider.

□ You have not had a clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years.

Attention Pharmacy: This is a template document. Please feel free to customize it to your pharmacy, however you must retain all elements set forth by this template.

PREVENTIVE CARE

HIV POST-EXPOSURE PROPHYLAXIS (PEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe post-exposure prophylaxis (PEP) drug regimen.
- The prescribing Pharmacist is responsible for all laboratory tests ordered, resulted and reporting as required.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PEP Patient Intake Form (pg. 2)
- Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-5)
- Utilize the standardized PEP Prescription Template *optional* (pg. 6)
- Utilize the standardized PEP Patient Informational Handout (pg. 7)
- Utilize the standardized PEP Provider Fax (pg. 8)

PHARMACIST TRAINING/EDUCATION:

- Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

REFERENCES

- Updated Guidelines for Antiretroviral Postexposure Prophylaxis after Sexual, Injection drug use, or Other Non-occupational Exposure to HIV—United States, 2016. Accessed February 14, 2023. https://stacks.cdc.gov/view/cdc/38856
- Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post-exposure Prophylaxis. Accessed February 14, 2023. https://stacks.cdc.gov/view/cdc/20711
- PEP | HIV Basics | HIV/AIDS | CDC. Published July 11, 2022. Accessed February 14, 2023. https://www.cdc.gov/hiv/basics/pep.html

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

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

Background Information:

1.	Are you UNDER 13 years old?	□ Yes □ No
2.	Do you weigh LESS than 77 pounds (lbs)?	□ Yes □ No □ Not sure
3.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
4.	What was the date of the exposure?	___/___/___
5.	What was the approximate time of the exposure?	___:___ *AM/PM*
6.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
7.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____	□ Yes □ No □ Not sure
8.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
9.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	□ Yes □ No □ Not sure
10.	Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	□ Yes □ No □ Not sure
11.	Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	□ Yes □ No □ Not sure
12.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? □persons with known HIV infection □men who have sex with men with unknown HIV status □persons who inject drugs □sex workers	□ Yes □ No □ Not sure
13.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____	Yes □ No □ Not sure

Medical History:

14.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
15.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
16.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like a vaccine today? *Yes/No*	□ Yes □ No □ Not sure
17.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
18.	Are you currently pregnant?	□ Yes □ No □ Not sure
19.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
20.	Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	□ Yes □ No □ Not sure
21.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

1) PEP Eligibility- Review Patient Intake Form #1, 2

Is the patient < 13 years old[i]
Is the Patient <77 lbs[ii]

☐ **NO** → ☐ **YES** → Refer

2) CURRENT HIV STATUS and HIV TEST (HIV Ag/Ab test optional) Review Patient Intake form #14

☐ **NO** history of HIV
HIV Ag/Ab Test ☐ non-reactive ☐ decline

☐ **YES** has history of HIV → Refer
HIV Ag/Ab Test result ☐ reactive ☐ indeterminate[iii,iv,v] → Refer and Report

3) TIME OF EXPOSURE Review Patient Intake Form #4, 5
-PEP is a time sensitive treatment with evidence supporting use 72 hours from time of exposure

☐ **≤72 hours ago**

☐ **>72 hours ago** → Refer to ER

4) SEXUAL ASSAULT SURVIVOR? Review Patient Intake Form #6
If the patient experienced a sexual assault, continue with the algorithm and then refer the patient to the emergency department for a sexual assault workup.**

☐ **NO**

☐ **YES** → Refer for Sexual Assault Evaluation

5) CONNECTION TO FOLLOW-UP CARE[iii,v]
Connection to care is critical for future recommended follow-up

-Primary Care Provider ☐ **YES**
-Directly Refer to Public Health Department ☐ **YES**

☐ **NO** → Refer to ER

6) HIV ACQUISITION RISK
Consider calling the HIV Warmline (888) 448- 4911 for guidance if unclear

a) Source person is known to be HIV-positive?
Review Patient Intake Form #3

☐ **YES** → Go to b)

☐ **UNKNOWN** → Go to b)

☐ **NO** → Go to b)

Bodily Fluid Exposure Review Patient Intake Form #7, #11

b) Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membranes, or non-intact skin, or percutaneous (needlestick) contact with the following body fluids?

Substantial-risk fluid exposure
☐Blood
☐Semen
☐Vaginal secretions
☐Rectal secretions
☐Breast milk
☐Any body fluid that is visibly contaminated with blood

Substantial risk fluid exposure <u>if contaminated with blood</u>
(*Note: only applicable if not visibly contaminated with blood*):
☐Urine
☐Nasal Secretions
☐Saliva
☐Sweat
☐Tears

c) Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status? Review Patient Intake Form #6
-This type of exposure puts the patient at substantial risk for HIV acquisition

☐ **YES** → Go to #7

☐ **NO** → Go to d)

d) Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status? Review Patient Intake Form # 9,10

☐ **YES**: Please check all that apply
☐Was the source person known to be HIV-positive?
☐Were there cuts/openings/sores/ulcers on the oral mucosa?
☐Was blood present?
☐Has this happened more than once without PEP treatment?
☐None of the above
→ Go to #7

☐ **NO**
- Risk of acquiring HIV is low.

-PEP may be offered regardless of HIV acquisition risk
If clinical determination is to prescribe PEP,
→ Go to #7

7) Medical and Medication History
Patient <u>must be warm referred</u> to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV) Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

<table>
<tr><td colspan="3">Hepatitis B
Review Patient Intake Form #15, 16
- Truvada® (FTC/TDF) treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare
-Review the risks of hepatitis B exacerbation with PEP with the patient</td><td colspan="2">Renal Function
Review Patient Intake Form #17
-Truvada® (FTC/TDF) requires renal dose adjustment when the CrCl <50ml/min</td><td>Pregnant or Breastfeeding
Review Patient Intake Form #18,19
- Pregnancy is not a contraindication to receiving PEP treatment</td></tr>
<tr><td colspan="2">History of known Hepatitis B infection (latent or active)?</td><td colspan="2">Confirmation of being fully vaccinated for hepatitis B via ALERT-IIS</td><td>-Chronic Kidney Disease
-Reduced Renal Function</td><td>☐ NO ☐ YES</td></tr>
<tr><td>☐ NO
↓</td><td>☐ YES
Refer to ER →</td><td>☐ NO
-Offer vaccine if appropriate</td><td>☐ YES</td><td>☐ NO
↓</td><td>☐ YES
Refer to ER →</td><td>↓</td></tr>
<tr><td colspan="7">STEP 8: PRESCRIBE
• Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) one tablet by mouth daily for 30 days PLUS Isentress® (raltegravir400 mg) one tablet by mouth twice daily for 30 days
-or-
• Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) one tablet by mouth daily for 30 days PLUS Tivicay® (dolutegravir 50mg) once daily for 30 days</td></tr>
</table>

[i]According to the CDC PEP treatment guidelines, Truvada® (FTC/TDF) plus Isentress®(raltegravir) or Tivicay® (dolutegravir) is a preferred regimen for individuals 13 years and older.

[ii] Truvada® (FTC/TDF) dosing is approved to prevent HIV infection in adults and adolescents weighing at least 35 kg (77 lb)

[iii] Refer patient to local primary care provider, infectious disease specialist, or public health department.

[iv] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA

[v] County Health Department Directory
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

Oregon AIDS Education and Training Center List of PEP Resources, PEP Navigation Services, STI and HIV testing and treatment sites and community organizations: https://www.oraetc.org/pepresource-list

Consider calling the HIV Warmline (888) 448- 4911 for guidance.

RECOMMENDED REGIMEN:

Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) one tablet by mouth daily for 30 days

PLUS

Tivicay® (dolutegravir 50mg) one tablet by mouth once daily for 30 days

-or-

Isentress® (raltegravir 400 mg) one tablet by mouth twice daily for 30 days

Notes:

- There may be other FDA-approved regimens available for treatment of PEP.
- Although labeling is for 28-day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such.
- Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Tivicay® or Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com
- If the patient is breastfeeding, the benefit of prescribing PEP outweighs the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

COUNSELING POINTS:

- Truvada® (emtricitabine/tenofovir disoproxil fumurate):
  - Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset.
  - Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.
  - NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with Truvada.
- Tivicay® (dolutegravir):
  - Take the tablet once daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
  - Concomitant use with aluminum-magnesium antacids is contraindicated.
  - Tivicay® (dolutegravir) must be administered 2 hours before or 6 hours after other polyvalent cations, but can be administered at the same time as calcium or iron if taken with food.
  - Metformin coadministration can increase metformin concentrations. Monitor blood glucose and for metformin side effects
- Isentress® (raltegravir)
  - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
  - Isentress® (raltegravir) must be administered 2 hours before or 6 hours after other polyvalent cations.
  - Concomitant use is contraindicated with aluminum-hydroxide antacids
  - Calcium carbonate: no dose adjustment or separation is necessary
- Both medications (Truvada® **plus** Tivicay® or Isentress®) must be taken together to be effective and to prevent possible resistance.
- You must follow up with appropriate provider for lab work.
- Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.
- Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

*Oregon licensed pharmacists are mandatory reporters of child abuse (ORS Chapter 419B). Pharmacists should also report elder abuse and vulnerable adult abuse. Reports must be made to the Oregon Department of Human Services @ **1-855-503-SAFE (7233)**.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as HIV RNA or 4th generation HIV Antigen/Antibody, Hepatitis B serology, Hepatitis C antibody, SCr, AST/ALT, Syphilis, Chlamydia and Gonorrhea testing and pregnancy.
- The pharmacist will provide a written individualized care plan to each patient.
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

PEP Prescription

Optional-May be used by pharmacy if desired

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

Note: RPh must refer patient if exposure occurred >72 hours prior to initiation of medication

Rx

- Drug: emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada®)
  Sig: Take one tablet by mouth once daily in combination with Isentress for 30 days
  Quantity: #30
  Refills: none

-AND-

- Drug: dolutegravir 50mg (Tivicay®)
  Sig: Take one tablet by mouth once daily in combination with Truvada for 30 days.
  Quantity: #30
  Refills: none

-OR-

- Drug: raltegravir 400mg (Isentress®)
  Sig: Take one tablet by mouth twice daily in combination with Truvada for 30 days.
  Quantity: #60
  Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:
Lot:_____Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

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

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

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are the medications and directions you have been prescribed, some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

Medications: You must start these within 72 hours of your exposure

- Truvada® (emtricitabine/tenofovir disoproxil) 200 mg/300 mg – take 1 tablet by mouth daily for 30 days, **AND**
- Tivicay® (dolutegravir) 50mg - take 1 tablet by mouth once daily for 30 days, **OR**
- Isentress® (raltegravir) 400 mg – take 1 tablet by mouth twice daily for 30 days

Key Points

- Take every dose. If you miss a dose, take it as soon as you remember.
  - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking either medication without first asking your healthcare provider or pharmacist.
- Truvada®, Tivicay® and Isentress® are well tolerated by most people. The most common side effects (if they do happen) are stomach upset. Taking Truvada®, Tivicay®, and Isentress® with food can help with stomach upset. Over-the-counter nausea and diarrhea medications are okay to use with PEP if needed.
- Acetaminophen is the preferred over-the-counter pain medication. Avoid medications such as ibuprofen or naproxen while taking PEP.

Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you.
2. Our pharmacist will contact your healthcare provider (or public health office if you do not have a primary healthcare provider) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 4-6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
   - ☐ HIV RNA or HIV antigen/antibody
   - ☐ Kidney function - Serum creatinine (SCr)
   - ☐ Liver function- Alanine transaminase (ALT) and aspartate aminotransferase (AST)
   - ☐ Sexually transmitted diseases- Syphilis, Chlamydia and Gonorrhea
   - ☐ Pregnancy
4. If you think that you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-Exposure Prophylaxis (PrEP) after finishing PEP.

Provider Notification
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

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

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

Your patient _____(name) _____/_____/_____ (DOB) has been prescribed HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

This regimen consists of:

- Truvada® (emtricitabine/tenofovir disoproxil) 200/300mg tablets - one tab by mouth daily for 30 days **AND**
- Tivicay® (dolutegravir) 50mg - take 1 tablet by mouth once daily for 30 days, **OR**
- Isentress® (raltegravir) 400mg tablets - one tab by mouth twice daily for 30 days.

This regimen was initiated on _____(Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

Provider pearls for HIV PEP:

- Truvada® needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Truvada®, Tivicay®, and Isentress® are safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with Truvada.
- Truvada® is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-Exposure Prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs after the initiation of HIV PEP:

Test	Baseline	4-6 weeks after exposure	3 months after exposure
HIV RNA or HIV antigen/antibody	x	x	x
Hepatitis B serology	x	-	-
Hepatitis C antibody	x	-	-
Serum creatinine	x	x	-
Alanine transaminase, aspartate aminotransferase	x	x	-
For Sexual Exposure Only			
Syphilis, gonorrhea, chlamydia testing	x	x	-
Pregnancy	x	x	-

Exposed person should be tested again at 6 months for hepatitis B serology and hepatitis C antibody, if they are susceptible to hepatitis B and hepatitis C, respectively. Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status at 6 months.

If you have further questions, please contact the prescribing pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.

PREVENTIVE CARE

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a Pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Following all elements outlined in OAR 855-020-0110, a Pharmacist licensed and located in Oregon may prescribe pre-exposure prophylaxis (PrEP) drug regimen.
- The prescribing Pharmacist is responsible for all laboratory tests ordered, resulted and for reporting as required.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PrEP Patient Intake Form (pg. 2-3)
- Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-8)
- Utilize the standardized PrEP Prescription Template *optional* (pg. 9)
- Utilize the standardized PrEP Provider Fax (pg.10)

PHARMACIST TRAINING/EDUCATION:

- Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

REFERENCES

- Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2021 Update. Accessed February 14, 2023. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
- PrEP | HIV Basics | HIV/AIDS | CDC. Published July 11, 2022. Accessed February 14, 2023. https://www.cdc.gov/hiv/basics/prep.html

ORAL Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Patient Information

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

Name on Documents_____ Name _____

Sex Assigned at Birth (circle) M / F / Intersex Gender:_____ Are you transgender? (circle) Y/N/_____

Pronouns: She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, _____

Street Address _____

Phone ( ) _____ Email Address _____

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

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

Any allergies to medications? Yes / No If yes, please list _____

Background Information: These questions are highly confidential and help the pharmacist to determine if ORAL PrEP may benefit you, be safe for you, and what lab screenings are recommended before starting or continuing on PrEP.

Section 1: Reason for HIV Pre-Exposure Prophylaxis (PrEP) and Eligibility

You do not have to indicate reason; please review and answer the question at the bottom of this box: ▪ I want to start PrEP ▪ I want to keep taking PrEP ▪ I had sex in the past 6 months ▪ I do not always use condoms when I have sex ▪ I had gonorrhea, chlamydia, or syphilis in the past 6 months ▪ I have had sex with someone living with HIV ▪ I have had sex with one or more partners and did not know their HIV status ▪ I injected drugs in the past 6 months ▪ I shared injection equipment (any)	
1a. Is your answer YES to one of the above statements?	☐ Yes ☐ No ☐ Unsure
1b. Are you UNDER 13 years old?	☐ Yes ☐ No
1c. Do you weigh LESS than 77 pounds (35 kg)?	☐ Yes ☐ No

Section 2: HIV Testing, PrEP, and HIV Post-Exposure Prophylaxis (PEP) Histories; Acute HIV Symptom Review

2a. Have you ever had a positive, reactive, detected, or indeterminate test for HIV?	☐ Yes ☐ No
2b. Have you had any of the following in the last 4 weeks: fever, feeling very tired, muscle or joint aches or pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms?	☐ Yes ☐ No
2c. Are you taking PrEP now or in the past? • If now, which PrEP medicine?_____. Skip question 2d and continue to question 2e. • If in the past, what was your reason for stopping? _____	☐ Yes ☐ No
2d. Are you currently finishing a course of PEP after a possible HIV exposure?	☐ Yes ☐ No
2e. When was your last sex, injection drug use, or other possible exposure to HIV?	☐ Less than 72 hours (3 days) ago ☐ More than 72 hours (3 days), but less than 4 weeks ago ☐ More than 4 weeks ago

ORAL Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Section 3: Brief Medical History to Determine Which PrEP Medication May Be Best for You

3a. Have you been told you have kidney disease (e.g. kidney failure, poor kidney function)?	☐ Yes ☐ No
3b. Have you been told you have a bone disease (e.g. osteoporosis, osteopenia, low bone mineral density, etc.?	☐ Yes ☐ No
3c. Have you ever had Hepatitis B infection? --Have you been vaccinated for Hepatitis B? If Yes, Date(s): #1 ___/___/___ #2 ___/___/___ #3 ___/___/___ If No, do you want to start the Hepatitis B vaccination today?	☐ Yes ☐ No ☐ Unsure ☐ Yes ☐ No ☐ Unsure ☐ Yes ☐ No
3d. Are you pregnant, breastfeeding or planning to become pregnant? --If no, what are you using to prevent pregnancy? _____	☐ Yes ☐ No ☐ Does not apply

3e. Please list the names of other prescriptions (medicines), over-the-counter, herbal, or supplement products that you take so that the pharmacist can check for drug interactions with PrEP. Please note doses and use of any non-steroidal anti-inflammatory medicines (NSAIDS): ibuprofen (Advil/Motrin), naproxen (Aleve), meloxicam, celecoxib, diclofenac and any estradiol containing gender-affirming hormone medicines:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

3f. Please list any other questions or medical concerns you would like to the pharmacist to know:

Section 4: What to Expect on Oral PrEP

The biggest risks of PrEP are:

1. Starting PrEP when you do not know that HIV is already there **and**
2. Staying on PrEP after contracting HIV. PrEP medicines are also used to *treat* HIV, but it's not full treatment. If someone starts the PrEP medicine while living with HIV -*or*- contracts HIV while taking PrEP, then the medicines in PrEP might not work for treatment.

Please be aware that:

1. HIV testing must be done every 3 months while taking PrEP. The pharmacist must document a negative HIV test result within the last 7 days before prescribing PrEP. If that is the only lab result available, then the pharmacist can only prescribe up to a 30-day supply until other labs are done. When all needed lab results are given to the pharmacist, then the pharmacist may be able to prescribe up to a 90-day supply each time.
2. Screenings for gonorrhea, chlamydia, and syphilis must be done at least every 6 months while taking PrEP. Undiagnosed sexually transmitted infections (STIs) may increase the risk of contracting HIV, even while you are taking PrEP, and PrEP does NOT protect against other STIs. Screening for gonorrhea and chlamydia must be done at each possible site of exposure via urine (genital) and swab (throat and rectum) collections.
3. Missing doses of PrEP increases the risk of contracting HIV. PrEP works the best when taken AS DIRECTED by the pharmacist. Please talk to your pharmacist if you are having trouble taking your PrEP and/or getting labs done.

Patient Signature:_____ Date:_____

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

ALGORITHM A: PrEP INITIATION

1) PrEP INDICATION AND ELIGIBILITY
- Review Patient Intake Form Questions #1a, 1b & 1c

Is the patient < 13 years old[i] Is the Patient < 77 lbs[ii] ☐ **NO**	☐ **YES** → Refer

2a) CURRENT HIV STATUS
- Review Patient Intake Form #2a and HIV test results

☐ **NO** history of HIV	☐ **YES** has history of HIV → Refer

2b) HIV TEST
- HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive
*HIV Ag/Ab blood test must be RESULTED within 7 days prior to prescribing and dispensing

- HIV RNA test resulted: □ detected □ indeterminate □ not detected □ result pending □ none
May order HIV RNA at initial intake (preferred) and as appropriate thereafter

☐ **NO** current HIV HIV Ag/Ab Test non-reactive HIV RNA Test not detected	☐ **YES** possibly living with HIV HIV Ag/Ab Test result reactive or indeterminate HIV RNA Test result detected or indeterminate •A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A) → Refer and Report

3) ASSESS FOR POSSIBLE HIV AQUISITION WITHIN THE PAST 4 WEEKS
-Review Patient Intake Form #2b, 2c, 2d, and 2e
•Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms.
•Could have acute HIV with negative screening HIV Ag/Ab result
-Consider calling the HIV Warmline (888) 448- 4911 for guidance if unclear

Time of last potential exposure:	☐ **≤ 72 hours**	☐ **>72 hours to ≤ 4 weeks**		☐ **> 4 weeks**
Symptoms of possible acute HIV infection:	HIV Post-Exposure Prophylaxis (PEP) → PEP Protocol	☐ **NO symptoms** -Eligible for up to a 30-day supply of PrEP -Order HIV RNA test now -Counsel on acute retroviral syndrome symptoms	☐ **YES symptoms** (Communication Example B) → Refer	

4) MEDICAL and MEDICATION HISTORY
- Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f

Kidney Disease - Review Patient Intake form #3a		**Bone Mineral Density** - Review Patient Intake form #3b		**Hepatitis B Status** - Review Patient Intake Form #3c •Tenofovir disoproxil fumarate 300mg/Emtricitabine 200mg (Truvada®) and Tenofovir alafenamide 25mg/Emtricitabne 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare. • People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.		**Pregnancy** - Review Patient Intake form #3d	**Medication** - Review Patient Intake form # 3e, 3f
☐ **YES** → Refer	☐ **NO**	☐ **YES** → Refer	☐ **NO**	Hepatitis B History → Refer	Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via ALERT IIS ☐ **YES**	☐ **NO** -Offer Hep B Vaccine series. -Order Hep B Surface Antigen (see Table 1)	Pregnancy and breastfeeding are not contraindications for PrEP. → Refer PRN	Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density. • Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

5) LABORATORY RESULTS- See Appendix A for detailed information on labs	
-Hepatitis B Vaccine series	□ completed
or	
-Hepatitis B serologies resulted:	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Serum creatinine	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Syphilis/Treponemal antibody	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Gonorrhea/Chlamydia	□ resulted, ok for protocol □ resulted, needs referral □ no result yet
Are all required Baseline labs resulted (Tables 2 and 3 below)?	□ **YES** □ **NO**

6) DETERMINE DURATION OF PrEP PRESCRIPTION	
-Required BASELINE labs resulted?	□ **YES** □ **NO**
-Was last possible exposure to HIV > 4 weeks ago (Patient intake Form #2e, Step 3 above)?	□ **YES** □ **NO**
If **YES**, - RPH may prescribe PrEP for up to a **90- day** supply	If **NO**, - RPH may prescribe PrEP for up to a **30-day** supply - Patient needs to complete all required labs within 30 days by the next refill

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

ALGORITHM B: PrEP CONTINUATION

1) HIV TEST

HIV Ag/Ab Test resulted* □ reactive □ indeterminate □ non-reactive
*HIV Ag/Ab must be RESULTED within 7 days prior to prescribing and dispensing

HIV RNA test resulted □ detected □ indeterminate □ not detected □ result pending □ none
May order HIV RNA as appropriate

HIV Ag/Ab Test non-reactive HIV RNA Test not detected	HIV Ag/Ab Test result reactive or indeterminate HIV RNA Test result detected or indeterminate •A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A) Refer & Report

2) ASSESS FOR POSSIBLE ACUTE HIV INFECTION WITHIN THE PAST 4 WEEKS

Review Patient Intake form #2b, 2c, 2d, 2e
•Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms.
•Could have acute HIV with negative screening HIV Ag/Ab result
-Consider calling the HIV Warmline (888) 448- 4911 for guidance

☐ **No symptoms**	☐ **Symptoms** -Eligible for PrEP for up to a 30-day supply. -Order HIV RNA and repeat HIV Ag/Ab within 7 days of the next prescription -Counsel on acute retroviral syndrome -May refer (See Communication Example C) Refer PRN

3) MEDICAL and MEDICATION HISTORY
- Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f

Kidney Disease - Review Patient Intake form #3a	**Bone Mineral Density** - Review Patient Intake form #3b	**Hepatitis B Status** Review Patient Intake Form #3c, 3d -Counsel about the risk of Hep B flare if stopping PrEP if living with an unknown previous or current Hep B infection. •Tenofovir disoproxil fumarate 300mg/Emtricitabine 200mg (Truvada®) and Tenofovir alafenamide 25mg/Emtricitabne 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare. • People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.	**Pregnancy** Review Patient Intake form #3e	**Medication** Review Patient Intake form # 3f

☐ **YES**	☐ **NO**	☐ **YES**	☐ **NO**	Hepatitis B History ☐ **YES**	Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via ALERT IIS ☐ **YES**	☐ **NO** -Offer Hep B Vaccine series.	Pregnancy and breastfeeding are not contraindications for PrEP.	Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density. • Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.
Refer		Refer		Refer			Refer PRN	

4) LABORATORY RESULTS- See Appendix B for detailed information on labs

-See **Table 1: REQUIRED PrEP Labs**
-Serum creatinine □ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Syphilis/Treponemal antibody □ resulted, ok for protocol □ resulted, needs referral □ no result yet
-Gonorrhea/Chlamydia □ resulted, ok for protocol □ resulted, needs referral □ no result yet

- Required PrEP Continuation labs resulted ? □ YES □ NO

5) DETERMINE DURATION OF PrEP PRESCRIPTION

-Required BASELINE labs resulted? □ YES □ NO

If **YES**, - RPH may prescribe PrEP for up to a **90- day** supply	If **NO**, - RPH may prescribe PrEP for up to a **30-day** supply - Patient needs to complete all required labs within 30 days by the next refill

RECOMMENDED REGIMENS:

Note: There are other FDA-Approved medications available and may be other dosing strategies for PrEP. Daily dosing of emtricitabine / tenofovir DF (Truvada®) and emtricitabine / tenofovir alafenamide (Descovy®) are the only regimens permitted for pharmacist prescribing at this time.

Emtricitabine/Tenofovir DF (F/TDF; Truvada®):	**Emtricitabine/Tenofovir alafenamide(F/TAF; Descovy®):**
Dose: 200/300 mg once daily	**Dose:** 200/25 mg once daily
FDA-Approved for: all HIV exposure risk indications	**FDA-Approved for**: use by men and transgender women only **Not recommended for**: HIV risk via vaginal sex or if injection substance use is the only HIV risk
Preferred if: pregnancy/breastfeeding, vaginal exposure risks, substance use risks	**Preferred if**: renal insufficiency, risk of renal insufficiency (e.g. uncontrolled hypertension or uncontrolled blood glucose), and/or bone density concerns for men or transgender women ONLY
Not preferred if: concomitant nephrotoxic medications, or risks for/known renal insufficiency or osteopenia/osteoporosis	
Cost: available as a generic, lower-cost option	**Cost:** no generic, may require prior authorization, patient may be eligible for manufacturer assistance program -or- copay card

COMMUNICATION EXAMPLES:

Example A Reactive, positive, indeterminate, -or- detected result for: HIV Ag/Ab -or- HIV RNA	Your HIV test is [reactive, positive, -or- indeterminate]. This is not a diagnosis of HIV infection, but you do need further testing to confirm if this is a true result. Do you want to go to your Primary Care Provider, urgent care clinic, county health department, or an HIV specialist for further evaluation? It is important that you STOP taking PrEP now as it is an incomplete treatment for HIV and can lead to drug resistance in the future. Until you know your HIV test results/status, please use condoms during sex and/or use sterile injection equipment, not share with others. You may start PrEP again with a PrEP provider if it is determined that this was a false result and you do NOT have an HIV infection. I can help you make an appointment for further evaluation.
Example B Concerns for acute HIV infection NOT on PrEP	Based on the [symptoms AND last possible exposure to HIV] that you reported, there is a chance that this is a sign of a recent HIV infection. These symptoms are also general and could be related to the flu, COVID19, or another viral illness. I would like to recheck the regular HIV screening test and add another test that looks directly for the virus before we can START PrEP. These tests should be done at 2 to 4 weeks after your possible exposure. I cannot prescribe PrEP today, but we can get you started once we have these other lab results. You should also consider if you want to see your PCP, PrEP provider, or urgent care clinic for evaluation, possible other viral illness testing, and follow-up of your symptoms. They could also start you on PrEP if they decide it's appropriate to start now. Please let me know if you want a referral and/or would like me to refer you to a community organization[1] that can help link you to care and evaluation.

Continued on next page →

Example B Concerns for acute HIV infection ON PrEP	Based on the [symptoms AND last possible exposure to HIV] that you reported, there is a chance that this is a sign of recent HIV infection. These symptoms are also very general and could be related to the flu, COVID19, or another viral illness. I would like to screen for HIV and add another test that looks directly for the virus. These should be done at 2 to 4 weeks after your possible exposure. While we wait for those lab results, I can prescribe up to a 30-day supply for this refill. You should also consider if you want to see your PCP, PrEP provider, or urgent care clinic for evaluation, possible other viral illness testing, and follow-up of your symptoms. Please let me know if you want a referral and/or would like me to refer you to a community organization[1] that can help link you to care and evaluation.
Example D Reactive, positive, -or- indeterminate result for: Gonorrhea -or- Chlamydia -or- Syphilis	There were [reactive, positive, -or- indeterminate] results for [gonorrhea, chlamydia, and/or syphilis]. This is not a diagnosis of [gonorrhea, chlamydia, and/or syphilis], but you need further evaluation and possibly testing to confirm if this is a true result. Please keep taking your PrEP, do not stop PrEP. Please use condoms during sexual activity until you have been evaluated and/or treated by a clinical provider. I can help you make an appointment for further evaluation/treatment to a Primary Care Provider, urgent care clinic, or county health department.

Table 1: PrEP Laboratory Requirements

REQUIRED:

Lab Data	BASELINE	In 1 month	Every 3 months	Every 6 months	Every 12 months
HIV Ag/Ab 4th generation test	X Required within 7 days before the start	X If first prescription is for 30 days	X Within 7 days before each new prescription		
HIV RNA[1]	X		X		
Hepatitis B -Review vaccine Status and serologies	X				
Chlamydia Screening	X		X MSM/TGW	X	
Gonorrhea Screening	X		X MSM/TGW	X	
Syphilis Screening	X		X MSM/TGW	X	
SCr and calculated creatinine clearance	X			X If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start	X
OPTIONAL:					
Hepatitis C Ab *	X MSM/TGW, PWID		X PWID	X PWID	X MSM/TGW, PWID
HCG pregnancy test*	X				

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1]HIV RNA is highly recommended at baseline, especially in certain situations, and if symptoms of possible acute retroviral syndrome develop while taking PrEP. It is recommended every 3 months as part of PrEP monitoring however, it is not a required test and should not be a barrier to prescribing PrEP.

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

APPENDIX A- ALGORITHM A: PrEP INITIATION 4) LABORATORY- Required Baseline Labs

Hepatitis B Status

-Confirm vaccination or order lab at intake only
-Counsel about the risk of Hep B flare if stopping PrEP if living with an unknown previous or current Hep B infection.
-Do not start PrEP if has current Hepatitis B infection
Please see: https://www.cdc.gov/hepatitis/HBV/PDFs/serologicChartv8.pdf for further information

Step 1:**Hepatitis B Vaccine** □ YES	•Confirmation of being fully vaccinated for hepatitis B via ALERT • Attempt to obtain past Hep B surface antibody result to confirm protection after completion of vaccine series or order to check Negative Hep B Surface
□ NO	•Lack of vaccination is not a contraindication for PrEP •Counsel on risk factors for Hepatitis B and recommend vaccination. OAR 855-019-0280.
Step 2: Hepatitis B surface antigen If no Hep B Vaccination, order Hepatitis B serologies □ non-reactive all OR only surface antiGEN and core antiBODY	□ reactive or indeterminate surface AntiGEN or core AntiBODY Refer and Report

Renal Function Status

Order lab at intake and annually thereafter If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start, order every 6 months

□ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ CrCl < 30 mL/min	□ CrCl is < 60 ml/min, do NOT use F/TDF • Consider F/TAF (Descovy®) in cis-gender men and TGW with risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min.
	□ CrCL is < 60 ml/min AND not a candidate for F/TAF (i.e., vaginal sex is an HIV exposure risk) * -or- □ CrCL is < 30 ml/min* Refer • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease

Syphilis/Treponemal Antibody Order lab at initial intake and every 90-180 days depending on risk. [5]Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) □ non-reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D above) Refer & Report [1,2]
Gonorrhea, and Chlamydia Screenings Order lab at initial intake and every 90-180 days depending on risk. Patients can determine which sites need to be screened. Urinalysis test result: □ reactive □ indeterminate □ non-reactive Pharyngeal test result: □ reactive □ indeterminate □ non-reactive Rectal test result: □ reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = - Pharmacist may proceed in prescribing PrEP (see Communication Example D above) Refer & Report [1,2]
Hepatitis C Ab----Optional Recommended for: -MSM minimum annually -TGW minimum annually -PWID every 3 to 6 months □ reactive □ indeterminate □ non-reactive	□ reactive, positive, detected or indeterminate Pharmacist may proceed with prescribing PrEP Refer & Report [1,2]
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	□ Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP Refer to PCP or OB

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA.

[2] County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

APPENDIX B- ALGORITHM B: PrEP CONTINUATION 4) LABORATORY- Required Baseline Labs

Renal Function Status

Order lab at intake and annually thereafter If ≥ 50 yrs old -or- eCrCl < 90 ml/min at PrEP start, order every 6 months

□ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ CrCl < 30 mL/min	□ CrCl is < 60 ml/min, do NOT use F/TDF • Consider F/TAF (Descovy®) in cis-gender men and TGW with risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min.
	□ CrCL is < 60 ml/min AND not a candidate for F/TAF (i.e., vaginal sex is an HIV exposure risk) * -or- □ CrCL is < 30 ml/min* -• Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease Refer

Syphilis/Treponemal Antibody Order lab at initial intake and every 90-180 days depending on risk. [5]Non-treponemal test (such as RPR) -or- treponemal test (such as FTA-ABS) □ non-reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D above) Refer & Reort [1,2]
Gonorrhea, and Chlamydia Screenings Order lab at initial intake and every 90-180 days depending on risk. Patients can determine which sites need to be screened. Urinalysis result: □ reactive □ indeterminate □ non-reactive Pharyngeal test result: □ reactive □ indeterminate □ non-reactive Rectal test result: □ reactive □ indeterminate □ non-reactive	□ reactive or indeterminate = -Pharmacist may proceed in prescribing PrEP (see Communication Example D above) Refer & Report [1,2]
Hepatitis C Ab----Optional Recommended for: -MSM minimum annually -TGW minimum annually -PWID every 3 to 6 months □ reactive □ indeterminate □ non-reactive	□ reactive, positive, detected or indeterminate Pharmacist may proceed with prescribing PrEP Refer & Report [1,2]
HCG Pregnancy Test—Optional Recommended for: Persons who may become pregnant Frequency: Every 3 to 12 months per patient preference and pharmacist clinical judgment	□ Positive = Refer to PCP or OB Pharmacist may proceed with prescribing PrEP Refer to PCP or OB

MSM = men who have sex with men; TGW = transgender women; PWID = People who inject drugs

[1] Lab Reporting: The disease reporting poster for clinicians summarizes rules and lists the diagnoses for which lab-confirmed and clinically suspect cases must be reported within one working day to the Local Public Health Authority (LPHA). People reporting cases are encouraged to use the online morbidity report system, but a fillable PDF is also available to fax to LPHA.

[2] County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

PrEP Prescription

Optional-May be used by pharmacy if desired

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

Note: RPh may not prescribe and must refer patient if HIV test reactive or indeterminate

Rx

☐ **Truvada® (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets**
- ☐ Take one tablet by mouth daily for 30 days, #30, 0 refills
- ☐ Take one tablet by mouth daily for 90 days, #90, 0 refills

-or-

☐ **Descovy® (emtricitabine/tenofovir alafenamide) 200/25mg tablets**
- ☐ Take one tablet by mouth daily for 30 days, #30, 0 refills
- ☐ Take one tablet by mouth daily for 90 days, #90, 0 refills

Written Date: _____

Expiration Date: (This prescription expires 90 days from the written date) _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:

Lot:_____ Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	

Provider Notification
Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

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

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

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

This regimen consists of the following (check one):

- ☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
  - Take one tablet by mouth daily
- ☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
  - Take one tablet by mouth daily

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	____/____/_____	☐ *reactive* ☐ *indeterminate* ☐ non-reactive	☐ *Yes*
• HIV RNA:	___/____/_____	☐ *detected* ☐ *indeterminate* ☐ not detected	☐ *Yes*
• Hepatitis B surface antigen:	____/____/_____	☐ *reactive* ☐ non-reactive	☐ *Yes*
• Hepatitis C antibody:	____/____/_____	☐ *reactive* ☐ non-reactive	☐ *Yes*
• Syphilis/Treponemal antibody:	____/____/_____	☐ *reactive* ☐ *indeterminate* ☐ non-reactive	☐ *Yes*
• Gonorrhea/Chlamydia:	____/____/_____		☐ *Yes*
Urinalysis result: ☐ *reactive* ☐ *indeterminate* ☐ non-reactive	Pharyngeal test result: ☐ *reactive* ☐ *indeterminate* ☐ non-reactive	Rectal test result: ☐ *reactive* ☐ *indeterminate* ☐ non-reactive	
• Renal function (CrCl): ☐ CrCl >60mL/min	____/____/_____ _____ mL/min ☐ CrCl 30mL/min - 60mL/min	☐ *CrCl <30mL/min*	☐ *Yes*
• HCG:	____/____/_____	☐ *positive* ☐ *indeterminate* ☐ negative	☐ *Yes*
• Signs/symptoms of acute retroviral syndrome (☐ *Present* ☐ Not Present) AND potential HIV exposure (☐ *Yes* ☐ No) in the last 4 weeks and not on PrEP (☐ *Yes* ☐ No).			☐ *Yes*
• Exposure risk less than 72 hours ago? ☐ *Yes* ☐ No			☐ *Yes*

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

Provider pearls for HIV PrEP:

- PrEP is prescribed for up to a 90 day supply for each prescription to align with appropriate lab monitoring guidelines.
- Truvada® is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada® and Descovy® are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada® is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacist monitoring of HIV PrEP and transition of care:

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

If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

PREVENTIVE CARE

TRAVEL MEDICATIONS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe pre-travel medications.
  - Malaria prophylaxis
  - Traveler's diarrhea
  - Acute mountain sickness
  - Motion sickness

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Travel Medications Patient Intake Form (pg. 2-3)
- Utilize the standardized Travel Medications Assessment and Treatment Care Pathway (pg. 4-10)
- Utilize the standardized Travel Medication Prescription Template *optional* (pg. 11)
- Utilize the standardized Travel Medication Provider Notification (pg. 12-13)
- Utilize the standardized Travel Medication Patient Visit Summary (pg. 14)

PHARMACIST TRAINING/EDUCATION:

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

REFERENCES:

- Centers for Disease Control and Prevention. CDC Yellow Book 2020: Health Information for International Travel. Oxford University Press; 2019. https://wwwnc.cdc.gov/travel/page/yellowbook-home-2020

RESOURCES:

- 2020 Yellow Book Home | Travelers' Health | CDC. Accessed February 14, 2023. https://wwwnc.cdc.gov/travel/page/yellowbook-home-2020
- Travelers' Health | CDC. Accessed February 14, 2023. https://wwwnc.cdc.gov/travel/

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

PATIENT INFORMATION

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

Legal Name_____ Name _____

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

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

Street Address _____

Phone ( ) _____ Email Address _____

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

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

Any allergies to medications? Yes / No If yes, please list _____

TRAVEL SPECIFICS

Purpose of Trip: _____

Activities: _____

Departure Date: _____ Return Date: _____

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

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

If yes, where and when?

_____

_____

1.	Will you ONLY be using airplane as your mode of transportation If no, explain: _____	□ Yes □ No □ Not sure
2.	Will you ONLY be visiting major cities? If no, explain: _____	□ Yes □ No □ Not sure
3.	Will you ONLY be staying in hotels? If no, explain: _____	□ Yes □ No □ Not sure
4.	Will you be visiting friends and family?	□ Yes □ No □ Not sure
5.	Will you be ascending to high altitudes? (> 7,000 ft or 2,300 meters) in the mountains	□ Yes □ No □ Not sure
6.	Will you be working in the medical or dental field with exposure to blood or bodily fluids?	□ Yes □ No □ Not sure

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

ALLERGIES

□ No known drug allergies □ No known food allergies

Drug Allergies: _____

Food Allergies: _____

VACCINE MEDICAL INFORMATION

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

Vaccinations	Yes – *(Enter vaccination date below)*	No	Not Sure
COVID (Manufacturer):_____	Dose 1: 2: Booster(s):		
Hepatitis A	Dose 1: 2:		
Hepatitis B (Manufacturer):_____	Dose 1: 2: 3:		
Influenza			
Japanese Encephalitis	Dose 1: 2:		
Meningococcal Meningitis	Dose 1: 2:		
MMR (Measles, Mumps, Rubella)	Dose 1: 2:		
Pneumonia	PPSV23: PCV20:		
Polio (Adult Booster)			
Rabies	Dose 1: 2:		
Shingles	Dose 1: 2:		
Tetanus (Tdap/Td/DTaP/DT)			
Typhoid (Oral / Shot)			
Varicella	Dose 1: 2:		
Yellow Fever			
Other:			
Other:			

MEDICAL HISTORY

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

Current Medical Conditions:_____

_____

Current Prescription Medications:_____

_____

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

7.	Are you currently using steroids?	□ Yes □ No □ Not sure
8.	Are you currently receiving radiation therapy?	□ Yes □ No □ Not sure
9.	Are you currently receiving immunosuppressive therapy?	□ Yes □ No □ Not sure
10.	Are you pregnant or are you planning to become pregnant within the next year?	□ Yes □ No □ Not sure
11.	Are you currently breast-feeding?	□ Yes □ No □ Not sure

QUESTIONS/CONCERNS

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

_____

Signature:_____ Date:_____

Travel Medications - Assessment and Treatment Care Pathway

STEP 1: Assess routine and travel vaccinations.
STEP 2: Choose and issue prescription(s) for appropriate prophylaxis medication(s), in adherence to the CDC's 2020 Yellow Book: Health Information for International Travel (v. 06/11/2019) and this protocol. Must also include documented screening for contraindications (see pgs. 6-7).
STEP 3: Prescribe medications and administer vaccinations.
STEP 4: Provide a written individualized care plan to each patient.

1. **Malaria Prophylaxis**
    a. **Patient assessment**
        i. Review detailed itinerary
        ii. Identify zones of resistance
        iii. Review recommendations by the CDC
        iv. Discuss planned activities
        v. Assess risk of acquiring malaria and body weight (kg)
    b. **Prophylaxis**
        i. Discuss insect precautions and review signs/symptoms of malaria with patient
        ii. Screen for contraindications
        iii. Assess travel areas for resistance:
            1. **Non-chloroquine resistant zone**
                a. *Chloroquine (Aralen®)*
                Adult dosing: Chloroquine 500 mg
                - Begin 1-2 weeks prior to travel-1 tablet weekly
                - Taken once weekly during trip and for 4 weeks after leaving risk area

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

                OR

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

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

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

                Pediatric Dosing: Atovaquone/Proguanil 62.5mg/25mg
                5–8 kg: 1/2 pediatric tablet daily
                9–10 kg: 3/4 pediatric tablet daily
                11–20 kg: 1 pediatric tablet daily
                21–30 kg: 2 pediatric tablets daily
                31–40 kg: 3 pediatric tablets daily

> 40 kg: 1 adult tablet daily

- Begin 1 dose daily 1-2 days prior to travel
- Taken daily during trip and 7 days after leaving risk area

OR

b. *Doxycycline monohydrate (Monodox®) or hyclate (Vibramycin®) (≥8 years)*
Adult Dosing: Doxycycline 100mg
- Begin 1 tablet or capsule daily 1-2 days prior to travel
- Taken daily during trip and for 4 weeks after leaving risk area

Pediatric Dosing:
≥8 years old: 2.2 mg/kg (maximum is 100 mg) daily
- Begin 1 dose daily 1-2 days prior to travel
- Taken daily during trip and for 4 weeks after leaving risk area

OR

c. *Mefloquine (Lariam®)*
Adult Dosing: Mefloquine 250mg
- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during and for 4 weeks after leaving risk area

Pediatric Dosing:
≤9 kg: 5 mg/kg
10-19 kg: ¼ tablet weekly
20-30 kg: ½ tablet weekly
31-45 kg: ¾ tablet weekly
> 45 kg: 1 tablet weekly
- Begin 1-2 weeks prior to travel-1 dose weekly
- Taken once weekly during and for 4 weeks after leaving risk area

3. Mefloquine-Resistant zone

a. *Doxycycline monohydrate (Monodox®) or hyclate (Vibramycin®) (≥8 years)*
Adult dosing: Doxycycline 100 mg
- Begin 1 tablet or capsule daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

Pediatric dosing:
≥8 years old: 2.2 mg/kg (maximum is 100 mg) daily
- Begin 1 dose daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

OR

b. Atovaquone/Proguanil (Malarone®)
Adult dosing: Atovaquone/Proguanil 250mg/100mg
Pediatric Dosing: Atovaquone/Proguanil 62.5mg/25mg
5–8 kg: 1/2 pediatric tablet daily
9–10 kg: 3/4 pediatric tablet daily
11–20 kg: 1 pediatric tablet daily
21–30 kg: 2 pediatric tablets daily
31–40 kg: 3 pediatric tablets daily
> 40 kg: 1 adult tablet daily
- Begin 1 dose daily 1-2 days prior to travel
- Taken daily during trip and 7 days after leaving

2. <u>Traveler's diarrhea (TD)</u>

a. Patient assessment
   i. Review detailed itinerary and identify travel areas of increased risk
   ii. Assess patient's risk of acquiring traveler's diarrhea and body weight (kg)
   iii. Screen for contraindications
   iv. Consult CDC guidelines for list of high-risk factors for TD

b. Prophylaxis education
   i. Discuss dietary counseling, avoidance of high-risk foods, food and beverage selection and sanitary practices, oral rehydration
   ii. Educate patient on how to recognize symptoms and severity of traveler's diarrhea
      1. **Mild:** diarrhea that is tolerable, not distressing, and does not interfere with planned activities
      2. **Moderate:** diarrhea that is distressing or interferes with planned activities
      3. **Severe:** dysentery (bloody stools) and diarrhea that is incapacitating or completely prevents planned activities
   iii. Pharmacotherapy prophylaxis

      Pepto-Bismol®: Two 262-mg tablets or 2 fluid oz (60 mL) QID for up to 3 weeks
      Note: Avoid in patients <12 years old, patients taking doxycycline for malaria prophylaxis, anticoagulants, allergic to aspirin, probenecid, methotrexate

c. Treatment *(Note: while Yellow Book includes ciprofloxacin, this protocol only permits azithromycin)*
   i. First line for mild TD and adjunctive treatment for moderate TD
      1. *Loperamide (OTC- Imodium® AD)*

      <u>Adult Dosing:</u> Loperamide 2 mg
      - Take 4 mg at onset of diarrhea, followed by additional 2 mg after each loose stool (Max of 16 mg per day)

      <u>Pediatric Dosing:</u>
      - 22 to 26 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 4 mg per day)
      - 27 to 43 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 6 mg per day)

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

3. <u>Acute Mountain Sickness</u>

a. Patient assessment/Education
   i. Review detailed itinerary and identify travel areas of increased risk
   ii. Assess patients' risk of acquiring Acute Mountain Sickness (AMS) and body weight (kg)
   iii. Review signs/symptoms of AMS, discuss safe ascent rates and tips for acclimating to higher altitudes (alcohol abstinence, limited activity)
   iv. Screen for contraindications
      1. AcetaZOLAMIDE
         a. Hypersensitivity to acetazolamide or sulfonamides

b. Prophylaxis
   i. Consult CDC guidelines for list of risk factors for AMS. If risk factors are present and warrant prophylaxis:
      1. *AcetaZOLAMIDE (Diamox®)*

         <u>Adult Dosing:</u> Acetazolamide 125 mg; 250 mg if >100 kg
         - Take 1 dose twice daily starting 24 hours before ascent, continuing during ascent, and 2-3 days after highest altitude achieved or upon return

         <u>Pediatric Dosing:</u>

         2.5 mg/kg/dose every 12 hours before ascent, continuing during ascent, and 2-3 days after highest altitude achieved or upon return. (Maximum of 125 mg/dose)

4. <u>Motion Sickness</u>

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

b. Prophylaxis
   i. Consult CDC guidelines for list of risk factors for Motion sickness. If risk factors present and warrant pharmacologic prevention:
   ii. Adults
      1. **First-line**: *Scopolamine transdermal patches* (Age <18 Requires prescription from PCP)
      • Apply 1 patch (1.5 mg) to hairless area behind ear at least 4 hours prior to exposure; replace every 3 days as needed

AND/OR

      2. **Second-line:**
         a. *Promethazine 25mg Tablets:* Take one tablet by mouth 30 – 60 minutes prior to exposure and then every 12 hours as needed
         b. *Promethazine 25mg Suppositories:* Unwrap and insert one suppository into the rectum 30-60 minutes prior to exposure and then every 12 hours as needed
         c. *Meclizine 12.5-25mg* (OTC/Rx):
         Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

   iii. Pediatrics
      1. **First-line**:
         a. 7-12 years old
            - *DimenhyDRINATE (OTC Dramamine®)* 1-1.5mg/kg/dose*:* Take one dose 1 hour before travel and every 6 hours during the trip. (Maximum 25 per dose)
            - *DiphenhydrAMINE (OTC Benadryl®)* 0.5-1mg/kg/dose*:* Take one dose 1 hour before travel and every 6 hours during the trip. (Maximum 25 mg per dose)
         b. ≥ 12 years old
            - *Meclizine 12.5-25mg* (OTC/Rx): Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

Travel Medications - Assessment and Treatment Care Pathway

Screen for Contraindications:

Malaria Prophylaxis

1. Chloroquine
    c. Age < 7 years old
    d. Hypersensitivity to chloroquine, 4-aminoquinolone compounds, or any component of the formulation
    e. Presence of retinal or visual field changes of any etiology
2. Hydroxychloroquine
    a. Age < 7 years old
    b. Hypersensitivity to hydroxychloroquine, 4 aminoquinoline derivatives, or any component of the formulation
3. Atovaquone/proguanil
    a. Age < 7 years old
    b. Weight < 5 kg
    c. Hypersensitivity to atovaquone, proguanil or any component of the formulation
    d. Prophylactic use in severe renal impairment (CrCl < 30 mL/min)
    e. Cannot be used by women who are pregnant or breastfeeding a child that weighs < 5 kg.
4. Doxycycline
    a. Age < 8 years old
    b. Hypersensitivity to doxycycline, other tetracyclines
    c. During second or third trimester of pregnancy
    d. Breast-feeding
5. Mefloquine
    a. Age < 7 years old
    b. Hypersensitivity to mefloquine, related compounds (i.e. quinine and quinidine)
    c. Prophylactic use in patients with history of seizures or psychiatric disorder (including active or recent history of depression, generalized anxiety disorder, psychosis, schizophrenia, or other major psychiatric disorders)
    d. Not recommended for people with cardiac conduction abnormalities.

Traveler's Diarrhea

1. Loperamide
    a. Age < 7 years old
    b. Hypersensitivity to loperamide or any component of the formulation
    c. Abdominal pain without diarrhea
    d. Acute dysentery
    e. Acute ulcerative colitis
    f. Bacterial enterocolitis (caused by *Salmonella, Shigella, Campylobacter)*
    g. Pseudomembranous colitis associated with broad-spectrum antibiotic use
    h. OTC—do not use if stool is bloody or black
2. Azithromycin
    a. Age < 18 years old will require a prescription from a PCP
    b. Hypersensitivity to azithromycin, erythromycin or other macrolide antibiotics
    c. History of cholestatic jaundice/hepatic dysfunction associated with prior azithromycin use

Acute Mountain Sickness

1. AcetaZOLAMIDE
    a. Age < 7 years old
    b. Marked hepatic disease or insufficiency
    c. Decreased sodium and/or potassium levels
    d. Adrenocortical insufficiency
    e. Cirrhosis

f. Hyperchloremic acidosis
g. Severe renal dysfunction or disease
h. Long term use in congestive angle-closure glaucoma

Motion Sickness

1. Scopolamine
   a. Age < 18 years old will require a prescription from a PCP
   b. Hypersensitivity to scopolamine
   c. Glaucoma or predisposition to narrow-angle glaucoma
   d. Paralytic ileus
   e. Prostatic hypertrophy
   f. Pyloric obstruction
   g. Tachycardia secondary to cardiac insufficiency or thyrotoxicosis
2. Promethazine
   a. Age < 7 years old
   b. Hypersensitivity to promethazine or other phenothiazines (i.e. prochlorperazine, chlorproMAZINE, fluPHENAZine, perphenazine, etc)
   c. Treatment of lower respiratory tract symptoms
   d. Asthma
3. Meclizine
   a. Age < 12 years old
   b. Hypersensitivity to meclizine
4. DimenhyDRINATE
   a. Age < 7 years old
   b. Hypersensitivity to dimenhyDRINATE or any component of the formulation
   c. Neonates
5. DiphenhydrAMINE
   a. Age < 7 years old
   b. Hypersensitivity to diphenhydrAMINE or other structurally related antihistamines or any component of the formulation
   c. Neonates or premature infants
   d. Breast feeding

Travel Medicine Prescription

Optional-May be used by pharmacy if desired

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

Rx

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

☐ **Drug:** ______________________________________

- Directions: ____
- Quantity: _______ + 0 refills

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

☐ **Drug:** ______________________________________

- Directions: ____
- Quantity: _______ + 0 refills

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

☐ **Drug:** ______________________________________

- Directions: ____
- Quantity: _______ + 0 refills

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

☐ **Drug:** ______________________________________

- Directions: ____
- Quantity: _______ + 0 refills

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

☐ **Drug:** ______________________________________

- Directions: ____
- Quantity: _______ + 0 refills

Written Date: __________________________________

Prescriber Name:_____________________________Prescriber Signature: ________________________

Pharmacy Address:___________________________________Pharmacy Phone: ____________________

Provider Notification
Travel Medicine

Pharmacy Name:_________________________ Pharmacist Name: __________________________________
Pharmacy Address:____
Pharmacy Phone:________________________ Pharmacy Fax: _____________________________________

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

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

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

☐ **Medications Prescribed**

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

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

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

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

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

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

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

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

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

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

☐ **Immunizations Administered**

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

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

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

- ☐ **Drug/Immunization:** _____
- ☐ **Reason for Referral:** _____

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

- ☐ **Drug/Immunization:** _____
- ☐ **Reason for Referral:** _____

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

- ☐ **Drug/Immunization:** _____
- ☐ **Reason for Referral:** _____

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

Pharmacist Signature:_____ Date:_____
Pharmacist Name (Print):_____

The prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-020-0300.

- **CDC Yellow Book 2020: Health Information for International Travel.** New York: Oxford University Press; 2019.Retrieved from https://wwwnc.cdc.gov/travel/page/yellowbook-home-2020.

Patient Visit Summary

Travel Medicine

Pharmacy Name:________________________________ Pharmacist Name:______________________________________

Pharmacy Address:____

Pharmacy Phone: _____________________________ Pharmacy Fax: _____________________________

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

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

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

☐ **Drug/Immunization:** ____

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

☐ **Drug/Immunization:** ____

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

☐ **Drug/Immunization:** ____

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

☐ **Drug/Immunization:** ____

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

☐ **Drug/Immunization:** ____

-- and/or --

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

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

☐ **Drug/Immunization:**
____

☐ **Reason for Referral:**
____

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

☐ **Drug/Immunization:**
____

☐ **Reason for Referral:**
____

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

☐ **Drug/Immunization:**
____

☐ **Reason for Referral:**
____

Divisions 019/041/043/045/080/139/141/143: Annual Self-Inspection Form Deadline

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Annual Self-Inspection Form completion deadline

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amends annual Self-Inspection form deadline from February 1 to July 1 and requires the Pharmacist-in-Charge (PIC) to use the board's Self-Inspection Form.

Documents Relied Upon per ORS 183.335(2)(b)(D): NABP November-2022 Oregon Newsletter

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed amendments may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Aligning the Self-Inspection Form due dates with biennial pharmacy inspections will allow for more intentionality and strategic focus toward high-risk locations and will result in better patient safety outcomes which positively impacts all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal impact is anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public), Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed revisions to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The board announced it would begin conducting biennial pharmacy inspections in 2021 and would move the annual self-inspection form deadline from February 1 to July 1 to align with pharmacy inspections.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments require the PIC to utilize the board's Self-Inspection Form, removes "February" and adds "July" deadline for Self-Inspection Forms to be completed. The board moved to biennial pharmacy inspections in 2021 to better align the inspection cycle with the state's fiscal calendar.

DIVISION 19
PHARMACISTS

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

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

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

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

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

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

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

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

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

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

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

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

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

(g) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

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

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

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

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

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;

(g) Implementing a quality assurance plan for the pharmacy.

(h) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

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

DIVISION 41
OPERATION OF PHARMACIES

855-041-1060
Non-Resident Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy is any establishment located out of Oregon that engages in the dispensing, delivery or distribution of drugs to Oregon. A non-resident pharmacy also includes entities that provide pharmacy services to Oregon, such as drugless/consulting outlets, even if the entity is not dispensing, delivering or distributing drugs into Oregon.

(2) Every non-resident pharmacy that provides drugs, devices or services to a resident in this state must be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every non-resident pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) Every out-of-state non-resident pharmacy must designate an Oregon licensed Pharmacist-in-Charge (PIC), who must be responsible for all pharmacy services provided to residents in Oregon, and to provide supervision and control in the pharmacy. To qualify for this designation, the person must:

(a) Hold a license to practice pharmacy in the resident state;

(b) Be normally present in the pharmacy for a minimum of 20 hours per week;

(c) Annually complete a self-inspection using the board's Non-Resident Retail Drug Outlet Self-Inspection Form prior to July 1; and

(d) Provide the PIC Self-Inspection report as requested by the board.

(5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within four months of initial licensure of the pharmacy.

(6) When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the board within ten business days and identify a contact person. The pharmacy will have an Oregon licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the pharmacy's state of residence and is responsible for the following:

(a) Supervision of pharmacy staff and ensuring compliance with laws and rules; and

(b) Responding to board correspondence and inquiries.

(7) A new Pharmacist-in-Charge must be appointed, and communication made to the board within 90 days, or the non-resident pharmacy will cease drug distribution and provision of pharmacy services in Oregon.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225

DIVISION 43
PRACTITIONER DISPENSING

855-043-0560
Dispensing Practitioner Drug Outlets - Inspections

(1) The DPDO must annually complete a self-inspection using the board's DPDO Self-Inspection Form by July1 and retain for board inspection.

(2) Each DPDO will be inspected per OAR 855-001-0040 on a routine basis and must be scheduled in advance with the DPDO, to occur during normal business hours.

(3) The inspection must focus on the acquisition, storage, labeling and recordkeeping of drugs intended for dispensing and any violation will apply to the DPDO registration and not to the practitioner.

(4) The Board of Pharmacy must notify the practitioner's licensing board of any disciplinary action taken against a DPDO.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305

DIVISION 45
DRUG COMPOUNDING

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

DIVISION 80
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0100
Animal Euthanasia

(1) The following requirements shall be met in order for a humane society or animal control agency to be registered or registration renewed to allow the purchase, possession and administration of sodium pentobarbital and sedative and analgesic medications for euthanizing injured, sick, homeless or unwanted domestic pets and other animals:

(a) Registration. Registration as an animal euthanasia drug outlet is limited to animal control agencies and humane societies for the purpose of purchasing, possessing, or administering sodium pentobarbital and sedative and analgesic medications to euthanize animals. The outlet must identify and provide to the Oregon Board of Pharmacy via application, a designated representative who will serve as the primary contact person responsible for managing the outlet operations. The outlet shall notify the Board within 15 days of any change in designated representative. Registration requires submission of an application, and a certificate of registration will be issued upon approval. All registrations and renewals shall be accompanied by an annual fee defined in Division 110 of this Chapter.

(b) Drug Storage. All supplies of sodium pentobarbital and sedative and analgesic medications shall be acquired from an Oregon registered distributor and kept in a locked cabinet. An assigned person designated in writing shall be responsible for the security of the sodium pentobarbital and sedative and analgesic medications. Such designated person shall allow access to and withdrawal of the drug only to a person certified by the Oregon State Veterinary Medical Examining Board to administer sodium pentobarbital and sedative and analgesic medications;

(c) Records. The following records shall be made at the time of the occurrence and shall be maintained for a minimum of three years, available for inspection by the Board of Pharmacy and its agents:

(A) A record of the withdrawal of sodium pentobarbital and sedative and analgesic medications, signed by the person who takes possession of the sodium pentobarbital and sedative and analgesic medications for administration;

(B) A record of the weight, species of animal and dosage of each drug administered for euthanasia signed by the person who administers the drug and by the designated person responsible for security;

(C) A record of all wastage of each drug signed by the person administering each drug and the designated person responsible for security; and

(D) A weekly record of verification of the amount of each drug on hand, minus the amounts withdrawn for administration, signed by the designated person responsible for security;

(E) A record of disposal of any expired or unwanted sodium pentobarbital and sedative and analgesic medications. Disposal shall be in conformance with federal regulations.

(F) Annually complete a self-inspection using the board's Animal Euthanasia Self-Inspection Form by July 1 and retain for board inspection.

(d) Audits. The registrant shall submit to random audits of records and analysis of prepared solutions by the Drug Enforcement Administration (DEA), and Board of Pharmacy or its agents.

(2) The outlet shall notify the Board of Pharmacy in the event of a significant drug loss or violation related to drug theft within one (1) business day.

(3) At the time a Report of Theft or Loss of Controlled Substances (DEA Form 106) is sent to the DEA, a copy shall be sent to the Board of Pharmacy.

(4) The Board of Pharmacy will suspend or revoke the registration of an animal euthanasia drug outlet which allows a person to administer sodium pentobarbital or sedative and analgesic medications who is not certified by the Oregon State Veterinary Medical Examining Board to administer such drug.

Statutory/Other Authority: ORS 475.095, ORS 475.190, ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

DIVISION 139
REMOTE DISPENSING SITE PHARMACY

855-139-0030
Non-Resident Affiliated Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes a RDSP Affiliated Pharmacy located outside of Oregon and providing pharmacy services through a telepharmacy system to a Retail Drug Outlet RDSP located in Oregon.

(2) Each non-resident RDSP Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every non-resident RDSP Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) Each out-of-state non-resident RDSP Affiliated Pharmacy must designate an Oregon licensed Pharmacist-in-Charge (PIC), who is responsible for all pharmacy services and to provide supervision and control of the RDSP. To qualify for this designation, the person must:

(a) Hold a license to practice pharmacy in the resident state;

(b) Be normally working for the RDSP Affiliated Pharmacy a minimum of 20 hours per week;

(c) Annually complete a self-inspection using the board's RDSP Self-Inspection Form prior to July 1; and

(d) Provide the Self-Inspection Form as requested by the board.

(5) Every non-resident RDSP Affiliated Pharmacy will have a Pharmacist-in-Charge (PIC) who is licensed in Oregon prior to initial registration of the RDSP.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225

DIVISION 141
PHARMACY PRESCRIPTION KIOSK

855-141-0030
Non-Resident PPK Affiliated Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes a PPK Affiliated Pharmacy located outside of Oregon and providing pharmacy services under OAR 855-141 with a PPK located in Oregon.

(2) Each non-resident PPK Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy as a Retail Drug Outlet Pharmacy.

(3) To qualify for registration under these rules, every non-resident PPK Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) The Pharmacist-in-Charge (PIC) of the non-resident PPK Affiliated Pharmacy is the PIC for each PPK.

(5) The PIC is responsible for annually completing a self-inspection using the board's PPK Self-Inspection Form prior to July 1.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225 & ORS 689.527

DIVISION 143
PHARMACY PRESCRIPTION LOCKER

855-143-0030
Non-Resident PPL Affiliated Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes a PPL Affiliated Pharmacy located outside of Oregon and providing pharmacy services to a PPL located in Oregon.

(2) Each non-resident PPL Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy as a Retail Drug Outlet Pharmacy.

(3) To qualify for registration under these rules, every non-resident PPL Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) The Oregon licensed Pharmacist-in-Charge (PIC) of the non-resident PPL Affiliated Pharmacy is the PIC for each PPL.

(5) The PIC is responsible for annually completing a self-inspection using the board's PPL Self-Inspection Form prior to July 1.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.527

Division 104: Universal Rules

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adopts new Division 104 for Universal Rules

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 104. Relocates and amends existing procedural rules from Division 001 to new Division 104. Relocates OAR 855-010-0130 to OAR 855-104-0150. After the board permanently adopts and publishes Division 104, repeals Division 001 and OAR 855-010-0130 on the effective date of Division 104.

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

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Proposed rules provide clarity for licensees, and registrants. It is anticipated that the proposed rules will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): Reporting, Recordkeeping and Administrative Activities Cost: Professional Services, Equipment/ Supplies, Labor Cost, Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of the proposed rule amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommends adopting the proposed rules for transparency and clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Creates new Division 104 for universal rules. Relocates and amends existing rules from Division 001 to Division 104. Newly proposed language adds requirements for duty to report, confidentiality, records and document retention and adds a placeholder for public records requests. Adds "intern" to Military Spouse Domestic Partner licensure process rules. Relocates OAR 855-041-1167 to OAR 855-104-0050, relocates OAR 855-010-0130 to OAR 855-104-0150. After the board permanently adopt and publishes Division 104, repeals OAR 855-041-1167, OAR 855-010-0130 and Division 001 on the effective date of Division 104.

Creation of Division 104 and adoption of universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

DIVISION 104
UNIVERSAL RULES

855-104-0005
Universal Rule: Duty to Cooperate

(1) Applicants, licensees, and registrants must timely comply with all board requests, including responding accurately, fully and truthfully to inquiries and providing requested materials within the time allowed by the board and complying with a subpoena.

(2) Applicants, licensees, and registrants must comply with the terms of board orders and agreements.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.612

855-104-0010 *
Universal Rule: Responsibilities- Duty to Report

(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each licensee must report to the board without undue delay, but within

(a) 10 days if they:

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

(B) Are arrested for a felony.; or

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

(b) 10 working days if they:

(A) Have reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct to that licensee's board; or

(B) Suspect records are lost or stolen.

(c) 15 days, any change in:

(A) Legal name;

(B) For Pharmacists and Interns, name used when engaging in the practice of pharmacy and for Certified Oregon Pharmacy Technicians and Pharmacy Technicians, name used when assisting in the practice of pharmacy.

(C) Preferred email address;

(D) Personal phone number;

(E) Personal physical address;

(F) Personal mailing address; or

(G) Employer.

(2) A licensee who reports to a board in good faith as required by ORS 676.150 is immune from civil liability for making the report.

(3) A Pharmacist, Certified Oregon Pharmacy Technician or Pharmacy Technician who reports to a board in good faith as required by ORS 689.455 is not subject to an action for civil damages as a result thereof.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.150, ORS 689.155, ORS 689.455, & ORS 689.486

855-104-0015 *
Universal Rule: Responsibilities- Confidentiality

(1) No licensee or registrant of the board who obtains any patient information may disclose that information to a third-party without the consent of the patient except as provided in (2)(a)-(e) of this rule.

(2) A licensee or registrant may disclose patient information:

(a) To the board;

(b) To a practitioner, Pharmacist, Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician or registrant, if disclosure is authorized by a Pharmacist and disclosure is necessary to protect the patient's health or well-being; or

(c) To a third-party when disclosure is authorized or required by law; or

(d) As permitted pursuant to federal and state patient confidentiality laws; or

(e) To the patient or to persons as authorized by the patient.

(3) A licensee or registrant of the board may not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (2)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-104-0050
Universal Rule: Patients Access to Pharmacy Records

(1) Licensees and registrants of the board must make health information in the pharmacy record available to the patient or the patient's representative upon their request, to inspect and obtain a copy of health information about the individual, except as provided by law and this rule. The patient may request all or part of the record. A summary may substitute for the actual record only if the patient agrees to the substitution. Board licensees and registrants are encouraged to use the written authorization form provided by ORS 192.566.

(2) For the purpose of this rule, "health information in the pharmacy record" means any oral, written or electronic information in any form or medium that is created or received and relates to:

(a) The past, present, or future physical or mental health of the patient.

(b) The provision of healthcare to the patient.

(c) The past, present, or future payment for the provision of healthcare to the patient.

(3) Upon request, the entire health information record in the possession of the board licensee will be provided to the patient. This includes records from other healthcare providers. Information which may be withheld includes:

(a) Information which was obtained from someone other than a healthcare provider under a promise of confidentiality and access to the information would likely reveal the source of the information;

(b) Psychotherapy notes;

(c) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(d) Other reasons specified by federal regulation.

(4) Registrants who have permanently closed must notify patients according to OAR 855-041-1092.

(5) A reasonable cost may be imposed for the costs incurred in complying with the patient's request for health information pursuant to ORS 192.563.

(6) A patient may not be denied summaries or copies of pharmacy records because of inability to pay.

(7) Requests for pharmacy records must be complied with within a reasonable amount of time not to exceed 30 days from the receipt of the request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 192.553, ORS 192.556, ORS 192.558, ORS 192.563 & ORS 192.566

855-104-0055
Universal Rule: 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 ;

(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

855-104-0060
Universal Rule: Public Records Request to the Board

Placeholder

Statutory/Other Authority: TBD
Statutes/Other Implemented: TBD

855-104-0100
Universal Rule: Time for Requesting a Contested Case Hearing

A request for a contested case hearing must be in writing and must be received by the board within 21 days from the date the contested case notice was served. When the board has issued a denial of a license, a request for a contested case hearing must be in writing and must be received by the board within 60 days from the date the licensure denial was served.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 183.435

855-104-0105
Universal Rule: Filing Exceptions and Argument to the Board

After a proposed order has been served on a party, the party has 30 days to file written exceptions with the board from receipt of the proposed order.

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

855-104-0110
Universal Rule: Petition for Reconsideration or Rehearing as Condition for Judicial Review

All parties, including limited parties, must file a petition for reconsideration or rehearing with the board as a condition for obtaining judicial review of any order of the board.

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

855-104-0115
Universal Rule: Inspections & Investigations

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

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

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

(b) Inspecting all drugs and devices;

(c) Taking photographs, recording video and audio; and

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

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

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

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

855-104-0150

Universal Rule: Military Spouse or Domestic Partner Licensure Process

(1) "Military spouse or domestic partner" means a spouse or domestic partner of an active member of the Armed Forces of the United States who is the subject of a military transfer to Oregon.

(2) To qualify for licensure under this rule, the military spouse or domestic partner must meet the following requirements:

(a) Meet the qualifications for licensure as stated in OAR 855-115, OAR 855-120 or OAR 855-125.

(b) Be married to, or in a domestic partnership with, a member of the Armed Forces of the United States who is assigned to a duty station located in Oregon by official active duty military order;

(c) Applicant must complete an application for licensure, provide the board with a valid email address, and complete and pass a national fingerprint-based criminal background check ;

(d) Provide evidence of current licensure as a pharmacist, intern or pharmacy technician issued by another state;

(e) Provide to the board, in a manner determined by the board, sufficient proof that the person is in good standing with the issuing out-of-state professional licensing board; and

(f) Demonstrate competency as a pharmacist, intern or pharmacy technician by having at least one year of active practice during the three years immediately preceding the application.

(3) A temporary authorization under this section is valid until the earliest of the following:

(a) Two years after the date of issuance;

(b) The date the spouse or domestic partner of the person to whom the authorization was issued completes the spouse's term of service in this state; or

(c) The date the person's authorization issued by the other state expires.

(4) A temporary authorization issued under this section is not renewable.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.265, ORS 670.400 & ORS 670.403

Division 102: Board Administration (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adopts new Division 102 for Board Administration rules

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 102. Relocates and amends existing board policy and administration rules from Division 010 to new Division 102. Relocates OAR 855-019-0125 to OAR 855-104-0035. After the board permanently adopts and publishes Division 102, repeals Division 010 on the effective date of Division 102.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 OBOP Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rules provide clarity for licensees, and registrants. It is anticipated that the proposed rules will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public), Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of the proposed rule amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommends adopting the proposed rules for transparency and clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Relocates existing rules from Division 010 to newly created Division 102 Board Administration. Relocates OAR 855-001-0000 to OAR 855-102-0125, relocates OAR 855-001-0005 to OAR 855-102-0045, relocates OAR 855-010-0130 to OAR 855-104-0150 and relocates OAR 855-019-0125 to OAR 855-102-0050. Proposed new language includes adding administration meeting requirements for the Public Health and Pharmacy Formulary Advisory Committee and adds compliance requirements for the board related to public records and public meetings laws. After the board permanently adopts and publishes Division 102, repeals Division 010 on the effective date of Division 102.

DIVISION 102
BOARD ADMINISTRATION

855-102-0010
Board Administration: Board Meetings

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

(2) The President of the board has the power to call special meetings, subject to ORS 689.185, when it may be deemed necessary or upon request of a majority of members.

(3) The board must hold an annual meeting each year for the election of officers, the reorganization of the board and the transaction of other business.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135, ORS 689.185

855-102-0015 *
Board Administration: Public Health and Pharmacy Formulary Committee (PHPFAC) Meetings

(1) A PHPFAC meeting must be held not less than once every six months.

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

(3) The PHPFAC must recommend to the board, for adoption by rule, a formulary of drugs and devices from which a Pharmacist can prescribe and dispense to a patient pursuant to a diagnosis by a qualified healthcare practitioner or a protocol from which a Pharmacist can prescribe and dispense.

Statutory/Other Authority: ORS 689.649
Statutes/Other Implemented: ORS 689.645, ORS 689.649

855-102-0020
Board Administration: Board and PHPFAC Member Compliance

Board members and PHPFAC members must comply with the requirements of all Oregon public records and public meetings laws.

Statutory/Other Authority: ORS 192.001, ORS 192.620
Statutes/Other Implemented: ORS 192.630

855-102-0030
Board Administration: Board and PHPFAC Member Compensation

(1) A board member and Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) member of the Oregon Board of Pharmacy who is entitled to compensation under ORS 292.495 is eligible to receive an amount equal to the per diem amount paid to members of the Legislative Assembly under ORS 171.072 when engaged in the performance of official duties for each day or portion thereof.

(2) For the purpose of compensation, a board member or PHPFAC member is considered engaged in the performance of official duties when:

(a) The activity furthers the board's mission, such as attending a board meeting;

(b) Engaged in an activity at the request of the board chair or authorized by a vote of the board in advance of the activity; or

(c) Attending an authorized meeting.

(3) Except as otherwise provided by law, all members, including those employed in full-time public service, may receive actual and necessary travel or other expenses actually incurred in the performance of their official duties within the limits provided by law or by the Oregon Department of Administrative services under ORS 292.210, ORS 292.220, ORS 292.230, and ORS 292.250.

(4) A board member or PHPFAC member is not required to accept compensation or reimbursement of travel expenses while performing their official duties as a board or appointed committee member.

Statutory/Other Authority: ORS 689.115 & ORS 689.205
Statutes/Other Implemented: ORS 689.115, ORS 292.495, ORS 689.175, ORS 689.645, ORS 689.649, ORS 171.072

855-102-0040
Board Administration: Adoption by Reference- General

(1) The board adopts standards and other publications by reference, as necessary, through administrative rule. When a matter is included in a referenced publication that is in conflict with Oregon Revised Statutes or Oregon Administrative Rules, the statute or rule applies and the standard provision does not. All remaining parts or application of the standard remain in effect.

(2) All outside standards, statutes, rules and publications referred to in any rules adopted by the board are by those references made a part of those rules as though fully set forth. Copies are available for inspection in the office of the Board of Pharmacy.

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

855-102-0045
Board Administration: Adoption by Reference- Model Rules of Procedure

Pursuant to the provisions of ORS 183.341, the Board of Pharmacy adopts the Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act effective 07/2019. These rules must be controlling except as otherwise required by statute or rule.

[ED. NOTE: The full text of the Attorney General's Model Rules of Procedure is available from the office of the Attorney General or Board of Pharmacy.]

Statutory/Other Authority: ORS 183.341 & ORS 689.205
Statutes/Other Implemented: ORS 183.341

855-102-0050
Board Administration: Coaching from Board Staff

A board member or board employee must not:

(1) Discuss the contents of an examination, its preparation or use with any candidate or other person;

(2) Coach a candidate or any other person on materials that may be used in the examination; or

(3) Accept any fees for any act of assistance that would bear on the examination.

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

855-102-0055
Board Administration: Board Compliance Officers and Director

The board's Compliance Director and Compliance Officers:

(1) Must be Pharmacists licensed in the State of Oregon; and

(2) Are authorized to provide appropriate deadline extensions.

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

855-102-0060
Board Administration: License Verification

For purposes of license verification, a person may rely upon the licensing information as it is displayed on the board's website that includes the issuance and expiration dates of any license issued by the board.

Statutory/Other Authority: ORS 689.151, ORS 689.205, ORS 689.490
Statutes/Other Implemented: ORS 689.151, ORS 689.490

855-102-0100
Board Administration: State and National Criminal Background Checks for Licensure and Registration

(1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure; and individuals subject to investigation by the board, in order to determine if they have a history of criminal behavior such that they are not fit to be granted or retain a license or registration issued by the board.

(2) "Subject individual" means a person from whom the board may require legible fingerprints for the purpose of a state or nationwide criminal records check and fitness determination. In this rule, subject individual means: applicants for licensure or renewal of a license; and individuals subject to an investigation by the board.

(3) Criminal records checks and fitness determinations are conducted according to ORS 181A.170, ORS 181A.190, ORS 181A.195, ORS 670.280, ORS 676.303, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, OAR 125-007-0310, and OAR 125-007-0330.

(a) The board will request that the Oregon Department of State Police conduct a state and nationwide criminal records check, using fingerprint identification of subject individuals. The board may conduct state criminal records checks on subject individuals and any licensee through the Law Enforcement Data System maintained by the Oregon Department of State Police in accordance with rules adopted, and procedures established, by the Oregon Department of State Police. Criminal history information obtained from the Law Enforcement Data System must be handled in accordance with ORS Chapter 181A, OAR 257-010 and OAR 257-015 and applicable Oregon Department of State Police procedures.

(b) The applicant or licensee must disclose all arrests, charges, and convictions regardless of the outcome or date of occurrence. Disclosure includes any military or criminal records.

(c) The board may require additional information from the applicant or licensee, such as, but not limited to, proof of identity, previous names, residential history or additional criminal, judicial or other background information.

(4) In making licensing fitness determinations subject to the requirements of ORS 670.280, the board will consider the following:

(a) The nature of any criminal record that reflects:

(A) Drug or alcohol offense;

(B) Felony;

(C) Misdemeanor;

(D) U.S. military or international crime;

(E) Offense involving fraud, theft, identity theft or other instance of dishonesty;

(F) Offense involving violation of federal importation or customs laws or rules;

(G) Offense requiring registration as a sex offender;

(H) Condition of parole, probation, or diversion program, or

(I) Unresolved arrest, charge, pending indictment or outstanding warrant.

(b) Intervening circumstances relevant to the responsibilities and circumstances of the license or registration. Intervening circumstances include but are not limited to:

(A) The passage of time since the commission of the crime;

(B) The age of the subject individual at the time of the crime;

(C) The likelihood of a repetition of offenses or of the commission of another crime;

(D) The subsequent commission of another relevant crime;

(E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and

(F) A recommendation of an employer.

(c) The facts that support the conviction or indictment, or that indicate the making of a false statement;

(d) The relevancy, if any, of the crime or the false statement to the specific requirements of the subject individual's license or registration; and

(e) Any false statement or omission made to the board regarding the individual's criminal history.

(f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint identification;

(g) Any other pertinent information obtained as part of an investigation.

(h) The board must evaluate a crime or offense on the basis of the law of the jurisdiction in which the crime or offense occurred.

(i) Under no circumstances must an applicant be denied under these rules because of a juvenile record that has been expunged or set aside pursuant to ORS 419A.260 and ORS 419A.262.

(j) Under no circumstances must an applicant be denied under these rules due to the existence or contents of an adult record that has been set aside pursuant to ORS 137.225.

(5) Criminal offender information is confidential. Dissemination of information received under this rule may only be made to people with a demonstrated and legitimate need to know the information. When the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS 676.175. Any fingerprint cards used to conduct a check must be destroyed by either the Federal Bureau of Investigation or the Oregon Department of State Police as specified in ORS 181A.195.

(6) The board will permit the subject individual for whom a fingerprint-based criminal records check was conducted to inspect the individual's own state and national criminal offender records and, if requested by the subject individual, provide the individual with a copy of the individual's own state and national criminal offender records.

(7) If an applicant, licensee or registrant is denied a license, they are entitled to a contested case hearing pursuant to ORS chapter 183.

(8) A challenge to the accuracy or completeness of information provided by the Oregon Department of State Police, Federal Bureau of Investigation and agencies reporting information must be made through the Oregon Department of State Police, Federal Bureau of Investigation or reporting agency and not through the contested case process.

(9) Request for re-evaluation following correction. If the subject individual successfully contests the accuracy or completeness of information provided by the Oregon Department of State Police, the Federal Bureau of Investigation or other agency reporting information to the board, the board will conduct a new criminal history check and re-evaluate the criminal history upon submission of a new criminal history request form.

(10) The applicant or licensee must pay a criminal records check fee for the actual cost of acquiring and furnishing the criminal offender information.

Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195
Statutes/Other Implemented: ORS 676.303, ORS 181A.195, ORS 181A.170, ORS 181A.215 & ORS 676.175

855-102-0105
Board Administration: State and National Criminal Background Checks for Employees, Volunteers and Employment Applicants

(1) The board requires a criminal records check and fitness determination for board employees, volunteers or applicants for employment with the board.

(2) Criminal records checks and fitness determinations are conducted pursuant to ORS 181A.170, ORS 181A.190, ORS 181A.195, ORS 670.280, ORS 676.303, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, OAR 125-007-0310 and OAR 125-007-0330.

(a) To complete the criminal records check and fitness determination, the board may require additional information from the employee, volunteer or applicant, such as, but not limited to, proof of identity or additional criminal, judicial or other background information.

(b) If the employee, volunteer or applicant has potentially disqualifying criminal offender information, the board will consider factors listed in ORS 181A.195 before making a fitness determination.

(c) An approved fitness determination does not guarantee employment.

(d) An incomplete fitness determination does not entitle the employee, volunteer or applicant the right to appeal under OAR 125-007-0300.

(3) Pursuant to ORS 181A.195, and OAR 125-007-0310, information obtained in the criminal records check is confidential and will not be disseminated by the board except to persons with a demonstrated and legitimate need to know the information.

Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195
Statutes/Other Implemented: ORS 181A.195, ORS 181A.170, ORS 676.303

855-102-0110
Board Administration: Criminal Background Checks – Costs

The applicant or licensee must pay the board the cost of acquiring and furnishing the criminal offender information. The amount will not exceed the cost to the board to obtain such information on behalf of the applicant or licensee, including fees charged to the board by the Oregon Department of State Police and the Federal Bureau of Investigation.

Statutory/Other Authority: ORS 676.303 & ORS 689.205
Statutes/Other Implemented: ORS 676.303, ORS 181A.195 & ORS 689.207

855-102-0125 *
Board Administration: Notice of Proposed Rule

(1) Prior to the permanent adoption, amendment, or repeal of any rule, the State Board of Pharmacy must give notice of its intended action as required in ORS 183.335;

(2) The board will notify and provide a reasonable opportunity for interested persons to be notified of the agency's proposed action in the following ways:

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

(b) To persons who have requested notice pursuant to ORS 183.335(8) at least 28 days before the effective date;

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

(d) To persons or organizations the board's Executive Director determines, pursuant to ORS 183.335, are interested persons in the subject matter of the proposed rule, or would be likely to notify interested persons of the proposal:

(A) Oregon State Pharmacy Association; and

(B) Oregon Society of Health System Pharmacists.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 183.335, ORS 183.341

Division 115: Pharmacists (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 115 for Pharmacists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 115 for Pharmacists. Relocates, reorganizes and amends existing Pharmacists rules from Divisions 019, 020, and 041. After the board permanently adopts and publishes Division 115, repeals Division 019 on the effective date of Division 115.

Documents Relied Upon per ORS 183.335(2)(b)(D):
- Oregon Board of Pharmacy 2022-2026 Strategic Plan
- Alkhateeb, Fadi M., et al. "Review of National and International Accreditation of Pharmacy Programs in the Gulf Cooperation Council Countries." *American Journal of Pharmaceutical Education* 82.10 (2018). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6325464/
- FPGEC Certification Candidate Application Bulletin Spring 2022-Spring 2023. National Association of Boards of Pharmacy. //read.nxtbook.com/nabp/bulletin/fpgec_2022/cover.html
- ACPE List of Programs Accredited by State https://www.acpe-accredit.org/accredited-programs-by-state/, see +For International for information on Lebanese American University

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): On 5/24/2023, board staff sent out a fiscal impact request via GovDelivery to licensees/registrants requesting estimated fiscal impacts associated with compliance, implementation and operation related to any of the following proposed rules:

-Requiring each pharmacist who provides counseling to a patient located in Oregon to be licensed with the board as a Pharmacist

-Providing counseling that includes an interactive communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device

-For a prescription delivered to a patient except at a Drug Outlet Pharmacy, Pharmacy Prescription Kiosk or Pharmacy Prescription Locker, requiring the pharmacist to attempt to:
1. Provide counseling prior to delivery
2. Provide drug information in a format accessible by the patient, including information on how to contact the Pharmacist with the delivery; and
3. Reattempt to provide counseling with 24 hours of delivery if counseling does not occur prior to delivery.

-Requiring each pharmacist that attempts counseling, provides counseling, or accepts the request not to be counseled to document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction;

- Requiring clinical pharmacy records to be securely retained for 7 years in written or electronic format and available to the board upon request

-Requiring the Pharmacist-in-Charge for each Drug Outlet Pharmacy located both in and out of Oregon to:
1. Complete 1000, 1500, or 2000 hours of pharmacy practice within the last 1, 2, or 3 years in a US state or its jurisdiction
2. Complete a board provided PIC training course either before the appointment or within 90 days after the appointment and every 5 years thereafter
3. Be employed by the outlet
4. Be physically onsite at the Drug Outlet Pharmacy a minimum of 20 hours per work week or fifty percent (50%) of the hours of operation of the pharmacy, whichever is less.

As of 6/2/2023, the board has received two estimated fiscal impact statements.
- A company with 13 retail pharmacies in Oregon estimates it will impact their operations ranging from $54,054 to $144,144 per outlet annually (the estimate did not provide information on the components that contributed to the estimate).
-An institutional pharmacy estimated it will cost $150,000/year for RPH to provide counseling to patients located in OR, they estimate $350,000 year/or 1-1.5 FTE to comply with the counseling with interactive communication, 1-2 FTE/or $400,000 year to comply with counseling requirements for delivered drugs, $75,000/or 0.5 FTE productivity to comply with documentation requirements for attempts or providing counseling, $75,000 year to manage and comply with securely retaining records for 7 yrs., $2000 annually for course time to complete a PIC training course before or within 90 days of being appointed PIC, $200,000 yearly for the employment cost of the PIC as 1.0 FTE to ensure compliance of the PIC being employed by the outlet, For PICs in the reserves, it may be a severe personal financial impact in excess of $400,000 per year as they have mandatory and required military training off-site which would cost the organization $50,000 annually to find and employ contract PICs to comply with the proposed rule related to being physically on-site 20 hours per week or 50% of the hours of operation.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed revisions to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Creates new Division 115 for Pharmacist rules. Relocates, reorganizes and amends existing Pharmacist rules from Division's 019, 020, and 041 to Division 115 in alignment with the board's strategy to systematically organize all Divisions.

Proposed amendments include revising titles, clarifying requirements for applicability, definitions, general qualifications for all Pharmacists license types, licensure requirements for all Pharmacist license

types, licensure application, license renewal, license reinstatement, licensure lapse, licensure retirement, licensure voluntary surrender, Pharmacist Preceptor registration, in-state and out-of-state volunteer Pharmacist, and Nuclear Pharmacist. General responsibilities, confidentiality responsibilities, duty to report responsibilities, training responsibilities, Drug Utilization Review (DUR), Counseling, PIC qualifications, limitations and duties. Services such as Pharmacist consulting practice, administration of vaccines, drugs or devices, Clinical Pharmacy Agreements, Medication Therapy Management, prescribing practices, and naloxone. After the board permanently adopts and publishes Division 115, repeals Division 019 on the effective date of Division 115. Upon adoption of Division 115, the board will consider amending and or repealing the following rules at a future board meeting: OAR 855-041-1018, OAR 855-020-0105, OAR 855-020-0110, OAR 855-020-0120, OAR 855-020-0200, OAR 855-020-0300, OAR 855-041-1018, OAR 855-041-3000, OAR 855-041-3300, OAR 855-041-3305, OAR 855-041-3310, OAR 855- 041-3315, OAR 855-041-3320, OAR 855-041-3325, OAR 855-041-3330, OAR 855-041-0335, and OAR 855-041-3340.

The practice of pharmacy in Oregon requires a license. Counseling of an Oregon patient who is located in Oregon is the practice of pharmacy in Oregon. Other health care boards in Oregon and other states consider counseling to patients who are located in Oregon to require licensure. This would bring us in alignment with other boards and ensure that the Board is following statutory mandates regarding licensure requirements for those practicing pharmacy in Oregon.

DIVISION 115
PHARMACISTS

855-115-0001
Applicability

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

(2) Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance with statutes and rules unless exempt under ORS 689.225.

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

OR

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

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

855-115-0005
Definitions

(1) "Drug utilization review" or "DUR" means evaluation of a prescription to identify and resolve potential problems through the review of information provided to the Pharmacist by the patient, patient's agent, prescriber and the patient's record.

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

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

855-115-0010
Licensure: Qualifications- General

(1) Before licensure as a Pharmacist, an applicant must meet the qualifications required that are applicable to their method of licensure;

(a) Examination or Score Transfer in OAR 855-115-0020; or

(b) Reciprocity in OAR 855-115-0025.

(2) If residing in the United States, proof of citizenship, legal permanent residency or qualifying visa, as required by 8 USC 1621

(3) Foreign pharmacy graduates must also meet the requirements of OAR 855-115-0015 prior to applying for a Pharmacist license.

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

855-115-0015
Licensure: Qualifications- Pharmacist Foreign Pharmacy Graduate Education

(1) An applicant for pharmacist licensure who graduated from a foreign school, college, or program of pharmacy must meet the following educational requirements:

(a) Obtain certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC); and

(b) Submit evidence of 1440 hours in pharmacy practice as an intern or pharmacist in the United States or its jurisdiction.

(2) (1)(a) is not required for graduates of:

(a) A Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program located in Canada or its jurisdiction with a curriculum taught in English and who graduated between 1993 and June 30, 2004.

(b) The ACPE-accredited program at the Lebanese American University in Byblos, Lebanon with a Doctor of Pharmacy degree and graduated after 2002.

(3) If (1)(a) is required, an applicant must not count internship hours or practice as a pharmacist towards the requirement in (1)(b) that was completed before achieving the FPGEC certification.

(4) Once the educational qualifications in this rule are met, an applicant must also comply with the requirements for licensure in OAR 855-115-0020 for examination or score transfer or OAR 855-115-0025 for reciprocity.

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

855-115-0020
Licensure: Qualifications- Pharmacist Examination or Score Transfer

(1) To receive licensure as a Pharmacist by examination or score transfer, an applicant must meet the following requirements:

(a) Provide evidence in the form of an official transcript from an Accreditation Council for Pharmacy Education (ACPE) accredited college or school of pharmacy or compliance with OAR 855-115-0015 that:

(A) A degree has been conferred; and

(B) The applicant has completed a minimum of 1440 hours in an Internship Program as that term is defined in OAR 855-006-0005.

(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;

(c) Pass the Oregon Multistate Pharmacy Jurisprudence Examination (MPJE) exam. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts.

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

(2) An applicant who has obtained their professional degree outside the United States is not eligible for licensure via examination or score transfer until they have met the requirements of OAR 855-115-0015.

(3) An applicant applying via score transfer must request the National Association of Boards of Pharmacy to transfer their NAPLEX score to Oregon.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 413.590, ORS 689.151,ORS 689.285

855-115-0025
Licensure: Qualifications- Pharmacist Reciprocity

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

(a) Be a graduate, as shown by an official transcript, of an ACPE accredited college or school of pharmacy or compliance with OAR 855-115-0015;

(b) Have passed the NAPLEX;

(c) Have passed the Oregon MPJE. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;

(d) Proof that each Pharmacist license granted to the applicant is not suspended, revoked, canceled or otherwise completely restricted from the practice of pharmacy for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the practice of pharmacy.

(e) Have either:

(A) Been engaged in the practice of pharmacy for period of at least 12 months including a minimum of 1440 hours of work experience as a licensed Pharmacist. Evidence supporting this work experience must be provided at time of application; or

(B) Completed 1440 hours in an Internship Program as that term is defined in OAR 855-006-0005 within the 12 month period immediately before the date of application. Evidence must be provided at time of application.

(2) An applicant who has obtained their professional degree outside the United States and jurisdiction is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-115-0015.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.265, ORS 689.405

855-115-0030

Licensure: Application- Pharmacist

(1) An application for licensure as a Pharmacist may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of:

(a) Evidence of compliance with OAR 855-115-0020 or 855-115-0025;

(b) A completed application including:

(A) Payment of the fee prescribed in OAR 855-110;

(B) A current, passport regulation size photograph (full front, head to shoulders);

(C) Personal identification or proof of identity;

(D) Certificate of completion for the one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority;

(c) A completed national fingerprint-based background check; and

(d) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of a Pharmacist expires June 30 in odd numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.225, ORS 689.285

855-115-0035

Licensure: Renewal or Reinstatement- Pharmacist

(1) An applicant for renewal of a Pharmacist license must:

(a) Pay the biennial license fee required in OAR 855-110;

(b) Complete the continuing pharmacy education requirements as outlined in OAR 855-135; and

(c) Be subject to a criminal background check; and

(d) Provide a completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(2) A Pharmacist who fails to renew their license by the expiration date and whose license has been lapsed for 12 months or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A person who fails to renew their license by the expiration date and whose license has been lapsed for greater than 12 months may apply to reinstate their Pharmacist license as follows:

(a) Apply per OAR 855-115-0030;

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

(c) Meet the requirements below, if applicable.

(4) A person must take and pass the Oregon MPJE if their pharmacist license has been lapsed for more than three years. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;

(5) If the Pharmacist license has been lapsed for more than five years and the person has not maintained an active pharmacist license in another US state or jurisdiction, a person must comply with (4) and take and pass the NAPLEX. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts.

(6) In lieu of reinstatement, a person may apply for licensure via reciprocity if the person has maintained an active pharmacist license in good standing in another US state or jurisdiction.

(7) A person whose Pharmacist license has been retired for more than 12 months need only pay the annual license fees for the year in which they seek a license, however they must also complete the requirements in (3).

(8) A person whose Pharmacist license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition to the board for reinstatement of such license pursuant to ORS 689.445 and in conjunction with the application process identified in OAR 855-115-0030.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.275, ORS 689.445

855-115-0040
Licensure: Lapse

(1) A Pharmacist may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.
(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person must not practice pharmacy if their license is lapsed.

(d) A person may apply for renewal or reinstatement of their license according to OAR 855-115-0035.

(2) If a Pharmacist requests to lapse their license prior to the expiration date, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board will not accept the lapse if an investigation of or disciplinary action against the licensee is pending.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0045
Licensure: Retire

(1) A Pharmacist may request that the board retire their license if the Pharmacist is in good standing, has been licensed as a Pharmacist for at least 20 years and is no longer practicing pharmacy.

(a) A retired license is not considered discipline;

(b) The board has continuing authority under ORS 689.153;

(c) A person must not practice pharmacy if the license is retired.

(d) A person may apply for renewal or reinstatement according to OAR 855-115-0035.

(2) If a Pharmacist requests to retire their license prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the request to retire the license.

(b) If the board accepts the request to retire the license, the board will notify the licensee of the date the license is no longer active.

(c) The board will not accept the request to retire the license if an investigation of or disciplinary action against the licensee is pending.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0050
Licensure: Voluntary Surrender

A Pharmacist may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date is the order is signed by all parties and served on the licensee.

(4) The licensee must cease practicing pharmacy from the date the license terminates.

(5) A voluntarily surrendered license cannot be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-115-0035 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0060
Registration: In-State Volunteer Pharmacist

(1) A Pharmacist may register with the board for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services without compensation under the terms of the law.

(2) A no cost registration may be issued by the board upon receipt of a completed application. Registration requires submission of a signed form provided by the board in accordance with ORS 676.345(2).

(3) Registration will expire at the licensee's next license renewal date and may be renewed biennially. It is the licensee's responsibility to ensure his or her active registration in this program.

(4) Nothing in this section relieves licensee from the responsibility to comply with board regulations and still may be subject to disciplinary actions.

(5) Pharmacists providing care under the provisions of ORS 676.340 and ORS 676.345 remain subject to the board complaint investigation process articulated in ORS 676.175.

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

855-115-0065
Notification: Out-of-State Volunteer Pharmacist

(1) A pharmacist who is not licensed in Oregon may, without compensation and in connection with a coordinating organization or other entity, practice pharmacy for 30 days each calendar year. The pharmacist is not required to apply for licensure or other authorization from the board to practice pharmacy under this section.

(2) To practice pharmacy under this section, the pharmacist who is not licensed in Oregon must submit on a form prescribed by the board, at least 10 days prior to commencing practice in this state, to the board:

(a) Proof that the pharmacist is in good standing and is not the subject of an active disciplinary action in any jurisdiction in which the Pharmacist is authorized to practice;

(b) An acknowledgement that the pharmacist must provide services only within the scope of practice of pharmacy and will provide services pursuant to the scope of practice of this state or the health care practitioner's licensing agency, whichever is more restrictive;

(c) An attestation that the pharmacist will not receive compensation for practice in this state;

(d) The name and contact information of the coordinating organization or other entity through which the Pharmacist will practice; and

(e) The dates on which the pharmacist will practice in this state.

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

Statutory/Other Authority: ORS 689.205, ORS 689.315, 2022 HB 4096
Statutes/Other Implemented: ORS 689.151, 2022 HB 4096

855-115-0070
Notification: Nuclear Pharmacists

In order to qualify under these rules as a nuclear Pharmacist, a Pharmacist must :

(1) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Protection Services of the Department of Human Services; and

(2) Be a Pharmacist licensed to practice in Oregon; and

(3) Submit to the Board of Pharmacy either:

(a) Evidence of current certification in nuclear pharmacy by the Board of Pharmacy Specialties; or

(b) Evidence that they meet both the following:

(A) Certification of a minimum of six month on-the-job training under the supervision of a qualified nuclear Pharmacist in a nuclear pharmacy providing radiopharmaceutical services; and

(B) Certification of completion of a nuclear pharmacy training program in a college of pharmacy or a nuclear pharmacy training program approved by the board.

(4) Receive a letter of notification from the board that the evidence submitted by the Pharmacist meets the above requirements and has been accepted by the board.

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

855-115-0105
Pharmacist: Responsibilities- General

When practicing pharmacy per ORS 689, each Pharmacist must:

(1) Use that degree of care, skill, diligence and reasonable professional judgment that is exercised by a careful and prudent Pharmacist in the same or similar circumstances;

(2) Be responsible for their own actions;

(3) Be responsible for the actions of each Intern, Certified Oregon Pharmacy Technician, Pharmacy Technician and non-licensed pharmacy personnel;

(4) Ensure compliance with all state and federal laws and rules governing the practice of pharmacy;

(5) Control each aspect of the practice of pharmacy;

(6) Perform appropriately the duties of a Pharmacist;

(7) Ensure access to reference material and equipment needed based on the services provided;

(8) Ensure services are provided with required interpretation and translation per ORS 689.564;

(9) Ensure services occur in a sanitary, secure and confidential environment; and

(10) Be clearly identified as a Pharmacist in all interactions and communications (e.g., nametag, phone interaction, chart notations);

(11) Display in plain sight the Pharmacist license within the pharmacy or place of business to which it applies;

(12) Engage in a continuous quality improvement program;

(13) Review, adhere to and enforce written policies and procedures. The review must:

(A) Occur prior to engaging in the practice of pharmacy;

(B) Occur with each update; and

(C) Be documented and records retained according to OAR 855-104-0055.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.025, ORS 689.151, ORS 689.155, ORS 689.645, ORS 689.682, ORS 689.689 & 2022 HB 4034

855-115-0110
Responsibilities: Confidentiality

Each Pharmacist must comply with OAR 855-104-0015 regarding confidentiality.

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

855-115-0115
Responsibilities: Duty to Report

Each Pharmacist must report to the board as required by OAR 855-104-0010. In addition, unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each Pharmacist must report to the board without undue delay, but within 1 business day of:

(1) Confirmed significant drug loss; or

(2) Any loss related to suspected drug theft of a controlled substance.

Statutory/Other Authority: ORS 689.205, ORS 689.455
Statutes/Other Implemented: ORS 676.150, ORS 689.151, ORS 689.155 & ORS 689.455

855-115-0120
Pharmacist: Responsibilities- Personnel

(1) When practicing pharmacy per ORS 689, each Pharmacist must:

(a) Ensure personnel that require licensure have been granted and maintain licensure with the board;

(b) Ensure licensed personnel work within the duties permitted by their licensure;

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

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

(e) Ensure each Intern only practices pharmacy under the supervision of a Pharmacist as outlined in OAR 855-120 including any applicable ratios;

(f) Ensure each Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a Pharmacist as outlined in OAR 855-125;

(g) Ensure licensed personnel do not engage in prohibited practices as outlined for Interns in OAR 855-120-0150 and for Certified Oregon Pharmacy Technicians and Pharmacy Technicians in OAR 855-125-0150;

(h) Ensure non-licensed personnel do not practice or assist in the practice of pharmacy;

(i) Ensure initial and ongoing training is completed that is commensurate with the tasks that the Pharmacist and persons under their supervision will perform, prior to the performance of those tasks;

(j) Ensure continued competency in tasks that are performed by the Pharmacist and persons under their supervision;

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

(3) When engaging in the practice of pharmacy per ORS 689, each Pharmacist may delegate the practice of pharmacy to other health care providers who are appropriately trained and authorized to perform the delegated tasks.

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

855-115-0125

Pharmacist: Responsibilities- Drugs, Records and Security

When practicing pharmacy per ORS 689, each Pharmacist must:

(1) Ensure the security of prescription drugs, pharmacy and patient records including:

(a) Providing adequate safeguards against loss, theft, or diversion;

(b) Ensuring only persons authorized by the Pharmacist access the areas where prescription drugs, pharmacy and patient records are stored by restricting access;

(2) Ensure that all records are maintained in accordance with state and federal laws and rules;

(3) Only receive drugs from an Oregon Registered Drug Outlet (e.g. Wholesaler, Manufacturer or Pharmacy);

(4) Comply with the drug storage rules for pharmacies in OAR 855-041-1036;

(5) Ensure drugs and devices that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or identified as suspect or illegitimate, or otherwise unfit for dispensing or administration must be documented, quarantined and physically separated from other drugs and devices until they are destroyed or returned to the supplier;

(6) Ensure each compounded drug is prepared in compliance with OAR 855-045;

(7) Ensure all computer equipment used for the practice of pharmacy:

(a) Establishes and maintains a secure connection to patient information including but not limited to patient demographics, medical records, pharmacy records and clinical visit documentation;

(b) Prevents unauthorized access to patient information; and

(c) Is configured so information from any patient records are not duplicated, downloaded, or removed from the electronic database if accessed remotely;

(8) Document accurately and maintain records in the practice of pharmacy including, but not limited to:

(a) Services provided;

(b) The date, time and identification of the licensee and the specific activity or functions performed; and

(c) Maintain records pertaining to the acquisition, storage, dispensing or administration, and disposal of drugs and devices; and

(9) Ensure reporting of data as required by federal and state regulations, including but not limited to:

(a) ALERT Immunization Information System (ALERT-IIS) per ORS 433.090, ORS 433.092, ORS 433.094, ORS 433.095, ORS 433.096, ORS 433.098, ORS 433.100, ORS 433.102, ORS 433.103, and ORS 433.104;

(b) Communicable diseases per ORS 433.004; and

(c) Vaccine Adverse Event Reporting System (VAERS) per 21 CFR 600.80 (v. 04/01/2022).

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

855-115-0130 *
Pharmacist: Responsibilities- 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;

(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. 04/01/2022); and

(D) Listed chemicals per 21 CFR 1310.05 (v. 04/01/2022); and

(h) A Pharmacist who utilizes licensees remotely, must comply with OAR 855-041-3200 through OAR 855-041-3250.

(2) When engaging in the practice of pharmacy per ORS 689, each Pharmacist may delegate final verification of drug and dosage form, device, or product to a Certified Oregon Pharmacy Technician or Pharmacy Technician per ORS 689.005 when the following conditions are met:

(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;

(b) The Certified Oregon Pharmacy Technician or Pharmacy Technician does not use discretion in conducting final verification;

(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and

(d) Ensure the Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.

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

855-115-0140
Drug Utilization Review (DUR)

(1) A Pharmacist must complete a drug utilization review (DUR) by reviewing the patient record prior to dispensing each prescription drug or device for the purpose of identifying the following:

(a) Over-utilization or under-utilization;

(b) Therapeutic duplication;

(c) Drug-disease contraindications;

(d) Drug-drug interactions;

(e) Incorrect drug dosage or formulation;

(f) Inappropriate duration of treatment;

(g) Drug-allergy interactions; and

(h) Drug abuse or misuse.

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

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

855-115-0145
Counseling

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

(2) The Pharmacist must counsel the patient or patient's agent on the use of a drug or device:

(a) Upon request;

(b) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;

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

(d) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or

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

(3) When communicating (e.g. counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the Pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the Pharmacist is proficient in the patient's preferred language.

(4) For a prescription delivered to a patient, except at a Drug Outlet Pharmacy, Pharmacy Prescription Kiosk or a Pharmacy Prescription Locker, the Pharmacist must:

(A) Attempt to provide counseling prior to delivery as required in (1);

(B) Provide drug information in a format accessible by the patient, including information on how to contact the Pharmacist with the delivery; and

(C) Reattempt to provide counseling within 24 hours of delivery if counseling does not occur prior to delivery.

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

(a) Only a Pharmacist can accept a patient's or patient's agent's request not to be counseled, when counseling is required;

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

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

(7) The Pharmacist that attempts counseling, provides counseling or accepts the request not to be counseled must document their identity, each attempt to counsel and the outcome at the time of the attempt or interaction;

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

(9) Counseling on a new prescription may include, but is not limited to, the following elements:

(a) Name and description of the drug;

(b) Dosage form, dose, route of administration, and duration of drug therapy;

(c) Intended use of the drug and expected action;

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) Techniques for adherence and self-monitoring drug therapy;

(g) Proper storage and appropriate disposal method(s) of unwanted or unused medication;

(h) Refill information;

(i) Action to be taken in the event of a missed dose; and

(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(10) Counseling on a refill prescription may include, but is not limited to, the following elements:

(a) Name and purpose of the medication;

(b) Directions for use, including technique;

(c) Perceived side effects; and

(d) Adherence.

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

855-115-0150
Prohibited Practices

Pharmacists must not:

(1) Engage in the dispensing, distribution or delivery of drugs unless working for a registered Drug Outlet pharmacy;

(2) Possess personally or store drugs other than in a registered Drug Outlet pharmacy except for those drugs legally prescribed for the personal use of the Pharmacist or when the Pharmacist possesses or stores the drugs in the usual course of business and within the Pharmacist's scope of practice; and

(3) Diagnose.

(4) Engage in any form of discrimination, harassment, intimidation, or assault;

(5) Permit any non-licensed pharmacy personnel to perform any function that constitutes the practice of pharmacy as defined in ORS 689 or the assistance of the practice of pharmacy. Non-licensed personnel may only perform functions permitted by the Pharmacist providing supervision.

(6) Permit any Intern to perform any task in which the supervising Pharmacist is not trained or qualified to perform.

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

855-115-0200 *
Pharmacist-in-Charge: Qualifications and Limitations

(1) In order to be a Pharmacist-in-Charge (PIC) a Pharmacist must:

(a) Complete at least 2000 hours of pharmacy practice as a Pharmacist within the last 2 years in a US state or jurisdiction; and

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

(c) Be employed by the outlet; and

(2) A Pharmacist must not be designated PIC of more than three pharmacies. The following drug outlet types do not count towards this limit:

(a) Pharmacy Prescription Kiosk in OAR 855-141;

(b) Pharmacy Prescription Locker in OAR 855-143.

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

855-115-0210
Pharmacist-in-Charge: Responsibilities

(1) In addition to the responsibilities of a Pharmacist outlined in OAR 855-115, a Pharmacist-in-Charge of a Drug Outlet pharmacy must:

(a) Be actively engaged in pharmacy activities at the Drug Outlet pharmacy;

(b) Be physically present at the Drug Outlet pharmacy on a regular basis for a sufficient amount of time as needed to ensure Drug Outlet pharmacy compliance;

(c) Be responsible for the ongoing conduct, operation, management and control of the Drug Outlet pharmacy;

(d) Ensure the outlet notifies the board of a change in PIC within 15 days of the occurrence;

(e) Establish, maintain, and enforce written policies and procedures governing the practice of pharmacy that are compliant with federal and state laws and rules;

(f) Ensure maintenance of complete and accurate records;

(g) Establish, maintain and enforce a continuous quality improvement program;

(h) Develop, implement and submit a plan of correction for observations noted on an inspection within the time allowed by the board;

(i) Complete an annual self-inspection of the pharmacy using the Self-Inspection Form provided by the board, by July 1 each year and within 15 days of becoming PIC. The completed self-inspection forms must be signed and dated by the PIC and retained for three years from the date of completion; and

(j) Ensure a controlled substance inventory with discrepancy reconciliation is accurately completed and documented:

(a) For all controlled drugs either prior to the opening or after the close of business on the inventory date;

(A) Within 15 days of a change in PIC; and

(B) At least every 367 days; and

(b) For all Schedule II controlled drugs:

(A) At least every 93 days in a Retail Drug Outlet Pharmacy; and

(B) At least every 31 days in an Institutional Drug Outlet Pharmacy.

(2) The PIC a Drug Outlet pharmacy affiliated with the following Drug Outlet types must also comply with the PIC responsibilities as outlined in:

(a) Pharmacy Prescription Kiosk in OAR 855-141;

(b) Pharmacy Prescription Locker in OAR 855-143; and

(c) Remote Dispensing Site Pharmacy in OAR 855-139.

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

855-115-0300
Pharmacist Consulting Practice

(1) A Pharmacist who provides services to an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure as well as by any relevant federal and state laws and rules.

(2) A Pharmacist who provides services to a correctional facility, long term care facility, community-based care facility, hospital drug room, or charitable pharmacy that does not have additional Pharmacist service requirements under the terms of its licensure with any other state agency, must provide services that include but are not limited to the following:

(a) Provide the facility with policies and procedure relating to security, storage and distribution of drugs within the facility;

(b) Provide guidance on the proper documentation of drug administration or dispensing;

(c) Provide educational materials or programs as requested.

(3) A Pharmacist who provides services to an Oregon licensed healthcare provider must follow all state and federal laws and rules related to the practice of pharmacy.

(4) A Pharmacist must maintain appropriate records of their services in (2) - (4) for three years, and make them available to the board for inspection.

(5) A Pharmacist may store health protected records outside an Oregon licensed facility as permitted in OAR 855-104-0055.

(6) Records and documents must be retained according to OAR 855-104-0055.

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

855-115-0305
Administration of Vaccines, Drugs, or Devices

(1) In accordance with ORS 689.645 and ORS 689.655, a Pharmacist may administer a vaccine, drug or device as specified in this rule.

(2) A Pharmacist who administers a vaccine, drug or device must:

(a) Provide documentation that they have received practical training on the vaccine, drug or device, injection site and administration technique that is to be utilized.

(A) For vaccines, the training must also include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

(B) For orally administered drugs, training is not required;

(C) The training in (a) may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board.

(D) Records of training must be retained according to OAR 855-104-0055.

(b) Hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years. The most current CPR certification record must be retained according to OAR 855-104-0055;

(c) Ensure that any drugs administered to a patient were stored in accordance with the drug storage rules for pharmacies in ORS 855-041-1036;

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

(e) Ensure that vaccine, drug or device administration is documented in the patient's permanent record; and

(f) Ensure records and documents are retained according to OAR 855-104-0055. Records of administration must include but are not limited to:

(A) Patient identifier;

(B) Vaccine, drug or device and strength;

(C) Route and site of administration;

(D) Date and time of administration; and

(E) Pharmacist identifier.

(3) For vaccines only, the requirements in (2) and the following apply, the Pharmacist must:

(a) Follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022);

(b) Have access to a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);

(c) Give the appropriate Vaccine Information Statement (VIS) to the patient or patient's agent with each dose of vaccine covered by these forms. The Pharmacist must ensure that the patient or patient's agent is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine;

(d) Report all vaccinations administered to the ALERT IIS in accordance with OAR 333-049-0050, and for COVID-19 immunizations, in accordance with OAR 333-047-1000;

(e) Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.

(4) The Pharmacist must be acting:

(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; or

(b) In accordance with a statewide drug therapy management protocol per OAR 855-115-0345 or clinical pharmacy agreement or collaborative drug therapy management agreement per OAR 855-115-0315; or

(c) In accordance with a written administration protocol issued by the Oregon Health Authority and approved by the board.

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

(6) Except as required in (2), records and documents must be retained according to OAR 855-104-0055.

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

855-115-0310 *
Services: Laboratory

(1) A Pharmacist must only order and receive laboratory test when:

(a) Managing drug therapy pursuant to the terms of a clinical pharmacy agreement or collaborative drug therapy management agreement with a provider under OAR 855-115-0315;

(b) Providing patient care services pursuant to the terms of the post diagnostic formulary listed in OAR 855-115-0340 that is developed under ORS 689.645 and adopted by the board under ORS 689.649;

(c) Providing patient care services pursuant to and as allowed by the terms of a protocol listed in OAR 855-115-0345 that is developed under ORS 689.645 and adopted by the board under ORS 689.649;

(d) Permitted under a Health Screen Testing Permit pursuant to ORS 438.010(8); ORS 438.060; ORS 438.130(2); ORS 438.150(5), (6) and (7); OAR 333-024-0370, OAR 333-024-0375, OAR 333-024-0380, OAR 333-024-0385, OAR 333-024-0390, OAR 333-024-0395 and OAR 333-024-0400; or

(e) Monitoring a therapeutic response or adverse effect to drug therapy under ORS 689.005.

(2) A pharmacy may perform a laboratory test as permitted under OAR 855-041-1190.

(3) Records and documents must be retained according to OAR 855-104-0055.

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

855-115-0315 *
Services: Collaborative Drug Therapy Management

(1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one practitioner and one Pharmacist; or

(b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more Pharmacists.

(2) A Pharmacist shall engage in collaborative drug therapy management with a practitioner only under a written arrangement that includes:

(a) The identification, either by name or by description, of each of the participating Pharmacists;

(b) The identification, by name or description, of each of the participating practitioners or group of practitioners;

(c) The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement;

(d) The types of decisions that the pharmacist is allowed to make, which may include:

(A) A detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case;

(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;

(C) A detailed description of the activities the pharmacist is to follow including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;

(D) Circumstances which will cause the pharmacist to initiate communication with the practitioner, including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect.

(e) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary;

(f) Quality assurance and periodic review by a panel of the participating Pharmacists and practitioners;

(g) Authorization by the practitioner for the pharmacist to participate in collaborative drug therapy; and

(h) A requirement for the collaborative drug therapy arrangement to be reviewed and updated, or discontinued at least every two years;

(3) The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request.

(4) Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.

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

855-115-0320
Services: Medication Therapy Management

(1) Medication Therapy Management (MTM) is a distinct service or group of services that is intended to optimize the therapeutic outcomes of a patient. Medication Therapy Management can be an independent service provide by a Pharmacist or can be in conjunction with the provision of a medication product with the objectives of:

(a) Enhancing appropriate medication use;

(b) Improving medication adherence;

(c) Increasing detection of adverse drug events;

(d) Improving collaboration between practitioner and Pharmacist; and

(e) Improving outcomes.

(2) A Pharmacist that provides MTM services must ensure that they are provided according to the individual needs of the patient and may include but are not limited to the following:

(a) Performing or otherwise obtaining the patient's health status assessment;

(b) Developing a medication treatment plan for monitoring and evaluating the patient's response to therapy;

(c) Monitoring the safety and effectiveness of the medication therapy;

(d) Selecting, initiating, modifying or administering medication therapy in consultation with the practitioner where appropriate;

(e) Performing a medication review to identify, prevent or resolve medication related problems;

(f) Monitoring the patient for adverse drug events;

(g) Providing education and training to the patient or the patient's agent on the use or administration of the medication where appropriate;

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

(A) Be accurate;

(B) Identify the person who completed each action;

(C) Records and documents must be retained according to OAR 855-104-0055.

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

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

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

855-115-0330
Services: Prescribing Practices- Formulary or Protocol Compendia

(1) A Pharmacist located and licensed in Oregon may prescribe and dispense a FDA-approved drug and device included on either the Formulary or Protocol Compendia, 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 the development of a protocol for the Protocol Compendia. A Pharmacist may provide feedback on the Formulary or Protocol Compendia 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 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, 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 healthcare 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; and

(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.

(f) Monitor and evaluate the effectiveness of the care plan and make modifications to the plan;

(g) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a Formulary or Protocol Compendia drug or device.

(6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.

(7) 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.

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

855-115-0335
Prescribing: Prohibited Practices

(1) A Pharmacist must not prescribe a drug or device via the Formulary or Protocol Compendia:

(a1) To self or a spouse, domestic partner, parent, guardian, sibling, child, aunt, uncle, grandchild and grandparent, including foster, in-law, and step relationships or other individual for whom a Pharmacist's personal or emotional involvement may render the Pharmacist unable to exercise detached professional judgment in prescribing; and

OR

(a2) To an individual for whom a Pharmacist's personal or emotional involvement may render the Pharmacist unable to exercise detached professional judgment in prescribing; and
(b) When the compendia requires referral to 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

855-115-0340
Formulary Compendium

A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, a FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented.

Devices and supplies:

(1) Diabetic blood sugar testing supplies;

(2) Injection supplies;

(3) Nebulizers and associated supplies;

(4) Inhalation spacers;

(5) Peak flow meters;

(6) International Normalized Ratio (INR) testing supplies;

(7) Enteral nutrition supplies;

(8) Ostomy products and supplies; and

(9) Non-invasive blood pressure monitors

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

855-115-0345
Protocol Compendium

A Pharmacist may prescribe, according to 855-115-0330 and OAR 855-115-0335, FDA-approved drugs and devices listed in the following compendium, pursuant to a statewide drug therapy management protocol.

(1) Continuation of therapy including emergency refills of insulin (v. 06/2023)

(2) Conditions

(a) Cough and cold symptom management

(A) Pseudoephedrine (v. 06/2021);

(B) Benzonatate (v. 06/2021);

(C) Short-acting beta agonists (v. 06/2021);

(D) Intranasal corticosteroids (v. 06/2021);

(b) Vulvovaginal candidiasis (VVC) (v. 06/2021);

(c) COVID-19 Antigen Self-Test (v. 12/2021);

(3) Preventative care

(a) Emergency Contraception (v. 06/2021);

(b) Male and female condoms (v. 06/2021);

(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT (v. 06/2022);

(d) Travel Medications (v. 06/2023);

(e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);

(f) HIV Pre-exposure Prophylaxis (PrEP) (v.06/2023); and

(g) Contraception (v. 06/2023).

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649 & ORS 689.689

855-115-0350
Naloxone- Delivery of Care and Prescribing

(1) A Pharmacist, having determined that there is an identified medical need, can prescribe naloxone and the necessary medical supplies to administer naloxone for opiate overdose:

(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME);

(b) To an individual seeking naloxone;

(c) To an entity seeking naloxone.

(2) The Pharmacist must determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.

(3) The Pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.

(4) The Pharmacist must dispense the naloxone product in a properly labeled container.

(5) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.

(6) The Pharmacist must document the encounter and the prescription, and maintain records for three years.

(7) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.684, ORS 689.305, ORS 689.681, ORS 689.682

Division 120: Interns and Preceptors (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 120 for Interns and Preceptors

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates a new Division 120 for Interns and Preceptors. Proposes relocating and reorganizing existing Intern rules from Division 031. After the board permanently adopts and publishes Division 120, repeals Division 031 on the effective date of Division 120.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed revisions to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Relocates rules from Division 031 to newly created Division 120 Interns. The proposed rule amendments include adding requirements for Interns for applicability, licensure qualification, application, renewal and reinstatement applications, license lapse, voluntary surrender of a license, general responsibilities, confidentiality, duty to report, permitted practices, grounds for discipline, internship program and out-of-state experience. Adds proposed rule requirements for Preceptors including licensure qualification, application, licensure lapse, voluntary surrender of a license, general responsibilities, confidentiality, duty to report, ratio and supervision, prohibited practices, grounds for discipline, qualifications and responsibilities for Internship Program supervisor.

Rule revisions are in alignment with the board's strategy to systematically organize all Divisions. After the board permanently adopts and publishes Division 120, repeals Division 031 on the effective date of Division 120. Upon adoption of Division 120 the board will consider amending OAR 855-006-0005 and relocating relevant definitions related to Interns and Preceptors to Division 120 as well as consider amending OAR 855-019-0200 at a future board meeting.

DIVISION 120
INTERNS AND PRECEPTORS

855-120-0001
Applicability

(1) This Division applies to:

(a) Any individual who is:

(A) Enrolled in or has completed a Bachelor or Doctor of Pharmacy at a COP or SOP or is certified by the Foreign Pharmacy Graduate Equivalency Committee (FPGEC), and who acts as Intern; or

(B) Licensed by the board as a Preceptor to supervise an Intern.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225

855-120-0005
Definitions

(1) "ACPE accredited" means a college or school of pharmacy that is accredited, accredited with probation, pre-candidate or candidate status by Accreditation Council for Pharmacy Education (v. 5/2023) including the Lebanese American University school in Byblos, Lebanon after 2002.

(2) "College of Pharmacy or School of Pharmacy (COP or SOP)" means an ACPE accredited college or school of pharmacy.

(3) "Healthcare Preceptor" means a pharmacist, or person with an active healthcare license in good standing that can independently practice pharmacy within the scope of their licensure and is licensed by the board to supervise the internship training of a licensed Intern.

(4) "Intern" means a person who is enrolled in or has completed a course of study at a board approved college or school of pharmacy and who is licensed with the board as an Intern.

(5) "Internship Program" means a professional experiential program that is approved by the board.

(6) "Internship Program Supervisor " is a Pharmacist licensed with the board as a Preceptor who supervises the Internship Program for a COP or SOP located in Oregon.

(7) "Other Preceptor" means a person who is not licensed as a pharmacist or other healthcare provider in Oregon and is licensed by the board to supervise the internship training of a licensed Intern.

(8) "Preceptor" means a Pharmacist or a person licensed by the board to supervise the internship training of a licensed Intern.

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

855-120-0010
Licensure: Qualifications

(1) To qualify for licensure as an Intern, an applicant must provide proof that they:

(a) Are enrolled in a Doctor of Pharmacy program at a COP or SOP; or

(b) Have graduated with a Bachelor or Doctor of Pharmacy degree from a COP or SOP for the purpose of obtaining the qualifications to apply for a Pharmacist license; or

(c) Have graduated with a Bachelor, Master or Doctor of Pharmacy degree from a foreign college or school of pharmacy and are:

(A) Pursuing an Intern license for the purpose of obtaining the qualifications to apply for a Pharmacist license; and

(B) Certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC). Graduates between 1993 and June 30, 2004 of a Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program located in Canada or its jurisdiction with a curriculum taught in English do not have to submit certification from the FPGEC but must meet all other requirements under this rule for an FPGEC certified intern.

(2) If residing in the United States, an applicant must provide proof of citizenship, legal permanent residency or qualifying visa as required by 8 USC 1621.

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

855-120-0030
Licensure: Application- Intern

(1) An application for licensure as an Intern may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of:

(a) Documentation required in OAR 855-120-0030 and for FPGEC certified documentation required in OAR 855-120-0015; and

(b) A completed application including:

(A) Payment of the fee prescribed in OAR 855-110;

(B) A current, passport regulation size photograph (full front, head to shoulders);

(C) Personal identification or proof of identity;

(D) A completed national fingerprint-based background check; and

(E) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of an Intern expires November 30 and may be renewed as follows:

(a) Biennially prior to graduation from a COP or SOP.

(b) Once after graduation from a COP or SOP.

(c) Once if FPGEC certified or a graduate of a CCAPP program between 1993 and June 30, 2004.

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

855-120-0035
Licensure: Renewal or Reinstatement Applications- Intern

(1) When applying for renewal of an Intern license, an applicant must:

(a) Pay the biennial license fee required in OAR 855-110.

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-135;

(c) Be subject to a criminal background check.; and

(d) Provide a completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(2) An Intern who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license.

(3) An Intern or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate per OAR 855-120-0010; and

(4) A person whose Intern license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition to the board in writing for reinstatement of such license pursuant to ORS 689.445 may apply to reinstate per OAR 855-120-0010.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.275, ORS 689.445

855-120-0040
Licensure: Lapse

(1) An Intern may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.
(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not practice as an Intern if the license is lapsed.

(d) A person may apply for renewal according to OAR 855-120-0035.

(2) If a person requests lapse prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board may not accept the lapse if an investigation of or disciplinary action against the licensee is pending.

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-0050
Licensure: Voluntary Surrender

An Intern may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date is signed by all parties and served on the licensee.

(4) The licensee must cease practicing as an Intern from the date the license terminates.

(5) A voluntarily surrendered license may not be renewed. A former licensee who wants to obtain a license must apply for a license per OAR 855-120-0030 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-0105
Intern: General Responsibilities

(1) Each Intern is responsible for their own actions; however, this does not absolve the supervising Pharmacist or Preceptor from responsibility for the Intern's actions.

(2) An Intern is responsible for recognizing the limits of their knowledge and experience and for resolving situations beyond their expertise by consulting with the supervising Pharmacist or Preceptor.

(3) An Intern must:

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

(b) Only engage in the practice of pharmacy under the supervision of a Pharmacist or Healthcare Preceptor:

(A) After successful completion of academic coursework corresponding to those tasks; and

(B) When permitted by the supervising Pharmacist or Healthcare Preceptor;

(c) Only work within the scope of duties permitted by their license and by the supervising Pharmacist or Healthcare Preceptor;

(d) Know the identity of the supervising Pharmacist or Preceptor at all times;

(e) Only perform tasks they are trained and competent to perform;

(f) Appropriately perform the tasks permitted;

(g) Only access the pharmacy area when a Pharmacist is physically present;

(h) Be clearly identified as an Intern in all interactions and communications (e.g., nametag, phone interaction, chart notations);

(i) Display in plain sight the Intern license within the pharmacy or place of business to which it applies;

(j) Review and adhere to written policies and procedures. The review must:

(A) Occur prior to engaging in the practice of pharmacy as an Intern;

(B) Occur with each update to the policies and procedures; and

(C) Be documented and records retained according to OAR 855-102-0050;

(k) Dispense and deliver prescriptions accurately and to the correct party; and

(l) For hours earned in an Internship Program, must verify that their preceptor is currently licensed with the board as a Preceptor.

(4) An Intern may not work more than 50 hours per week in an Internship Program and must comply with all supervision and ratio requirements.

(5) An intern may perform the duties of a pharmacy technician under the supervision of a Pharmacist so long as they adhere to the rules in OAR 855-125. When solely performing technician duties under the supervision of a Pharmacist the ratios in OAR 855-120-1122 do not apply.

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

855-120-0110
Responsibilities: Confidentiality

Each Intern must comply with OAR 855-104-0015 regarding confidentiality.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-120-0115
Responsibilities: Duty to Report

Each Intern must report to the board as required by OAR 855-104-0010. In addition, unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each Intern must report to the board without undue delay, but within 10 working days if they:

(1) Have been removed from an Internship Program site for reasons including but not limited to patient safety, unprofessional conduct or suspected violation of ORS 475, ORS 689 or OAR 855; or

(2) Have been dismissed from the Doctor of Pharmacy degree program.

(3) For (1) and (2) the Intern must report the date and reason for the removal or dismissal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.150, ORS 689.151, ORS 689.155 & ORS 689.455

855-120-0135
Responsibilities: Permitted Practices

Interns must only practice pharmacy as authorized by the rules of the board and as permitted by the supervising Pharmacist or Healthcare Preceptor with the practice of pharmacy in their scope. When practicing pharmacy, an Intern must adhere to all the applicable rules in OAR 855-115 for Pharmacists.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.155 & 2022 HB 4034

855-120-0150
Prohibited Practices

(1) An Intern must not:

(a) Practice pharmacy as defined in ORS 689.005 except as permitted by the Pharmacist or Healthcare Preceptor who is supervising the Intern;

(b) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace;

(c) Communicate (e.g. counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, unless the Intern is a health care interpreter registered by the Oregon Health Authority under ORS 413.558 or the supervising Preceptor is also fluent in the language being interpreted.

(d) Engage in patient care services when the supervising Pharmacist is not trained and qualified to perform the service.

(2) Until an Intern has successfully completed their first academic year, an Intern may observe, but must not:

(a) Conduct a Drug Utilization Review or Drug Regimen Review;

(b) Counsel a patient or the patient's agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in the patient's record or chart;

(c) Advise on therapeutic values, content, hazards and use of drugs and devices;

(d) Conduct Medication Therapy Management;

(e) Practice pursuant to a Clinical Pharmacy Agreement or engage in Collaborative Drug Therapy Management;

(f) Practice pursuant to Statewide Drug Therapy Management Protocols;

(g) Prescribe a vaccine, drug or device; or

(h) Perform verification as defined in OAR 855-006-0005.

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

855-120-0155
Grounds for Discipline

The following are grounds for discipline:

(1) Continuing to practice as an Intern when one of the following has occurred:

(a) Dismissal from the Doctor of Pharmacy degree program enrolled in to obtain the Intern license; or

(b) Failure to maintain an active Intern license; or

(2) Any other grounds found in ORS 689.405.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.405

855-120-0190
Internship Programs

(1) Interns must complete 1440 hours of internship in an Internship Program to qualify for licensure as a Pharmacist in OAR 855-115-0010 and 855-115-0015.

(2) For obtaining internship hours necessary to apply for a Pharmacist license, the board approves programs:

(a) Administered by an COP or SOP;

(b) Administered for a foreign graduate with FPGEC certification by a Pharmacist registered with the board as a Preceptor;

(c) Administered by another Board of Pharmacy or equivalent in any US state or jurisdiction.

(3) The Internship Program for:

(a) Students enrolled in a COP or SOP located in Oregon must be supervised by an Internship Program Supervisor; or

(b) Foreign graduates with FPGEC certification located in Oregon must be supervised by a licensed Preceptor;

(c) Foreign graduates with FPGEC certification located in Oregon must document the hours obtained on a board approved form.

(4) All Internship Programs must include, but are not limited to:

(a) Direct patient care;

(b) Interprofessional interaction and practice;

(c) Medication dispensing, distribution, administration, and systems management; and

(d) Professional development.

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

855-120-0195
Out-of-State Internship Experience

(1) In order for an Intern to obtain credit for experience obtained outside of Oregon as part of an COP or SOP with an Internship Program based in Oregon, an Intern must be licensed as required by state laws and rules in the state in which they practice.

(2) In order for an out-of-state intern to engage in the practice of pharmacy in the State of Oregon, the intern must:

(a) Be licensed as an Intern by the State of Oregon; and

(b) Comply with ORS 475, ORS 689 and OAR 855.

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

PRECEPTORS

855-120-1010
Licensure: Qualifications

To qualify for licensure as a Preceptor, an applicant who is a:

(1) Pharmacist must have been actively practicing as a pharmacist in any state for at least one year immediately prior to applying for a Preceptor license unless the pharmacist has been licensed for at least 6 months and is actively participating in an ASHP-accredited, pre-candidate, candidate or conditional accredited PGY1 residency program. The pharmacist license must be in good standing;

(2) Licensed healthcare professional must possess a license in good standing;

(3) Not a licensed healthcare professional must possess a Master or Doctorate degree in the academic discipline for which they are precepting.

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

855-120-1030
Licensure: Application- Preceptor

(1) An application for licensure as a Preceptor may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of:

(a) Attestation to the requirements in OAR 855-120-1010;

(b) A completed application;

(c) Personal identification that includes a photograph;

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of a Preceptor expires June 30 in odd numbered years and may be renewed biennially.

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

855-120-1040
Licensure: Lapse

(1) A Preceptor may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not practice as a Preceptor if the license is lapsed.

(d) A person may apply to reinstate a Preceptor license according to OAR 855-120-1035.

(2) If a person requests lapse the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board may not accept the lapse if an investigation of or disciplinary action against the licensee is pending.

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-1050
Licensure: Voluntary Surrender

A Preceptor may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date the licensee is sent the executed final order.

(4) The licensee must cease acting as a Preceptor from the date the license terminates.

(5) A voluntarily surrendered license may not be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-120-1035 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-120-1070
Preceptor: General Responsibilities

(1) Each Preceptor is responsible for their own actions.

(2)Each Preceptor is responsible for supervising the actions of each Intern.

(3) A Preceptor must:

(a) Display in plain sight the Preceptor license within the pharmacy or place of business to which it applies;

(b) Provide the Intern with experiences, which in the Preceptor's judgment will increase the Intern's competency in the practice of pharmacy or as a member of the healthcare team; and

(c) Verify that each Intern being supervised by the Preceptor is currently licensed with the board as an Intern.

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

855-120-1110
Responsibilities: Confidentiality

Preceptors must follow all applicable confidentiality laws.

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

855-120-1115
Responsibilities: Duty to Report

Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each:

(1) Internship Program Supervisor must report the following on behalf of a COP or SOP within 10 working days if it:

(a) Has removed a Preceptor or Internship Program site from the Internship Program for reasons including but not limited to patient safety, unprofessional conduct or suspected violation of ORS 475, ORS 689 or OAR 855; or

(b) Has dismissed an Intern from a Doctor of Pharmacy degree program.

(2) Preceptor at an Internship Program site within 10 working days, must report if they have dismissed an Intern from an Internship Program site for reasons including but not limited to patient safety, unprofessional conduct or suspected violation of ORS 475, ORS 689 or OAR 855.

(3) For (1) and (2) the Internship Program Supervisor and Preceptor must report the date and reason for the removal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.150, ORS 689.151, ORS 689.155 & ORS 689.455

855-120-1122
Responsibilities: Ratio & Supervision

(1) The following ratios apply regarding the supervision of an Intern:

(a) A Pharmacist who is a Preceptor may supervise up to two Interns.

(b) A Pharmacist who is not a Preceptor may supervise up to one Intern.

(c) A Healthcare or Other Preceptor may supervise up to one Intern.

(2) For direct patient care activities (e.g., immunization, health screenings), a Pharmacist or Healthcare Preceptor who is not otherwise engaging in the practice of pharmacy may supervise up to four Interns.

(3) For non-direct patient care activities, a Pharmacist or a Preceptor may supervise as many Interns as they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare.

(4) The majority of an Intern's overall experience in an Internship Program must be under the supervision of a licensed Pharmacist Preceptor.

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

855-120-1150
Prohibited Practices

(1) A Preceptor must not engage in any form of discrimination, harassment, intimidation, or assault in the workplace.

(2) A Preceptor who is not a Pharmacist must not supervise an Intern in the practice of pharmacy as defined in ORS 689.005 unless the:

(a) Practice is within the scope of the Healthcare Preceptor's professional license;

(b) Intern is practicing as a part of an Internship Program at a COP or SOP; and

(c) Intern has successfully completed their first academic year.

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

855-120-1155
Grounds for Discipline

The board may suspend, revoke, or restrict the license of a Preceptor or may impose a civil penalty upon the Preceptor upon the following grounds:

(1) Continuing to supervise an Intern in an Internship Program when one of the following has occurred:

(a) School has removed the Preceptor or Internship Program site from the Internship Program for reasons including but not limited to patient safety, unprofessional conduct or suspected violation of ORS 475, ORS 689 or OAR 855.

(b) Licensee is not permitted to supervise an Intern per Board order.

(c) Registrant is not permitted to utilize Interns per Board order.

(2) Any other grounds found in ORS 689.405.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.405

855-120-1205
Preceptor: Qualifications and Responsibilities- Internship Program Supervisor

(1) The Internship Program Supervisor for a COP or SOP located in Oregon must:

(a) Be licensed as a Pharmacist;

(b) Be licensed as a Preceptor;

(c) Maintain a record of each internship completed as part of the Internship Program . This record must be made available to the board upon request.

(d) Submit a report on their Internship Program to the board at the end of each academic year. This report must include the names of students who have:

(A) Successfully completed the degree program including:

(i) Date of graduation; and

(ii) Hours earned in Internship Program; and

(B) Extended their course of study

(e) Maintain a list of preceptors and Internship Program sites, in and out-of-state, approved by the school and must make this list available to the board upon request.

(2) The Pharmacist who supervises the Internship Program for a FPGEC certified Intern located in Oregon must:

(a) Be licensed as a Pharmacist;

(b) Be licensed as a Preceptor;

(c) Certify hours completed for internship credit in the Internship Program on a board-approved form. This record must be made available to the board upon request.

(3) The Internship Program Supervisor in (1) and the supervising Preceptor in (2) must ensure the Internship Program includes the following components:

(A) Direct patient care;

(B) Interprofessional interaction and practice;

(C) Medication dispensing, distribution, administration, and systems management; and

(D) Professional development.

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

Division 125: Pharmacy Technicians (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 125 for Pharmacy Technicians

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 125 for Certified Oregon Pharmacy Technicians (COPT) and Pharmacy Technicians (PT). Proposes relocating and reorganizing existing COPT and PT rules from Division 025. Adds new requirements related to general responsibilities, licensure, and prohibited practices. After the board permanently adopts and publishes Division 125, repeals Division 025 on the effective date of Division 125.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed revisions to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Relocates existing rules from Division 025 to newly created Division 125 Certified Oregon Pharmacy Technicians and Pharmacy Technicians. The proposed new language includes adding requirements for lapsing a license, voluntary surrender of a license, general responsibilities, confidentiality, duty to report and prohibited practices. Rule revisions are in alignment with the board's strategy to systematically organize all Divisions. After the board permanently adopts and publishes Division 125, repeals Division 025 on the effective date of Division 125.

DIVISION 125

CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-125-0001
Applicability

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

(2) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may assist a Pharmacist in the practice of pharmacy and must act in compliance with statutes and rules under the supervision, direction, and control of a Pharmacist.

(3) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification when delegated to do so by a Pharmacist and done in compliance with all applicable statutes and rules and under the supervision, direction, and control of that Pharmacist.

(4) Only a person licensed as a Certified Oregon Pharmacy Technician may use the titles "Certified Oregon Pharmacy Technician" and "COPT."

Statutory/Other Authority: ORS 689.205; ORS 689.225.
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-125-0005
Definitions

Placeholder

855-125-0010
Licensure: Qualifications – Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) To qualify for licensure as a Certified Oregon Pharmacy Technician or Pharmacy Technician, an applicant must demonstrate that the applicant is at least 18 years of age and has completed high school (or equivalent).

(2) To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must also demonstrate that the applicant has taken and passed a national pharmacy technician certification examination offered by:

(a) Pharmacy Technician Certification Board (PTCB); or

(b) National Healthcareer Association (NHA).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-125-0030

Licensure: Application- Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) An application for licensure as a Certified Oregon Pharmacy Technician or Pharmacy Technician may be accessed on the board website.

(2) The board may issue a license to a qualified applicant after the receipt of:

(a) A completed application including:

(A) Payment of the fee prescribed in OAR 855-110;

(B) A current, passport regulation size photograph (full front, head to shoulders);

(C) Personal identification or proof of identity;

(D) A completed national fingerprint-based background check; and

(E) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(b) An applicant for a Certified Oregon Pharmacy Technician license, must provide a passing result from PTCB or NHA on a national pharmacy technician certification examination.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application or requests resulting from the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405 or ORS 689.490.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of a Certified Oregon Pharmacy Technician or Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-125-0035

Licensure: Renewal or Reinstatement Applications- Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) An applicant for renewal of a Certified Oregon Pharmacy Technician or Pharmacy Technician license must:

(a) Pay the biennial license fee required in OAR 855-110.

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-021;

(c) Be subject to an annual criminal background check; and

(d) Provide a completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A Certified Oregon Pharmacy Technician or Pharmacy Technician or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-125-0020; and

(b) Provide certification of completion of 10 continuing education hours earned in the prior 12 months. These hours may not be counted toward a future renewal; and must include:

(A) One hour of continuing pharmacy education in pharmacy law;

(B) One hour of continuing pharmacy education in patient safety or error prevention; and

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

(4) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405 or ORS 689.490.

(5) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.

(6) Any person whose Certified Oregon Pharmacy Technician or Pharmacy Technician license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition the board for reinstatement of such license pursuant to ORS 689.445 and in conjunction with the application process identified in OAR 855-125-0020.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, ORS 689.445, ORS 689.486 & ORS 413.450

855-125-0040
Licensure: Lapse

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not assist in the practice of pharmacy if the license is lapsed.

(d) A person may apply for renewal or reinstatement according to OAR 855-125-0030.

(2) If a person requests lapse prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board may not accept the lapse if an investigation of, or disciplinary action against the licensee is pending.

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-125-0050
Licensure: Voluntary Surrender

A Certified Oregon Pharmacy Technician or Pharmacy Technician may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date is the order is signed by all parties and served on the licensee.

(4) The licensee must cease assisting in the practice of pharmacy from the date the license terminates.

(5) A voluntarily surrendered license may not be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-125-0030 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation, action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-125-0105
Responsibilities: General- Certified Oregon Pharmacy Technician and Pharmacy Technician

(1) Each Certified Oregon Pharmacy Technician and Pharmacy Technician is responsible for their own actions; however, this does not absolve the Pharmacist and the pharmacy from responsibility for the Certified Oregon Pharmacy Technician or Pharmacy Technician's actions.

(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician may not engage in the practice of pharmacy as defined in ORS 689.005.

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

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

(b) Only assist in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;

(c) Know the identity of the Pharmacist who is providing supervision, direction and control at all times;

(d) Only work within the scope of duties permitted by their license;

(e) Only work within the scope of duties permitted by the Pharmacist providing supervision, direction and control;

(f) Only perform duties they are trained to perform;

(g) Appropriately perform the duties permitted;

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

(i) Be clearly identified as a Certified Oregon Pharmacy Technician or Pharmacy Technician in all interactions and communications (e.g., nametag, phone interaction, chart notations);

(j) Display in plain sight the Certified Oregon Pharmacy Technician or Pharmacy Technician license within the pharmacy or place of business to which it applies;

(k) Ensure initial and ongoing training is completed that is commensurate with the tasks that the Certified Oregon Pharmacy Technician or Pharmacy Technician will perform, prior to the performance of those tasks and with each update to the written policies and procedures;

(l) Review and adhere to written policies and procedures. The review must:

(A) Occur prior to assisting in the practice of pharmacy;

(B) Occur with each update; and

(C) Be documented and records retained according to OAR 855-102-0050;

(m) Dispense and deliver prescriptions accurately and to the correct party.

(4) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification of the drug and dosage, device or product when:

(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;

(b) No discretion is needed;

(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and

(d) The Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.

Statutory/Other Authority: ORS 689.205, 2022 HB 4034
Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

855-125-0110
Responsibilities: Confidentiality

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must comply with OAR 855-104-0015 regarding confidentiality.

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

855-125-0115
Responsibilities: Duty to Report

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must comply with OAR 855-104-0010 regarding duty to report.

Statutory /Other Authority: ORS 689.455
Statutes/Other Implemented: ORS 689.455

855-125-0135
Responsibilities: Permitted Practices

Certified Oregon Pharmacy Technicians or Pharmacy Technicians:

(1) Must only assist in the practice of pharmacy as authorized by the rules of the board and as permitted by the Pharmacist providing supervision, direction, and control.

(2) Must ensure that work is verified by a Pharmacist if judgment is utilized when assisting in the practice of pharmacy.

(3) May perform final verification as permitted under OAR 855-125-0070(4).

Statutory /Other Authority: ORS 689.005, ORS 689.225
Statutes/Other Implemented: ORS 689.151, 2022 HB 4034

855-125-0150
Prohibited Practices

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:

(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0070(5), including but not limited to the following tasks:

(a) Evaluate and interpret a prescription;

(b) Conduct a Drug Utilization Review or Drug Regimen Review;

(c) Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to his or her prescription;

(d) Counsel a patient or the patient's agent regarding a prescription;

(e) Accept a patient or patient's agent's request to decline counseling;

(f) Advise on therapeutic values, content, hazards and use of drugs and devices;

(g) Interpret the clinical data in a patient record system or patient chart;

(h) Conduct Medication Therapy Management;

(i) Practice pursuant to a Clinical Pharmacy Agreement or Collaborative Drug Therapy Management;

(j) Practice pursuant to Statewide Drug Therapy Management Protocols;

(k) Prescribe a vaccine, drug or device;

(l) Administer a vaccine, drug or device;

(m) Order, interpret or monitor a laboratory test;

(n) Receive or provide a new or transferred prescription orally;

(o) Supervise, direct, or control another licensee in the licensee practicing or assisting in the practice of pharmacy;

(p) Delegate tasks to healthcare providers; and

(q) Deny the patient or the patient's agent request to speak to the Pharmacist.

(2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.

(3) Perform any task while assisting in the practice of pharmacy that requires judgment unless it is verified by a Pharmacist.

(4) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace.

(5) Refuse a request from a patient, patient's agent, or practitioner to interact with a Pharmacist.

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.155

Divisions: 041/043/183: Drug Compounding

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural review; Creates new Division 183 for Drug Compounding

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)and Correctional Facilities and Community Health Clinics (CHC) related to dispensing compounded drugs in Divisions 041 and 043. Proposed 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.

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

USP Chapters: USP Compounding Compendium

ISMP Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology (2016 and 2022)

For Use by a Veterinarian: Compounding Animal Drugs from Bulk Drug Substances Guidance for Industry (August 2022), Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

Essential Copies: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (January 2018), FDA drug shortages database, ASHP drug shortages database

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Reorganizing proposed rules may provide clarity, transparency and promote patient safety. No effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate registration and compliance requirements will positively impact all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): 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.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public), Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government, or members of the public. In order to comply, drug outlet pharmacies, DPDOs, CFs and CHCs who engage in compounding will need to pay for access to the USP Compounding Compendium estimated to cost $250 per year per user.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed revisions to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. A Workgroup was convened per the board's direction.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): 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. Proposed amendments include revising the definition of "Compounding" in Division 006 to match the definition in the USP standards adopted by reference. Creates new Division 183 by revising and relocating existing rules from Division 045. Creates proposed rules related to requirements for Compounding in the areas of "Applicability", "Definitions", "Designation", "Personnel", "General Requirements", "Compounding Technology", "Delivery", "Compounding Labeling" for both sterile (CSP) and non-sterile preparations (CNSP) and labeling requirements for future use, "Drug Disposal", "Policies and Procedures", "Compounded Drug Recalls", "Records" requirements including general, master formulation records (MFR), records for CNSP and CSP, "Prohibited Practices", "Compounding Services" for preparation according to FDA approved labeling requirements, copies of approved drugs and for use by a Veterinarian. Amends existing rules in Division 043 by adding "Drug Outlet Dispensing" general requirements for DPDOs, Correctional Facilities and Community Health Clinics. Will repeal Division 045 upon adoption of new Division 183.

FOR REFERENCE ONLY:

Selected USP definitions relevant to Div 183.

Note: CNSP/CSP used below whereas the standard only uses CNSP for the definition in <795> and CSP in <797>.

Active pharmaceutical ingredient (API): *Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as Bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).*

Compounding: *The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a CNSP/CSP.*

Designated person(s): *A person assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs/CSPs.*

Beyond-use date (BUD): *The date, or hour and date, after which a CNSP/CSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.*

Compounded nonsterile preparation (CNSP): *Preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.*

Compounded sterile preparation (CSP): *Preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.*

Compounding record (CR): *Record that documents the compounding of each CNSP/CSP.*

Master formulation record (MFR): *A detailed record of procedures that describes how each CNSP/CSP is to be prepared.*

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.

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 other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a compounded preparation.

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

855-183-0010
Designation: General

Each Drug Outlet must maintain an accurate compounding status in the board's online registration system.

POLICY DISCUSSION: Registration type, CNSP/CSP

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 obtain the education, training, and experience to demonstrate competency as required by the USP standards applicable to the preparation of compounded sterile and non-sterile products and be capable and qualified to perform assigned duties.

(2) Training must be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that compounding pharmacy personnel remain familiar with applicable operations and policies and procedures.

(3) The training must be documented and records retained according to OAR 855-183-0550.

(4) A Pharmacist must be the designated person as required by the USP standards for each act that requires independent judgment or is the practice of pharmacy as defined ORS 689.005.

(5) Each Drug Outlet must:

(a) Have a designated person as required by the USP standards who is a:

(A) Pharmacist for a Drug Outlet Pharmacy

(B) Practitioner with prescriptive and dispensing authority for a Dispensing Practitioner Drug Outlet or Community Health Center.

(b) Ensure only personnel authorized by the person supervising compounding are in the compounding area.

[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
Compounding: General Requirements

(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 (11/01/2023), 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); and

(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);

(2) A drug must only be compounded and dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs except as provided in OAR 855-183-0730. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(3) A drug may be compounded for a commercially available product according to OAR 855-183-0710.

(4) All sterile compounding must utilize a system that incorporates:

(a) Barcoding to verify ingredients; and

(b) Imaging or gravimetrics to verify ingredient quantity and finished CSP volumes.

POLICY DISCUSSION: Patient Safety- should vs. must, effective date

(5) For CNSPs, the compounding area must have a line of visible demarcation.

[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

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

(1) A Drug Outlet Pharmacy, DPDO, or CHC may use an ACD to:

(a) Assist with the compounding of a drug product; or

(b) Produce a final compounded drug product.

(2) If a Drug Outlet Pharmacy, DPDO, 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 use 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 manufacturing the final compounded drug product within tolerances of not more than plus or minus 5 percent.

(3) If a Drug Outlet Pharmacy, DPDO, or CHC uses an ACD to assist with the compounding of a drug product for parenteral nutrition, the Drug Outlet Pharmacy, DPDO, 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 cease 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 cease 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, 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.

(4) If the Drug Outlet Pharmacy, DPDO, 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.

(5) A Drug Outlet Pharmacy, DPDO, or CHC must make and maintain records that evidence compliance by the outlet with the policies and procedures required by this section.

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

855-183-0370
Delivery

Each Drug Outlet Pharmacy, DPDO and CHC, must ensure the environmental control, stability, and sterility of all preparations shipped. Therefore, any compounded preparation must be shipped or delivered to a patient or patient's agent in appropriate temperature-controlled delivery containers and stored appropriately according to USP <659> Packaging and Storage Requirements (04/01/2021). Information on appropriate storage must be provided to the patient or patient's agent.

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

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

855-183-0400
Labeling: Compounded Non-Sterile Preparations (CNSPs)

In addition to the labeling requirements specified in USP <795> (v. 11/1/2022), OAR 855-041, and 855-139, the label of a compounded preparation must also prominently and legibly contain the following, at a minimum:

(1) The strength of each active ingredient, to include the base;

(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)

In addition to the labeling requirements specified in USP <797> (v. 11/1/2022), OAR 855-041, and 855-139, the label of a compounded preparation must also prominently and legibly contain the following, at a minimum:

(1) The strength of each active ingredient, to include 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: Preparations CNSP and CSP for Future Use

Labels for a compounded drug 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;

(2) Internal lot number;

(3) The assigned beyond-use date;

(4) Indication that the preparation is compounded; and

(5) 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
Drug: Disposal

The Drug Outlet Pharmacy, DPDO and CHC is responsible for ensuring that there is a system for the disposal of hazardous and infectious waste 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

(1) Each Drug Outlet Pharmacy, DPDO and CHC must establish, maintain and enforce written 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:

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

(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, receipt, handling, and storage and disposal;

(g) 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 or CHC;

(h) Creating compounding records;

(i) Establishing beyond-use dates (BUDs);

(j) Labeling;

(k) 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

(l) 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
Compounded Drug Recalls

(1) Each Drug Outlet Pharmacy, DPDO and CHC that issues a recall regarding a compounded drug must, in addition to any other duties, contact each recipient pharmacy, prescriber and patient of the recalled drug and notify the board as soon as possible within 12 hours of the recall if both of the following apply:

(a) Use of or exposure to the recalled drug may cause serious adverse health consequences or death; and

(b) The recalled drug was dispensed, or is intended for use, in this state.

(2) A recall issued pursuant to (1)(a) must be made as follows:

(a) If the recalled drug was dispensed directly to the patient, notification must be made to the patient and the prescriber.

(b) If the recalled drug was dispensed directly to the prescriber, notification must be made to the prescriber who must notify the patient, as appropriate.

(c) If the recalled drug was dispensed directly to a pharmacy, notification must be made to the pharmacy, who must notify the prescriber or patient, as appropriate.

(d) After issuing a recall, the Drug Outlet Pharmacy, DPDO, or CHC must attempt to notify the recipient pharmacy, prescriber, and patient of the recalled drug within 12 hours. If contact cannot be established within this timeframe, the Drug Outlet Pharmacy, DPDO, or CHC must make two additional attempts to provide notification within 48 hours of the initial recall. In the event that all attempts to inform the recipient are unsuccessful, the Drug Outlet Pharmacy, DPDO, or CHC must send notification via certified mail. Each recall attempt must be documented.

(3) A Drug Outlet Pharmacy, DPDO or CHC that has been advised that a patient has been harmed by using a compounded product potentially attributable to the Drug Outlet Pharmacy, DPDO or CHC must report the event to MedWatch within 72 hours of the Drug Outlet Pharmacy, DPDO or CHC being advised.

POLICY DISCUSSION: Timeframe

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

855-183-0550
Records: General

In addition to record-keeping and reporting requirements of OAR 855, the following records must be maintained:

(1) All dispensing of CNSP and CSPs.

(2) Any other records required to conform to and demonstrate compliance with USP standards and federal law.

(3) Required records include, but are not limited to:

(a) Standard operating procedures, including documented annual review;

(b) Personnel training according to the type of compounding performed, including competency assessment, and qualification records, including corrective actions for any failures. The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations.

(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;

(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

(1) 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:

(a) Appropriate calculations to determine and verify quantities and concentrations of components and strength or activity of the APIs;

(b) Compatibility and stability information, including references as available;

(c) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.

(d) Other information needed to describe the compounding process and ensure repeatability

(e) Any other information required by the pharmacy'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): CSP

(1) In addition to the MFR requirements specified in USP <797> (v. 11/1/2022), the MFR for a CSP must contain the following, at a minimum:

(a) 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;

(b) Compatibility and stability information, including references;

(c) Quality control procedures that include the expected results and limits of tolerability for quantitative results;

(d) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(e) Any other information required by the pharmacy'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): CNSP

(1) In addition to the CR requirements specified in USP <795> (11/1/2022), the CR for a CNSP must contain the following, at a minimum:

(a) Pharmacist performance and documented verification that each of the following are correct:

(A) Formula;

(B) Calculations;

(C) Quantities;

(D) Concentration of components;

(E) If applicable, strength or activity of the API;

(F) Compounding technique; and

(G) Accurate preparation of the CNSP.

(b) Final yield;

(c) 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;

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

(e) Any other information required by the pharmacy'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): CSP

(1) In addition to the CR requirements specified in USP <797> (11/1/2022), the CR for a CSP must contain the following, at a minimum:

(a) Final yield;

(b) Total quantity compounded;

(c) Pharmacist performance and documented verification that each of the following are correct:

(A) Formula;

(B) Calculations;

(C) Quantities;

(D) Concentration of components;

(E) If applicable, strength or activity of the API;

(F) Compounding technique; and

(G) Accurate preparation of the CSP.

(d) Final yield;

(e) 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;

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

(g) Any other information required by the pharmacy'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

The following practices are prohibited in the compounding of a drug preparation:

(1) Verification of components after their addition to the final container (e.g., proxy verification, syringe pull-back method);

POLICY DISCUSSION: Should not vs. must not, effective date

(2) Use of preservative free component vials that exceeds 12 hours from initial puncture;

(3) Carpet in compounding area; and

(4) Animals in the compounding area.

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

855-183-0700
Compounding Services: Preparation According to FDA Approved Labeling

(1) Compounding does not include 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 the:

(a) Product must be prepared as a single dose for an individual patient; and

(b) Labeling must include information for the diluent, the resultant strength, the container closure system, and storage time.

(3) If the drug is hazardous, must follow USP <800>.

(4) Proprietary bag and vial systems: Docking and activation of proprietary bag and vial systems in accordance with the FDA approved labeling for immediate administration to an individual patient is not considered compounding and may be performed outside of an International Organization for Standardization (ISO) Class 5 environment.

(a) Docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in an ISO Class 5 environment in accordance with USP <797>.

(b) Beyond-use dates (BUDs) for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling

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

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

855-183-0710
Compounding Services: Copies of an Approved Drug

A Drug Outlet Pharmacy, DPDO, CHC or outsourcing facility may only compound a drug preparation that is essentially a copy of a FDA approved drug if:

(1) The compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. The relevant change and the significant clinical difference produced for the patient must be indicated on the prescription.

(2) The approved drug is identified as currently in shortage on the:

(a) FDA drug shortages database published on the FDA website, www.accessdata.fda.gov/scripts/drugshortages/default.cfm; or

(b) Drug shortages database published on the American Society of Health-System Pharmacists (ASHP) website, www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages

(3) The Drug Outlet Pharmacy is unable to obtain the approved drug from a Wholesale Distributor Drug Outlet. Documentation of good faith effort must be retained by the Drug Outlet Pharmacy.

POLICY DISCUSSION: Essential Copies

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

855-183-0730
Compounding Services: For Use by a Veterinarian

(1) This rule only applies to compounded drugs intended for animal use by licensed veterinarians.

(2) Compounded preparations must comply with state and federal law, USP standards and FDA guidance.

(3) A Drug Outlet Pharmacy may compound drugs intended for animal use:

(a) Based on a patient-specific prescription from a licensed veterinarian.

(b) For in-office use by a licensed veterinarian, specifically for a single treatment episode, not to exceed 120-hour supply.

(4) The compounded preparations must not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations.

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

855-183-0740
Compounding Services: Sterile Compounding with Non-Sterile Ingredients

NOTE: Board staff are in the process of writing these rules

DIVISION 41
OPERATION OF PHARMACIES

855-041-1018
Outlet: General Requirements

A drug outlet pharmacy must:

(1) Ensure each:

(a) **P**rescription is dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031**,** OAR 855-041 **and** **OAR 855-080**;

(b) Compounded preparation is dispensed in compliance with OAR 855-183; and

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

(5) Comply with the Pharmacist's determination in OAR 855-019-0200(4)(e).

(6) 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 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.151, 2022 HB 4034, ORS 689.508 & ORS 689.155

DIVISION 43
PRACTITIONER DISPENSING

855-043-0545
Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery

NOTE: In rulemaking, Standards Adopted by Reference

(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by the practitioner's licensing board.

(2) Drugs dispensed from the DPDO must be dispensed in compliance with the requirements of the practitioner's licensing board.

(3) A DPDO must comply with all requirements of State or federal law.

(4) A DPDO must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

(5) Dispensed drugs must be packaged by the DPDO, a pharmacy, or a manufacturer registered with the board.

(6) A DPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(7) A DPDO may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(8) The DPDO must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

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

(**10**) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.305

855-043-0630
Correctional Facility - Drug Delivery and Control

(1) Policies and Procedures: The **P**harmacist and the practitioner representing the facility **must** be responsible for establishing written policies and procedures for medication management including, but not limited to, drug procurement, dispensing, administration, labeling, medication counseling, drug utilization review, medication records, parenterals, emergency and nonroutine dispensing procedures, stop orders, over-the-counter drugs, security, storage and disposal of drugs withing the facility. Policies and procedures **must** be reviewed and updated annually by the **P**harmacist and the practitioner, maintained in the facility; and be made available to the **b**oard for inspection. The facility **must** submit to the **b**oard 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 **b**oard of any change of **P**harmacist within 15 days of the change.

(2) Dispensing: Prescription drugs **must** be dispensed by a **P**harmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system. **The Correctional Facility 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 correctional facility 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 **b**oard:

(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 OAR 855-041-0177(4).

(c) The **P**harmacist **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: 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 **P**harmacist of the patient's record, the **P**harmacist **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 **P**harmacist 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 **P**harmacist 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 **P**harmacist is not required to provide oral counseling when a patient refuses the pharmacist's attempt to counsel, or when the **P**harmacist, 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 patient/inmates who self administer or who are given prescription drugs when they are released from the correctional facility.

(6) Administration: Drugs **must** be administered to inmate/ patients by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined in Nursing Board administrative rule 851-047-0020. Drugs selected by registered nurses from manufacturer's or **P**harmacist's bulk drug containers **must** not be administered by 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

855-043-0740

Community Health Clinic (CHC) - Dispensing and Drug Delivery

NOTE: In rulemaking, Standards Adopted by Reference

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.

(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.

(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.

(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.

(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

(7) Dispensed drugs must be packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the board.

(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(9) A CHC must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

(10) A CHC may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The CHC offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(11) The CHC must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

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

(13) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

Division 006: Definitions (Unprofessional Conduct)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds unprofessional conduct definitions

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Adds definitions for unprofessional conduct for drug and alcohol consumption related to the practice of pharmacy or the assistance of the practice of pharmacy.

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

14 CFR 91.17 / FAA: Alcohol & Flying Resource

2023 HB 2291- Authorizes State Board of Pharmacy to require person under investigation by board to undergo mental, physical, chemical dependency or competency evaluation.

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others. Adopting the proposed amendments may increase patient safety for all Oregonians in every community by ensuring that licensees practice pharmacy with reasonable skill and safety.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public) Effect on Small Businesses: None anticipated. The rulemaking imposes no additional mandatory reporting, recordkeeping, or other administrative requirements on small businesses.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommends adopting the proposed amendments for transparency and clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments include adding that no person may practice pharmacy or assist in the practice of pharmacy within 8 hours after the consumption of any alcoholic beverage, while under the influence of alcohol, while using any drug that affects a person's faculties in any way contrary to safety or while having an alcohol concentration of 0.04 or greater in a blood or breath specimen. Defines "alcohol concentration." The board requested a legislative concept (2023 HB 2991) that did not progress due to committee workload in the 2023 legislative session. Other Oregon health boards can require mental, physical, chemical dependency or competency evaluations- OMB, OSBN, OBD, etc. except for OBNM.

DIVISION 006
DEFINITIONS

855-006-0020

Unprofessional Conduct Defined

"Unprofessional conduct" means conduct unbecoming of a licensee or detrimental to the best interests of the public, including conduct contrary to recognized standards of ethics of pharmacy or conduct that endangers the health, safety or welfare of a patient or client. Unprofessional conduct includes but is not limited to:

(a) Fraud or misrepresentation in dealings relating to pharmacy practice with:

(A) Customers, patients or the public;

(B) Practitioners authorized to prescribe drugs, medications or devices;

(C) Insurance companies;

(D) Wholesalers, manufactures or distributors of drugs, medications or devices;

(E) Health care facilities;

(F) Government agencies; or

(G) Drug outlets.

(b) Illegal use of drugs, medications or devices without a practitioner's prescription, or otherwise contrary to federal or state law or regulation;

(c) Any use of intoxicants, drugs or controlled substances that endangers or could endanger the licensee or others**. No person may practice pharmacy or assist in the practice of pharmacy:**

(A) Within 8 hours after the consumption of any alcoholic beverage;

(B) While under the influence of alcohol;

(C) While using any drug that affects the person's faculties in any way contrary to safety; or

(D) While having an alcohol concentration of 0.04 or greater in a blood or breath specimen. Alcohol concentration means grams of alcohol per deciliter of blood or grams of alcohol per 210 liters of breath.

(d) Theft of drugs, medications or devices, or theft of any other property or services under circumstances which bear a demonstrable relationship to the practice of pharmacy;

(e) Dispensing a drug, medication or device where the **P**harmacist knows or should know due to the apparent circumstances that the purported prescription is bogus or that the prescription is issued for other than a legitimate medical purpose, including circumstances such as:

(A) Type of drug prescribed;

(B) Amount prescribed; or

(C) When prescribed out of context of dose.

(f) Any act or practice relating to the practice of pharmacy that is prohibited by state or federal law or regulation;

(g) The disclosure of confidential information in violation of **b**oard rule;

(h) Engaging in collaborative drug therapy management in violation of ORS Chapter 689 and the rules of the **b**oard;

(i) Authorizing or permitting any person to practice pharmacy in violation of the Oregon Pharmacy Act or the rules of the **b**oard;

(j) Any conduct or practice by a licensee or registrant which the **b**oard determines is contrary to accepted standards of practice; or

(k) Failure to cooperate with the **b**oard pursuant to OAR 855-001-0035.

Statutory/Other Authority: **ORS** 689.205
Statutes/Other Implemented: ORS 689.005**, ORS** 689.155

Division 080: Scheduling Xylazine as a Schedule I

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Schedule I; adds Xylazine

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amends Schedule I rule by adding language related to xylazine.

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

Scheduling Xylazine-
Federal Bill: Combating Illicit Xylazine Act – Discussion Draft
DEA Public Safety Alert 3/21/2023
National Institute on Drug Abuse- Xylazine
OAR 875-015-0040 Minimum Standards for Veterinary Drugs
Xylazine: FDA Prescription Animal Drug Label

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. This is an urgent public health need that does not affect licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Amends OAR 855-080-0021 by adding "Xylazine, unless in the form of a FDA-approved product" to Schedule I. Proposed amendments are necessary due to the widespread public health threat that xylazine poses. According to the DEA, xylazine and fentanyl drug mixtures place users at a higher risk of suffering a fatal drug poisoning. Because xylazine is not an opioid, naloxone (Narcan) does not reverse its effects. People who inject drug mixtures containing xylazine also can develop severe wounds, including necrosis—the rotting of human tissue—that may lead to amputation.

855-080-0021
Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.11 (04/01/2022), and unless specifically exempt or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;

(b) Gamma-butyrolactone

(c) Methamphetamine, except as listed in OAR 855-080-0022;

(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)

(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.

(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,

(A) Methylmethcathinone (Mephedrone);

(B) Methylenedioxypyrovalerone (MDPV);

(C) Methylenedioxymethylcathinone (Methylone);

(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);

(E) Fluoromethcathinone (Flephedrone);

(F) 4-Methoxymethcathinone (Methedrone).

(g) Xylazine, unless in the form of a FDA-approved product.

(2) Schedule I also includes any compounds in the following structural classes (2a–2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);

(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;

(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and

(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) is not an FDA approved drug or is exempted from the definition of controlled substance in ORS 475.005(6)(b)(A)-(E).

(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.

(5) Schedule I also includes any compounds in the following structural classes (a – b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Benzodiazepine class: A fused 1,4-diazepine and benzene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Clonazolam, Flualprazolam

(b) Thienodiazepine class: A fused 1,4-diazepine and thiophene ring structure with a phenyl connected to the 1,-4-diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Etizolam

(6) Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;

(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;

(c) The following substances per ORS 475.005(6)(b):

(A) The plant Cannabis family Cannabaceae;

(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;

(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;

(D) The seeds of the plant Cannabis family Cannabaceae; or

(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055 & ORS 475.065

Programs By Status

Programs By Status

ACPE requires the programs it accredits to meet the expectations of all 25 standards of ACPE's accreditation standards. Any standard the board finds to be partially compliant or non-compliant can be seen by clicking on the Detailed PharmD Accreditation History link for each College or School. The program has two years to bring the standard into compliance as per US Department of Regulation. If no standard is noted, the program is in compliance with all 25 ACPE Accreditation Standards.

Accredited (140)

School Name	
Albany College of Pharmacy and Health Sciences	View
American University of Health Sciences School of Pharmacy	View
Appalachian College of Pharmacy	View
Auburn University Harrison College of Pharmacy	View
Belmont University College of Pharmacy	View
Binghamton University State University of New York School of Pharmacy and Pharmaceutical Sciences	View
Butler University College of Pharmacy and Health Sciences	View
California Northstate University College of Pharmacy	View
Campbell University College of Pharmacy and Health Sciences	View
Cedarville University School of Pharmacy	View
Chapman University School of Pharmacy	View
Concordia University Wisconsin School of Pharmacy	View
Creighton University School of Pharmacy and Health Professions	View
Drake University College of Pharmacy and Health Sciences	View
Duquesne University School of Pharmacy	View
D'Youville University School of Pharmacy	View
East Tennessee State University Bill Gatton College of Pharmacy	View
Fairleigh Dickinson University School of Pharmacy & Health Sciences	View
Ferris State University College of Pharmacy	View
Florida A&M University College of Pharmacy and Pharmaceutical Sciences, Institute of Public Health	View
Harding University College of Pharmacy	View
High Point University Fred Wilson School of Pharmacy	View
Howard University College of Pharmacy	View

Husson University College of Health and Pharmacy School of Pharmacy	View
Idaho State University College of Pharmacy	View
Keck Graduate Institute (KGI) School of Pharmacy and Health Sciences	View
Lake Erie College of Osteopathic Medicine School of Pharmacy	View
Larkin University College of Pharmacy	View
Lebanese American University School of Pharmacy	View
Lipscomb University Health Sciences Center College of Pharmacy	View
Loma Linda University School of Pharmacy	View
Long Island University Arnold and Marie Schwartz College of Pharmacy and Health Sciences	View
Manchester University College of Pharmacy, Natural and Health Sciences	View
Marshall B. Ketchum University College of Pharmacy	View
Marshall University School of Pharmacy	View
MCPHS University School of Pharmacy - Worcester	View
MCPHS University School of Pharmacy - Boston	View
Medical College of Wisconsin School of Pharmacy	View
Medical University of South Carolina College of Pharmacy	View
Mercer University College of Pharmacy	View
Midwestern University College of Pharmacy	View
North Dakota State University College of Health Professions School of Pharmacy	View
Northeast Ohio Medical University College of Pharmacy	View
Northeastern University Bouvé College of Health Sciences School of Pharmacy and Pharmaceutical Sciences	View
Notre Dame of Maryland University School of Pharmacy	View
Nova Southeastern University Barry and Judy Silverman College of Pharmacy	View
Ohio Northern University Raabe College of Pharmacy	View
Ohio State University College of Pharmacy	View
Oregon State University College of Pharmacy	View
Pacific University School of Pharmacy	View
Palm Beach Atlantic University Lloyd L. Gregory School of Pharmacy	View
Philadelphia College of Osteopathic Medicine - Georgia School of Pharmacy	View
Presbyterian College School of Pharmacy	View
Purdue University College of Pharmacy	View
Regis University Rueckert-Hartman College for Health Professions School of Pharmacy	View
Roosevelt University College of Science, Health and Pharmacy	View
Rosalind Franklin University of Medicine and Science College of Pharmacy	View
Roseman University of Health Sciences College of Pharmacy	View
Rutgers, the State University of New Jersey Ernest Mario School of Pharmacy	View
Saint Joseph's University Philadelphia College of Pharmacy	View
Samford University McWhorter School of Pharmacy	View
Shenandoah University Bernard J. Dunn School of Pharmacy	View
South College School of Pharmacy	View
South Dakota State University College of Pharmacy and Allied Health Professions	View

South University School of Pharmacy	View
Southern Illinois University Edwardsville School of Pharmacy	View
Southwestern Oklahoma State University College of Pharmacy	View
St. John Fisher University Wegmans School of Pharmacy	View
St. John's University College of Pharmacy and Health Sciences	View
Sullivan University College of Pharmacy and Health Sciences	View
Temple University School of Pharmacy	View
Texas A & M University Health Science Center Irma Lerma Rangel School of Pharmacy	View
Texas Southern University Joan M. Lafleur College of Pharmacy and Health Sciences	View
Texas Tech University Health Sciences Center Jerry H. Hodge School of Pharmacy	View
Thomas Jefferson University Jefferson College of Pharmacy	View
Touro University Touro College of Pharmacy	View
Touro University - California College of Pharmacy	View
Union University College of Pharmacy	View
University at Buffalo The State University of New York School of Pharmacy & Pharmaceutical Sciences	View
University of Arizona R. Ken Coit College of Pharmacy	View
University of Arkansas for Medical Sciences College of Pharmacy	View
University of California, San Diego Skaggs School of Pharmacy & Pharmaceutical Sciences	View
University of California, San Francisco School of Pharmacy	View
University of Charleston School of Pharmacy	View
University of Cincinnati James L. Winkle College of Pharmacy	View
University of Colorado Anschutz Medical Campus Skaggs School of Pharmacy and Pharmaceutical Sciences	View
University of Connecticut School of Pharmacy	View
University of Findlay College of Pharmacy	View
University of Florida College of Pharmacy	View
University of Georgia College of Pharmacy	View
University of Hawaii at Hilo Daniel K. Inouye College of Pharmacy	View
University of Health Sciences and Pharmacy in St. Louis St. Louis College of Pharmacy	View
University of Houston College of Pharmacy	View
University of Illinois at Chicago College of Pharmacy	View
University of Iowa College of Pharmacy	View
University of Kansas School of Pharmacy	View
University of Kentucky College of Pharmacy	View
University of Louisiana at Monroe College of Pharmacy	View
University of Maryland School of Pharmacy	View
University of Maryland Eastern Shore School of Pharmacy and Health Professions	View
University of Michigan College of Pharmacy	View
University of Minnesota College of Pharmacy	View
University of Mississippi School of Pharmacy	View
University of Missouri-Kansas City School of Pharmacy	View
University of Montana College of Health Skaggs School of Pharmacy	View

University of Nebraska Medical Center College of Pharmacy	View
University of New England Westbrook College of Health Professions School of Pharmacy	View
University of New Mexico College of Pharmacy	View
University of North Carolina Eshelman School of Pharmacy	View
University of North Texas Health Science Center UNT System College of Pharmacy	View
University of Oklahoma Health Sciences Center College of Pharmacy	View
University of Pittsburgh School of Pharmacy	View
University of Puerto Rico Medical Sciences Campus School of Pharmacy	View
University of Rhode Island College of Pharmacy	View
University of Saint Joseph School of Pharmacy and Physician Assistant Studies	View
University of South Carolina College of Pharmacy	View
University of South Florida Health Taneja College of Pharmacy	View
University of Southern California Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences	View
University of Tennessee Health Science Center College of Pharmacy	View
University of Texas at Austin College of Pharmacy	View
University of Texas at El Paso School of Pharmacy	View
University of Texas at Tyler Fisch College of Pharmacy	View
University of the Incarnate Word Feik School of Pharmacy	View
University of the Pacific Thomas J. Long School of Pharmacy	View
University of Toledo College of Pharmacy and Pharmaceutical Sciences	View
University of Utah College of Pharmacy	View
University of Washington School of Pharmacy	View
University of Wisconsin-Madison School of Pharmacy	View
University of Wyoming School of Pharmacy	View
Virginia Commonwealth University at the Medical College of Virginia Campus School of Pharmacy	View
Washington State University College of Pharmacy and Pharmaceutical Sciences	View
Wayne State University Eugene Applebaum College of Pharmacy and Health Sciences	View
West Coast University School of Pharmacy	View
West Virginia University School of Pharmacy	View
Western New England University College of Pharmacy and Health Sciences	View
Western University of Health Sciences College of Pharmacy	View
Wilkes University Nesbitt School of Pharmacy	View
William Carey University School of Pharmacy	View
Wingate University School of Pharmacy	View
Xavier University of Louisiana College of Pharmacy	View

Accredited with Probation (1)

School Name	
Chicago State University College of Pharmacy	View

Candidate Status (1)

School Name	
University of California, Irvine School of Pharmacy & Pharmaceutical Sciences	View

Discontinued/Merged (3)

School Name	
Midwestern University - Chicago College of Pharmacy	View
Midwestern University - Glendale College of Pharmacy-Glendale	View
South Carolina College of Pharmacy	View

No Status Awarded (1)

School Name	
California Health Sciences University College of Pharmacy - 2021 Accreditation Application	View

Withdrawn (2)

School Name	
California Health Sciences University College of Pharmacy- 2013 Accreditation Application	View
Hampton University School of Pharmacy	View

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ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

About Programs Calendar Communications CONTACT

Accredited Providers By Name

Accredited Providers By Name

ACPE is the sole accreditation agency to accredit providers of continuing pharmacy education. ACPE's directory is the **only** recognized directory of accredited providers of continuing pharmacy education.Many providers are involved in activities and functions other than the provision of continuing education. However, any activity for which the provider is offering continuing pharmacy credit has been developed and presented in compliance with the Standards for Continuing Pharmacy Education.

These providers are continually monitored for maintenance of quality and efforts toward improvement. Participants in activities sponsored by these providers are encouraged to offer their comments and suggestions regarding activities to the provider and/or ACPE. The directory includes contact information and accreditation status and history for all ACPE-accredited providers. An (I) following a provider's name indicates that the Provider is on Inactive Status. An asterisk (*) following a provider's name indicates that the Provider is on probation as an accredited provider by the Accreditation Council for Pharmacy Education. Providers that have decided to discontinue or that their accreditation status has been withdrawn in the past three years may be found here. ACPE hereby authorizes reproduction of the following listing.

Accredited Providers By Name

Academy for Continued Healthcare Learning, The	View
Academy of Managed Care Pharmacy	View
Accredo Health Incorporated	View
AchieveCE	View
AdvanCE	View
Advocate Aurora Health, Department of Pharmacy	View
AffinityCE	View

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

Alaska Pharmacists Association	View
Albany College of Pharmacy and Health Sciences	View
Albertsons Companies, Inc.	View
Allegheny General Hospital Department of Pharmacy Services	View
Alpha Zeta Omega National Pharmaceutical Fraternity Philadelphia Alumni Chapter	View
Alpha Zeta Omega Pharmaceutical Fraternity New York Alumni Chapter	View
American Association of Colleges of Pharmacy	View
American Association of Psychiatric Pharmacists	View
American College of Apothecaries, Inc.	View
American College of Clinical Pharmacology	View
American College of Clinical Pharmacy	View
American Pharmacists Association	View
American Society of Consultant Pharmacists	View
American Society of Health-System Pharmacists	View
Arizona Pharmacy Association	View
Arnold and Marie Schwartz College of Pharmacy and Health Sciences of Long Island University	View
Ascension Health Resource and Supply Management Group, LLC	View
Association for Medication Education, Inc.	View
Atlanta Academy of Institutional Pharmacists	View
Atrium Health Division of Pharmacy	View
Auburn University Harrison College of Pharmacy	View
Austin Community College Pharmacy Technician Program	View
Avant Institute	View
Banner Health	View
Baptist Memorial Health Care Corporation	View
Barnett International	View
Baylor Scott & White Health	View

Brigham and Women's Hospital Pharmacy	View
Brookdale Hospital Medical Center Department of Pharmacy Services	View
California Northstate University	View
California Pharmacists Association	View
California Society of Health-System Pharmacists	View
Cambridge Health Alliance (CHA) Department of Pharmacy	View
Campbell University College of Pharmacy and Health Sciences	View
Cardinal Health Pharmacy Services, LLC	View
CE Synergy, LLC.	View
CEimpact	View
Center for Independent Healthcare Education	View
Centers for Medicare and Medicaid Services	View
Chicago State University College of Pharmacy	View
Children’s National Medical Center	View
Children's Health	View
Children's Healthcare of Atlanta	View
City of Hope National Medical Center	View
Cleveland Clinic Abu Dhabi	View
CMEsolutions	View
Colegio de Farmaceuticos de Puerto Rico	View
Colibri Healthcare, LLC	View
CompleteRx	View
Concordia University Wisconsin School of Pharmacy	View
Conduent Healthcare Knowledge Solutions, Inc.	View
Connecticut Pharmacists Association	View
Cook County Health	View
CPE Consultants, LLC	View
CPS Solutions, LLC	View
CVS Health	View

Drug Effectiveness Review Project	View
Drug Experts Inc.	
Drug Information Association (DIA)	View
Duquesne University School of Pharmacy	View
D'Youville College School of Pharmacy	View
Educational Review Systems	View
Emory University Hospital Department of Pharmaceutical Services	View
Essentia Health	View
European Association of Hospital Pharmacists (EAHP)	View
Florida A&M University College of Pharmacy and Pharmaceutical Sciences	View
Florida Pharmacy Association	View
Florida Society of Health-System Pharmacists, Inc.	View
Froedtert Hospital	View
Georgia Pharmacy Association, Inc.	View
Georgia Society of Health-System Pharmacists, Inc.	View
Global Education Group	View
Grady Health System Pharmacy	View
Hamad Medical Corporation	View
Harris Health System	View
Hematology/Oncology Pharmacy Association (HOPA)	View
HonorHealth	View
Houston Methodist Hospital	View
Howard University College of Pharmacy	View
Humana, Inc.	View
Idaho Society of Health-System Pharmacists	View
Illinois Council of Health-System Pharmacists	View
Illinois Pharmacists Association	View
Independent Pharmacy Alliance, Inc.	View

Institute for Brain Potential	View
Institute for Natural Resources (INR)	View
Institute for Wellness and Education, Inc., The	View
Intermountain Health	View
Jesse Brown VA Medical Center	View
Johns Hopkins Hospital Department of Pharmacy	View
JPS Health Network	View
Kaiser Permanente National Pharmacy	View
Karmanos Cancer Center	View
Kentucky Pharmacy Education and Research Foundation, Inc.	View
King Faisal Specialist Hospital & Research Center - Ryiadh	View
Korean American Pharmacists Association of U.S.A	View
Lee Health	View
Lehigh Valley Hospital Pharmacy Department	View
Lippincott Continuing Medical Education Institute, Inc.	View
Lone Star College - Tomball Pharmacy Technology	View
Louisiana Independent Pharmacies Association	View
Louisiana Pharmacists Association	View
Louisiana Society of Health-System Pharmacists	View
MAD-ID, Inc.	View
Marshall University School of Pharmacy	View
Marshfield Clinic Health System, Inc.	View
Massachusetts College of Pharmacy and Health Sciences	View
MED2000, Inc.	View
Medical Center of the Rockies Pharmacy University of Colorado Health - North	View
MediCom WorldWide, Inc.	View
MED-IQ	View
MedStar Washington Hospital Center	View
Memorial Hermann	View

Michigan Pharmacists Association	View
Midwestern University College of Pharmacy	View
Missouri Pharmacy Association	View
National Association of Boards of Pharmacy and NABP Foundation, Inc.	View
National Community Pharmacists Association	View
National Headache Foundation	View
National Jewish Health	View
National Pharmaceutical Association, Inc.	View
National Pharmacy Technician Association (NPTA)	View
NBLS, Inc.	View
NCODA, Inc.	View
Nebraska Pharmacists Association (NPA)	View
Nesbitt School of Pharmacy at Wilkes University	View
New Jersey Pharmacists Association	View
New Jersey Society of Health-System Pharmacists	View
New Mexico Pharmacists Association	View
New York Presbyterian Hospital Department of Pharmacy	View
New York State Council of Health-System Pharmacists	View
Northeast Kentucky Area Health Education Center	View
Northeastern University Bouve College of Health Sciences School of Pharmacy and Pharmaceutical Sciences	View
Nova Southeastern University College of Pharmacy	View
Ochsner LSU Health Shreveport	View
Ohio Northern University College of Pharmacy	View
Ohio Pharmacists Foundation, Inc.	View
OhioHealth Pharmacy Services	View
Omnicare, Inc.	View
Oregon State University	View
Orlando Health, Inc.	View

Pediatric Pharmacy Association	View
Penn State Milton S. Hershey Medical Center	View
Pennsylvania Pharmacists Association	View
PESI, Inc.	View
Pharmaceutical Education & Research Institute, Inc. (PERI)	View
Pharmacists Society of the State of New York	View
Pharmacy Institute (I)	View
Pharmacy Society of Wisconsin	View
Pharmacy Stars, LLC	View
Pharmacy Times Office of Continuing Professional Education	View
PharmCon	View
Philadelphia College of Pharmacy	View
Physicians' Education Resource, LLC	View
Postgraduate Healthcare Education, LLC	View
Premier, Inc	View
Pro CE, LLC	View
Providence Swedish Pharmacy	View
Purdue University College of Pharmacy	View
Rite Aid Hdqtrs. Corp.	View
RxCe.com LLC	View
Saint Thomas West Hospital	View
Samford University McWhorter School of Pharmacy	View
San Jacinto College	View
Saudi Society of Clinical Pharmacy (SSCP)	View
ScientiaCME	View
Select CE	View
Sharp HealthCare	View
Shenandoah University Bernard J. Dunn School of Pharmacy	View
Skaggs School of Pharmacy at the University of Montana	View

Society of Nuclear Medicine and Molecular Imaging	View
South Carolina Pharmacy Association	View
South Dakota State University College of Pharmacy and Allied Health	View
South University School of Pharmacy	View
Southeastern Continuing Medical Education Consultants, LLC	View
Southeastern Michigan Society of Health-System Pharmacists	View
Southern Illinois University Edwardsville School of Pharmacy	View
Sparrow Hospital	View
Specialty Pharma Education Center	View
St. John Fisher University Wegmans School of Pharmacy	View
St. John's University College of Pharmacy and Health Sciences	View
St. Jude Children's Research Hospital Pharmaceutical Department MS150	View
St. Louis College of Pharmacy at University of Health Sciences and Pharmacy in St. Louis	View
Stony Brook University Medical Center	View
Temple University School of Pharmacy	View
Tennessee Pharmacists Consortium for Education	View
Texas A&M Health Science Center Coastal Bend Health Education Center	View
Texas Children's Hospital Pharmacy	View
Texas Pharmacy Association	View
Texas Society of Health-System Pharmacists, The	View
Texas Southern University College of Pharmacy and Health Sciences	View
Texas Tech University Health Sciences Center School of Pharmacy	View
The George Washington University School of Medicine and Health Sciences	View
The Medical Letter, Inc.	View
The Ohio State University College of Pharmacy	View
The University of Texas at El Paso School of Pharmacy	View

TRINU Corporation	View
Tufts Medicine – Department of Pharmacy	View
UAB Hospital Department of Pharmacy	View
Union University College of Pharmacy	View
UnitedHealth Group Center for Clinician Advancement	View
University at Buffalo School of Pharmacy and Pharmaceutical Sciences	View
University Health System Department of Pharmacotherapy and Pharmacy Services	View
University Learning Systems, Inc.	View
University of California, San Francisco, School of Pharmacy	View
University of Cincinnati College of Pharmacy	View
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences	View
University of Connecticut School of Pharmacy	View
University of Florida College of Pharmacy	View
University of Hawaii at Hilo, Daniel K. Inouye College of Pharmacy	View
University of Illinois at Chicago College of Pharmacy	View
University of Kentucky College of Pharmacy	View
University of Maryland School of Pharmacy	View
University of Mississippi School of Pharmacy	View
University of New England School of Pharmacy	View
University of New Mexico College of Pharmacy	View
University of North Carolina Eshelman School of Pharmacy	View
University of Oklahoma College of Pharmacy	View
University of Rhode Island College of Pharmacy	View
University of South Carolina College of Pharmacy	View
University of Southern California School of Pharmacy	View
University of Tennessee College of Pharmacy	View
University of Texas at Austin College of Pharmacy	View

University of Toledo College of Pharmacy	View
University of Utah College of Pharmacy	
University of Wyoming, School of Pharmacy	View
USF Health	View
Utah Society of Health-System Pharmacists	View
VA Western New York Healthcare System	View
Vanderbilt University Hospital Department of Pharmaceutical Services	View
Virginia Pharmacists Association	View
Virginia Society of Health-System Pharmacists	View
Walgreens University	View
Washington State Pharmacy Association	View
Washington State University College of Pharmacy and Pharmaceutical Sciences	View
WellStar Health System Pharmacy	View
West Virginia University School of Pharmacy	View
Western New England University College of Pharmacy	View
Western University of Health Sciences, College of Pharmacy	View
Xavier University of Louisiana College of Pharmacy	View

* Please Note - Our Suite Number Has Changed *

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ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

About Programs Calendar Communications CONTACT

Oregon Board of Pharmacy

Disciplinary Action Report

4/1/2023 - 4/30/2023

The Board has issued disciplinary action against the following licensees/respondents. These are public records and available for review pursuant to public disclosure laws. For those with a license number, please use the online licensure verification to search by a person/facility name or license number; if an Order has been executed, it will be available to view under the Board Orders section. For those without a license number, you may submit a public records request.

Orders Executed:

Name	License Number	Case Number
CH	RPH-0000000	2021-0067
RP	Unlicensed	2021-0237
LL	RPH-0000000	2021-0352
PSP	RP-0000000	2021-0667
FMP	RP-0000000	2022-0142
FMP	RP-0000000	2022-0143
FMP	RP-0000000	2022-0144
FMP	RP-0000000	2022-0145
GMP	RP-0000000 IP-0000000	2022-0448
MC	RPH-0000000	2022-0756
TM	CPT-0000000	2022-0774
CP	RP-0000000	2022-0803
CS	T-0000000	2022-0968
PW	RPH-00000000	2022-0990
TH	T-0000000	2022-1039
VL	RPH-00000000	2022-1041
TC	CPT-00000000	2022-1042
CB	T-0000000	2022-1044

If additional information is needed, please submit a public records request via The Board of Pharmacy's request form. State law prohibits the disclosure of complaint information.

Activity Report

Report Date: June 2, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 2002 B	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	6/1/2023 - Recommendation: Do pass the B-Eng. bill. 5/2/2023 - Referred to Ways and Means. 5/2/2023 - Vote explanation(s) filed on vote to sustain the ruling of the President by Boquist, Knopp, Linthicum, Robinson, Thatcher.	
Modifies provisions relating to reproductive health rights.				
HB 2112 EN	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	5/16/2023 - Chapter 35, (2023 Laws): Effective date January 1, 2024. 5/8/2023 - Governor signed. 4/27/2023 - President signed.	
Updates definitions and terminology used in public records law pertaining to records retention.				
HB 2278 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	6/1/2023 - Recommendation: Do pass. 5/8/2023 - Work Session held. 5/1/2023 - Public Hearing held.	
Authorizes pharmacists to administer influenza vaccine to persons six months of age or older.				
HB 2279 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	6/1/2023 - Recommendation: Do pass. 5/10/2023 - Work Session held. 4/19/2023 - Public Hearing held.	
Repeals residency requirement in Oregon Death with Dignity Act.				
HB 2395 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	6/1/2023 - Recommendation: Do pass the A-Eng. bill. 5/8/2023 - Work Session held. 4/24/2023 - Public Hearing held.	
Allows specified persons to distribute and administer short-acting opioid antagonist and distribute kits.				
HB 2397 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/10/2023 - Referred to Ways and Means by order of Speaker. 4/10/2023 - Recommendation: Do pass with amendments, be printed A-Engrossed, and be referred to Ways and Means. 4/3/2023 - Work Session held.	
Establishes Harm Reduction Clearinghouse Project within Oregon Health Authority for purposes of purchasing in bulk harm reduction supplies for use by entities that serve populations vulnerable to overdose, infections or injuries due to opioid use and use of other controlled substances.				

Activity Report

Report Date: June 2, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 2421 B	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	5/17/2023 - Recommendation: Do pass with amendments to the A-Eng. bill, to resolve conflicts. (Printed B-Eng.) 5/10/2023 - Work Session held. 4/26/2023 - Public Hearing held.	
Directs Health Licensing Office to establish guidelines for professional methods and procedures used by registered behavior analysis interventionists.				
HB 2486 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	6/1/2023 - Recommendation: Do pass. 5/8/2023 - Work Session held. 5/1/2023 - Public Hearing held.	
Allows certain pharmacy technicians to administer vaccines.				
HB 2538 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	3/29/2023 - Work Session held. 2/8/2023 - Public Hearing held. 1/13/2023 - Referred to Behavioral Health and Health Care with subsequent referral to Ways and Means.	
Requires health insurance coverage of health care interpretation services that are legally mandated.				
HB 2574 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	6/7/2023 - Work Session scheduled. 5/25/2023 - Work Session held. 5/22/2023 - Assigned to Subcommittee On Human Services.	8:00 AM 06/07/2023 Joint Subcommittee Human Services Work Session H-170
Requires hospitals to adopt policies and procedures to ensure provision of human immunodeficiency virus post-exposure prophylactic drugs or therapies following patient's possible exposure to human immunodeficiency virus.				
HB 2626 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	3/30/2023 - Referred to Tax Expenditures by prior reference. 3/30/2023 - Recommendation: Do pass with amendments, be printed A-Engrossed, and be referred to Tax Expenditures by prior reference. 3/27/2023 - Work Session held.	
Adds licensed mental health professionals, naturopathic physicians and pharmacists and certified medical laboratory scientists and medical laboratory technicians to types of providers eligible for tax credit allowed to rural medical care provider.				
HB 2645 B	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	5/31/2023 - Work Session held. 5/25/2023 - Returned to Full Committee. 5/25/2023 - Work Session held.	
Increases penalties for possession of certain amounts of fentanyl.				

Activity Report

Report Date: June 2, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 2650 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/10/2023 - Referred to Ways and Means by order of Speaker. 4/10/2023 - Recommendation: Do pass with amendments, be printed A-Engrossed, and be referred to Ways and Means. 4/4/2023 - Work Session held.	
Establishes requirements for work groups and task forces established by statute or member of Legislative Assembly.				
HB 2805 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	6/2/2023 - Work Session held. 5/30/2023 - Returned to Full Committee. 5/30/2023 - Work Session held.	9:30 AM 06/02/2023 Joint Committee Ways and Means Work Session HR F
Provides that use of serial electronic written communication or use of intermediaries to communicate may constitute meeting of governing body subject to public meetings law if other specified conditions are satisfied.				
HB 2806 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	6/1/2023 - Recommendation: Do pass the A-Eng. bill. 5/2/2023 - Work Session held. 4/25/2023 - Public Hearing held.	
Authorizes governing body of public body to meet in executive session to consider matters relating to safety of governing body, public body staff and public body volunteers and to security of public body facilities and meeting spaces, and relating to cyber security infrastructure and responses to cyber security threats.				
HB 3258 B	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/23/2023 - Recommendation: Do pass with amendments to the A-Eng. bill. (Printed B-Eng.) 5/17/2023 - Work Session held. 5/10/2023 - Public Hearing and Work Session held.	
Requires pharmacy to report dispensation of prescription drugs classified in schedules II through V under federal Controlled Substances Act to electronic system established for monitoring and reporting prescription drugs when drug is prescribed and dispensed to individual for use by individual or individual's animal.				
HB 3401 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	3/3/2023 - Referred to Behavioral Health and Health Care. 2/28/2023 - First reading. Referred to Speaker's desk.	
Requires health professional regulatory board to issue authorization by endorsement to qualified applicant within 30 days of date health professional regulatory board receives application.				
HB 3534 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	3/3/2023 - Referred to Judiciary. 2/28/2023 - First reading. Referred to Speaker's desk.	
Defines terms.				

Activity Report

Report Date: June 2, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
SB 11 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/23/2023 - Third reading. Carried by Tran. Passed. Ayes, 50; Nays, 1--Cate; Excused, 1--Evans; Excused for Business of the House, 8--Boshart Davis, Lewis, Morgan, Ruiz, Sanchez, Scharf, Sosa, Speaker Rayfield. 5/22/2023 - Rules suspended. Carried over to May 23, 2023 Calendar. 5/18/2023 - Rules suspended. Carried over to May 22, 2023 Calendar.	
Requires certain executive department boards or commissions that conduct public meetings through electronic means to record and promptly publish recording on website or hosting service so that public may observe or listen to meetings free of charge.				
SB 207 EN	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/16/2023 - Effective date, January 1, 2024. 5/16/2023 - Chapter 68, 2023 Laws. 5/8/2023 - Governor signed.	
Authorizes Oregon Government Ethics Commission to proceed on own motion to review and investigate, if commission has reason to believe that public body conducted meetings in executive session that were not in compliance with laws authorizing executive sessions.				
SB 216 EN	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	5/16/2023 - Effective on the 91st day following adjournment sine die. 5/16/2023 - Chapter 69, 2023 Laws. 5/8/2023 - Governor signed.	
Prohibits disclosure of individually identifiable data collected in accordance with uniform standards adopted by Oregon Health Authority for collection of data on race, ethnicity, preferred spoken and written languages, disability status, sexual orientation and gender identity.				
SB 226 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/23/2023 - Third reading. Carried by Javadi. Passed. Ayes, 48; Nays, 1--Cate; Excused, 1--Evans; Excused for Business of the House, 10--Boshart Davis, Cramer, Lewis, Osborne, Pham H, Reschke, Ruiz, Sanchez, Scharf, Speaker Rayfield. 5/22/2023 - Rules suspended. Carried over to May 23, 2023 Calendar. 5/18/2023 - Rules suspended. Carried over to May 22, 2023 Calendar.	
Allows nurse employed by or contracted with certain facilities to execute medical order from out-of-state physician in				

Activity Report

Report Date: June 2, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
specified circumstances.				
SB 229 EN	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	5/23/2023 - Effective date, January 1, 2024. 5/23/2023 - Chapter 89, 2023 Laws. 5/16/2023 - Governor signed.	
Updates terminology concerning reporting of serious adverse events.				
SB 410 EN	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/23/2023 - Effective on the 91st day following adjournment sine die. 5/23/2023 - Chapter 90, 2023 Laws. 5/16/2023 - Governor signed.	
Allows State Board of Pharmacy to adopt rules to issue temporary license to perform duties of pharmacy technician.				
SB 411 EN	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/23/2023 - Effective date, May 16, 2023. 5/23/2023 - Chapter 91, 2023 Laws. 5/16/2023 - Governor signed.	
Adds certain hospital, medical and infectious waste incinerators to facilities at which covered drugs under drug takeback program may be disposed of.				
SB 450 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/25/2023 - Read third time under Consent Calendar. Passed. Ayes, 53; Nays, 1--Cate; Excused, 6--Boshart Davis, Evans, Holvey, Javadi, Scharf, Sosa. 5/24/2023 - Rules Suspended, taken from 05-24 Calendar and placed on Consent Calendar for 05-25. 5/23/2023 - Rules suspended. Carried over to May 24, 2023 Calendar.	
Exempts from labeling requirements drug intended to reverse opioid overdose when drug is dispensed by health care provider.				
SB 517 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/1/2023 - Referred to Ways and Means by order of the President. 5/1/2023 - Recommendation: Do pass with amendments. (Printed A-Eng.) 4/4/2023 - Work Session held.	
Prohibits licensing board, commission or agency from denying, suspending or revoking occupational or professional license solely for reason that applicant or licensee was convicted of crime or subject to qualifying juvenile adjudication that does not substantially relate to specific duties and responsibilities for which license is required.				

Activity Report

Report Date: June 2, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
SB 538 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	5/25/2023 - Motion to refer to Rules carried. Referred. 5/25/2023 - Read. 5/24/2023 - Rules suspended. Carried over to May 25, 2023 Calendar.	
Provides that state agency that accepts or collects payment by means of credit card or debit card may add fee or surcharge to sum of payment in amount that is reasonably calculated to offset amounts charged to or withheld from state agency for accepting credit card or debit card as payment.				
SB 558 EN	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/30/2023 - Effective date, May 19, 2023. 5/26/2023 - Chapter 109, 2023 Laws. 5/19/2023 - Governor signed.	
Exempts from regulation by Advisory Council on Hearing Aids and Health Licensing Office over-the-counter hearing aid.				
SB 849 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	3/16/2023 - Referred to Ways and Means by order of the President. 3/16/2023 - Recommendation: Do pass with amendments and be referred to Ways and Means. (Printed A-Eng.) 3/14/2023 - Work Session held.	
Requires professional licensing boards to provide culturally responsive training to specified staff members, publish guidance on pathways to professional authorization for internationally educated individuals and waive requirement for English proficiency examination for specified internationally educated individuals.				
SB 891 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/17/2023 - Referred to Health Care by order of the President. 4/17/2023 - Minority Recommendation: Do pass with amendments. (Printed A-Eng Minority) 4/17/2023 - Recommendation: Without recommendation as to passage and requesting referral to Rules. Request denied by Order of the President. Referred to Health Care by Order of the President..	
Modifies provisions relating to Oregon Death with Dignity Act.				
SB 970 EN	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/23/2023 - Effective on the 91st day following adjournment sine die. 5/23/2023 - Chapter 93, 2023 Laws. 5/16/2023 - Governor signed.	
Revises definitions related to pharmacy for consistency with applicable federal law.				

Activity Report

Report Date: June 2, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
SB 1043 B	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/25/2023 - Read third time under Consent Calendar. Passed. Ayes, 44; Nays, 10--Breese-Iverson, Cate, Cramer, Elmer, Goodwin, McIntire, Morgan, Osborne, Reschke, Wallan; Excused, 6--Boshart Davis, Evans, Holvey, Javadi, Scharf, Sosa. 5/24/2023 - Rules Suspended, taken from 05-24 Calendar and placed on Consent Calendar for 05-25. 5/23/2023 - Rules suspended. Carried over to May 24, 2023 Calendar.	
Requires hospitals and other specified facilities that provide substance use disorder treatment to provide to specified patients upon discharge or release two doses of opioid overdose reversal medication and necessary medical supplies to administer medication.				
SB 1085 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/3/2023 - Public Hearing held. 3/29/2023 - Public Hearing held. 3/16/2023 - Referred to Health Care.	
Allows pharmacist to test and provide treatment for certain health conditions.				
SB 5529 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/15/2023 - Recommendation: Do pass with amendments. (Printed A-Eng.) 5/12/2023 - Work Session held. 5/9/2023 - Returned to Full Committee.	
Limits biennial expenditures from fees, moneys or other revenues, including Miscellaneous Receipts, but excluding lottery funds and federal funds, collected or received by State Board of Pharmacy.				
SB 5546 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	5/15/2023 - Recommendation: Do pass with amendments. (Printed A-Eng.) 5/12/2023 - Work Session held. 5/9/2023 - Returned to Full Committee.	
Approves certain new or increased fees adopted by State Board of Pharmacy.				

Oregon Board of Pharmacy

Budget Report: March 2023 (Month 21)

Revenue:

Through March, revenue is $6,856,336 (-13.8%) **under** budget

Expenditures:

Through March, **total expenditures** are $7,857,660 (7.3%) **under** budget

Personal services are $5,649,956 (3.8%) **under** budget

Services and Supplies are $2,207,704 (17.6%) **under** budget

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

Revenues less Expenditures: ($1,001,324)

Cash Balance:

Cash balance through March is $4,032,935 which represents (9.99) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through March 2023. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,632,429, which represents (12.32) months of operating expense*)

Cash balance target is $2,256,364, (6.0 months of operating expense)

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

Oregon Board of Pharmacy				
Total All Funds - LAB 2021-2023				
Actuals through March 2023				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**3,679,852**	**4,714,145**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	8,716,500.00	8,585,905.99	130,594.01
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	291,920.00	(98,925.00)
505	FINES AND FORFEITS	410,000.00	335,508.44	74,491.56
605	INTEREST AND INVESTMENTS	131,250.00	117,667.67	13,582.33
975	OTHER REVENUE	84,335.00	62,573.20	21,761.80
	TOTAL REVENUE	**9,535,080.00**	**9,393,575.30**	**141,504.70**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	443,120.00	449,834.00	(6,714.00)
	TOTAL TRANSFER OUT	**443,120.00**	**449,834.00**	**(6,714.00)**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,283,003.00	4,215,235.46	67,767.54
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	11,119.25	(11,119.25)
3180	SHIFT DIFFERENTIAL	-	18.50	(18.50)
3190	ALL OTHER DIFFERENTIAL	198,616.00	174,144.07	24,471.93
3210	ERB ASSESSMENT	1,276.00	1,240.80	35.20
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	763,352.24	(2,615.24)
3221	PENSION BOND CONTRIBUTION	236,241.00	235,165.58	1,075.42
3230	SOCIAL SECURITY TAX	334,236.00	315,106.23	19,129.77
3240	UNEMPLOYMENT ASSESSMENT	-	219.10	(219.10)
3241	PAID LEAVE OREGON-EMPLOYER	-	5,071.38	(5,071.38)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	885.04	126.96
3260	MASS TRANSIT	27,053.00	26,031.36	1,021.64
3270	FLEXIBLE BENEFITS	841,104.00	781,058.32	60,045.68
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,530,846.90**	**179,737.10**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	63,110.14	52,783.86
4125	OUT-OF-STATE TRAVEL	17,024.00	6,680.09	10,343.91
4150	EMPLOYEE TRAINING	22,320.00	25,311.61	(2,991.61)
4175	OFFICE EXPENSES	134,566.00	56,933.03	77,632.97
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	57,039.75	(6,109.75)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	202,541.00	-
4250	DATA PROCESSING	318,678.00	355,378.70	(36,700.70)
4275	PUBLICITY & PUBLICATIONS	43,329.00	21,539.15	21,789.85
4300	PROFESSIONAL SERVICES	339,713.00	227,681.53	112,031.47
4315	IT PROFESSIONAL SERVICES	134,467.00	13,530.00	120,937.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	539,362.46	82,472.54
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,179.00	2,239.00
4425	FACILITIES RENT & TAXES	229,042.00	284,945.83	(55,903.83)
4475	FACILITIES MAINTENANCE	55.00	1,851.13	(1,796.13)
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	500.00	702.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	216,242.44	34,236.56
4650	OTHER SERVICES AND SUPPLIES	411,285.00	406,077.13	5,207.87
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	5,423.49	8,684.51
4715	IT EXPENDABLE PROPERTY	45,228.00	7,284.25	37,943.75
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,494,610.73**	**464,184.27**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,691,342.00**	**9,025,457.63**	**665,884.37**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**4,632,429**	
	End of biennium projected cash balance in months		12.32	
	Cash balance target of 6.0 months (working capital)		2,256,364	

Oregon Board of Pharmacy

Budget Report: April 2023 (Month 22)

Through April, revenue is $7,508,905 (-9.9%) **under** budget

Expenditures:

Through April, **total expenditures** are $8,225,432 (7.4%) **under** budget

Personal services are $5,934,374 (3.5%) **under** budget

Services and Supplies are $2,291,058 (18.7%) **under** budget

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

Revenues less Expenditures: ($716,527)

Cash Balance:

Cash balance through April is $4,032,199 which represents (9.99) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through April 2023. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,584,112, which represents (12.21) months of operating expense*)

Cash balance target is $2,252,883, (6.0 months of operating expense)

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

Oregon Board of Pharmacy				
Total All Funds - LAB 2021-2023				
Actuals through April 2023				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**3,679,852**	**4,714,145**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	8,716,500.00	8,523,019.74	193,480.26
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	289,658.75	(96,663.75)
505	FINES AND FORFEITS	410,000.00	327,200.56	82,799.44
605	INTEREST AND INVESTMENTS	131,250.00	127,988.85	3,261.15
975	OTHER REVENUE	84,335.00	63,466.38	20,868.62
	TOTAL REVENUE	**9,535,080.00**	**9,331,334.28**	**203,745.72**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	443,120.00	449,834.00	(6,714.00)
	TOTAL TRANSFER OUT	**443,120.00**	**449,834.00**	**(6,714.00)**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,283,003.00	4,204,286.18	78,716.82
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	11,435.75	(11,435.75)
3180	SHIFT DIFFERENTIAL	-	18.50	(18.50)
3190	ALL OTHER DIFFERENTIAL	198,616.00	173,647.42	24,968.58
3210	ERB ASSESSMENT	1,276.00	1,240.80	35.20
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	760,930.40	(193.40)
3221	PENSION BOND CONTRIBUTION	236,241.00	234,572.26	1,668.74
3230	SOCIAL SECURITY TAX	334,236.00	313,810.04	20,425.96
3240	UNEMPLOYMENT ASSESSMENT	-	219.10	(219.10)
3241	PAID LEAVE OREGON-EMPLOYER	-	5,072.93	(5,072.93)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	877.19	134.81
3260	MASS TRANSIT	27,053.00	25,968.23	1,084.77
3270	FLEXIBLE BENEFITS	841,104.00	781,042.42	60,061.58
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,515,320.77**	**195,263.23**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	63,917.64	51,976.36
4125	OUT-OF-STATE TRAVEL	17,024.00	6,680.09	10,343.91
4150	EMPLOYEE TRAINING	22,320.00	26,076.71	(3,756.71)
4175	OFFICE EXPENSES	134,566.00	51,752.08	82,813.92
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	57,509.83	(6,579.83)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	202,541.00	-
4250	DATA PROCESSING	318,678.00	353,729.25	(35,051.25)
4275	PUBLICITY & PUBLICATIONS	43,329.00	22,452.78	20,876.22
4300	PROFESSIONAL SERVICES	339,713.00	249,609.33	90,103.67
4315	IT PROFESSIONAL SERVICES	134,467.00	9,530.00	124,937.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	536,184.26	85,650.74
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,879.00	1,539.00
4425	FACILITIES RENT & TAXES	229,042.00	273,222.75	(44,180.75)
4475	FACILITIES MAINTENANCE	55.00	1,851.13	(1,796.13)
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	500.00	702.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	219,477.76	31,001.24
4650	OTHER SERVICES AND SUPPLIES	411,285.00	405,438.69	5,846.31
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	5,423.49	8,684.51
4715	IT EXPENDABLE PROPERTY	45,228.00	6,436.87	38,791.13
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,496,212.66**	**462,582.34**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,691,342.00**	**9,011,533.43**	**679,808.57**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**4,584,112**	
	End of biennium projected cash balance in months		12.21	
	Cash balance target of 6.0 months (working capital)		2,252,883	