Oregon Board of Pharmacy
*REVISED BOARD MEETING AGENDA
April 12-14, 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: 347 117 007#**

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, April 12, 2023 @ 8:30AM
Thursday, April 13, 2023 @ 8:30AM
Friday, April 14, 2023 @ 8:30AM

- All OBOP meetings, except Executive Sessions, are open to the public. Pursuant to ORS 192.660(1)(2)(f)(L), Executive Sessions are closed to the public, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the board will return to Open Session
- To sign up for Public Comment, email your request to pharmacy.board@bop.oregon.gov by **12:00PM on 4/14/2023**

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, APRIL 12, 2023

I. OPEN SESSION, Rachael DeBarmore RPh, Presiding

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

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

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

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

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

Adjourn *Action Necessary*

THURSDAY, APRIL 13, 2023

I. OPEN SESSION, Rachael DeBarmore RPh, Presiding

***Please note that the board will meet in Executive Session all morning and anticipates resuming Open Session at 1:00PM.**

a. Roll Call

Oregon Board of Pharmacy
***REVISED BOARD MEETING AGENDA**
April 12-14, 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, ORS 676.175.

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

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

IV. GENERAL ADMINISTRATION

a. Rules
   i. Consider Adoption of Temporary Rules
      1. **Div 045**- USP Compliance – *Davis* **#B** *Action Necessary*
   ii. Consider Adoption of Rules – *None*
   iii. Rules in Development - *Davis*
   iv. Rulemaking Policy Discussion Items – *Davis*
      1. **Div 019/041/043/045/080/139/141/143-** Self Inspection Forms July 1- **#A** *Action Necessary*
      2. **Div 006/041/043/045/080/139/141/143-** Adopted Standards by Reference- **#A1** *Action Necessary*
      3. **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- **#A2, A2a, A2b, A2c, A2d, A2e** *Action Necessary*
      4. **Div 031/120-** Interns - Procedural Rule Review **#A3**
      5. **Div 010/104-** Board Administration & Policies Procedural Rule Review **#A4**
      6. **Div 001/102-** Procedural and Universal Rules **#A5**
      7. **Div 025/125-** Pharmacy Technicians - Procedural Rule Review **#A6**
      8. **Div 019/115-** Pharmacists - Procedural Rule Review **#A7**
      9. **Div 006-** Unprofessional Conduct **#A8**

Adjourn *Action Necessary*

FRIDAY, APRIL 14, 2023

I. OPEN SESSION, Rachael DeBarmore 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. GENERAL ADMINISTRATION

a. Executive Director Recruitment *Action Necessary*
b. Resume Rulemaking Policy Discussion Items - *Davis*
c. Discussion Items
   i. Immunization Services under DHHS Guidance Statement – *Davis* *Action Necessary*

ii. SBAR- Board Action Report – *Davis* **#C**
iii. Public Health and Pharmacy Formulary Advisory Committee Update - *Davis*
iv. Workgroup Update - *Davis*
v. Strategic Plan Update - *Schnabel*
vi. Legislative Update – *Schnabel* **#D**
vii. Financial/Budget Report – *MacLean* **#E**

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

2023 Board Meeting Dates

- June 7-9, 2023 Portland
- August 9-11, 2023 Portland
- October 11-13, 2023 Portland
- November 8-9, 2023 TBA (Strategic Planning)
- December 13-15, 2023 Portland

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.)

- May 23, 2023
- November 21, 2023

Conferences/Meetings

- Oregon Society of Health-System Pharmacists (OSHP) Annual Seminar – April 21-22, 2023, Sunriver
- NABP 119th Annual Meeting – May 11-13, 2023, Nashville, TN

V. 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 - **# CONSENT-1**
b. Board Meeting Minutes – February 2023 - **# CONSENT-2**
c. Special Board Meeting Minutes – March 2023 **#CONSENT-3**

VI. PUBLIC COMMENT

Adjourn *Action Necessary*

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.
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(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 ~~PIC A~~annual Self-Inspection Form provided by the board, by ~~February~~ **July** 1 each year. The completed self-inspection forms must be signed and dated by the PIC and ~~maintained~~ **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) ~~Complete the a~~**A**nnual**ly complete a self-inspection using the board's** ~~n~~**N**on-~~r~~**R**esident **Retail Drug Outlet** ~~PIC s~~**S**elf-~~i~~Inspection ~~report~~ **Form** prior to ~~February~~ **July** 1 ~~each year~~; and

(d) Provide the ~~s~~**S**elf-~~i~~Inspection ~~report~~ **Form** ~~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 ~~B~~**b**oard 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 ~~B~~**b**oard 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 ~~February~~ **July** 1~~,~~ **and retain for board inspection** ~~annually~~.

(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 the 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** ~~C~~**c**omplete **a self-inspection using** the **board's Animal Euthanasia** ~~annual~~ Self-Inspection **F**~~f~~orm by ~~February~~ **July** 1 ~~each year,~~ and retain for ~~B~~**b**oard 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** ~~C~~complete **a self-inspection using** the **board's** ~~annual~~ RDSP ~~PIC~~ **S**elf-**I**nspection **Form** ~~report~~ prior to ~~February~~ **July** 1 ~~each year~~; and

(d) Provide the **S**elf-**I**nspection **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 ~~ensuring that the~~ **annually completing a self-inspection using the Board's** PPK ~~PIC~~ **S**elf-**I**nspection **Form** ~~is correctly completed~~ prior to ~~February~~ **July** 1 ~~each year~~.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225 & ORS 689.527

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 ~~ensuring that the~~ **annually completing a self-inspection using the Board's** PPL ~~PIC~~ **S**elf-**I**nspection **Form** ~~is correctly completed~~ prior to ~~February~~ **July** 1 ~~each year~~.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.527

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

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.

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 the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019).

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

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. Amendments are required per ORS 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.

NOTES:

- History of rule package review
  - The April 2023 meeting is the 1st review of this package.

- Highlights
  - Rule language highlighted in yellow denote staff proposed amendments.

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. ~~03/15/2022~~ **03/21/2023**).

(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. ~~03/15/2022~~ **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. ~~03/15/2022~~ **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. v. ~~03/15/2022~~ **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 ~~2022~~**2023**, Issue 1), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. ~~2022~~**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. v. ~~03/15/2022~~ **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 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.35 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.40 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.55 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.60 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.65 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.70 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.75 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.80 (~~04/01/2021~~**04/01/2022**), and 21 CFR 1317.85 (~~04/01/2021~~**04/01/2022**); and

(d) 21 USC 822 (~~03/15/2022~~**03/20/2023**), 21 USC 822a (~~03/15/2022~~**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 (~~04/01/2021~~**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 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.22 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.05 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.90 (~~04/01/2021~~**04/01/2022**) and 21 CFR 1317.95 (~~04/01/2021~~**04/01/2022**).

(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 (~~04/01/2021~~**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 (~~01/01/2021~~**01/01/2022**), 16 CFR 1701 (~~01/01/2021~~**01/01/2022**), and 16 CFR 1702 (~~04/01/2021~~**01/01/2022**).

[Publications: Publications referenced are available ~~from~~ **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 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.12 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.13 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.14 (~~04/01/2021~~**04/01/2022**), and 21 CFR 1306.15 (~~04/01/2021~~**04/01/2022**), the DEA definition of "long term care facility" as defined in 21 CFR 1300.01 (~~04/01/2021~~**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 (~~01/01/2021~~**01/01/2022**), 16 CFR 1701 (~~01/01/2021~~**01/01/2022**) and 16 CFR 1702 (~~01/01/2021~~**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 (~~01/01/2021~~**01/01/2022**), 16 CFR 1701 (~~01/01/2021~~**01/01/2022**) and 16 CFR 1702 (~~01/01/2021~~**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 (~~08/01/2016~~**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 (~~03/15/2022~~**03/20/2023**), 21 USC 812 (~~03/15/2022~~**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 (~~04/01/2021~~**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 (~~04/01/2021~~**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 (~~04/01/2021~~**04/01/2022**).

[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 (~~04/01/2021~~**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 (~~04/01/2021~~**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 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.02 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.03 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.05 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.10 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.15 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.20 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.25, (~~04/01/2021~~**04/01/2022**); 21 CFR 1314.30 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.35 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.40 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.42 (~~04/01/2021~~**04/01/2022**), 21 CFR 1314.45 (~~04/01/2021~~**04/01/2022**); and 21 CFR 1314.50 (~~04/01/2021~~**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 (~~04/01/2021~~**04/01/2022**).

(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (~~04/01/2021~~**04/01/2022**).

(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (~~02/11/2022~~**08/22/2022**) pursuant to 21 CFR 1308.32 (~~04/01/2021~~**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 (~~04/01/2021~~**04/01/2022**).

(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (~~04/01/2021~~**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 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.02 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.71 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.72 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.73 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.74 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.75 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.76 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.77 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.90 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.91 (~~04/01/2021~~**04/01/2022**), 21 CFR 1301.92 (~~04/01/2021~~**04/01/2022**), and 21 CFR 1301.93 (~~04/01/2021~~**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~~**04/01/2022**), 21 CFR 1304.02 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.03 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.04 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.05 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.06 (~~04/01/2021~~**04/01/2022**); 21 CFR 1304.11 (~~04/01/2021~~**04/01/2022**); 21 CFR 1304.21 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.22 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.23 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.24 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.25 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.26 (~~04/01/2021~~**04/01/2022**); 21 CFR 1304.31 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.32 (~~04/01/2021~~**04/01/2022**), 21 CFR 1304.33 (~~04/01/2021~~**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 (~~03/15/2022~~**03/20/2023**) and 21 CFR 1305.01 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305. 02 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.03 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.04 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.05 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.06 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.07 (~~04/01/2021~~**04/01/2022**); 21 CFR 1305.11 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.12 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.13 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.14 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.15 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.16 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.17 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.18 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.19 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.20 (~~04/01/2021~~**04/01/2022**); 21 CFR 1305.21 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.22 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.23 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.24 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.25 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.26 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.27 (~~04/01/2021~~**04/01/2022**), 21 CFR 1305.28 (~~04/01/2021~~**04/01/2022**), and 21 CFR 1305.29 (~~04/01/2021~~**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 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.02 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.03 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.04 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.05 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.06 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.07 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.08 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.09 (~~04/01/2021~~**04/01/2022**); 21 CFR 1306.11 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.12 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.13 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.14 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.15 (~~04/01/2021~~**04/01/2022**); 21 CFR 1306.21 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.22 (~~04/01/2021~~**04/01/2022**); 21 CFR 1306.23 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.24 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.25 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.27 (~~04/01/2021~~**04/01/2022**); and 21 CFR 1304.03(d) (~~04/01/2021~~**04/01/2022**).

(2) Controlled substances listed in 21 CFR 1308.15 (~~04/01/2021~~**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 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.22 (~~04/01/2021~~**04/01/2022**); 21 CFR 1306.23 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.24 (~~04/01/2021~~**04/01/2022**), 21 CFR 1306.25 (~~04/01/2021~~**04/01/2022**), and 21 CFR 1306.27 (~~04/01/2021~~**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 (~~04/01/2021~~**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 (~~04/01/2021~~**04/01/2022**), 21 1304.22 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.05 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.90 (~~04/01/2021~~**04/01/2022**) and 21 CFR 1317.95 (~~04/01/2021~~**04/01/2022**).

(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 (~~04/01/2021~~**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 (~~01/01/2021~~**01/01/2022**), 16 CFR 1701 (~~01/01/2021~~**01/01/2022**), and 16 CFR 1702 (~~01/01/2021~~**01/01/2022**).

[Publications: Publications referenced are available ~~from~~ **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 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.35 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.40 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.55 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.60 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.65 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.70 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.75 (~~04/01/2021~~**04/01/2022**), 21 CFR 1317.80 (~~04/01/2021~~**04/01/2022**), and 21 CFR 1317.85 (~~04/01/2021~~**04/01/2022**); and

(d) 21 USC 822 (~~03/15/2022~~**03/20/2023**), 21 USC 822a (~~03/15/2022~~**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 (~~01/01/2021~~**01/01/2022**), 16 CFR 1701 (~~01/01/2021~~**01/01/2022**), and 16 CFR 1702 (~~01/01/2021~~**01/01/2022**).

[Publications: Publications referenced are available ~~from~~ **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. Federal regulations require COVID-19 Monoclonal and COVID-19 Antiviral be removed until further noticed by the FDA. 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. 06/202**3**~~1~~)

(2) Conditions

(a) Cough and cold symptom management

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

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

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

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

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

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

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

~~(e) COVID-19 Antiviral (v. 12/2022).~~

(3) Preventative care

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

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

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

(d) Travel Medications (v. ~~12/2022~~**06/2023**);

(e) HIV Post-exposure Prophylaxis (PEP) (v. ~~12/2022~~**06/2023**);

(f) HIV Pre-exposure Prophylaxis (PrEP) (v. ~~12/2022~~**06/2023**); and

(g) Contraception (v. ~~12/2022~~**06/2023**).

[**Publications:** Publications referenced are available **from the agency** ~~for inspection in the office of the Board of Pharmacy per OAR 855-010-0021~~.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689 & **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. X)
- Utilize the standardized Continuation of Therapy Assessment and Treatment Care Pathway (pg. X-X)
- Utilize the standardized Continuation of Therapy Prescription Template *optional* (pg. X)
- Utilize the standardized Patient Informational Handout *optional* (pg. X)
- Utilize the standardized Continuation of Therapy Provider Fax *optional* (pg. X)

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 <u>prescribed/dispensed</u>, please complete the following:

Drug: _____

Directions: _____

Quantity: _____

Refills:_____

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

2b. If contraception was <u>administered</u>, 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

-Previously prescribed contraception by RPH **-and-**
has not had clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years

No Exclusion Criteria

Any Exclusion Criteria → Refer

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

- If YES to AT LEAST ONE and is free of pregnancy symptoms

- If NO to ALL of these questions, pregnancy can NOT be ruled out

Patient is not pregnant

Patient is possibly pregnant → Refer

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

- If ALL boxes are labeled 1 or 2 (green) on the US MEC for the type of contraception that RPH plans to prescribe (e.g., CHC, POP)

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

No Contraindicated Condition(s) or Medication(s)

Any Contraindicated Condition(s) or Medication(s) → Refer

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

CHC + BP < 140/90 **-or-**
POP + Any BP

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

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

Not currently on birth control

Currently on birth control

6a) Choose Contraception

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

6b) Choose Contraception

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

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

7) Provide Counseling

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

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

Standardized Assessment and Treatment Care Pathway - Contraception

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

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

No Exclusion Criteria

Any Exclusion Criteria → Refer

2) Pregnancy Screen- Review questionnaire #8-13

- If YES to AT LEAST ONE and is free of pregnancy symptoms

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

Patient is not pregnant

Patient is possibly pregnant → Refer

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

- If ALL boxes are labeled 1 or 2 (green) on the US MEC for the type of contraception that RPH plans to prescribe (e.g., CHC, POP)

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

No Contraindicated Condition(s) or Medication(s)

Any Contraindicated Condition(s) or Medication(s) → Refer

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

BP < 160/100

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

5) Discuss DMPA therapy and provide counseling

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

Initial dose of DMPA IM or SQ

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

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

- Instruct patient that if this injection is not within 7 days of start of their period, then abstain or use backup method for 7 days.
- If *administering* DMPA IM or SQ, observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device. **-or-**
- If *dispensing* DMPA SQ for self-administration, the first self-administration must be observed by RPH 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.

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

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

-or-

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

Prescribe and administer up to 3 months ***or dispense*** up to 12 months of desired contraception product. This must be done as soon as practicable after the pharmacist issues the prescription and must include any relevant educational materials.

ORS 743A.066 requires prescription drug benefit programs to reimburse for 3 months for the first dispensing and 12 months for subsequent dispensing of the same contraceptive.

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

Standardized Assessment and Treatment Care Pathway - Contraception

Standardized Assessment and Treatment Care Pathway - Contraception

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

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

Key:

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

Corresponding to the Contraception Patient Intake Form:

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

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

CONTINUES NEXT PAGE →

Standardized Assessment and Treatment Care Pathway - Contraception

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

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**	☐ **NO** → Refer to ER
-Directly Refer to Public Health Department	☐ **YES**	

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 if contaminated with blood
(*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 must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.

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 colspan="2">-Chronic Kidney Disease
-Reduced Renal Function</td><td>☐ NO ☐ YES</td></tr>
<tr><td>☐ NO</td><td>☐ YES</td><td>☐ NO
-Offer vaccine if appropriate</td><td>☐ YES</td><td>☐ NO</td><td>☐ YES</td><td></td></tr>
<tr><td>↓</td><td>Refer to ER →</td><td></td><td></td><td>↓</td><td>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 fumurate 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.

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

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

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.

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

(CONFIDENTIAL-Protected Health Information)

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 → Refer and Report •A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A)

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

□ **YES** → Refer
□ **NO**

Bone Mineral Density
- Review Patient Intake form #3b

□ **YES** → Refer
□ **NO**

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.

Hepatitis B History
□ **YES** → Refer

Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via ALERT IIS

□ **YES**

□ **NO**
-Offer Hep B Vaccine series.

Pregnancy
Review Patient Intake form #3e

Pregnancy and breastfeeding are not contraindications for PrEP.

Refer PRN

Medication
Review Patient Intake form # 3f

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.

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

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

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):	____/____/_____	_____ mL/min	□ *Yes*
□ CrCl >60mL/min	□ CrCl 30mL/min - 60mL/min	□ *CrCl <30mL/min*	
• 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

         ~~**OR**~~

         ~~b. *Azithromycin 1000mg*~~
            ~~• Single dose of one tablet (if symptoms are not resolved after 24 hours, continue daily dosing for up to 3 days)~~
            ~~• 1 course/14 days, Max 2 courses for trips >14 days~~

3. Acute Mountain Sickness

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®)*

         Adult Dosing: 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

         Pediatric Dosing:

         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:**
____

Division 031/120: 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

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates a new Division 120 for Interns. Proposes relocating existing Intern rules from Division 031 as a result of the board's 2022-2026 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

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

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

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed rule amendments include relocating and reorganizing existing rules from Division 031 to new Division 120 in alignment with the board's strategy to systematically organize all Divisions. Amendments include revising titles, clarifying requirements for applicability, definitions, general qualifications, licensure requirements, license renewal, license reinstatement, license termination, and general responsibilities.

DIVISION 6
DEFINITIONS

855-006-0005
Definitions

(XX) "Board-approved school or college of pharmacy" means an ACPE accredited, accredited with probation, pre-candidate or candidate status (v. 6/2022) or with Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program (v. 6/2022) with a curriculum taught in English;

(XX) "Intern" means a person who is enrolled in or has completed a course of study at a school or college of pharmacy approved by the board and who is licensed with the board as an Intern.

(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.

(XX) "Preceptor" means a Pharmacist or a person licensed by the board to supervise the internship training of a licensed Intern.

(XX) "Internship Program" means a professional experiential program administered by a Board-approved school or college of pharmacy or approved by the board under the supervision of a Pharmacist registered with the board as a Preceptor.

POLICY DISCUSSION: SRI, TPI, Internship Program, Professional Experiential Program

DIVISION ~~31~~ **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 board-approved school or college of pharmacy or is certified by the Foreign Pharmacy Graduate Equivalency Committee (FPGEC), and who acts as Intern under the supervision of an Oregon licensed Pharmacist; or

(B) Licensed by the board as a Preceptor to supervise an Intern in an Internship Program.

Statutory/Other Authority: 689.205
Statutes/Other Implemented: 689.225

~~855-031-0005~~ **855-120-0005**
Definitions

Note: Placeholder- No definitions specific to Division 120 at this time.

~~(1) An "intern" means any person who:~~

~~(a) Is enrolled in a course of study and is in good academic standing at a school or college of pharmacy that is approved by the Oregon Board of Pharmacy; or~~

~~(b) Is a graduate of a school or college of pharmacy that is approved by the board; or~~

~~(c) Is a foreign pharmacy graduate and holds a certificate from the Foreign Pharmacy Graduate Equivalency Committee (FPGEC); and~~

~~(d) Is licensed with the board as an intern.~~

~~(2) A "preceptor" means a pharmacist or a person licensed by the board to supervise the internship training of an intern.~~

~~(3) "Internship" means a professional experiential program or work experience.~~

~~(a) "Traditional Pharmacy practice Internship (TPI)" means experience toward achieving competency in the practice of pharmacy for which no academic credit is granted to the intern.~~

~~(b) "School-based Rotational Internship (SRI)" means experience toward achieving competency in the practice of pharmacy in programs developed and administered by a school of pharmacy.~~

~~(c) "Other Internship" means experience toward achieving competency in the practice of pharmacy, other than in an internship as defined in (a) or (b), in a program approved by a school of pharmacy or the board.~~

~~(4) "School of pharmacy": In this division of rules, "school of pharmacy" means a school or college of pharmacy that is approved by the board.~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.255~~

855-120-0010
Licensure: Qualifications

(1) To qualify for licensure as an Intern, an applicant must provide proof that they:

(a) Are enrolled in a Doctor of Pharmacy program at a board-approved school or college of pharmacy; or

(b) Have graduated with a Bachelor or Doctor of Pharmacy degree from a board-approved school or college of pharmacy for the purpose of obtaining the qualifications to apply for a Pharmacist license; or

(c) Have graduated with a Bachelor or Doctor of Pharmacy degree from a foreign school or college 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), unless exempt pursuant to OAR 855-115-0015.

(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

~~855-031-0010~~ **855-120-0030**

Licensure: ~~Intern License~~ **Application- Intern**

(1) A**n a**pplications for licensure as an i**I**ntern may be ~~obtained from~~ **accessed on** the board website.

~~(a) Failure to completely, accurately and honestly answer all questions on the application form for licensure or renewal of licensure is grounds for discipline;~~

~~(b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

(2) The board may issue a license to a qualified ~~intern~~ **applicant** after the receipt of:

(a) Documentation required in OAR 855-120-0030 and for FPGEC certified documentation required in OAR 855-120-0015; and

(~~a~~**b**) A completed application **including:**~~;~~

(~~b~~**A**) Payment of the fee prescribed in OAR 855-110;

(~~c~~**B**) A current, passport regulation size photograph (full front, head to shoulders);

(C) Personal identification or proof of identity;

(~~d~~**D**) ~~Furnish documentation required to conduct a~~**A completed** national fingerprint-based background check; and

(E) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of an Intern expires November 30 and may be renewed as follows:

(a) Biennially prior to graduation from a board-approved school or college of pharmacy.

(b) Once after graduation from a board-approved school or college of pharmacy.

(c) Twice after obtaining FPGEC certification.

POLICY DISCUSSION: Length

~~(e) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study, except for foreign pharmacy graduates who must:~~

~~(A) Provide a copy of a valid visa permitting full-time employment;~~

~~(B) Provide a copy of the original certificate issued by the Foreign Pharmacy Graduate Equivalency Examination Committee; and~~

~~(C) Provide evidence that they have passed the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT).~~

~~(3) The board may issue an intern license after processing the application, however unless the applicant is a foreign graduate or an applicant for licensure by reciprocity, it is not valid until the intern has started a course of study. The initial license is valid until the last day of November following the second anniversary of issue unless terminated automatically by any one of the following events. Renewed licenses are valid for two years unless terminated automatically by any one of the following events:~~

~~(a) Licensure to practice pharmacy is granted in any state; or~~

~~(b) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, fails to maintain enrollment or active registration in a pharmacy degree program for a period greater than one year; or~~

~~(c) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, has been graduated from a school of pharmacy for 12 months;~~

~~(d) The intern is dismissed, terminated or expelled by the school of pharmacy, or withdraws from the program.~~

~~(4) An intern must surrender their license to the board within 30 days of one of the above events.~~

~~(5) Notwithstanding the requirements of section (3) above, upon written request the board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section must only be effective when it is issued in writing.~~
~~[Publications: Publications referenced are available from the agency.]~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

~~855-031-0016~~ **855-120-0035**

Licensure: Renewal or Reinstatement Applications ~~of Licensure as an~~ **Intern**

(1) **When** ~~An~~ apply**ing**~~ication~~ for renewal of an ~~i~~**I**ntern license, **an applicant** must ~~include documentation of~~:

~~(a) Completion of continuing pharmacy education requirements as directed in OAR 855-021; and~~

(~~b~~**a**) Pay~~ment of~~ the **biennial** license fee required in OAR 855-110.

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-021;

(~~2~~**c**) ~~An intern will~~ ~~b~~**B**e subject to an ~~annual~~ criminal background check.**; and**

(d) Provide a completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(2) An Intern who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license.

(3) An Intern or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply for a new license per OAR 855-120-0030; 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 and in conjunction with the application process identified in OAR 855-120-0030.

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

~~855-031-0020~~
~~Intern Requirements and Responsibilities~~
Note: In process of moving these requirements within the new division.

~~(1) A licensed intern may practice in any one or a combination of the following approved internship experience areas:~~

~~(a) Traditional Pharmacy-practice Internship (TPI): an intern may not work in a TPI until after satisfactorily completing the first academic year in a school of pharmacy. An intern working in a TPI must be supervised by a licensed pharmacist or pharmacist preceptor;~~

~~(b) School-based Rotational Internship (SRI): an intern must be supervised by a licensed pharmacist or other person approved by a school of pharmacy to obtain credit for SRI hours;~~

~~(c) Other Internship.~~

~~(2) An intern may not work more than 48 hours per week in SRIs and must comply with all supervision and ratio requirements.~~

~~(3) An intern must verify that their preceptor is currently licensed with the board.~~

(4) ~~An intern may not work in the practice of pharmacy unless supervised by a licensed pharmacist, except when an intern is working in a federal facility, however, to obtain credit for SRI experience in a federal facility located in Oregon, the intern must be licensed with the board.~~

~~(5) An intern who is working in a pharmacy or other place of business must conspicuously display their intern license in the pharmacy or place of business and must be clearly identified as an intern at all times.~~

~~(6) An intern may perform only the duties listed in Division 025 of this Chapter before completion of the first academic year in a school of pharmacy.~~

~~(7) An intern may, after successful completion of their first academic year, perform the duties of an intern listed in Division 019 of this Chapter, but only after successful completion of coursework corresponding to those duties at their school of pharmacy and only with the permission of their supervising pharmacist.~~

~~(8) An intern is responsible for his or her own actions and must comply with all board regulations.~~

~~(9) An intern must notify the board within 15 days of any change in their academic status that might affect their eligibility to work as an intern.~~

~~(10) An intern must notify the board in writing within 15 days of a change in permanent residence and TPI site.~~

~~(11) An intern must report to the board within 10 days if they are:~~

~~(a) Convicted of a misdemeanor or a felony; or~~

~~(b) Arrested for a felony.~~

~~(12) An intern who has reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The intern must report the conduct without undue delay, but in no event later than 10 working days after the intern learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.~~

~~(13) If needed by an intern for compliance with another board's requirement, an intern must maintain written or electronic records that support the number of TPI hours claimed by an intern and have those hours certified by a preceptor.~~

~~(14) An intern may make a voluntary report to the board on any preceptor's aptitude and professionalism in performing the duties of a preceptor. An intern must make such a report upon request by the board.~~

855-120-0105

Intern: General Responsibilities

(1) Each Intern is responsible for their own actions; however, this does not absolve the Pharmacist providing supervision 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.

(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:

(A) After successful completion of academic coursework corresponding to those tasks; and

(B) When permitted by the Pharmacist providing supervision.

(c) Know the identity of the Pharmacist who is providing supervision at all times;

(d) Only work within the scope of duties permitted by their license;

(e) Only work within the scope permitted by the Pharmacist providing supervision;

(f) Only perform tasks they are trained and competent to perform;

(g) Appropriately perform the tasks permitted;

(h) Only access the pharmacy area when a Pharmacist is physically present;

(i) Be clearly identified as an Intern all interactions and communications (e.g., nametag, phone interaction, chart notations);

(j) Display in plain sight the Intern license within the pharmacy or place of business to which it applies;

(k) 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; and

(C) Be documented and records retained according to OAR 855-102-0050;

(l) Dispense and deliver prescriptions accurately and to the correct party;

(m) Verify that their preceptor is currently licensed with the board as a preceptor.

(4) An Intern may not work more than 48 hours per week in an Internship Program and must comply with all supervision and ratio requirements.

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

855-115-0110
Responsibilities: Confidentiality

(1) No licensee of the board who obtains any patient information can disclose that information to a third-party without the consent of the patient except as provided in (2)(a)-(e) of this rule.

(2) A licensee can disclose patient information:

(a) To the board;

(b) To a practitioner, Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, if disclosure is authorized by a Pharmacist and disclosure is necessary to protect the patient's health or well-being;

(c) To a third-party when disclosure is authorized or required by law;

(d) As permitted pursuant to federal and state patient confidentiality laws or;

(e) To the patient or to persons as authorized by the patient.

(3) A licensee or registrant of the board must not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-115-0115
Responsibilities: Duty to Report

(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each Pharmacist must report to the board without undue delay, but within:

(a) 1 business day:

(A) Confirmed significant drug loss; or

(B) Any loss related to suspected drug theft of a controlled substance.

(b) 10 days if they:

(A) Are convicted of a misdemeanor or a felony;

(B) Are arrested for a felony; or

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

(c) 10 working days if they:

(A) Have reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct to that licensee's board; or

(B) Have been dismissed from an internship site or Doctor of Pharmacy degree program. The Intern must report the date and reason for the dismissal; or

(C) Suspect records are lost or stolen.

(d) 15 days of any change in:

(A) Legal name;

(B) Name used when practicing pharmacy;

(C) Preferred email address;

(D) Personal phone number;

(E) Personal physical address;

(F) Personal mailing address;

(G) Employer;

(2) An Intern who reports to a board in good faith as required by ORS 676.150 is immune from civil liability for making the report.

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 Pharmacist providing supervision.

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

855-120-0150
Prohibited Practices

~~855-019-0200~~
~~Pharmacist: General Responsibilities~~

(~~6~~**1**) ~~A Pharmacist may permit an Intern under their direction and supervision to perform any task listed in OAR 855-019-0200(3), except that an~~ **An** Intern ~~may~~ **must** not:

(a) Practice pharmacy as defined in ORS 689.005 unless permitted by the Pharmacist who is supervising the Intern;

(b) Diagnose;

(c) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace;

(2) Until an Intern has successfully completed their first academic year, ~~and only after successful completion of coursework corresponding to those duties;~~ **an Intern 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;

(~~bg~~) Prescribe a **vaccine**, drug or device **as authorized by statutes and rules**; or

(h) Administer a vaccine, drug or device;

(i) Perform verification as defined in OAR 855-006-0005.

POLICY DISCUSSION: First Academic Year

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) All Interns must complete an Internship Program.

(2) The Internship Program for a college or school of pharmacy located in Oregon is approved by the board in accordance with ACPE accreditation and must be administered under the supervision of a Pharmacist licensed as a Preceptor;

(3) The Internship Program for a college or school of pharmacy located outside of Oregon but within the US and jurisdiction is approved by the board in accordance with ACPE accreditation.

(4) The post-graduate Internship Program administered by another Board of Pharmacy or equivalent in any US state or jurisdiction is approved by the board.

POLICY DISCUSSION: Internship Programs, ACPE, BOP

(5) The Internship Program for a foreign graduate with FPGEC certification must be:

(a) Supervised by a licensed Preceptor;

(b) Include but not be 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

~~855-031-0030~~ 855-120-0195
Out-of-State Internship Experience

(1) In order for an Intern to obtain credit ~~for~~ experience ~~obtained~~ outside the State of Oregon, an Intern must~~:~~

~~(a) B~~**b**e licensed as required by state laws and rules in the state in which they ~~will~~ practice;

~~(b) Meet or exceed the minimum SRI requirements of the board;~~ **Be supervised by an Oregon-licensed Preceptor.**

(2) In order for an out-of-state intern to practice in the State of Oregon, the intern must ~~meet all requirements of these rules~~**:**

(a) Be licensed as an Intern by the State of Oregon

(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

~~855-031-0050~~
~~Eligibility for Exams — Foreign Pharmacy Graduates~~

~~In addition to the other requirements of this Division, a foreign pharmacy graduate must complete 1440 internship hours before applying to take the Multistate Pharmacy Jurisprudence Examination (MPJE) and before applying for licensure as a pharmacist as specified in OAR 855-019-0150. Evidence of completing this requirement must be provided to the board by the applicant and must be authenticated by each preceptor.~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.255~~

~~855-031-0055~~
~~Eligibility for Exams and Pharmacist Licensure~~

~~(1) An intern is eligible to take the North American Pharmacist Licensure Examination (NAPLEX) and the MPJE, upon graduation and notification to the board by the school of pharmacy that their degree, with not less than 1440 hours of SRI, has been conferred.~~

~~(2) Upon meeting all requirements for pharmacist licensure, and before practicing pharmacy in the State of Oregon, a person must:~~

~~(a) Complete an application for licensure including providing any fingerprint card or other documentation required by the board to conduct a criminal background check;~~

~~(b) Pay the license fee as prescribed in OAR 855-110; and~~

~~(c) Obtain a license, which will expire on June 30 in odd numbered years.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.135, ORS 689.207, ORS 689.225 & ORS 689.275~~

----------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.

(2) Non-Pharmacist must possess the highest degree available in any given academic discipline or possess a healthcare professional license.

(3) Licensee of this board or any other applicable board must have an active license in good standing.

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;

~~**(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 that includes a photograph;

~~**(D) Be subject to a 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.**~~

POLICY DISCUSSION: Requirements

(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 and as a member of the healthcare team.

~~855-031-0045~~
(~~8~~**c**) ~~A preceptor must v~~**V**erify that ~~the~~ **each** Intern **being supervised by the Preceptor** is currently licensed with the board **as an Intern**~~.~~

~~(9) A pharmacist acting as a preceptor in a federal facility is not required to be licensed as a pharmacist in Oregon, but is required to be licensed as a preceptor with the board.~~

(~~10~~**d**) ~~The school of pharmacy must m~~**M**aintain a record of each intern**ship**~~'s SRIs~~ **under their supervision**. This record must be made available to the board upon request.

Statutory/Other Authority: ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.255

855-115-1110
Responsibilities: Confidentiality

Preceptors must follow all applicable confidentiality laws.

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

855-115-1115
Responsibilities: Duty to Report

(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each Preceptor must report to the board without undue delay, but within:

(a) 10 days:

(A) The Pharmacist Preceptor for an Internship Program must report the following on behalf of a school or college of pharmacy if it:

(i) Has terminated or allowed a Preceptor to cease precepting for the Internship Program in lieu of termination;

(ii) Has dismissed an Intern from a Doctor of Pharmacy degree program;

(B) The Preceptor at an Internship Program site, must report if they have dismissed an Intern from an internship site;

(C) For (A) and (B) the Preceptor must report the date and reason for the dismissal or termination.

(d) 15 days of any change in:

(A) Legal name;

(B) Name used when supervising an Intern

(C) Preferred email address;

(D) Personal phone number;

(E) Personal physical address;

(F) Personal mailing address;

(G) Employer.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 676.150, ORS 689.151, ORS 689.155 & ORS 689.455

~~855-031-0026~~ **855-120-1122**
Responsibilities: Ratio & Supervision

~~(1) A Pharmacist may not supervise more than one Intern at a time at a TPI site who performs the duties of an Intern as listed in OAR 855-019-0200(6). A Pharmacist may supervise more than one Intern if only one intern performs the duties of an Intern as listed in OAR 855-019-0200(6) and if other Interns supervised by the Pharmacist perform the duties listed in OAR 855-025-0040.~~

~~(2) A preceptor may not supervise more than two Interns simultaneously during a shift at an SRI site where patient specific recommendations for care or medications are provided without prior written authorization of the board.~~

~~(3) With the written approval of a school of pharmacy, and when in their reasonable professional judgment it is appropriate, a preceptor may supervise up to 10 Interns at public health outreach programs such as informational health fairs that provide general information but not direct patient care.~~

~~(4) For immunization clinics, an immunizing Pharmacist may supervise up to two immunizing Interns.~~

~~(5) A licensed preceptor may delegate the preceptor responsibilities to another licensed Pharmacist or preceptor.~~

(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 non-Pharmacist who is a Preceptor may supervise up to one Intern.

(2) For non-direct patient care experiences within an Internship Program, 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.

POLICY DISCUSSION: Ratios

(~~6~~**3**) The majority of an Intern's overall experience **in a professional experiential program** must be with a licensed Pharmacist ~~p~~**P**receptor.

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 that 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 Preceptor's health care professional license;

(b) Intern is only working as part of an Internship Program at a board-approved school or college of pharmacy;

(c) Intern has successfully completed their first academic year.

POLICY DISCUSSION: Non-Pharmacist Preceptors

(2) A Preceptor may not engage in any form of discrimination, harassment, intimidation, or assault in the workplace;

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

855-120-1155
Grounds for Discipline

The State Board of Pharmacy 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 determined that the Preceptor or Internship Program site is no longer valid.

(b) Licensee is not permitted to supervise an Intern per Board order.

(c) Registrant is not permitted to utilize Interns per Board order.

POLICY DISCUSSION: Add to OAR 855-115 and OAR 855-041

(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- Supervisor of an Academic Internship Program

(~~2~~1) **The Pharmacist who supervises the academic Internship Program for a college or school of pharmacy located in Oregon must:**

(a) Be licensed as a Preceptor.

~~855-031-0045~~
~~School and Preceptor Registration and Responsibilities~~

(~~10~~b) ~~The school of pharmacy must m~~**M**aintain a record of each **internship completed as part of the Internship Program** ~~intern's SRIs~~. This record must be made available to the board upon request.

(~~11~~c) ~~A school of pharmacy located in Oregon must s~~**S**ubmit a report on their ~~experiential education~~ **Internship** ~~p~~**P**rogram to the board at the end of each academic year. ~~This report must include the names of students who successfully completed the program and graduated from the school.~~

POLICY DISCUSSION: Report Components

(d) ~~The school must m~~**M**aintain a list of preceptors and ~~SRI~~ **experiential** sites, in and out-of-state, approved by the school and must make this list available to the board upon request.

(e) 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 010/019/104: Board Administration and Policies (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 104, repeals Division 010

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 104, repeals Division 010. Relocates and amends board administration and policies rules from Division 010 to new Division 104. Relocates OAR 855-019-0125 to OAR 855-104-0035.

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): Repeals Division 010. Relocates existing rules from Division 010 to newly created Division 104 Board Administration and Policies. Relocates OAR 855-019-0125 to OAR 855-104-0035. Amendments include removing 3(a)(b)(c) in OAR 855-104-0010, revises rule references in OAR 855-104-0065 Military Spouse Domestic Partner Licensure Process and adds "intern".

DIVISION 10**4**
BOARD ADMINISTRATION AND POLICIES

~~855-010-0005~~**855-104-0010**
Meetings

(1) The board meetings must be held not less than once every three months as designated by the board.

(2) The President of the board must have 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~~., which may include but is not limited to:~~

~~(a) Approval of providers of continuing pharmacy education accredited by the Accreditation Council for Pharmacy Education (ACPE);~~

~~(b) Approval of schools and colleges of pharmacy accredited, accredited with probation, pre-candidate or candidate status by ACPE; and~~

~~(c) Review and adopt standards by reference.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135, ORS 689.151, ORS 689.185 & ORS 689.255

~~855-010-0015~~**855-104-0015**
Individual Commitments

(1) Board members must be governed by board action and must make no individual commitments or promises on matters of board policies.

(2) No declaration must be made or vote taken on any question, except at board meetings.

Statutory/Other Authority: ORS 689 & ORS 183
Statutes/Other Implemented: ORS 183

~~855-010-0016~~**855-104-0020**
Board Administration and Policies: Pharmacy Board Member and Public Health and Pharmacy Formulary Advisory Committee Member Compensation

(1) A board member and Public Health and Pharmacy Formulary Advisory Committee 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 member of the Public Health and Pharmacy Formulary Advisory Committee 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 Public Health and Pharmacy Formulary Advisory Committee 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

~~855-010-0018~~ **855-010-0025**
Public Health and Pharmacy Formulary Advisory Committee

(1) The Public Health and Pharmacy Formulary Advisory Committee must consist of:

(a) Two physicians licensed to practice medicine under ORS 677.100 to 677.228;

(b) Two advanced practice registered nurses who have prescriptive authority and who are licensed by the Oregon State Board of Nursing; and

(c) Three Pharmacists licensed by the State Board of Pharmacy, at least one of whom is employed as a community Pharmacist and one of whom is employed as a health system Pharmacist.

(2) A Pharmacist may submit a concept, on a form prescribed by the board to the committee for consideration, for the development of a protocol or the addition of a drug or device to the formulary.

(3) The committee must recommend to the board, for adoption by rule, a protocol or formulary of drugs and devices from which a Pharmacist can prescribe and dispense to a patient pursuant to a diagnosis by a qualified healthcare practitioner.

(4) The committee must periodically review the formulary and protocol compendium and recommend the revisions to the board for adoption by rule.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649 & ORS 689.155

~~855-010-0021~~**855-104-0030**
Adoption by Reference

(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

~~855-010-0035~~**104-0030**
Board Compliance Program

The board's Compliance Director and Compliance Officers must be **P**~~p~~harmacists licensed in the State of Oregon.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.195

~~855-019-0125~~**855-104-0035**
Coaching from Board and Staff

No member or employee of the ~~B~~**b**oard ~~shall~~ **may:**

(1) D~~d~~iscuss the contents of an examination, its preparation or use with any candidate or other person**;** ~~No member or employee of the Board shall~~

(2) C~~c~~oach a candidate or any other person on materials that may be used in the examination**;** ~~n~~**or** ~~shall they~~

(3) A~~a~~ccept 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

855-104-0040
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: TBD
Statutes/Other Implemented: TBD

~~855-010-0100~~**855-104-0050**
~~State and Nationwide~~ Criminal Background Checks for Licensure **and Registration**

(1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure; directors, officers and designated representatives of drug outlets applying for registration; 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; directors, officers and designated representatives of drug outlets applying for registration or renewal of a registration; 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.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205 ORS 181A.210, ORS 181A.215, ORS 670.280, ORS 676.303, OAR 125-007-0200, 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) The following are examples of crimes likely to result in denial unless there are significant mitigating circumstances:

(A) Aggravated murder;

(B) Murder;

(C) Rape I;

(D) Sodomy I;

(E) Unlawful sexual penetration I;

(F) Sexual abuse I

(j) 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.

(k) 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 183.413, ORS 183.415, ORS 183.417, ORS 183.425, ORS 183.430, ORS 183.435, ORS 183.440, ORS 183.445, ORS 183.450, ORS 183.452, ORS 183.453, ORS 183.457, ORS 183.458, ORS 183.459, ORS 183.460, ORS 183.462, ORS 183.464, and ORS 183.470 and in accordance with OAR 855-001-0005, OAR 855-001-0012, OAR 855-001-0016, and OAR 855-001-0017.

(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

~~855-010-0110~~**855-104-0055**
~~State and Nationwide~~ 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.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205 ORS 181A.210, ORS 125-181A.215 and OAR 125-007-0200, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, and OAR 125-007-0310.

(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 181A.215 & ORS 676.303

~~855-010-0120~~**855-104-0060**
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

~~855-010-0130~~**855-104-0065**
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 Division 855-~~019~~**115, OAR 855-120** or OAR 855-~~025~~**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

855-104-0070

Public Request for Board Records

NOTE: Board staff are working on this new rule set. Adding rules for clarity to the public on how to request public records. These rules will likely result in revisions to OAR 855-110-0015 Administrative Fees.

Division 001/102: Procedural and Universal Rules

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Procedural and Universal Rules; Adopts new Division 102, repeals Division 001

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 102 and adopts existing procedural rules related to rulemaking, model rules of procedure, time for requesting a contested case hearing, filing exceptions to the board, petition for reconsideration or rehearing as condition for judicial review, duty to cooperate, inspections and records and document retention requirements. Repeals Division 001.

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

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

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

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): Reporting, Recordkeeping and Administrative Activities Cost: Professional Services, Equipment/ Supplies, Labor Cost, Effect on Small Businesses: There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommends adopting the proposed rules for transparency and clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Creates new Division 102 for procedural and universal rules. Proposed rules relocate existing procedural rules from Division 001 and adds rules related to records and document retention requirements. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public. Repeals Division 001.

Repeals Division 001. Relocates existing rules from Division 001 to newly created Division 102 Procedural and Universal Rules. Creation of Division 102 and adoption of procedural and universal rules is a part of the board's strategic plan which will streamline rules and make rules easier to locate for licensees, registrants and the public.

NOTES:

- Highlights
  - Rule language highlighted in blue denote staff proposed amendments made between the board's review of this package at the February 2023 board meeting and the April 2023 board meeting.

DIVISION 102

PROCEDURAL AND UNIVERSAL RULES

~~855-001-0000~~ **855-102-0005**

Notice of Proposed Rule

Prior to the permanent adoption, amendment, or repeal of any rule, the State Board of Pharmacy must give notice of its intended action as required in ORS 183.335:

(1) In a manner established by rule adopted by the board under ORS 183.341(4), which provides a reasonable opportunity for interested persons to be notified of the agency's proposed action;

(2) In the bulletin referred to in ORS 183.360 at least 21 days prior to the effective date;

(3) To persons who have requested notice pursuant to ORS 183.335(8) at least 28 days before the effective date; and

(4) To persons specified in ORS 183.335(15) at least 49 days before the effective date; and

(5) To persons or organizations the Board's Executive Director determines, pursuant to ORS 183.335, are interested persons in the subject matter of the proposed rule, or would be likely to notify interested persons of the proposal; and

(a) Oregon State Pharmacy Association;

(b) Oregon Society of Health System Pharmacists;

(6) To the Associated Press and the Capitol Press Room.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 183.335

~~855-001-0005~~ **855-102-0010**

Model Rules of Procedure

Pursuant to the provisions of ORS 183.341, the Board of Pharmacy adopts the Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act effective 07/2019. These rules must be controlling except as otherwise required by statute or rule.

[ED. NOTE: The full text of the Attorney General's Model Rules of Procedure is available from the office of the Attorney General or Board of Pharmacy.]

Statutory/Other Authority: ORS 183.341 & ORS 689.205
Statutes/Other Implemented: ORS 183.341

~~855-001-0012~~ **855-102-0015**
Time for Requesting a Contested Case Hearing

A request for a contested case hearing must be in writing and must be received by the board within 21 days from the date the contested case notice was served. When the board has issued a denial of a license, a request for a contested case hearing must be in writing and must be received by the board within 60 days from the date the licensure denial was served.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 183.435

~~855-001-0016~~ **855-102-0020**
Filing Exceptions and Argument to the Board

After a proposed order has been served on a party, the board must notify the party when written exceptions must be filed to be considered by the board.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

~~855-001-0017~~ **855-102-0025**
Petition for Reconsideration or Rehearing as Condition for Judicial Review

All parties, including limited parties, must file a petition for reconsideration or rehearing with the board as a condition for obtaining judicial review of any order of the board.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

~~855-001-0030~~ **855-102-0035**
Duty to Cooperate

(1) Applicants, licensees, and registrants must **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

~~855-001-0040~~ **855-102-0040**

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.

(5) The Compliance staff is authorized to provide appropriate deadline extensions upon request.

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

855-102-0050

Record and Document Retention

(1) All records and documents required by ORS 475, ORS 689, and OAR 855:

(a) May be in written or electronic format;

(b) Must be stored securely

(c) Must be made available to the board upon request; and

(A) Must be retained for 3 years except that:

(B) Clinical pharmacy records must be retained for 7 years;

(d) 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 in the practice of pharmacy for a Drug Outlet:

(a) Must be stored at the Drug Outlet 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 Drug Outlet and must be provided to the board upon request within 3 business days;

(3) Records generated in the practice of pharmacy separate from a Drug Outlet:

(a) Must be stored at a pharmacy, health care organization, practitioner office, pharmacist office or in a secure manner by the Pharmacist, for at least 12 months;

(b) May be stored in a secured off-site location after 12 months of storage according to (a) and must be 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

~~855-041-1167~~ 855-102-00XX
Patients Access to Pharmacy Records

(1) Licensees and registrants of the board must make ~~protected~~ 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 ~~protected~~ 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

Division 025/125: Pharmacy Technicians (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 125 for Pharmacy Technicians

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Creates new Division 125 for Certified Oregon Pharmacy Technicians (COPT) and Pharmacy Technicians (PT). Proposes relocating and reorganizing existing COPT and PT rules from Division 025. If the board adopts Division 125, existing rules related to COPT and PT would be repealed in Division 025.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

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

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

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed rule adoption includes relocating and reorganizing existing COPT and PT rules from Division 025 to newly created Division 125 in alignment with the board's strategy to systematically organize all Divisions. Proposed amendments include revising titles, clarifying requirements for COPT and PT applicability, licensure qualifications, licensure application, licensure renewal and reinstatement, licensure lapse and voluntary surrender of license. Amendments also clarify general responsibilities, confidentiality, duty to report, training responsibilities and permitted and prohibited practices.

Repeals Division 025. Existing COPT and PT rules from Division 025 are being reorganized and relocated to new Division 125 Certified Oregon Pharmacy Technicians and Pharmacy Technicians.

NOTES:

- History of rule package review
  - The board completed a 1st review of this package in June 2022.
  - The board completed a 2nd review of this package in August 2022

- The board completed a 3rd review of this package in February 2023
- The April 2023 meeting is the 4th review of this package.

- Highlights
  - Rule language highlighted in blue denote staff proposed amendments made between the board's review of this package at the February 2023 board meeting and the April 2023 board meeting.

----------3rd REVIEW----------

DIVISION **1**25
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

~~855-025-0001~~**855-125-0001**
~~**Purpose and Scope**~~ **Applicability**

~~The purpose of the Pharmacy Technician (PT) license is to provide an opportunity for an individual to obtain competency in the role as a Pharmacy Technician. This license will allow an individual time to take and pass a national pharmacy technician certification examination, which is required to be eligible for licensure as a Certified Oregon Pharmacy Technician (CPT). These rules facilitate the initial licensure of a nationally certified Pharmacy Technician seeking licensure in Oregon.~~

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

(2) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may assist a Pharmacist in the practice of pharmacy and must act in compliance with statutes and rules under the supervision, direction, and control of a Pharmacist.

(3) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification when delegated to do so by a Pharmacist and done in compliance with all applicable statutes and rules and under the supervision, direction, and control of that Pharmacist.

(4) Only a person licensed as a Certified Oregon Pharmacy Technician may use the titles "Certified Oregon Pharmacy Technician" and "COPT."

Statutory/Other Authority: ORS 689.205; ORS 689.225.
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-125-0005
Definitions

Note: Placeholder- No definitions specific to Division 125 at this time.

~~855-025-0005~~**855-125-0010**

Licensure: Qualifications - ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) To qualify for licensure as a ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **or Pharmacy Technician,** an applicant must demonstrate that the applicant is at least 18 years of age and has completed high school (or equivalent).

(2) To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must also demonstrate that the applicant has taken and passed a national pharmacy technician certification examination offered by:

(a) Pharmacy Technician Certification Board (PTCB); or

(b) National Healthcareer Association (NHA).

~~(3) No person whose license has been denied, revoked, suspended or restricted by any healthcare professional regulatory board may be licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician unless the board determines that licensure will pose no danger to patients or to the public interest.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

~~855-025-0010~~**855-125-0030**

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) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline;~~

~~(3) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

(**4~~2~~**) The board may issue a license to a qualified applicant after the receipt of:

(a) A completed application **including:**~~;~~

(~~b~~**A**) Payment of the fee prescribed in OAR 855-110;

(~~c~~**B**) A current, passport regulation size photograph (full front, head to shoulders);

(~~d~~**C**) Personal identification or proof of identity; ~~and~~

(~~e~~**D**) A completed national fingerprint-based background check~~.~~**; and**

(E) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(b) An applicant for a Certified Oregon Pharmacy Technician license, must provide a passing result from PTCB or NHA on a national pharmacy technician certification examination.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application or requests resulting from the application;

(c) 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

~~855-025-0012~~
~~Licensure: Application- Certified Oregon Pharmacy Technician~~

~~(1) An application for licensure as a Certified Oregon Pharmacy Technician may be accessed on the board website.~~

~~(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline.~~

~~(3) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(4) The board may issue a license to a qualified applicant after the receipt of:~~

~~(a) A completed application;~~

~~(b) Payment of the fee prescribed in OAR 855-110;~~

~~(c) A current, passport regulation size photograph (full front, head to shoulders);~~

~~(d) Personal identification or proof of identity;~~

~~(e) A completed national fingerprint-based background check; and~~

~~(f) Proof that the applicant has taken and passed a national pharmacy technician certification offered by the PTCB or the NHA.~~

~~(5) The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225 & ORS 689.486~~

~~855-025-0011~~**855-125-0035**
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

~~855-025-0015~~
~~Licensure: Renewal or Reinstatement- Certified Oregon Pharmacy Technician~~

~~(1) A person who has taken and passed a national pharmacy technician certification examination listed in OAR 855-025-0012(1)(a)–(b) may use the following title, and is referred to in these rules as, and is licensed as a "Certified Oregon Pharmacy Technician."~~

~~(2) An applicant for renewal of a Certified Oregon Pharmacy Technician license must:~~

~~(a) Pay the biennial license fee required in OAR 855-110;~~

~~(b) Complete the continuing pharmacy education requirements as directed in OAR 855-021; and~~

~~(c) Be subject to an annual criminal background check.~~

~~(3) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.~~

~~(4) A Certified Oregon Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may renew their license and must pay a late fee required in OAR 855-110.~~

~~(5) A Certified Oregon Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:~~

~~(a) Must apply per OAR 855-025-0010; and~~

~~(b) Provide certification of completion of 10 continuing education hours earned in the prior 12 months. These hours may not be counted toward a future renewal; and must include:~~

~~(A) One hour of continuing pharmacy education in pharmacy law;~~

~~(B) One hour of continuing pharmacy education in patient safety or error prevention; and~~

~~(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and~~

~~(D) Seven other hours of pharmacy technician-specific continuing education.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225, ORS 689.486 & ORS 413.450~~

855-125-0040
Licensure: Lapse

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not assist in the practice of pharmacy if the license is lapsed.

(d) A person may apply for renewal or reinstatement according to OAR 855-125-0030.

(2) If a person requests lapse prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board 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

~~855-025-0023~~**855-125-0105**
~~Certified Oregon Pharmacy Technician and Pharmacy Technician: General~~ **Responsibilities: General- Certified Oregon Pharmacy Technician and Pharmacy Technician**

(1) ~~A~~ **Each** Certified Oregon Pharmacy Technician ~~or~~ **and** Pharmacy Technician is responsible for their own actions; however, this does not absolve the Pharmacist and the pharmacy from responsibility for the Certified Oregon Pharmacy Technician or Pharmacy Technician's actions.

(~~3~~**2**) A Certified Oregon Pharmacy Technician or Pharmacy Technician may not engage in the practice of pharmacy as defined in ORS 689.005.

(~~2~~**3**) A Certified Oregon Pharmacy Technician ~~or~~ **and** Pharmacy Technician must:

(a) Comply with all state and federal laws and rules governing the practice of pharmacy;

(b) Only assist in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;

(c) Know the identity of the Pharmacist who is providing supervision, direction and control at all times;

(d) Only work within the scope of duties permitted by their license;

(e) Only work within the scope of duties permitted by the Pharmacist providing supervision, direction and control;

(~~e~~**f**) Only perform duties they are trained to perform~~; and~~

(g) Appropriately perform the duties permitted;

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

(i) Be clearly identified as a Certified Oregon Pharmacy Technician or Pharmacy Technician in all interactions and communications (e.g., nametag, phone interaction, chart notations);

(j) 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;

(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

~~855-025-0030~~**855-125-0110**
Responsibilities: Confidentiality

~~(1)~~ No licensee of the ~~B~~**b**oard who obtains any patient information ~~shall~~ **may** disclose that information to a third-party without the consent of the patient except as provided in ~~section two~~ **(a)-(e)** of this rule.

(**1**~~2~~) A licensee may disclose patient information:

(a) To the ~~B~~**b**oard;

(b) To a practitioner, Pharmacist, **Intern,** ~~Pharmacy Technician, or~~ Certified Oregon Pharmacy Technician **or Pharmacy Technician**, if disclosure is authorized by a Pharmacist ~~who reasonably believes that~~ **and** disclosure is necessary to protect the patient's health or well-being; or

(c) To a third-party when disclosure is authorized or required by law; or

(d) As permitted pursuant to federal and state patient confidentiality laws~~.~~ **or;**

(e) To the patient or to persons as authorized by the patient.

(2) A licensee or registrant of the board may not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, **ORS 689.305, ORS 689.315**
Statutes/Other Implemented: ORS 689.155

~~855-025-0020~~**855-125-0115**
Responsibilities: Duty to Report

~~(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.~~

~~(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

(~~3~~**1**) **Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each** ~~A Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **and Pharmacy Technician** must report to the board **without undue delay, but** within

(a) 10 days if they:

(~~a~~**A**) Are ~~c~~**C**onvicted of a misdemeanor or a felony; or

(~~b~~**B**) ~~If they a~~**A**re arrested for a felony~~.~~**; or**

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

(b) 10 working days if they:

(4**A**) ~~A Pharmacy Technician or Certified Oregon Pharmacy Technician who has~~ **Have** reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct ~~as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting Pharmacy Technician or Certified Oregon Pharmacy Technician must report the conduct without undue delay, but in no event later than 10 working days after the reporting Pharmacy Technician or Certified Oregon Pharmacy Technician learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.~~ **to that licensee's board; or**

(B) Suspect records are lost or stolen.

(c) 15 days, any change in:

(A) Legal name;

(B) Name used when assisting in the practice of pharmacy;

(C) Preferred email address;

(D) Personal phone number;

(E) Personal physical address;

(F) Personal mailing address; or

(G) Employer.

(~~5~~**2**) A ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **or Pharmacy Technician** who reports to a board in good faith as required by:

(a) ORS 676.150 ~~section (4) of this rule~~ is immune from civil liability for making the report~~.~~**; and**

(b) ORS 689.455 is not subject to an action for civil damages as a result thereof.

~~(6) A Pharmacy Technician or Certified Oregon Pharmacy Technician who has reasonable grounds to believe that prescription drugs or records have been lost or stolen, or any violation of these rules has occurred, must notify the board within 1 day.~~

~~(7) A Pharmacy Technician or Certified Oregon Pharmacy Technician must notify the board in writing, within 15 days, of any change in email address, employment location or residence address except that a Pharmacy Technician who is employed at more than one pharmacy need only report the name and address of the pharmacy at which the technician normally works the most hours.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: **ORS 676.150,** ORS 689.155**, ORS 689.455**~~,~~ ~~&~~ ORS 689.486

~~**855-125-0076**~~
~~**Responsibilities: Training**~~

~~855-025-0025~~
~~Use of Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~(1) A Pharmacist or pharmacy may use Pharmacy Technicians or Certified Oregon Pharmacy Technicians only as authorized by the rules of the Board.~~

~~(2) Pharmacy Technicians or Certified Oregon Pharmacy Technicians must be supervised by a Pharmacist.~~

~~(3) Pharmacists, Pharmacist Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians must be clearly identified as such to the public.~~

~~(4) Work performed by Pharmacy Technicians and Certified Oregon Pharmacy Technicians assisting the Pharmacist to prepare medications must be verified by a Pharmacist prior to release for patient use. Verification must be documented, available and consistent with the standard of practice.~~

~~(5) The pharmacist-in-charge must prepare and maintain in the pharmacy written procedures that describe the tasks performed by Pharmacy Technicians or Certified Oregon Pharmacy Technicians, and the methods of verification and documentation of work performed by Pharmacy Technicians or Certified Oregon Pharmacy Technicians. Written procedures must be available for inspection by the Board or its representatives. The pharmacist-in-charge must review written procedures annually and document that review on the annual pharmacist-in-charge inspection sheet.~~

~~(6) Training:~~

~~(a) The pharmacist-in-charge must outline, and each Pharmacy Technician or Certified Oregon Pharmacy Technician must complete initial training that includes on-the-job and related education that is commensurate with the tasks that the Pharmacy Technician or Certified Oregon Pharmacy Technician will perform, prior to the performance of those tasks.~~
~~(b) The pharmacist-in-charge must ensure the continuing competency of Pharmacy Technicians or Certified Oregon Pharmacy Technicians.~~

~~(c) The pharmacist-in-charge must document initial training of each Pharmacy Technician or Certified Oregon Pharmacy Technician and make that documentation available to the Board or its representatives upon request.~~

~~(7) Upon written request, the Board may waive any of the requirements of this rule upon a showing that a waiver will further public health or safety or the health or safety of a patient or other person. A waiver granted under this section is effective only when issued by the Board in writing.~~

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

~~855-025-0035~~
~~Pharmacy and Pharmacist Responsibility for Supervising Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~(1) The supervising Pharmacist and the pharmacist-in-charge are responsible for the actions of Pharmacy Technicians or Certified Oregon Pharmacy Technicians. The use of Pharmacy Technicians or Certified Oregon Pharmacy Technicians to perform tasks not included in written procedures maintained by the pharmacy constitutes unprofessional conduct on the part of the supervising Pharmacist and the pharmacist-in-charge.~~

~~(2) The pharmacy must maintain on file and post the current license of each Pharmacy Technician or Certified Oregon Pharmacy Technician.~~

~~(3) Before allowing any person to work as a Pharmacy Technician or Certified Oregon Pharmacy Technician, the pharmacy and Pharmacist shall verify that the person is currently licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician.~~

~~(4) Prior to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician, a person must provide to the Pharmacist or pharmacist-in-charge a copy of the person's current Pharmacy Technician license or current Certified Oregon Pharmacy Technician license.~~

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

~~855-025-0040~~**855-125-0135**
~~Certified Oregon Pharmacy Technician and Pharmacy Technician: Tasks and Guidelines~~
Responsibilities: Permitted Practices

~~(1)~~ ~~Non-licensed pharmacy personnel may enter non-prescription information into a computer record system and may perform clerical duties such as filing prescriptions, delivery, housekeeping, and general record keeping, but the responsibility for the accuracy of the non-licensed pharmacy personnel's work lies with the Pharmacist~~.

(~~2~~) ~~Only persons licensed with the board as a~~ Certified Oregon Pharmacy Technician**s** or Pharmacy Technician**s**~~, acting in compliance with all applicable statutes and rules and under the supervision of a Pharmacist, may assist in the practice of pharmacy by the following~~:

(1) May only assist in the practice of pharmacy as authorized by the rules of the board and as permitted by the Pharmacist providing supervision, direction, and control.

(2) Must ensure that work is verified by a Pharmacist if ~~independent~~ judgment is utilized when assisting in the practice of pharmacy.

(3) May perform final verification as permitted under OAR 855-125-0070(4).

POLICY DISCUSSION: COPT vs. PT

~~(a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.~~

~~(b) Reconstituting prescription medications. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.~~

~~(d) Entering information into the pharmacy computer. The Certified Oregon Pharmacy Technician or Pharmacy Technician shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising Pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.~~

~~(e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;~~

~~(f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The Pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.~~

~~(g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The Pharmacist must verify the accuracy of the finished task unless the requirements of OAR 855-025-0023(4) are met.~~

~~(h) Checking nursing units in a hospital or nursing home for nonjudgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a Pharmacist.~~

~~(i) Recording patient or medication information in computer systems for later verification by the Pharmacist.~~

~~(j) Bulk Compounding; Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(k) Preparation of parenteral products as follows:~~

~~(A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(I) Performing related activities approved in writing by the board.~~

~~(3) In order to protect the public, safety, health and welfare, Certified Oregon Pharmacy Technicians or Pharmacy Technicians shall not:~~

~~(a) Communicate or accept by oral communication a new or transferred prescription of any nature;~~

~~(b) Receive or transfer a prescription to another pharmacy without the prior verification of a Pharmacist.~~

~~(c) Provide a prescription or medication to a patient without a Pharmacist's verification of the accuracy of the dispensed prescription;~~

~~(d) Counsel a patient on medications or perform a drug utilization review;~~

~~(e) Perform any task that requires the reasonable professional judgment of a Pharmacist; or~~

~~(f) Engage in the practice of pharmacy as defined in ORS 689.~~

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

855-125-0150
Prohibited Practices

Certified Oregon Pharmacy Technicians and Pharmacy Technicians may not:

(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0070(5), 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;

(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 ~~independent~~ judgment unless it is verified by a Pharmacist~~;~~.

(4) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace.

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

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

~~855-025-0050~~
~~Grounds for Discipline of Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~The State Board of Pharmacy may refuse to issue or renew; or may suspend, revoke, or restrict the license of a Pharmacy Technician or Certified Oregon Pharmacy Technician; or may impose a civil penalty upon a Pharmacy Technician or Certified Oregon Pharmacy Technician upon the following grounds including but not limited to:~~

~~(1) Unprofessional conduct as defined in OAR 855-006-0020;~~

~~(2) Repeated or gross negligence in performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician;~~

~~(3) Impairment, which means an inability to assist in the practice of pharmacy with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;~~

~~(4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;~~

~~(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a Pharmacy Technician or Certified Oregon Pharmacy Technician license;~~

~~(8) Allowing an individual to engage in the duties of a Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician without a license or to use falsely the title of Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician;~~

~~(9) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto;~~

~~(10) Failure to appropriately perform the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician as outlined in OAR 855-025-0040 while assisting a Pharmacist in the practice of pharmacy as defined in ORS 689.005;~~

~~(11) Any act or practice relating to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician which is prohibited by state or federal law or regulation; or~~

~~(12) Any conduct or practice by a Pharmacy Technician, Certified Oregon Pharmacy Technician or pharmacy that the Board determines is contrary to the accepted standards of practice.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.405~~

Division 006/019/020/031/041/115: Pharmacists (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Creates new Division 115 for Pharmacists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): The proposed rules create a new Division 115 for Pharmacists, relocates and reorganizes existing Pharmacists rules from Division 019, Division 020, Division 031 and Division 041 into this new division. If the board adopts Division 115, existing rules related to Pharmacists would be repealed in Division's 019, 020, 031 and 041.

Documents Relied Upon per ORS 183.335(2)(b)(D):
- 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): To be determined.

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

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed rule adoption includes relocating and reorganizing existing Pharmacist rules from Division's 019, 020, 031 and 041 to newly created Division 115 in alignment with the board's strategy to systematically organize all Divisions. Proposed amendments include revising titles, clarifying requirements for applicability, definitions, general qualifications for all Pharmacists license types, licensure requirements for all Pharmacist license types, licensure application, license renewal, license reinstatement, licensure lapse, licensure retirement, licensure voluntary surrender, Pharmacist Preceptor registration, in-state and out-of-state volunteer Pharmacist, and Nuclear Pharmacist. General responsibilities, confidentiality responsibilities, duty to report responsibilities, training responsibilities, Drug Utilization Review (DUR),

Counseling, PIC qualifications, limitations and duties. Services such as Pharmacist consulting practice, administration of vaccines, drugs or devices, Clinical Pharmacy Agreements, Medication Therapy Management, prescribing practices, naloxone, and emergency insulin.

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.

Repeals Division 019 and Division 020.

Repeals OAR 855-041-3000(4) and OAR 855-041-3300, 041-3305, 041-3310, 041-3315, 041-3320, 041-3325, 041-3330, 041-3335 and 041-3340 related to Consulting/Drugless Pharmacies.

A few rules in 041 are related specifically to a Pharmacist and need to be relocated to the newly created Division 115 Pharmacists.

NOTES:

- History of rule package review
  - The board completed a 1st review the licensing rules of this package in June 2022.
  - The board completed a 2nd review of the licensing rules and a 1st review of the definitions and responsibilities rules (ending with 855-115-0086(1)) of this package at the August 2022 board meeting.
  - The board completed a 3rd review of the licensing rules and a 2nd review of the definitions and responsibilities rules (ending with 855-115-0105(1)) of this package at the October 2022 board meeting.
  - The board completed a 3rd review of responsibilities rules (ending with 855-115-0150(1)(c) and 1st review of services rules of this package at the December 2022 board meeting.
  - The board completed a 4th review of licensing and responsibilities rules (ending with 855-115-0150(1)(c) and 2nd review of services rules of this package at the February 2023 board meeting.
  - Today is the board's 5th review of licensing and responsibilities rules and 3rd/4th review of services rules.

- Highlights
  - Rule language highlighted in blue denote staff proposed amendments made between the board's review of this package at the February 2023 board meeting and the April 2023 board meeting.
  - Rule language highlighted in green denote language that has been moved within the package between the board's review of this package at the February 2023 board meeting and the April 2023 board meeting.

---------- DEFINITIONS (3rd REVIEW) ----------

DIVISION 6
DEFINITIONS

855-006-0005
Definitions

(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.
Note: Adopted effective 12/21/2022

(10) "Collaborative Drug Therapy Management" means the ~~participation by~~ **process in which a** Pharmacist **or pharmacy and providers on behalf of a health care organization, a physician as defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010 agree to a pre-specified** ~~in the management of~~ drug therapy **management** ~~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~~ **is initiated for an individual patient on the** prescription order **of a participating provider.** ~~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.~~

(XX) "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.

~~(33) Participation in Drug Selection and Drug Utilization Review:~~

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

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

~~(A) Over-utilization or under-utilization;~~

~~(B) Therapeutic duplication;~~

~~(C) Drug-disease contraindications;~~

~~(D) Drug-drug interactions;~~

~~(E) Incorrect drug dosage;~~

~~(F) Incorrect duration of treatment;~~

~~(G) Drug-allergy interactions; and~~

~~(H) Clinical drug abuse or misuse.~~

(XX) "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.

~~(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.~~

~~(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.~~

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

---------- LICENSING (5th REVIEW) ----------

DIVISION ~~19~~**115**
PHARMACISTS

~~855-019-0100~~ **855-115-0001**
~~Application~~ **Applicability**

(1) This Division applies to any ~~p~~**P**harmacist **who engages in the practice of pharmacy** ~~who is licensed to practice pharmacy in Oregon including any pharmacist located in another state who is consulting, or providing any other pharmacist service, for a patient, pharmacy or healthcare facility in Oregon~~.

~~(2) Where so indicated, these rules also apply to an intern who is licensed in Oregon.~~

(~~3~~**2**) ~~Any pharmacist who engages in the~~ **Only persons licensed with the board as a Pharmacist may** practice ~~of~~ pharmacy ~~in Oregon~~ **and** must ~~be licensed by the Board in accordance with the following~~ **act in compliance with statutes and** rules.

(43) A Ppharmacist 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 Bboard in accordance with the following rules, except that a Ppharmacist **located in another state who is** working in **for** an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their **out-of-state pharmacy** dispensing of a drug **in**to a patient in Oregon, is not required to be licensed by the Bboard unless they are the pharmacist-in-charge (PIC).

POLICY DISCUSSION: Reciprocity

(5) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.

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

855-019-0110 **855-115-0005**
Definitions
Note: Placeholder- No definitions specific to Division 115 at this time.

In this Division of Rules:

(1) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.

(2) "Collaborative Drug Therapy Management (CDTM)" has the same meaning as defined in OAR 855-006-0005.

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

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

(5) "Drug Utilization Review (DUR)" has the same meaning as defined in OAR 855-006-0005.

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

~~(7) "Practice of Clinical Pharmacy" means:~~

~~(a) The health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;~~

~~(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and~~

~~(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.~~

~~(8) "Practice of Pharmacy" is as defined in ORS 689.005.~~

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

855-115-0010
Licensure: Qualifications: General

(1) Before licensure as a Pharmacist, an applicant must meet the qualifications required that are applicable to their method of licensure;

(a) Examination or Score Transfer in OAR 855-115-0020; or

(b) Reciprocity in OAR 855-115-0025.

(2) If residing in the United States, proof of citizenship, legal permanent residency or qualifying visa, as required by 8 USC 1621

(3) Foreign pharmacy graduates must also meet the requirements of OAR 855-115-0015 prior to applying for a Pharmacist license.

Statutes/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 2021 HB 2078

~~855-019-0150~~ **855-115-0015**
Licensure: Qualifications: Pharmacist **Foreign Pharmacy Graduate Education**

(1) ~~Foreign Pharmacy Graduates applying~~ **An applicant** for **pharmacist** licensure **who graduated from a foreign school, college, or program of pharmacy** ~~in Oregon~~ must meet the following **educational** requirements:

~~(a) Provide a copy of a valid visa permitting full time employment;~~

(~~b~~a) **Obtain** ~~Provide a copy of the original certificate issued by the NABP~~ **certification from the** Foreign Pharmacy Graduate Examination Committee (FPGEC); and

~~(c) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 91 days. This score shall only be valid for one year unless the Board grants an extension;~~

~~(d) After having completed the required number of intern hours, pass the MPJE with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 30 days. The MPJE score shall only be valid for 6 months unless extended by the Board.~~

(~~2~~**b**) ~~An applicant must complete~~ **Submit evidence on form provided by the board of** 1440 hours in pharmacy practice as an ~~i~~**I**ntern **or Pharmacist in the United States or its jurisdiction** ~~that must be certified to the Board by the preceptors.~~

(2) An applicant who graduated from:

(a) A foreign school, college, or program of pharmacy must complete (1)(a) and (1)(b).

(b) A Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program located in Canada or its jurisdiction:

(A) With a curriculum taught in English; and

(i) Who graduated before 1993 or after June 30, 2004 must complete (1)(a) and (1)(b).

(ii) Who graduated between 1993 and June 30, 2004 must complete (1)(b).

(B) With a curriculum that was not taught in English must complete (1)(a) and (1)(b).

(c) The ACPE-accredited program at the Lebanese American University in Byblos, Lebanon:

(A) With a Doctor of Pharmacy degree; and

(B) Graduated after 2002 is exempt from (1)(a) and (1)(b).

(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.

~~(3) An applicant may not count internship hours or practice as a pharmacist completed outside the United States toward Oregon's internship requirement.~~

~~(4) An applicant may not count internship hours or practice as a pharmacist that is completed before passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE), and either the TOEFL with TSE, or TOEFL (IBT) exams toward Oregon's internship requirement.~~

~~(5) The Board may waive any requirement of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & ORS 689.255

~~855-019-0120~~ **855-115-0020**
Licensure: Qualifications: Pharmacist Examination or Score Transfer

(1) ~~Before~~ **To receive** licensure as a ~~p~~**P**harmacist **by examination or score transfer**, an applicant must meet the following requirements:

(a) Provide evidence from a **board-approved** school or college of pharmacy ~~approved by the board~~ that**:** ~~they have successfully completed all the requirements for graduation and, starting with the graduating class of 2011, including not less than 1440 hours of School-based Rotational Internships as that term is defined in OAR 855-031-0005, and that~~

(**A**) ~~a~~**A** degree ~~will be~~ **has been** conferred; **and**

(B) The applicant has completed a minimum of 1440 hours in an Internship Program as that term is defined in OAR 855-006-0005.

(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam**.** ~~with a score of not less than 75. This score~~ **A passing result** is valid for ~~only one year~~ **12 months** ~~unless the board grants an extension~~. A candidate who does not ~~attain this score~~ **pass** may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 **failed attempts** ~~times~~;

(c) Pass the **Oregon** Multistate Pharmacy Jurisprudence Examination (MPJE) exam**. A passing result is valid for 12 months** ~~The applicant may not take the MPJE until they have graduated from a school or college of pharmacy.~~ A candidate who does not ~~attain this score~~ **pass** may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 **failed attempts**. ~~The MPJE score is valid for 6 months unless extended by the board;~~

~~(d) Complete an application for licensure, provide the board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check; and~~

(~~e~~**d**) Complete one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority.

~~(2) A license, once obtained, will expire on June 30 in odd numbered years and must be renewed biennially.~~

(2) An applicant who has obtained their professional degree outside the United States is not eligible for licensure via examination or score transfer until they have met the requirements of OAR 855-115-0015.

(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 689.151**, ORS 413.590** ~~& 2021 HB 2078~~ **ORS 689.285**

~~855-019-0140~~
~~NAPLEX Score Transfer~~

~~(1) An applicant for score transfer must be a graduate of a school or college of pharmacy approved by the Board and must have passed the NAPLEX or equivalent examination with a score of at least 75.~~

~~(2) Prior to taking the NAPLEX examination for their initial state of licensure, an applicant must have requested the National Association of Boards of Pharmacy to score transfer their NAPLEX score to Oregon.~~

~~(3) An applicant must provide the following documentation:~~

~~(a) Oregon Score Transfer Application;~~

~~(b) A passport regulation photograph;~~

~~(c) A copy of a birth certificate, US passport or naturalization documents, or a foreign passport endorsed with a US visa permitting full time employment;~~

~~(d) Evidence of successful completion of all graduation requirements from a school or college of pharmacy approved by the Board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.265~~

~~855-019-0130~~ **855-115-0025**
Licensure**: Qualifications: Pharmacist** ~~by~~ Reciprocity

(1) An applicant for licensure as a **P**~~p~~harmacist by reciprocity must meet the requirements of ORS 689.265 and the following requirements:

(a) Be a graduate of a **board-approved** school or college of pharmacy ~~approved by the Board~~;

(b) Have passed the NAPLEX ~~or equivalent examination with a score of not less than 75~~;

(c) Have passed the **Oregon** MPJE**.** ~~with a score of not less than 75;~~ **A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;**

POLICY DISCUSSION: ORS 689.265(1)(g) Examination in jurisprudence

(d) ~~Be licensed and in good standing in the state from which the applicant bases the reciprocity application;~~ **Provide proof that each Pharmacist license granted to the applicant is not suspended, revoked, canceled or otherwise completely restricted from the practice of pharmacy for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the practice of pharmacy.**

(e) Have either:

(A) Been engaged in the practice of pharmacy for period of at least ~~one year~~ **12 months** including a minimum of 1440 hours of work experience as a licensed ~~p~~**P**harmacist. Evidence supporting this work experience ~~shall~~ **must** be provided at time of application; or

(B) ~~Met~~ **Completed 1440 hours in an Internship Program as that term is defined in OAR 855-006-0005** ~~of the internship requirements of this state~~ within the ~~one-year~~ **12 month** period immediately before the date of ~~this~~ application. Evidence from the **board-approved** school or college of pharmacy supporting this internship ~~shall~~ **must** be provided at time of application.

~~(2) Licensure as a pharmacist in another state precludes licensure to practice as an intern in the State of Oregon, except an applicant that has been accepted into an Oregon pharmacy residency program or for licensure by examination or by reciprocity who must acquire internship hours to become eligible for licensure, and then only until the required hours have been acquired.~~

(~~3~~**2**) An applicant who has obtained their professional degree outside the United States **and jurisdiction** is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-~~019-0150~~**115-0015**.

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) Official transcript from a board-approved school or college of pharmacy;

(b) Passing result from NABP for the NAPLEX and MPJE;

(c) A completed application including:

(A) Payment of the fee prescribed in OAR 855-110;

(B) A current, passport regulation size photograph (full front, head to shoulders);

(C) Personal identification or proof of identity;

(D) Certificate of completion for the one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority;

(d) A completed national fingerprint-based background check; and

(e) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(3) Penalties may be imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application;

(c) Failure to respond to requests for information resulting from the application;

(d) Any other grounds found in ORS 689.405.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of a Pharmacist expires June 30 in odd numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.225, ORS 689.285

~~855-019-0122~~ **855-115-0035**
~~Renewal of~~ **Licensure: Renewal or Reinstatement-** ~~as a~~ Pharmacist

(1) An applica**nt**~~tion~~ for renewal of a ~~p~~**P**harmacist license must ~~include documentation of~~:

~~(a) Completion of continuing pharmacy education requirements as outlined in OAR 855-021; and~~

(~~b~~a) Pay~~ment of~~ the biennial license fee required in OAR 855-110;~~.~~

(b) Complete the continuing pharmacy education requirements as outlined in OAR 855-135; and

(~~2~~c) ~~A pharmacist will b~~Be subject to a~~n annual~~ criminal background check**; and**

(d) Provide a completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.

(2) A Pharmacist who fails to renew their license by the expiration date and whose license has been lapsed for 12 months or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A person who fails to renew their license by the expiration date and whose license has been lapsed for greater than 12 months may apply to reinstate their Pharmacist license as follows:

~~855-019-0170~~
~~Reinstatement of License~~

~~(1) A pharmacist who fails to renew their license by the deadline may reinstate their license as follows:~~

(a) ~~By payment of the license fees and delinquency fees for all years during which the license was lapsed and for the current year; and~~ **Apply per OAR 855-115-0030;**

(b) ~~By p~~**P**rovid~~e~~ing certification of completion of the continuing pharmacy education requirement in OAR 855-~~021~~**135** for all years in which the license was lapsed ~~and for the current year;~~ and;

(c) Meet the requirements below, if applicable.

(~~d~~**4**) **A person must pass the Oregon MPJE** ~~I~~if their **pharmacist** license has been lapsed for more than ~~one~~ **three** years~~, pass the MPJE~~**.** ~~With a score of not less than 75; and~~ **A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;**

(~~d~~**5**) ~~Complete an application for licensure, provide the board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check.~~ **If the Pharmacist license has been lapsed for more than five years and the person has not maintained an active pharmacist license in another US state or jurisdiction, a person must comply with (4) and take and pass the NAPLEX. A passing result is valid for 12 months. A candidate who does not pass may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts.**

(6) In lieu of reinstatement, a person may apply for licensure via reciprocity if the person has maintained an active pharmacist license in good standing in another US state or jurisdiction.

(~~2~~**7**) ~~A pharmacist in good standing who retired from the practice of pharmacy after having been licensed for not less than 20 years need only pay the annual license fees for the year in which they seek a license, however they must provide certification of completion of continuing pharmacy education requirement in OAR 855-021 for all years since their retirement and pass the MPJE with a score of not less than 75.~~ **A person whose Pharmacist license has been retired for more than 12 months need only pay the annual license fees for the year in which they seek a license, however they must also complete the requirements in (3).**

~~855-019-0171~~
~~Reinstatement of a Revoked or Surrendered License~~

(8) A person whose **P**~~p~~pharmacist license has been **suspended,** revoked or **restricted** ~~surrendered~~ ~~shall have~~ **has** the right, at reasonable intervals, to petition to the ~~B~~**b**oard ~~in writing~~ for reinstatement of such license **pursuant to ORS 689.445**. ~~The written petition to the Board shall be made~~ **and** in conjunction with the application process identified in OAR 855-~~019-0120~~**115-0030**.
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

~~855-031-0045~~
~~School and Preceptor Registration and Responsibilities~~ **~~Registration: Pharmacist Preceptor~~**
NOTE: Determined to leave in Div 031. Will not be moved to Div 115

~~855-019-0123~~ **855-115-0060**
~~Liability Limitations for Volunteers~~ **Registration: In-State Volunteer Pharmacist**

(1) A **P**~~p~~harmacist may register with the ~~B~~**b**oard for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services without compensation under the terms of the law.

(2) A no cost registration may be issued by the ~~B~~**b**oard upon receipt of a completed application. Registration requires submission of a signed form provided by the ~~B~~**b**oard in accordance with ORS 676.345(2).

(3) Registration will expire at the licensee's next license renewal date and may be renewed biennially. It is the licensee's responsibility to ensure his or her active registration in this program.

(4) Nothing in this section relieves licensee from the responsibility to comply with ~~B~~**b**oard regulations and still may be subject to disciplinary actions.

(5) Pharmacists providing care under the provisions of ORS 676.340 and **ORS** 676.345 remain subject to the ~~B~~**b**oard complaint investigation process articulated in ORS 676.175.

Statutory/Other Authority: ORS 676.340 & **ORS** 689.205
Statutes/Other Implemented: ORS 676.340 & **ORS** 676.345

~~855-019-0124~~ **855-115-0065**
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

~~855-019-0125~~
~~Coaching from Board and Staff~~

NOTE: Moving rule to Division 10: Board Administration and Policies

~~No member or employee of the Board shall discuss the contents of an examination, its preparation or use with any candidate or other person. No member or employee of the Board shall coach a candidate or any other person on materials that may be used in the examination nor shall they accept any fees for any act of assistance that would bear on the examination.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-019-0160~~ **855-115-0070**
Notification: Nuclear Pharmacists

NOTE: Will be updated for future board review. No changes proposed at this time.

In order to qualify under these rules as a nuclear **P**~~p~~harmacist, a **P**~~p~~harmacist ~~shall~~ **must** :

(1) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Protection Services of the Department of Human Services; and

(2) Be a **P**~~p~~harmacist licensed to practice in Oregon; and

(3) Submit to the Board of Pharmacy either:

(a) Evidence of current certification in nuclear pharmacy by the Board of Pharmac**y**~~eutical~~ Specialties; or

(b) Evidence that they meet both the following:

(A) Certification of a minimum of six month on-the-job training under the supervision of a qualified nuclear **P**~~p~~harmacist in a nuclear pharmacy providing radiopharmaceutical services; and

(B) Certification of completion of a nuclear pharmacy training program in a college of pharmacy or a nuclear pharmacy training program approved by the ~~B~~**b**oard.

(4) Receive a letter of notification from the ~~B~~**b**oard that the evidence submitted by the **P**~~p~~harmacist meets the above requirements and has been accepted by the ~~B~~**b**oard.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151

~~855-019-0310~~
~~Grounds for Discipline~~

~~The State Board of Pharmacy may suspend, revoke, or restrict the license of a pharmacist or intern or may impose a civil penalty upon the pharmacist or intern upon the following grounds:~~

~~(1) Unprofessional conduct as defined in OAR 855-006-0020;~~

~~(2) Repeated or gross negligence;~~

~~(3) Impairment, which means an inability to practice with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;~~

~~(4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;~~

~~(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a license to practice pharmacy or a drug outlet registration;~~

~~(8) Permitting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;~~

~~(9) Aiding and abetting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;~~

~~(10) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto; or~~

~~(11) Failure to perform appropriately the duties of a pharmacist while engaging in the practice of pharmacy as defined in ORS 689.005.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, 689.155 & 689.405~~

---------- RESPONSIBILITIES (4th REVIEW)----------

~~855-019-0200~~ **855-115-0105**
Pharmacist: ~~General~~ Responsibilities**~~-~~ General**

When practicing pharmacy per ORS 689, each Pharmacist must:

~~ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes.~~

(1) ~~A Pharmacist licensed to practice pharmacy by the board has the duty to u~~**U**se that degree of care, skill, diligence and reasonable professional judgment that is exercised by a~~n ordinarily~~ careful **and prudent** Pharmacist in the same or similar circumstances~~.~~**;**

(~~1~~**2**) ~~A Pharmacist is~~ **Be** responsible for their own actions;~~ however, this does not absolve the pharmacy from responsibility for the Pharmacist's actions.~~

(~~2~~**3**) ~~A Pharmacist and pharmacy are~~ **Be** responsible for the actions of **each** Intern~~s~~, Certified Oregon Pharmacy Technician~~s~~, Pharmacy Technician~~s~~ **and non-licensed pharmacy personnel;**

~~(3) Only a Pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require reasonable professional judgment of a Pharmacist include but are not limited to:~~

~~(a) Drug Utilization Review;~~

~~(b) Counseling;~~

~~(c) Drug Regimen Review;~~

~~(d) Medication Therapy Management;~~

~~(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;~~

~~(f) Practice pursuant to State Drug Therapy Management Protocols;~~

~~(g) Prescribing a drug or device, as authorized by statute;~~

~~(h) Ordering, interpreting and monitoring of a laboratory test;~~

~~(i) Oral receipt or transfer of a prescription; and~~

~~(j) Verification of the work performed by those under their supervision.~~

~~(4) A Pharmacist must:~~

(~~a~~**4**) **Ensure** ~~C~~**c**ompl**iance**~~y~~ 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)~~ ~~Conduct themselves in a professional manner at all times and not engage in any form of discrimination, harassment, intimidation, or assault;~~

(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 Intern 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 855-102-0050;

Statutory/Other Authority: TBD
Statutes/Other Implemented: TBD

855-115-0110
Responsibilities: Confidentiality

(1) No licensee of the board who obtains any patient information can disclose that information to a third-party without the consent of the patient except as provided in except as provided in (a)-(e) of this rule.

(2) A licensee can disclose patient information:

(a) To the board;

(b) To a practitioner, Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, if disclosure is authorized by a Pharmacist and disclosure is necessary to protect the patient's health or well-being;

(c) To a third-party when disclosure is authorized or required by law;

(d) As permitted pursuant to federal and state patient confidentiality laws or;

(e) To the patient or to persons as authorized by the patient.

(3) A licensee or registrant of the board must not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

~~855-019-0205~~ **855-115-0115**
Responsibilities: Duty to Report

~~(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.~~

~~(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

(~~3~~**1**) **Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each** ~~A p~~**P**harmacist must report to the board **without undue delay, but** within: ~~10 days if they:~~

(a) 1 business day:

(A) Confirmed significant drug loss; or

(B) Any loss related to suspected drug theft of a controlled substance.

(b) 10 days if they:

(~~a~~**A**) Are convicted of a misdemeanor or a felony; or

(~~b~~**B**) ~~If they a~~**A**re arrested for a felony~~.~~**; or**

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

(c) 10 working days if they:

(~~4~~**A**) ~~A pharmacist who has~~ **Have** reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct~~as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting pharmacist must report the conduct without undue delay, but in no event later than 10 working days after the pharmacist learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.~~ **to that licensee's board; or**

(B) Suspect records are lost or stolen.

(d) 15 days of any change in:

(A) Legal name;

(B) Name used when practicing pharmacy;

(C) Preferred email address;

(D) Personal phone number;

(E) Personal physical address;

(F) Personal mailing address; or

(G) Employer.

(~~5~~**2**) A ~~p~~**P**harmacist who reports to a board in good faith as required by **ORS 676.150** ~~section (4) of this rule~~ is immune from civil liability for making the report.

~~(6) A pharmacist who has reasonable grounds to believe that any violation of these rules has occurred, must notify the board within 10 days. However, in the event of a significant drug loss or violation related to drug theft, the pharmacist must notify the board within one (1) business day.~~

~~(7) A pharmacist must notify the board in writing, within 15 days of any change in e-mail address, employment location or residence address.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: **ORS 676.150,** ORS 689.151, ORS 689.155 & ORS 689.455

855-115-0120
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;

~~855-019-0200~~
~~Pharmacist: General Responsibilities~~
~~(4) A Pharmacist must:~~

~~(b) Ensure each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;~~

(c) 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;

(~~b~~**f**) Ensure each ~~Intern,~~ Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;

(g) Ensure licensed personnel do not engage in prohibited practices as outlined for Interns in OAR 855-120-0150 and for Certified Oregon Pharmacy Technician 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;

(~~e~~k) **Ensure that the supervision of non-Pharmacist personnel does not exceed their capacity to safely supervise** ~~When supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, determine how many licensed individuals the Pharmacist is capable of supervising, directing and controlling~~ based on the **workload and** services being provided~~.~~**; and**

~~**(k) Ensure there is sufficient staff to provide services in a safe manner. The Pharmacist may temporarily shut down a service or services if the Pharmacist determines, in their reasonable professional judgment, that there is insufficient staff to practice in a safe manner.**~~

~~**(2) A Pharmacist who utilizes licensees remotely, must comply with OAR 855-041-3200 through OAR 855-041-3250**~~

~~(f) Ensure and enforce the drug outlet written procedures for use of Certified Oregon Pharmacy Technicians and Pharmacy Technicians as required by OAR 855-025-0035;~~

(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: TBD
Statutes/Other Implemented: TBD

855-115-0125
Pharmacist: Responsibilities- Drugs, Records and Security

When practicing pharmacy per ORS 689, each Pharmacist must:

~~855-019-0200~~
~~Pharmacist: General Responsibilities~~

~~(4) A Pharmacist must:~~

(g**1**) Ensure the security of ~~the pharmacy area~~ **prescription drugs, pharmacy and patient records** including:

(A**a**) Providing adequate safeguards against **loss,** theft**,** or diversion ~~of prescription drugs, and records for such drugs~~;

(b) Ensuring only persons authorized by the Pharmacist access the areas where prescription drugs, pharmacy and patient records are stored by restricting access;

(B**2**) Ensur**e**~~ing~~ that all records ~~and inventories~~ are maintained in accordance with state and federal laws and rules;

~~(C) Ensuring that only a Pharmacist has access to the pharmacy when the pharmacy is closed.~~

(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: TBD
Statutes/Other Implemented: TBD

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;

~~**(h) Review, adhere to and enforce the drug outlet written policies and procedures. The review must:**~~

~~**(A) Occur upon employment and with each update; and**~~

~~**(B) Be documented and records retained by the outlet;**~~

(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.

~~855-019-0200~~
~~Pharmacist: General Responsibilities~~

(~~5~~**2**) **When engaging in the practice of pharmacy per ORS 689, each** ~~A~~ Pharmacist may delegate final verification of drug and dosage form, device, or product to a Certified Oregon Pharmacy Technician or Pharmacy Technician per ORS 689.005 when the following conditions are met:

(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;

(b) The Certified Oregon Pharmacy Technician or Pharmacy Technician does not use discretion in conducting final verification;

(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and

(d) Ensure the Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.

Statutory/Other Authority: TBD
Statutes/Other Implemented: TBD

~~**855-115-0070 E**~~
~~**Pharmacist: Responsibilities- Tasks Only a Pharmacist May Perform**~~
NOTE: Moved to Div 120 Interns and Div 125 Technicians

~~855-019-0210~~

~~Duties of the Pharmacist: Duties Receiving a Prescription~~

NOTE: Moving elements of (1)-(2) to OAR 855-115-0200, Repealing (3), moving elements of (4)-(7) to a new rule in OAR 855-041 and (8) to OAR 855-041-2115.

~~(1) A pharmacist must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed or prepared for administration in accordance with the prescribing practitioner's authorization.~~

~~(2) A pharmacist receiving a prescription is responsible for:~~

~~(a) Using professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist, in their professional judgment, believes that the prescription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner shall include a clinical associate of the practitioner or any other practitioner acting in the practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and not result solely from a questionnaire or an internet-based relationship; and~~

~~(b) Ensuring that the prescription contains all the information specified in Division 41 of this chapter of rules including the legible name and contact phone number of the prescribing practitioner for verification purposes.~~

~~(3) A pharmacist may refuse to dispense a prescription to any person who lacks proper identification.~~

~~(4) Oral Prescription: Upon receipt of an oral prescription, the pharmacist shall promptly reduce the oral prescription to writing or create a permanent electronic record by recording:~~

~~(a) The date when the oral prescription was received;~~

~~(b) The name of the patient for whom, or the owner of the animal for which, the drug is to be dispensed;~~

~~(c) The full name and, in the case of controlled substances, the address and the DEA registration number, of the practitioner, or other number as authorized under rules adopted by reference under Division 80 of this chapter of rules;~~

~~(d) If the oral prescription is for an animal, the species of the animal for which the drug is prescribed;~~

~~(e) The name, strength, dosage form of the substance, quantity prescribed;~~

~~(f) The direction for use;~~

~~(g) The total number of refills authorized by the prescribing practitioner;~~

~~(h) The written signature or initials or electronic identifier of the receiving pharmacist or intern and the identity of the person transmitting the prescription;~~

~~(i) The written or electronic record of the oral prescription must be retained on file as required by Division 41 of this chapter of rules, and in the case of controlled substances, under rules adopted by reference in Division 80 of this chapter of rules.~~

~~(5) Facsimile Prescription: Upon receipt of a facsimile prescription, the pharmacist must be confident that the prescription was sent by an authorized practitioner or practitioner's agent, and they must verify that:~~

~~(a) The facsimile contains all the information specified in division 41 and division 80 of this chapter of rules; and~~

~~(b) The facsimile prescription is not for a Schedule II controlled substance unless so permitted under federal regulations or division 80 of this chapter of rules; and~~

~~(c) If the facsimile prescription is for a controlled substance, the prescription contains an original, manually-signed signature of the prescriber. In this rule, manually-signed specifically excludes a signature stamp or any form of digital signature unless permitted under federal regulations.~~

~~(6) Electronic Prescription: Before filling a prescription that has been received electronically, the pharmacist must be confident that:~~

~~(a) The prescription was originated by an authorized practitioner or practitioner's agent;~~

~~(b) The prescription contains all the information specified in Division 41 of this chapter of rules.~~

~~(c) The prescription is not for a controlled substance unless permitted by federal regulations.~~

~~(7) The pharmacist must ensure that a written prescription that is hand-carried or mailed into the pharmacy contains an original manually-signed signature of the prescribing practitioner or practitioner's agent.~~

~~(8) Computer Transfer of Prescription Information between Pharmacies: A pharmacist that transmits or receives prescription information to or from another pharmacy electronically must ensure as appropriate:~~

~~(a) The accurate transfer of prescription information between pharmacies;~~

~~(b) The creation of an original prescription or image of an original prescription containing all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability and that the pharmacist will use in verifying the prescription;~~

~~(c) The prescription is invalidated at the sending pharmacy; and~~

~~(d) Compliance with all relevant state and federal laws and rules regarding the transfer of controlled substance prescriptions.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, 689.155 & 689.508~~

~~855-019-0220~~ **855-115-0140**
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.

~~(1) A pharmacist shall maintain a record for each patient that contains easily retrievable information necessary for the pharmacist to perform a DUR and to identify previously dispensed drugs at the time a prescription or drug order is presented for dispensing or preparing for administration. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:~~

~~(a) Full name of the patient for whom the drug is prescribed;~~

~~(b) Address and telephone number of the patient;~~

~~(c) Patient's gender, age or date of birth;~~

~~(d) Chronic medical conditions and disease states of the patient;~~

~~(e) A list of all drugs or devices the patient is currently obtaining at that pharmacy showing the name of the drug or device, strength of the drug, the quantity and date received, and the name of the prescribing practitioner;~~

~~(f) Known allergies, adverse drug reactions, and drug idiosyncrasies;~~

~~(g) Pharmacist comments relevant to the individual's drug therapy, including any other information specific to that patient or drug; and~~

~~(h) Additional information, which may relate to DUR, or for the monitoring of the patient as appropriate.~~

~~(2) Patient records shall be maintained for at least three years.~~

~~(3) The pharmacist or intern shall perform a DUR prior to dispensing or preparing for administration any prescription or refill.~~

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

~~855-019-0230~~ **855-115-0145**
Counseling

(~~f~~**1**) For each **prescription** ~~patient~~, the Pharmacist ~~or Intern~~ must determine the **manner and** amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(~~1~~**2**) The ~~p~~**P**harmacist ~~or intern~~ must ~~orally~~ counsel the patient or patient's agent on the use of a drug or device ~~as appropriate~~:

(a) **Upon request;** ~~The Pharmacist or intern must counsel the patient on a new prescription and any changes in therapy, including but not limited to a change in directions or strength, or a prescription which is new to the pharmacy~~;

(b) When the drug or device has not been previously dispensed to the patient by the 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.

(g**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 ~~or Intern~~ must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the Pharmacist is proficient in the patient's preferred language.

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

(~~e~~**4**) For a prescription delivered to a patient, except at a **Drug Outlet** ~~p~~**P**harmacy, **Pharmacy Prescription Kiosk** or a ~~p~~**P**harmacy ~~p~~**P**rescription ~~l~~**L**ocker, the Pharmacist must:

(A) Attempt to provide counseling prior to delivery;

(B) Provide written ~~offer in writing, to provide direct counseling and~~ **drug** information ~~about the drug~~, 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.

POLICY DISCUSSION: 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:

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

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

(4**6**) A Pharmacist ~~or Intern shall~~ **must** initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

(~~c~~**7**) The Pharmacist ~~or Intern~~ 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.

(~~2~~**10**) Counseling on a refill prescription **may include, but is not limited to, the following elements:** ~~must be such as a reasonable and prudent pharmacist would provide including but not limited to changes in strength or directions.~~

(a) Name and purpose of the medication;

(b) Directions for use, including technique;

(c) Perceived side effects; and

(d) Adherence.

POLICY DISCUSSION: Standards of Practice

~~(3) A pharmacist may provide counseling in a form other than oral counseling when, in their reasonable professional judgment, a form of counseling other than oral counseling would be more effective.~~

~~(5) For a discharge prescription from a hospital, the Pharmacist must ensure that the patient receives appropriate counseling.~~

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

---------- RESPONSIBILITIES (3rd REVIEW)----------

855-120-0150
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.

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

~~**855-115-0100**~~
~~**Services: Independent Practice of Pharmacy**~~

~~855-019-0300~~ **855-115-0200**
~~Duties of a~~ Pharmacist-in-Charge**: Qualifications and Limitations**

~~(1) In accordance with OAR 855-041 and OAR 855-139, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) who is normally present in the pharmacy on a regular basis.~~

(~~2~~**1**) In order to be a **Pharmacist-in-Charge (**PIC**)**, a Pharmacist must ~~have~~:

(a) Complete~~d~~ at least ~~one year~~ **2000 hours** of pharmacy practice **as a Pharmacist within the last 2 years in a US state or jurisdiction**; ~~or~~ **and**

(b) Complete~~d~~ a board ~~approved~~**provided** PIC training course either before the appointment or within ~~30~~ **90** days after the appointment **and every 5 years thereafter effective July 1, 2025** ~~With the approval of the board, this course may be employer provided and may qualify for continuing education credit~~.

(c) Be employed by the outlet; and

(~~3~~**2**) A Pharmacist m**ust**~~ay~~ not be designated PIC of more than three pharmacies ~~without prior written approval by the board. If such approval is given, the Pharmacist must comply with the requirements in sub-section (4)(e) of this rule.~~ **The following drug outlet types do not count towards this limit**:

(a) Pharmacy Prescription Kiosk in OAR 855-141;

(b) ~~A~~ Pharmacy Prescription Locker in OAR 855-143 ~~does not count toward this limit~~.

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;

(b1) 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;

(b2) Be physically onsite at the Drug Outlet pharmacy a minimum of 20 hours per work week or fifty per cent (50%) of the hours of operation of the pharmacy, whichever is less. A record of the onsite hours of the PIC must be produced upon request by the board. Exceptions will be recognized for practical reasons (e.g., vacation, illness) that are limited to 30 days or less.

POLICY DISCUSSION: b1 v. b2 - FAQ

(c) Be responsible for the ongoing conduct, operation, management and control of the Drug Outlet pharmacy;

~~855-019-0300~~
~~Duties of a Pharmacist-in-Charge~~

~~(4) The PIC must perform the following the duties and responsibilities:~~

(~~a~~**d**) ~~When a change of PIC occurs, both the outgoing and incoming PICs must report the change to~~ **Ensure the outlet notifies** the board **of a change in PIC** within 15 days of the occurrence~~, on a form provided by the board~~;

(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;

(~~b~~**i**) ~~The new PIC must c~~**C**omplete **an annual self**-inspection **of the pharmacy** on the ~~PIC~~ **board's** ~~Annual~~ Self-Inspection Form **by July 1 each year and** within 15 days of becoming PIC. **The completed self-inspection forms must be signed and dated by the PIC and retained for three years from the date of completion**; **and**

~~(c) The PIC may not authorize non-Pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;~~

~~(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a Pharmacist;~~

~~(e) A Pharmacist designated as PIC for more than one pharmacy must personally conduct and document a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit Form provided by the board;~~

~~(f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within:~~

~~(A) 15 days of receiving a deficiency notice; or~~

~~(B) 30 days of receiving a non-compliance notice.~~

~~(g) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.~~

~~(5) The PIC is responsible for ensuring that the following activities are correctly completed:~~

~~(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;~~

~~(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the board;~~

~~(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;~~

(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

(~~d~~**B**) **At least every 367 days** ~~Conducting an annual inventory of all controlled drugs as required by OAR 855-080~~; **and**

(b) For all Schedule II controlled drugs:

(e**A**) **At least every 93 days in a Retail Drug Outlet Pharmacy** ~~Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.~~**; and**

(B) At least every 31 days in an Institutional Drug Outlet Pharmacy.

~~(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.~~

(2) The PIC a Drug Outlet pharmacy affiliated with the following Drug Outlet types must 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

----------SERVICES (3rd LOOK)----------

~~855-019-0240~~ **855-115-0300**
~~Consulting~~ Pharmacist **Consulting** Practice

~~(1) Subject to the provisions of OAR 855-019-0100(4), a consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist.~~

(~~2~~**1**) A ~~consulting~~ **P**~~p~~harmacist **who provides services to** ~~for~~ an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure as well as by any relevant federal and state laws and rules.

(2) A Pharmacist who provides services to a correctional facility, long term care facility, community-based care facility, hospital drug room, or charitable pharmacy that does not have additional Pharmacist service requirements under the terms of its licensure with any other state agency, must provide services that include but are not limited to the following:

(a) Provide the facility with policies and procedure relating to security, storage and distribution of drugs within the facility;

(b) Provide guidance on the proper documentation of drug administration or dispensing;

(c) Provide educational materials or programs as requested.

(3) A Pharmacist who provides services to an Oregon licensed healthcare provider must follow all state and federal laws and rules related to the practice of pharmacy.

(~~3~~**4**) A ~~consulting~~ **P**~~p~~harmacist must maintain appropriate records of their ~~consulting activities~~ services **in (2) - (4)** for three years, and make them available to the Board for inspection.

~~(4) A consulting pharmacist is responsible for the safe custody and security of all their records and must comply with all relevant federal and state laws and regulations concerning the security and privacy of patient information.~~

(~~5~~**5**) A ~~consulting~~ **P**~~p~~harmacist may store health protected records outside an Oregon licensed facility ~~if~~ **as permitted in OAR 855-102-0050** ~~registered as an Oregon Consulting or Drugless Pharmacy outlet as defined by OAR Chapter 855, division 41.~~

~~(6) A consulting pharmacist for a facility that is required by the Board to have a consultant pharmacist but which does not have additional consulting requirements under the terms of its licensure with any other state agency, shall provide services that include but are not limited to the following:~~

~~(a) Provide the facility with policies and procedure relating to security, storage and distribution of drugs within the facility;~~

~~(b) Provide guidance on the proper documentation of drug administration or dispensing;~~

~~(c) Provide educational materials or programs as requested.~~

(6) Records and documents must be retained according to OAR 855-102-0050.

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

~~855-019-0265~~ **855-115-0305**
Administration of **Vaccines,** Drugs**, or Devices**

(1) In accordance with **ORS 689.645 and** ORS 689.655, a **P**~~p~~harmacist may administer a **vaccine,** drug or device as specified in this rule.

(2) A **P**~~p~~harmacist who administers a **vaccine,** drug or device must:

(a) 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 855-102-0050.

(b) Hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years. The most current CPR certification record must be retained according to OAR 855-102-0050.

(c) Ensure that any drugs administered to a patient were stored in accordance with the drug storage rules for pharmacies in ORS 855-041-1036.

(~~a~~**d**) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the **vaccine,** drug or device; and

(e) Ensure that vaccine, drug or device administration is documented in the patient's permanent record.

(~~b~~**f**) Ensure **records and documents are retained according to OAR 855-102-0050.** ~~a record is kept for three years of such activities~~. ~~This r~~**R**ecords **of administration** ~~shall~~ **must** include but ~~is~~ **are** not limited to:

(A) Patient identifier;

(B) **Vaccine,** ~~D~~**d**rug or device and strength;

(C) Route and site of administration;

(D) Date and time of administration;

(E) Pharmacist identifier.

(3) For vaccines only, the requirements in (2) and the following apply, the Pharmacist must:

(a) 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.

(~~3~~**4**) The **P**~~p~~harmacist must be acting:

(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice**;** or~~;~~

(b) In accordance with a ~~written~~ **statewide drug therapy management** protocol **per OAR 855-020-0330 or** ~~collaborative~~ **clinical pharmacy agreement** ~~drug therapy agreement with a licensed practitioner~~ **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.

~~(4) The pharmacist must be able to document that they have received training on the drug or device to be administered and the route of administration. Such training may include a program approved by the ACPE, curriculum based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the Board.~~

(5) The **P**~~p~~harmacist may administer a drug or device in conjunction with training the patient or the patient's ~~caregiver~~ **agent** how to administer or self-administer the drug or device.

(6) Except as required in (2), records and documents must be retained according to OAR 855-102-0050.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.655

~~855-019-0270~~
~~Immunization Qualifications~~

~~(1) In this rule and in OAR 855-019-0280, an intern who is appropriately trained and qualified in accordance with Section (3) of this rule may perform the same duties as a pharmacist, provided that the intern is supervised by an appropriately trained and qualified pharmacist.~~

~~(2) A pharmacist may administer vaccines to persons who are at least 7 years of age as provided by these rules. For the purposes of this rule, a person is at least 7 years of age on the day of the person's seventh birthday.~~

~~(3) A pharmacist may administer vaccines under section (1) or section (2) of this rule only if:~~

~~(a) The pharmacist has completed a course of training approved by the Board and maintained competency;~~

~~(b) The pharmacist training includes, injection site, and Cardiopulmonary Resuscitation (CPR) specific to the age and population the pharmacist treats;~~

~~(c) The pharmacist holds active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that contains a hands-on training component and is valid for not more than three years, and documentation of the certification is placed on file in the pharmacy;~~

~~(d) The vaccines are administered in accordance with an administration protocol written and approved by the Oregon Health Authority (OHA); and~~

~~(e) The pharmacist has a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."~~

~~(4) A pharmacist otherwise in compliance with section three of this rule may, during a declared emergency, administer a vaccine to a person who is at least three (3) years of age when;~~

~~(a) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or~~

~~(b) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.~~

~~(5) A pharmacist may not delegate the administration of vaccines to another person.~~

~~Statutory/Other Authority: ORS 689.205 433.441, 433.443 & 2015 OL Ch 295~~
~~Statutes/Other Implemented: ORS 689.151, 689.155, 689.645 & 2015 OL Ch 295~~

~~855-019-0280~~
~~Immunization Protocols, Policies and Procedures~~

~~(1) Prior to administering a vaccine to a person who is at least 7 years of age a pharmacist must follow protocols written and approved by the Oregon Health Authority (OHA) for administration of vaccines and the treatment of severe adverse events following administration of a vaccine.~~

~~(2) A pharmacist during a declared emergency may administer a vaccine to a person who is at least three~~

~~(3) years of age when;~~

~~(a) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or~~

~~(b) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.~~

~~(3) The pharmacy must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.~~

~~(4) The pharmacist must give the appropriate Vaccine Information Statement (VIS) to the patient or legal representative with each dose of vaccine covered by these forms. The pharmacist must ensure that the patient or legal representative is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine.~~

~~(5) The pharmacist must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.~~

~~(6) The pharmacist may prescribe, administer or dispense immunizations, including oral vaccines, as established by written protocols approved by OHA.~~

~~Statutory/Other Authority: ORS 689.205, 433.441, 433.443 & 2015 OL Ch 295~~
~~Statutes/Other Implemented: ORS 689.151, 689.155, 689.645 & 2015 OL Ch 295~~

~~855-019-0290~~
~~Immunization Record Keeping and Reporting~~

~~(1) A pharmacist who administers a vaccine to a patient must fully document the administration in the patient's permanent record.~~

~~(2) A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider.~~

~~(a) The name, address, gender and date of birth of the patient;~~

~~(b) The date of administration of the vaccine;~~

~~(c) The NDC number of the vaccine, or other acceptable standardized vaccine code set;~~

~~(d) The address of the pharmacy where vaccine was administered unless automatically embedded in the electronic report provided to the OHA ALERT Immunization System;~~

~~(e) The phone number of the patient when available;~~

~~(f) The dose amount, manufacturer, site of administration, lot number and expiration date of the vaccine when available;~~

~~(3) A pharmacist who administers any vaccine will keep documentation of current CPR training. This documentation will be kept on site and available for inspection.~~

~~(4) A pharmacist who administers any vaccine will follow storage and handling guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC).~~

~~(5) For the purpose of participation in the Oregon Vaccines for Children program,~~

~~(a) The vaccine eligibility code for each dose must be reported to the ALERT Immunization Information System in the manner prescribed by OHA, and~~

~~(b) The pharmacist is recognized as a prescriber.~~

~~(6) If providing state or federal vaccines during a pandemic as determined by the CDC, the event and priority code as specified by OHA must be provided upon request in the manner prescribed by OHA.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, 689.155 & 689.645~~

855-115-0310
Services: Laboratory

NOTE: A corresponding rule has been added to this package in Division 041 concerning when a drug outlet may perform a laboratory test.

(1) A Pharmacist must only order and receive laboratory test when:

(a) Managing drug therapy pursuant to the terms of a clinical pharmacy agreement with a provider under OAR 855-115-0315;

(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 855-102-0050.

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

~~855-019-0260~~ **855-115-0315**
Services: ~~Collaborative Drug Therapy Management~~ **Clinical Pharmacy Agreement**

~~(1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:~~

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

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

(**1**~~2~~) A **P**~~p~~harmacist **or pharmacy** ~~shall~~ **may** engage in ~~collaborative drug therapy management~~ **the practice of clinical pharmacy under a Clinical Pharmacy Agreement** with a ~~practitioner~~ **health care organization, physician or naturopathic physician** only under a written ~~arrangement~~ **agreement** that includes:

(~~c~~**a**) The name of the principal **P**~~p~~harmacist and ~~practitioner~~ **physician, naturopathic physician or provider on behalf of the healthcare organization** who are responsible for development, training, administration, and quality assurance of the ~~arrangement~~ **agreement**;

(~~a~~**b**) The identification, either by name or by description, of each ~~of the~~ participating **P**~~p~~harmacist~~s~~;

(~~b~~**c**) The identification, **either** by name or description, of each ~~practitioner~~ **participating physician, naturopathic physician, or providers of a healthcare organization** ~~of the participating practitioners or group of practitioners~~;

(d) Methods by which a participating physician or naturopathic physician or a provider on behalf of a healthcare organization enters a patient into the agreement;

(~~d~~**e**) The types of ~~decisions~~ **clinical pharmacy activities** that the **P**~~p~~harmacist is allowed to **perform** ~~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;~~ **~~. The drug information must include the dosage, frequency, duration and route of administration of the drug.~~**

~~(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities~~

(C**(f)**) ~~A detailed description of the~~ **Documentation the Pharmacist is to complete** ~~activities the pharmacist is to follow including documentation of~~ **concerning** decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. ~~In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;~~

(~~D~~**g**) Circumstances which will cause the **P**~~p~~harmacist to initiate communication with the practitioner~~,~~ ~~including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect~~.

(~~e~~**h**) Training requirement for **P**~~p~~harmacist participation and ongoing assessment of competency, if necessary;

(~~f~~**i**) Quality ~~assurance~~ **improvement** and periodic review by a panel of the participating **P**~~p~~harmacists and practitioners;

(~~g~~**j**) Authorization by the practitioner for the **P**~~p~~harmacist to participate in collaborative drug therapy; and

(~~h~~**k**) A requirement for the ~~collaborative drug therapy arrangement~~ **Clinical Pharmacy Agreement** to be reviewed and updated, or discontinued at least every two years

POLICY DISCUSSION: CDTM/CPA Workgroup

(2) A **P**~~p~~harmacist ~~shall~~ **may** engage in ~~c~~**C**ollaborative ~~d~~**D**rug ~~t~~**T**herapy ~~m~~**M**anagement**, a type of Clinical Pharmacy Agreement,** with a ~~practitioner~~ **health care organization, physician or naturopathic physician** only under a written ~~arrangement~~ **agreement** that includes **all of the elements in (1)(a)-(k) and must include the dosage, frequency, duration and route of administration of the drug.**

(3) **The Pharmacist must document and keep a record of each patient encounter where an agreement in (1) or (2) is utilized.** ~~The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request.~~ **In addition to the agreement, documentation must occur on the prescription record, patient profile, electronic medical record, or in some other appropriate system.**

(4) **Records and documents must be retained according to OAR 855-102-0050**.~~Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151~~,~~ ~~&~~ **ORS** 689.155

~~855-019-0250~~ **855-115-0320**
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 **P**~~p~~harmacist or can be in conjunction with the provision of a medication product with the objectives of:

(a) Enhancing appropriate medication use;

(b) Improving medication adherence;

(c) Increasing detection of adverse drug events;

(d) Improving collaboration between practitioner and **P**~~p~~harmacist; and

(e) Improving outcomes.

(2) A **P**~~p~~harmacist that provides MTM services ~~shall~~ **must** ensure that they are provided according to the individual needs of the patient and ~~may~~ **must** include but are not limited to the following:

(a) Performing or otherwise obtaining the patient's health status assessment;

(b) Developing a medication treatment plan for monitoring and evaluating the patient's response to therapy;

(c) Monitoring the safety and effectiveness of the medication therapy;

(d) Selecting, initiating, modifying or administering medication therapy in consultation with the practitioner where appropriate;

(e) Performing a medication review to identify, prevent or resolve medication related problems;

(f) Monitoring the patient for adverse drug events;

(g) Providing education and training to the patient or the patient's agent on the use or administration of the medication **where appropriate**;

(h) Documenting the delivery of care, communications with other involved healthcare providers and other appropriate documentation and records as required. Such records ~~shall~~ **must**:

(A) **Be accurate;** ~~Provide accountability and an audit trail; and~~

(B) Identify the person who completed each action;

(~~B~~**C**) **Records and documents must be retained according to OAR 855-102-0050.** ~~Be preserved for at least three years and be made available to the Board upon request except that when records are maintained by an outside contractor, the contract must specify that the records be retained by the contractor and made available to the Board for at least three years.~~

(i) Providing necessary services to enhance the patient's adherence with the therapeutic regimen; **and**

(j) Integrating the medication therapy management services within the overall health management plan for the patient.~~; and~~

~~(k) Providing for the safe custody and security of all records and compliance with all relevant federal and state laws and regulations concerning the security and privacy of patient information.~~

POLICY DISCUSSION: Standards of Practice

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151**,** ~~&~~ **ORS** 689.155

~~855-020-0105~~
~~Public Health and Pharmacy Formulary Advisory Committee~~

~~(1) The Public Health and Pharmacy Formulary Advisory Committee shall consist of:~~

~~(a) Two physicians licensed to practice medicine under ORS 677.100 to 677.228;~~

~~(b) Two advanced practice registered nurses who have prescriptive authority and who are licensed by the Oregon State Board of Nursing; and~~

~~(c) Three pharmacists licensed by the State Board of Pharmacy, at least one of whom is employed as a community pharmacist and one of whom is employed as a health system pharmacist.~~

~~(2) A pharmacist may submit a concept, on a form prescribed by the Board to the committee for consideration, for the development of a protocol or the addition of a drug or device to the formulary.~~

~~(3) The committee shall recommend to the Board, for adoption by rule, a protocol or formulary of drugs and devices from which a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a qualified healthcare practitioner.~~

~~(4) The committee shall periodically review the formulary and protocol compendium and recommend the revisions to the Board for adoption by rule.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.645, ORS 689.649 & ORS 689.155~~

~~855-020-0110~~ **855-115-0345**
Services: Prescribing Practices**- Formulary or Protocol Compendia**

(1) A **P**~~p~~harmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division.

(2) A **P**~~p~~harmacist **must**~~ay~~ only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.

~~(2) A pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services pursuant to statewide drug therapy management protocols. The policies and procedures must describe current and referenced clinical guidelines, and include but not be limited to:~~

~~(a) Patient inclusion and exclusion criteria;~~

~~(b) Explicit medical referral criteria;~~

~~(c) Care plan preparation, implementation, and follow-up;~~

~~(d) Patient education; and~~

~~(e) Provider notification; and~~

~~(f) Maintaining confidentiality.~~

(3) The **P**~~p~~harmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.

(4) For each drug or device the **P**~~p~~harmacist prescribes **via the Formulary or Protocol Compendia**, the **P**~~p~~harmacist must:

(a) Ensure training and education requirements have been met prior to engaging in prescribing activities. A copy of all required training and education must be retained according to OAR 855-102-0050;

(~~a~~**b**) ~~Assess patient and c~~**C**ollect subjective and objective information~~, including the diagnosis for Formulary Compendia items,~~ about the patient's health history and clinical status. **If prescribing pursuant to the Formulary Compendia in OAR 855-115-0340, a diagnosis from the patient's healthcare provider is required.** ~~The pharmacist's physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means; and~~

(c) Assess the information collected in (b). Any physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means.

(~~b~~**d**) **Create an individualized patient-centered care plan that** ~~U~~**u**tilize**s** information obtained in the assessment to evaluate and develop ~~an individualized patient-centered~~ **a** care plan~~, pursuant to the protocol listed in the statewide drug therapy management protocol and policies and procedures~~; and

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

(A) Addressing medication and health-related problems and engaging in preventive care strategies;

(B) Initiating, modifying, discontinuing, or administering medication therapy as permitted by the Formulary or Protocol Compendia;

(C) Providing education and self-management training to the patient or caregiver;

(D) Contributing to coordination of care, including the referral or transition of the patient to another health care professional; and

(E) Scheduling follow-up care as needed to achieve goals of therapy;

(~~d~~**f**) Monitor and evaluate the effectiveness of the care plan and make modifications to the plan ~~pursuant to a protocol listed in a statewide drug therapy management protocol.~~**;**

POLICY DISCUSSION: Standards of Practice

~~(f) Refer the patient to another health care provider as required by the protocol.~~

(g) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a **Formulary or Protocol** Compendia drug or device.

~~(5) The pharmacist must maintain all records associated with prescribing and other related activities performed for a minimum of 10 years, and a copy must be made available to the patient and provider upon request. Pharmacy records must be retained and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.~~

(~~6~~**5**) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.

(6) All records and documents must be retained according to OAR 855-102-0050 and must be made available to the patient and provider upon request.

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

~~855-020-0120~~ **855-115-0335**
Prescribing**:** **Prohibited** Practices

(1) A **P**~~p~~harmacist ~~may~~ **must** not **prescribe a Formulary or Protocol Compendia** ~~**vaccine,**~~ drug or device:

(a) ~~t~~**T**o self or a spouse, domestic partner, parent, guardian, sibling, child, aunt, uncle, grandchild and grandparent, including foster, in-law, and step relationships or other individual for whom a

P~~p~~harmacist's personal or emotional involvement may render the **P**~~p~~harmacist unable to exercise detached professional judgment in prescribing ~~pursuant to the Formulary and Protocol Compendia.~~**; and**

POLICY DISCUSSION: Exceptions

(b) When the compendia requires referral to non-Pharmacist provider.

~~(2) An **I**intern m**ust**ay not prescribe a **vaccine,** drug or device.~~

(~~3~~**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

~~855-020-0200~~ **855-115-0340**
Formulary Compendium

A **P**~~p~~harmacist may prescribe, according to **OAR 855-115-0330 and OAR 855-115-0335**, a~~n~~ FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented.

Devices and supplies:

(1) Diabetic blood sugar testing supplies;

(2) Injection supplies;

(3) Nebulizers and associated supplies;

(4) Inhalation spacers;

(5) Peak flow meters;

(6) International Normalized Ratio (INR) testing supplies;

(7) Enteral nutrition supplies;

(8) Ostomy products and supplies; and

(9) Non-invasive blood pressure monitors

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

~~855-020-0300~~ **855-115-0340**

Protocol Compendium

Note: Updated to match rules adopted effective 2/1/2023.

A Pharmacist may prescribe, **according to 855-115-0330 and OAR 855-115-0335**, ~~via statewide drug therapy management protocol and according to rules outlined in this Division~~, ~~an~~ FDA-approved drug and device listed in the following compendium, **pursuant to a statewide drug therapy management protocol.** ~~listed in the following compendium~~:

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

(2) Conditions

(a) Cough and cold symptom management

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

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

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

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

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

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

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

~~(e) COVID-19 Antiviral (v. 12/2022).~~

(3) Preventative care

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

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

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

(d) Travel Medications (v. ~~12/2022~~**06/2023**);

(e) HIV Post-exposure Prophylaxis (PEP) (v. ~~12/2022~~**06/2023**);

(f) HIV Pre-exposure Prophylaxis (PrEP) (v. ~~12/2022~~**06/2023**); and

(g) Contraception (v. ~~12/2022~~**06/2023**).

[**Publications:** Publications referenced are available **from the agency** ~~for inspection in the office of the Board of Pharmacy per OAR 855-010-0021~~.]

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

~~855-019-0460~~ **855-115-0350**
Naloxone - Delivery of Care and Prescribing
NOTE: Plan to move to formulary or protocol compendia

(1) A **P**~~p~~harmacist, having determined that there is an identified medical need, can prescribe naloxone and the necessary medical supplies to administer naloxone for opiate overdose:

(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME);

(b) To an individual seeking naloxone;

(c) To an entity seeking naloxone.

(2) The **P**~~p~~harmacist ~~shall~~ **must** determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.

(3) The **P**~~p~~harmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.

(4) The **P**~~p~~harmacist ~~shall~~ **must** dispense the naloxone product in a properly labeled container.

(5) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.

(6) The **P**~~p~~harmacist must document the encounter and the prescription, and maintain records for three years.

(7) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.684, ORS 689.305, ORS 689.681, ORS 689.682 ~~& 2019 OL Ch. 470~~

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

~~*NOTE: Plan to move to formulary or protocol compendia*~~

~~Emergency Insulin. A **P**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 **P**pharmacist shall **must** prescribe the lesser of a 30-day supply or the smallest available package size, and not more than three emergency refills and supplies in a calendar year.~~

~~Statutory/Other Authority: ORS 689.205, **ORS 689.696**~~
~~Statutes/Other Implemented: **ORS 689.696, ORS 689.645** 2019 OL Ch. 95~~

DIVISION 41
OPERATION OF PHARMACIES

855-041-1018
Outlet: General Requirements

A ~~d~~**D**rug ~~o~~**O**utlet pharmacy must:

(1) Ensure each prescription is dispensed in compliance with OAR 855-~~019~~**115**, **OAR 855-120,** OAR 855-~~025~~**125**, ~~OAR 855-031 and~~ OAR 855-041, **OAR 855-139, OAR 855-141 and OAR 855-143**;

(2) Comply with all applicable federal and state laws and rules;

(3) Ensure all licensees are trained to appropriately perform their duties prior to engaging or assisting in the practice of pharmacy.

(4) Ensure each licensed and non-licensed individual only perform duties they are licensed and trained to perform.

(5) Be responsible for the actions of each licensed and non-licensed individual.

(~~4~~6) ~~Ensure~~ **Establish, maintain and** enforce the drug outlet written procedures **required in OAR 855-041-1040** ~~for use of Certified Oregon Pharmacy Technicians or Pharmacy Technicians as required by OAR 855-025-0035;~~

(~~5~~7) Comply with the Pharmacist's determination in OAR ~~855-019-0200(4)(e)~~ **855-115-0120(1)(k)**.

(~~6~~8) Develop, implement and enforce a continuous quality improvement program for dispensing services from a drug outlet pharmacy designed to objectively and systematically:

(a) Monitor, evaluate, document the quality and appropriateness of patient care;

(b) Improve patient care; and

(c) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.151, 2022 HB 4034, ORS 689.508 & ORS 689.155

855-041-1190
Operation of a Laboratory in Drug Outlet Pharmacy

(1) A Drug Outlet pharmacy may perform a laboratory test when:

(a) The Drug Outlet pharmacy possesses a valid laboratory license, including a certificate of a 42 CFR 49.35 waiver;

(b) The laboratory test is permitted under the laboratory license; and

(c) Requested by a physician, dentist, or other person authorized by law to use the findings of laboratory examinations or without a practitioner order as permitted in ORS 438.010, ORS 438.030, ORS 438.040, ORS 438.050, ORS 438.055, ORS 438.060, ORS 438.070, ORS 438.110, ORS 438.120, ORS 438.130, ORS 438.140, ORS 438.150, ORS 438.160, ORS 438.210, ORS 438.220, ORS 438.310, ORS 438.320, ORS 438.420, ORS 438.430, ORS 438.435, ORS 438.440, ORS 438.450, 438.510.

(2) The Drug Outlet pharmacy must:

(a) Display the laboratory license in a prominent place in view of the public; and

(b) Report, to the local health department or state, reportable conditions as required in OAR 333-018.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.661

855-041-3000
Central Fill and Remote Processing Outlet Designations ~~and Consulting/Drugless Pharmacy Outlets~~ - Purpose and Scope

(1) The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of operation for centralized prescription drug filling by a pharmacy.

(2) The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription processing by a pharmacy.

(3) Prior to initiating one of the above drug outlet models, a description of how the model will be utilized must be submitted to the Board.

~~(4) The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a consulting or drugless pharmacy. Prior to initiating this model, a description of how the model will be utilized to improve patient safety must be submitted to the Board.~~

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

~~855-041-3300~~
~~Consulting/Drugless Pharmacy - Purpose and Scope~~

~~The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a single physical location. This location may be an office located in a home or other secure location. Registration is not required if records used or generated by a consulting pharmacist are stored in a location registered by the Board as a retail or institutional drug outlet or if the location is under the control of a practitioner who uses the services of the consulting pharmacist. The consulting pharmacist must be able to provide the Board with documentation of their pharmaceutical care activities. These rules are intended to ensure that a location where a pharmacist is engaged in Independent Pharmacy Practice may safely store records and protected health information. An applicant must submit to the Board for approval policies and procedures and a description of how their consulting or drugless pharmacy will be utilized to improve patient safety.~~

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

~~855-041-3305~~
~~Consulting/Drugless Pharmacy - Definitions~~

~~The following words and terms, when used OAR 855-041-3300 through 855-041-3340 shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the OAR chapter 855, division 6.~~

~~(1) "Consulting or Drugless Pharmacy" means any single physical location where pharmaceutical care services are performed or protected health information may be stored without the storage, possession, or ownership of any drug.~~

~~(2) "Consulting Pharmacist" means any pharmacist as defined by OAR chapter 855, division 6 and is described by chapter 855, division 19.~~

~~(3) "Independent Pharmacy Practice" means the provision of pharmaceutical services not related to physically handling or dispensing pharmaceuticals drugs or devices. This practice is characterized by the practice of an Oregon licensed pharmacist acting as an independent contractor whether or not directly~~

~~employed or affiliated with an entity that is licensed by the Board. This service also does not include the provision of pharmaceutical care that is conducted within the physical confines or location of a licensed pharmacy registered with the Board.~~

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

~~855-041-3310~~
~~Consulting/Drugless Pharmacy - Registration~~

~~(1) The Consulting Pharmacy shall be registered as a retail or institutional drug outlet and comply with all the requirements of licensure as defined in OAR 855-041-1080 through 855-041-1100.~~
~~(2) The location must be available for inspection by the Board.~~

~~(3) A consulting pharmacist for an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure, as well as any applicable federal and state laws and rules.~~

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

~~855-041-3315~~
~~Consulting/Drugless Pharmacy - Personnel~~

~~(1) Each pharmacy must have a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the state in which the pharmacy is located if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;~~

~~(2) The pharmacy must comply with all applicable state and federal laws and rules governing the practice of pharmacy and maintain records in compliance with requirements of federal law and Board rules;~~

~~(3) A consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon; and~~

~~(4) Prospective drug utilization reviews, refill authorizations, interventions and patient counseling not associated with the dispensing of a drug for an Oregon patient must be performed by an Oregon licensed pharmacist.~~

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

~~855-041-3320~~
~~Consulting/Drugless Pharmacy - Confidentiality~~

~~(1) Each consulting pharmacy must comply with all applicable federal and state laws and rules regarding confidentiality, integrity and privacy of patient information.~~

~~(2) Each consulting pharmacy must ensure that electronic data systems are secure and comply with applicable federal and state laws and rules.~~

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

~~855-041-3325~~
~~Consulting/Drugless Pharmacy - General Provisions and Minimum Standards~~

~~(1) A consulting pharmacy shall:~~

~~(a) Maintain appropriate reference materials for drug information according to the scope of consulting services.~~

~~(b) Be located in a secure room with a door and suitable lock, and accessible only to persons authorized by the pharmacist-in-charge.~~

~~(c) Provide storage sufficient to secure confidential documents and any hardware necessary to access information.~~

~~(d) Be constructed in a manner of materials that make the space separate and distinct from the rest of the home or office building, and that protects the records from unauthorized access.~~

~~(2) A consulting pharmacy located in a residence must be approved by the Board.~~

~~(3) The consulting pharmacist must be able to provide the Board, upon request, with documentation of their pharmaceutical care activities.~~

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

~~855-041-3330~~
~~Consulting/Drugless Pharmacy - Security Requirements~~

~~(1) All consulting services must occur in a secure environment that includes but is not limited to:~~

~~(a) A closed system or other electronic storage device that is password protected;~~

~~(b) A secure room or safe that is locked to store records when the pharmacist is not directly monitoring them;~~

~~(c) Sufficient encryption for securing confidential documents and any hardware used in accessing authorized patient health information by electronic connection; and~~

~~(d) A data processing system that complies with all federal and state laws and rules to ensure compliant security software.~~

~~(2) Records stored at a practitioner's office must be kept secure either with other records at the facility or independently in a locked room where only the pharmacist, and physician and their agents have access;~~

~~(3) All records must be stored at the approved consulting or drugless pharmacy; and~~

~~(4) Any breach in the security of the system or breach of confidentiality must be documented and reported to the Board within seven days.~~

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

~~855-041-3335~~
~~Consulting/Drugless Pharmacy - Policies and Procedures~~

~~The consulting pharmacy must maintain a current policy and procedures manual that includes at a minimum:~~

~~(1) A policy on protecting confidentiality and integrity of patient information;~~

~~(2) An outline of responsibilities and scope of services;~~

~~(3) A policy on compliance with federal and state laws and rules;~~

~~(4) An operational Quality Assurance Program;~~

~~(5) A policy that describes use of computer systems.~~

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

~~855-041-3340~~
~~Consulting/Drugless Pharmacy - Records~~

~~(1) The recordkeeping and storage requirements in OAR 855-041-3300 through 855-041-3340 are in addition to the requirements of other recordkeeping and storage rules of the Board. Records and documentation may be written, electronic or a combination of the two.~~

~~(2) Each recordkeeping system must include quality improvement program documentation;~~

~~(3) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure~~

~~patient health, safety, and welfare. Records must include but need not be limited to:~~

~~(a) Patient profiles and records;~~

~~(b) A list of current employees and their license numbers;~~

~~(A) Verification of each license and registration;~~

~~(B) The name of the individual responsible for verification of licensure and registration status.~~

~~(c) Copies of all contracts for consulting services and collaborative therapy agreements;~~

~~(d) Copies of all consultation reports submitted to practitioners and facilities.~~

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

Division 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 pharmacist 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 Board rule;

(h) Engaging in collaborative drug therapy management in violation of ORS Chapter 689 and the rules of the Board;

(i) Authorizing or permitting any person to practice pharmacy in violation of the Oregon Pharmacy Act or the rules of the Board;

(j) Any conduct or practice by a licensee or registrant which the Board determines is contrary to accepted standards of practice; or

(k) Failure to cooperate with the Board pursuant to OAR 855-001-0035.

Statutory/Other Authority: **ORS** 689.205
Statutes/Other Implemented: ORS 689.005**,** ~~and~~ **ORS** 689.155

Division 045: Drug Compounding (USP <795> and USP <797>)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Incorporates additional USP <795> and USP <797> standards adopted by reference

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Temporarily permits Drug Outlet pharmacies to implement USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (v. 11/01/2022) and <797> Pharmaceutical Compounding—Sterile Preparations (v. 11/01/2022) as an alternative to USP <795> (05/01/2020 v. 2014) and USP <797> (05/01/2020 v. 2008).

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): There are numerous and complex process changes required for compliance with the revised USP Chapters <795> and <797>. These process changes require the new rule to be effective immediately and continue to be effective until the board can permanently adopt the rule.

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

- USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (v. 11/01/2022) – Publication Announcement

- USP <797> Pharmaceutical Compounding—Sterile Preparations (v. 11/01/2022)- Publication Announcement

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): The United States Pharmacopeia (USP) published its revised standards for USP General Chapters <795> and <797> on November 1, 2022. These new USP standards will be effective on November 1, 2023. In addition, USP <800> will become enforceable on November 1, 2023. The board anticipates adopting these updated USP Chapters (<795> and <797>) by reference effective November 1, 2023. USP <800> issued July 1, 2020 is already required in rule. Due to the numerous and complex process changes required for compliance, registrants may implement the revised USP Chapters <795> and <797> prior to that date.

NOTES:

- The current version of OAR 855-045-0200 is used here only as a reference.
- For Board Consideration: Adopt Temporary Rule, to be effective upon filing (expires in 180 days), review at the June board meeting, consider sending to a July rulemaking hearing, consider permanent adoption in August 2023 in order to be effective by November 2023.

DIVISION 45
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 (08/01/2016), 1231 (12/01/2021), and 1821 (05/01/2017).

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

855-045-0205
Compliance with New Standards

As an alternative to the requirements in OAR 855-045-0200(3)(a) and (3)(b) registrants may comply with any or all standards contained in:

(a) USP <795> Pharmaceutical Compounding—Non-Sterile Preparations (11/1/2022).

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

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

SBAR: Board Action Report

This is mailing **#C**

S	**Situation:** • OBOP currently utilizes a web-based search tool (license verification) for the public to search for licensee and registrant information, including discipline. This system is passive, can be difficult for the public to navigate and access accurate/intended information. The site does not provide active notification to the public of licensee and registrant discipline and currently does not list discipline for licensee or registrants that have not been licensed or registered with the board. Search capability is limited to individual licensees/registrants. • Examples to be provided.
B	**Background:** • Staff have continued to work to improve and increase public transparency of board actions. We are currently working to ensure that all discipline is available on our website, but we have also identified areas where we could do more to increase public transparency. Oregon State Agencies: • OMB website that list actions for the past 10 years. OMB Board Action Terms. • OSBN website that list actions for the past year. OSBN Practicing without a License List. • OBNM website that lists actions for the past 5 years. Other state board of pharmacy: • CA BOP website that lists actions for the past 18 years. • WA DOH website that lists actions in the last 90 days. • VA BOP website that lists actions in the last 90 days. *Related Statutes* • **ORS 670.310 Rulemaking authority; board seal.** (1) Except as otherwise provided by law and in accordance with any applicable provisions of ORS chapter 183, each professional licensing board and advisory board may make such rules as are necessary or proper for the administration of the laws such board is charged with administering. Oregon State Board of Nursing (OSBN)Rules: • OAR 851-001-0010 Notification Procedure (1) Notice of the Board's final disciplinary action shall be sent to the National Council State Boards of Nursing (NCSBN) for inclusion in the NURSYS® dataset and the National Practitioner Data Bank (NPDB). (2) A public copy of the Board's final order of discipline will be posted on the license verification page of the Board's website and **a summary of discipline will be posted in the Board's quarterly publication.**
A	**Assessment:** • It appears that many Oregon healthcare agencies and other state boards of pharmacy report disciplinary information more robustly and clearly to the public. • There are options staff could implement to bring the board into alignment with other Oregon healthcare agencies and other state boards of pharmacy. • Staff is actively addressing issues that can be remedied through technology but not all issues can be resolved through this mechanism. A manual report would need to be created to assist in resolving all situations discussed earlier.

R	**Recommendation:** Board staff believe to meet the intent of state agency transparency requirements, we need to clearly inform the public of board action that eliminates current barriers to accessing this information. Staff recommends the following proactive actions: • Create a **monthly** report with 2 sections and informational directions: o 1. Notices of Proposed Disciplinary Action Issued o 2. Final Orders Executed o Informational Directions: ▪ Information regarding public records request. • How to make one and what scenarios would require one. ▪ Information on how to utilize the online verification page effectively. • The new report will be added to the board website each month. o Under the "Board" bucket, create a page for Board Disciplinary Actions • Staff will review online License Verification page and update language as needed. • Once a viable process has been created, discuss with board if rules are needed. o See OSBN rules as an example.

Board Review Date: 4/14/2023

Activity Report

Report Date: April 10, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 2002 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	4/12/2023 - Work Session scheduled. 4/6/2023 - Assigned to Subcommittee On Human Services. 4/5/2023 - Referred to Ways and Means by prior reference.	8:00 AM 04/12/2023 Joint Subcommittee Human Services Work Session H-170
Modifies provisions relating to reproductive health rights.				
HB 2112 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	4/6/2023 - Carried over to 04-10 by unanimous consent. 4/5/2023 - Carried over to 04-06 by unanimous consent. 4/4/2023 - Carried over to 04-05 by unanimous consent.	
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	2/16/2023 - Referred to Health Care. 2/15/2023 - First reading. Referred to President's desk. 2/14/2023 - Rules suspended. Third reading. Carried by Pham H. Passed. Ayes, 57; Nays, 3--Cate, McIntire, Reschke.	
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	3/27/2023 - Referred to Judiciary. 3/21/2023 - First reading. Referred to President's desk. 3/21/2023 - Third reading. Carried by Nosse. Passed. Ayes, 35; Nays, 21--Boice, Boshart Davis, Breese-Iverson, Cate, Cramer, Diehl, Elmer, Goodwin, Helfrich, Hieb, Javadi, Levy B, Lewis, Mannix, McIntire, Morgan, Osborne, Owens, Scharf, Stout, Wallan; Excused, 4--Nelson, Reschke, Smith G, Wright.	
Repeals residency requirement in Oregon Death with Dignity Act.				
HB 2291 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	1/16/2023 - Referred to Behavioral Health and Health Care. 1/9/2023 - First reading. Referred to Speaker's desk.	
Authorizes State Board of Pharmacy to require person under investigation by board to undergo mental, physical, chemical dependency or competency evaluation.				

Activity Report

Report Date: April 10, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 2316 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	3/15/2023 - Referred to Ways and Means by prior reference. 3/15/2023 - Recommendation: Do pass with amendments, be printed A-Engrossed, and be referred to Ways and Means by prior reference. 3/13/2023 - Work Session held.	
Expands offense of driving while under influence of intoxicants to include any substance that, when taken into human body, can impair the ability of person to operate vehicle safely.				
HB 2395 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/12/2023 - Public Hearing Scheduled. 3/8/2023 - Referred to Health Care. 3/7/2023 - First reading. Referred to President's desk.	1:00 PM 04/12/2023 Senate Committee Health Care Public Hearing HR B
Allows specified persons to distribute and administer short-acting opioid antagonist and distribute kits.				
HB 2421 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	4/6/2023 - Recommendation: Do pass with amendments and be printed A-Engrossed. 4/3/2023 - Work Session held. 3/27/2023 - 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	3/20/2023 - Referred to Health Care. 3/15/2023 - First reading. Referred to President's desk. 3/14/2023 - Third reading. Carried by Nosse. Passed. Ayes, 48; Nays, 9--Boice, Cate, Cramer, Elmer, Lewis, McIntire, Morgan, Osborne, Reschke; Excused, 2--Javadi, Scharf; Excused for Business of the House, 1--Pham H.	
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.				

Activity Report

Report Date: April 10, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 2574 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	3/17/2023 - Referred to Ways and Means by prior reference. 3/17/2023 - Recommendation: Do pass with amendments, be printed A-Engrossed, and be referred to Ways and Means by prior reference. 3/13/2023 - Work Session held.	
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 2642 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	3/27/2023 - Public Hearing held. 1/13/2023 - Referred to Behavioral Health and Health Care. 1/9/2023 - First reading. Referred to Speaker's desk.	
Requires practitioner to query electronic prescription monitoring system with respect to patient prior to issuing to, or renewing for, patient prescription for certain prescription drugs.				
HB 2645 B	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	3/29/2023 - Referred to Ways and Means by order of the President. 3/29/2023 - Recommendation: Do pass with amendments to the A-Eng. and requesting referral to Ways and Means. (Printed B-Eng.) 3/27/2023 - Work Session held.	
Increases penalties for possession of certain amounts of fentanyl.				
HB 2650 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/4/2023 - Work Session held. 3/2/2023 - Public Hearing held. 2/23/2023 - Public Hearing cancelled.	
Establishes requirements for informal workgroups and task forces.				

Activity Report

Report Date: April 10, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 2805 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	3/23/2023 - Referred to Ways and Means by order of Speaker. 3/23/2023 - Recommendation: Do pass and be referred to Ways and Means. 3/14/2023 - Work Session held.	
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	3/30/2023 - Referred to Veterans, Emergency Management, Federal and World Affairs. 3/27/2023 - First reading. Referred to President's desk. 3/23/2023 - Third reading. Carried by Sosa. Passed. Ayes, 58; Excused, 2--Nguyen H, Reschke.	
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 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/7/2023 - Recommendation: Do pass with amendments and be printed A-Engrossed. 4/4/2023 - Work Session held. 3/27/2023 - Public Hearing 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.				

Activity Report

Report Date: April 10, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 3520 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	3/23/2023 - Motion to withdraw from Emergency Management, General Government, and Veterans failed. Ayes, 25; Nays, 33--Andersen, Bowman, Bynum, Chaichi, Dexter, Evans, Fahey, Gamba, Gomberg, Grayber, Helm, Holvey, Hudson, Kropf, Levy E, Lively, Marsh, McLain, Nathanson, Nelson, Neron, Nguyen D, Nosse, Pham H, Pham K, Reynolds, Ruiz, Sanchez, Sosa, Tran, Valderrama, Walters, Speaker Rayfield; Excused, 2--Nguyen H, Reschke. 3/3/2023 - Referred to Emergency Management, General Government, and Veterans. 2/28/2023 - First reading. Referred to Speaker's desk.	
Directs agencies of state government to revoke remote work arrangements that were put in place due to COVID-19 pandemic.				
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.				
SB 11 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/6/2023 - Carried over to 04-10 by unanimous consent. 4/5/2023 - Carried over to 04-06 by unanimous consent. 4/4/2023 - Second reading.	
Requires state 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 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/4/2023 - Public Hearing held. 3/23/2023 - Referred to Rules. 3/23/2023 - First reading. Referred to Speaker's desk.	
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 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	4/19/2023 - Work Session scheduled. 4/17/2023 - Public Hearing scheduled. 3/15/2023 - Referred to Behavioral Health and Health Care.	3:00 PM 04/17/2023 House Committee Behavioral Health and Health Care Public Hearing HR F
Prohibits disclosure of individually identifiable data collected in accordance with uniform standards adopted by Oregon				

Activity Report

Report Date: April 10, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
Health Authority for collection of data on race, ethnicity, preferred spoken and written languages, disability status, sexual orientation and gender identity.				
SB 226 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/17/2023 - Work Session scheduled. 4/12/2023 - Public Hearing scheduled. 2/9/2023 - Referred to Behavioral Health and Health Care.	3:00 PM 04/12/2023 House Committee Behavioral Health and Health Care Public Hearing HR F
Removes requirement that Oregon State Board of Nursing notify State Board of Pharmacy upon authorizing nurse practitioner or clinical nurse specialist to dispense prescription drugs.				
SB 229 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	4/19/2023 - Work Session scheduled. 4/17/2023 - Public Hearing scheduled. 2/9/2023 - Referred to Behavioral Health and Health Care.	3:00 PM 04/17/2023 House Committee Behavioral Health and Health Care Public Hearing HR F
Updates terminology concerning reporting of serious adverse events.				
SB 404 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	3/22/2023 - Work Session held. 2/22/2023 - Public Hearing held. 1/14/2023 - Referred to Health Care.	
Requires State Board of Pharmacy to study prescription drugs.				
SB 410 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/24/2023 - Work Session scheduled. 4/19/2023 - Public Hearing scheduled. 2/16/2023 - Referred to Behavioral Health and Health Care.	3:00 PM 04/19/2023 House Committee Behavioral Health and Health Care Public Hearing HR F
Allows State Board of Pharmacy to adopt rules to issue temporary license to perform duties of pharmacy technician.				
SB 411 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/24/2023 - Work Session scheduled. 4/19/2023 - Public Hearing scheduled. 3/28/2023 - Referred to Behavioral Health and Health Care.	3:00 PM 04/19/2023 House Committee Behavioral Health and Health Care Public Hearing HR F
Adds certain hospital, medical and infectious waste incinerators to facilities at which covered drugs under drug takeback program may be disposed of.				
SB 450 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/24/2023 - Work Session scheduled. 4/19/2023 - Public Hearing scheduled. 3/28/2023 - Referred to Behavioral Health and Health Care.	3:00 PM 04/19/2023 House Committee Behavioral Health and Health Care Public Hearing HR F
Exempts from labeling requirements drug intended to reverse opioid overdose when drug is dispensed by physician or				

Activity Report

Report Date: April 10, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
physician assistant.				
SB 517 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/4/2023 - Work Session held. 3/28/2023 - Public Hearing held. 2/23/2023 - Public Hearing Cancelled.	
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.				
SB 538 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 3	4/13/2023 - Public Hearing scheduled. 3/3/2023 - Referred to Emergency Management, General Government, and Veterans. 2/28/2023 - First reading. Referred to Speaker's desk.	1:00 PM 04/13/2023 House Committee Emergency Management, General Government, and Veterans Public Hearing HR A
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 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/24/2023 - Public Hearing scheduled. 3/28/2023 - Referred to Behavioral Health and Health Care. 3/28/2023 - First reading. Referred to Speaker's desk.	3:00 PM 04/24/2023 House Committee Behavioral Health and Health Care Public Hearing HR F
Exempts from regulation by Advisory Council on Hearing Aids and Health Licensing Office over-the-counter hearing aid.				
SB 559 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 2	3/6/2023 - Public Hearing held. 1/13/2023 - Referred to Health Care. 1/9/2023 - Introduction and first reading. Referred to President's desk.	
Requires veterinarians to participate in prescription drug monitoring program.				
SB 763 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	3/28/2023 - Work Session held. 2/14/2023 - Public Hearing held. 1/23/2023 - Referred to Judiciary.	
Prohibits employer, state agency or licensing board from taking certain actions on basis of record created or maintained under jurisdiction of juvenile court.				
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.	

Activity Report

Report Date: April 10, 2023

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
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	4/4/2023 - Work Session held. 3/6/2023 - Public Hearing held. 2/13/2023 - Referred to Judiciary.	
Modifies provisions relating to Oregon Death with Dignity Act.				
SB 970 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/24/2023 - Work Session scheduled. 4/19/2023 - Public Hearing scheduled. 3/21/2023 - Referred to Behavioral Health and Health Care.	3:00 PM 04/19/2023 House Committee Behavioral Health and Health Care Public Hearing HR F
Revises definitions related to pharmacy for consistency with applicable federal law.				
SB 1043 A	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	4/7/2023 - Subsequent referral rescinded by order of the President. 4/7/2023 - Recommendation: Do pass with amendments and subsequent referral to Ways and Means be rescinded. (Printed A-Eng.) 4/3/2023 - Work Session held.	
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 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	3/28/2023 - Work Session cancelled. 2/13/2023 - Public Hearing held. 2/2/2023 - Assigned to Subcommittee On Education.	
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.				

Oregon Board of Pharmacy

Budget Report: December 2022 (Month 18)

Revenue:

Through December, revenue is $6,008,759 (-11.99%) **under** budget

Expenditures:

Through December, **total expenditures** are $6,733,346 (7.4%) **under** budget

Personal services are $4,792,208 (4.8%) **under** budget

Services and Supplies are $1,941,137 (14.7%) **under** budget

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

Revenues less Expenditures: ($724,587)

Cash Balance:

Cash balance through December is $4,035,155 which represents (9.9) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through December 2023. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,779,586, which represents (12.66) months of operating expense*)

Cash balance target is $2,264,365, (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

Budget Report: January 2023 (Month 19)

Revenue:

Through January, revenue is $6,152,674 (-14.5%) **under** budget

Expenditures:

Through January, **total expenditures** are $7,113,437 (7.39%) **under** budget

Personal services are $5,073,702 (4.5%) **under** budget

Services and Supplies are $2,039,735 (15.2%) **under** budget

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

Revenues less Expenditures: ($960,763)

Cash Balance:

Cash balance through January is $4,034,428 which represents (9.99) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through January 2023. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,695,530, which represents (12.48) months of operating expense*)

Cash balance target is $2,257,328, (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

Budget Report: February 2023 (Month 20)

Revenue:

Through February, revenue is $6,564,999 (-13.4%) **under** budget

Expenditures:

Through February, **total expenditures** are $7,463,188 (7.6%) **under** budget

Personal services are $5,393,372 (3.6%) **under** budget

Services and Supplies are $2,069,816 (19.5%) **under** budget

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

Revenues less Expenditures: ($898,190)

Cash Balance:

Cash balance through February is $4,033,678 which represents (9.99) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through February 2023. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $4,783,529, which represents (12.75) months of operating expense*)

Cash balance target is $2,251,112 (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.