Oregon Board of Pharmacy
REVISED BOARD MEETING AGENDA
Meeting Location: Conference Call
October 13-15, 2021

Public Attendance by Phone (503) 446-4951 Phone Conference ID: 209 693 910#

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

Wednesday, October 13, 2021 @ 8:30AM
Thursday, October 14, 2021 @ 8:30AM
Friday, October 15, 2021 @ 8:30AM

- All Board meetings except Executive or Closed Sessions are open to the public. Pursuant to ORS 192.660, Executive Sessions are closed, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the Board will return to Open Session
- To sign up for Public Comment, email your request to Karen MacLean by **12:00PM on 10/14/2021**.

The meeting is accessible to persons with disabilities. A request for hearing impaired assistance and accommodations for persons with disabilities may be made via email to Karen MacLean or by calling 971-673-0001 with at least 48 hours' notice.

WEDNESDAY, October 13, 2021

I. OPEN SESSION, Wassim Ayoub RPh, Presiding
- a. Roll Call
- b. Agenda Review and Approval *Action Necessary*

II. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.165, ORS 676.175, ORS 192.660(1)(2)(f)(L), ORS 192.690(1)
- a. Legal Advice pursuant to ORS 192.660(2)(f)
- b. Deliberation on Disciplinary Cases and Investigations
- c. Contested Case Deliberation pursuant to ORS 192.690(1)

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

Adjourn *Action Necessary*

THURSDAY, October 14, 2021

I. OPEN SESSION, Wassim Ayoub RPh, Presiding
- a. Roll Call

II. MOTIONS RELATED TO DISCIPLINARY ACTIONS *Action Necessary*

III. GENERAL ADMINISTRATION
- a. Discussion Items
  - i. SBAR – Technician License – *Schnabel* **#B**

ii. SBAR – Bay Area Hospital Approval Request – *Hennigan* **#F** *Action Necessary*
iii. Staff Delegated Authority - *Efremoff* **#C** *Action Necessary*
iv. FDA MOU - *Schnabel*
v. 2021-2023 Affirmative Action Diversity & Inclusion Plan - *Schnabel*
vi. Strategic Plan Update - *Schnabel*
vii. Financial/Budget Report – *MacLean* **#E**

IV. ISSUES AND ACTIVITIES* (*Items in this section may occur anytime during the meeting as time allows*)

a. Reports
i. Board Members
ii. Executive Director
iii. Compliance Director
iv. Administrative Director
v. Licensing Manager
vi. Pharmacist Consultant
vii. Operations Policy Analyst
viii. Office Manager

b. Rules
i. Review Rulemaking Hearing Report & Comments – none
ii. Consider Adoption of Rules – none
iii. Consider Adoption of Temporary Rules –

1. Div 007 – Compliance with OHA COVID rules - *Schnabel* **#A** *Action Necessary*

iv. Rulemaking Policy Discussion Items - *Davis*
1. Division & Rule Number Vision **#A1**
2. Div 007 – Compliance with OHA COVID rules **#A2** *Action Necessary*
3. Div 006/007/041/045/065 - USP Storage Labeling Repackaging **#A3** *Action Necessary*
4. Div 010 - Board Administration/Policies **#A4** *Action Necessary*
5. Div 041/043/044 - LEP Informational Inserts **#A5** *Action Necessary*
6. Div 019/041/139/141 - Remote Dispensing Site Pharmacy/Telepharmacy **#A6** *Action Necessary*

V. PUBLIC COMMENT

a. The Board will not deliberate any issues or requests during Public Comment such as formal requests, issues currently under investigation, requests pending before the Board or currently proposed rules.

Adjourn *Action Necessary*

FRIDAY, October 15, 2021

I. OPEN SESSION, Wassim Ayoub RPh, Presiding

a. Roll Call

II. GENERAL ADMINISTRATION – Continued*

a. Rules
i. Rulemaking Policy Discussion Items –

7. Div 041/080 - Pseudoephedrine/Ephedrine **#A7** *Action Necessary*
8. Div 019/021 – Pain Management CE **#A8** *Action Necessary*
9. Div 020 – Pharmacist Prescriptive Authority **#A9, #A9-a, #A9-b, #A9-c** *Action Necessary*
10. Div 043 – SPDO/DPDO **#A10** *Action Necessary*
11. Div 060/110 – Procedural Rule Review/PDMP Fee Increase **#A11** *Action Necessary*
12. Div 006/041 – Telework/Remote Processing/TCVP **#A12** *Action Necessary*

v. Public Health and Pharmacy Formulary Advisory Committee Update - *Davis*
vi. Rules Advisory Committee Update – *Davis*
ii. PharmCon Contraception CE Program Review – *Davis* **#D** *Action Necessary*

III. ISSUES AND ACTIVITIES Continued* (*Items in this section may occur anytime during the meeting as time allows*)

2021 Board Meeting Dates

- November 17-18, 2021 Portland (Strategic Planning)
- December 8-9, 2021 Portland

2022 Board Meeting Dates

- February 9-11, 2022* Portland
- April 13-14, 2022 Portland
- June 8-9, 2022 Portland
- August 10-12, 2022* Portland
- October 12-13, 2022 Portland
- November 9-10, 2022 TBA (Strategic Planning)
- December 14-15, 2022 Portland

2023 Board Meeting Proposed Dates - *MacLean* *Action Necessary*

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

Rulemaking Hearing Dates

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

- November 23, 2021
- May 24, 2022
- November 22, 2022

Conferences/Meetings – *Schnabel*

PAST MEETINGS

1. District 6/7/8 NABP Meeting (Carefree, AZ) – August 29 - September 1, 2021
2. NABP Executive Officer Conference – (Chicago, IL) September 28-29, 2021
3. OSPA Annual Meeting (Portland, OR) – October 2-3, 2021

FUTURE MEETINGS

1. Lane County Mid-Winter Seminar – February 19-20, 2022

IV. Approve Consent Agenda* *Action Necessary*

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

a. License/Registration Ratification - **# CONSENT - 1**
b. Pharmacy Technician Extensions - None
c. Board Meeting Minutes – August 2021 **# CONSENT-2**

Adjourn *Action Necessary*

TEMPORARY ADMINISTRATIVE ORDER

CHAPTER 855
BOARD OF PHARMACY

FILING CAPTION: Requires compliance with Oregon Health Authority rules to control the communicable disease COVID-19

EFFECTIVE DATE: 10/15/2021 THROUGH 04/11/2022

AGENCY APPROVED DATE: 10/14/2021

NEED FOR THE RULE(S):
Requires licensees and registrants to comply with Oregon Health Authority (OHA) requirements issued pursuant to the OHA requirements. Allows the board to take disciplinary action if a licensee or registrant fails to comply with OHA's requirements.

JUSTIFICATION OF TEMPORARY FILING:
Oregon Health Authority rules to control COVID-19 apply to licensees and registrants of the Board of Pharmacy to protect the public health. Enforcing these rules is necessary to assure compliance and reduce transmission of COVID-19. The Board of Pharmacy may utilize this rule to enforce licensee and registrant compliance.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:
OAR 333-019-1010 https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=280799,OAR 333-019-1011 https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=280518 and OAR 333-019-1025 https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=280702

CONTACT:
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Portland, OR 97232

ADOPT: **855-007-0088**
RULE TITLE: Compliance with the Oregon Health Authority's COVID-19 Requirements
RULE SUMMARY: Oregon Board of Pharmacy licensees and registrants must comply with OHA's requirements during a declared emergency.

RULE TEXT:

(1) The Oregon Health Authority (OHA) has adopted certain rules to control the communicable disease COVID-19. Unprofessional conduct includes failing to comply with any applicable provision of an OHA COVID-19-related rule or any provision of this rule.

(2) Failing to comply as described in subsection (1) includes, but is not limited to:

(a) Failing to comply with OHA's rules requiring masks, face coverings or face shields, including OAR 333-019-1011 and OAR 333-019-1025.

(b) Failing to comply with OHA's rules requiring vaccinations, including OAR 333-019-1010.

(3) No disciplinary action or penalty action will be taken under this rule if the rule alleged to have been violated is not in effect at the time of the alleged violation.

(4) Imposition of discipline for violating this rule is as authorized by ORS 689.405 and ORS 689.445. Any such discipline will be imposed in accordance with ORS Ch. 183.

STATUTORY/OTHER AUTHORITY: ORS 689.205
STATUTES/OTHER IMPLEMENTED: ORS 689.151

Division Vision

Creating consistency in OAR 855

1

Goals and Objectives

- 2020-2024 Strategic Plan Regulation Goal:
  - Systematically refresh rules and standardize the rule development approach to improve clarity and compliance.

2

How a Law or Policy Directive Becomes a Rule

- STEP 1 • **Initiating Event**, such as a new law or ongoing problem identified
- STEP 2 • **Analysis of Issue**, including research, stakeholder landscape, gathering data
- STEP 3 • **Draft Proposed Rule**, based on input and other directives
- STEP 4 • **Board Discussion**, seek consensus in public session for specific directive, focused on safety
- STEP 5 • **Rulemaking**, public comment, Rules Advisory Committee input, Rulemaking Hearing
- STEP 6 • **Adoption**, Board adopts rule by motion in public session

Steps 3 & 4 are repeated as necessary to build consensus

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STEP 3

•**Draft Proposed Rule**, based on input and other directives

- 3a • Review rule revision spreadsheet
- 3b • Consultant (and others) draft language for new rules and rule revisions
- 3c • Rule Writing Group (RWG) meets weekly and works on proposed rules incrementally and continuously
- 3d • Consultant review/edits
- 3e • Compliance Staff review/edits
- 3f • AAG review/edits

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Objectives

- Each licensee and registrant type assigned a division
- Within each division create consistency order of rules

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Today's Situation

- Example: Division 041 currently contains rules for Operation of Pharmacies (Ambulatory and Residential Drug Outlets)
  - 1000's: *Mostly* applies to both retail and institutional drug outlets
  - 2000's: *Mostly* applies to services offered by a retail drug outlet
  - 3000's: Central Fill, Remote Processing, Consulting/Drugless
  - 4000's: Home Dialysis, Remote Dispensing Machine
  - 5000's: Remote Distribution Facility, Technician Checking Validation Program
  - 6000's: Institutional drug outlets
  - 7000's: Long Term Care, Community Based Facilities
  - 8000's: Home Health Agencies

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How Did We Get Here?

- Div 041: Institutional drug outlet rules - 2010
- Div 041: Retail drug outlet rules - 2012
- Statutory changes
- Practice changes

7

Current Work Progress

- Board staff whiteboard exercise
  - List all outlet types
  - List all current divisions
  - Create list of divisions needed
- Draft
  - Division list
  - Rule order list for IP/RP outlet types

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Division Vision- DRAFT

100	Definitions
103	Procedural
106	Board Policies
110	Fees
112	Public Health Emergency
115	HPSP
118	CE
121	Pharmacist
127	Prescribing
130	Intern
133	Tech
136	DO Pharmacy (RP)
139	DO Remote Dispensing Site Pharmacy (RP)
141	DO Locker (RP)
144	DO Charitable Pharmacy (RP)
156	DO Pharmacy (IP)
159	DO Drug Room (IP)
161	DO RDF/RDM (IP)
164	DO Nuclear (IP)
167	DO LTC/Residential (IP)
170	DO Home Infusion (IP)
173	DO Home Dialysis (IP)
176	DO Home Health Care (IP)
177	DO Correctional Facility (IP)
180	Controlled Substances
183	Compounding
186	DO Nonprescription
189	DO Prophylactic
191	DO Devices
194	DO Practitioner Dispensing (RP)
197	DO CHC's
199	DO Animal Euthanasia
200	Facility- Manufacturer
203	Facility- Wholesaler
206	Facility- DDA

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Rule Number Order (RP)- DRAFT

1	Purpose and Scope	300	Prescription: General Requirements	500	Policies & Procedures
5	Definitions	305	Prescription: Tamper Resistant	550	Records: General Requirements
10	Registration: General	310	Prescription: Authenticity	555	Records: Patient
15	Registration: Application	315	Prescription: Refills	600	Prohibited Practices: General
20	Registration: Change of Owner	320	Prescription: Expiration		Prohibited Practices: Disclosure of Patient
25	Registration: Change of Busine	325	Prescription: Transfers	605	Information
30	Non-Resident Pharmacies	350	Dispensing: Containers	650	Grounds for Discipline
50	Personnel		Dispensing: Customized Patient Me		Service: Non-Prescription Drugs- Double
100	Security	355	Packages	700	Set-Up
120	Drug: Receipt	400	Labeling: General Requirements	705	Service: Pharmacy Depots
125	Drug: Storage	405	Labeling: Prescription Reader Acces	710	Service: Epinephrine- Definitions
130	Drug: Loss		Labeling: Limited English Proficienc		Service: Epinephrine- General
150	Outlet: Sanitation	410	Accessibility	715	Requirements
155	Outlet: Minimum Equipment R	415	Labeling: Repackaged Drugs	720	Service: Naloxone- General Requirements
200	Outlet: General Requirements	450	Drug and Devices: Disposal		Service: Expedited Partner Therapy (EPT)-
205	Outlet: Technology	455	Drug and Devices: Return	725	Purpose
210	Outlet: Supervision		Drugs and Devices: Take-back Colle		Service: Expedited Partner Therapy (EPT)
215	Outlet: Pharmacist Utilization	460	Program	730	- Procedures
220	Outlet: Non-Prescription Drugs				
225	Outlet: Controlled Substances				
230	Outlet: Non-Sterile Compounding				

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Division 007: Public Health Emergency (Compliance with OHA Requirements)

Filing Caption (max 15 words): Requires compliance with Oregon Health Authority rules to control the communicable disease COVID-19.

Need for Rules:

Requires licensees and registrants to comply with Oregon Health Authority (OHA) requirements issued pursuant to the OHA requirements. Allows the board to take disciplinary action if a licensee or registrant fails to comply with OHA's requirements.

Justification for Temporary Filing:

Oregon Health Authority rules to control COVID-19 apply to licensees and registrants of the Board of Pharmacy to protect the public health. Enforcing these rules is necessary to assure compliance and reduce transmission of COVID-19. The Board of Pharmacy may utilize this rule to enforce licensee and registrant compliance.

Fiscal Impact:

None anticipated

Documents Relied Upon:

OAR 333-019-1010, OAR 333-019-1011 and OAR 333-019-1025

Rules Summary:

Oregon Board of Pharmacy licensees and registrants must comply with OHA's requirements during a declared emergency.

DIVISION 007
PUBLIC HEALTH EMERGENCY

855-007-0088
Compliance with the Oregon Health Authority's COVID-19 Requirements

(1) The Oregon Health Authority (OHA) has adopted certain rules to control the communicable disease COVID-19. Unprofessional conduct includes failing to comply with any applicable provision of an OHA COVID-19-related rule or any provision of this rule.

(2) Failing to comply as described in subsection (1) includes, but is not limited to:

(a) Failing to comply with OHA's rules requiring masks, face coverings or face shields, including OAR 333-019-1011 and OAR 333-019-1025.

(b) Failing to comply with OHA's rules requiring vaccinations, including OAR 333-019-1010.

(3) No disciplinary action or penalty action will be taken under this rule if the rule alleged to have been violated is not in effect at the time of the alleged violation.

(4) Imposition of discipline for violating this rule is as authorized by ORS 689.405 and ORS 689.445. Any such discipline will be imposed in accordance with ORS Ch. 183.

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

Division 006/007/041/045/065– Definitions/Public Health Emergency/Operation of Pharmacies /Pharmacy Drug Compounding/Wholesale Drug Outlets (USP/Drug Storage/Labeling/Repackaging)

Need for Rules: The proposed revisions are to clarify the date of incorporated standards of reference, as discussed in with the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019).

Each year the board will adopt the updated USP-NF standards and USCs. The board is tasked with verifying that every USP-NF standard and USC is current and referenced appropriately.

Fiscal Impact:
Related to 855-041-1036 Drug Storage- To be determined.
Related to 855-041-1080 New Containers- None anticipated.

Documents Relied Upon:
United States Pharmacopeia -National Formulary <NF> (USP 43-NF38 v. 2021) https://www.uspnf.com/

Homeopathic Pharmacopoeia of the United States (HPUS) (v. 2021): https://www.hpus.com/
Related Federal Statutes/Rules:

Poison Prevention Packaging Act: 16 CFR 1700 (XX/XX/XXXX) Poison Prevention Packaging, 16 CFR 1701 (XX/XX/XXXX) Statements of Policy and Interpretation, and 16 CFR 1702 (XX/XX/XXXX) Petitions for Exemptions from Poison Preventing Packaging Act Requirements; Petition Procedures and Requirements

21 USC 351 (XX/XX/XXXX) Adulterated drugs and devices, 21 USC 352 (XX/XX/XXXX) Misbranded drugs and devices

42 USC 262 (XX/XX/XXXX) Regulation of biological products

Rules Summary:
Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Note: If language changes are made to OAR 855-006-0005, OAR 855-041-1001, 855-041-1035, 855-041-1036 or 855-041-1145 in other rule packages, this rule will be updated to reflect the same language in the other rule packages.

1

Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).

(~~1~~**2**) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(~~2~~**3**) "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 **b**~~B~~oard 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 pharmacy technicians.

(~~3~~**4**) "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.

(~~4~~**5**) "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.

(~~5~~**6**) "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.

(~~6~~**7**) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(~~7~~**8**) "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.

(~~8~~**9**) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(~~9~~**10**) "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.

(~~10~~**11**) "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.

(~~11~~**12**) "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.

(13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).

(~~12~~**14**) "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~~**must** not be construed to prohibit monitoring by practitioners or their agents.

(~~13~~**15**) "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.

(~~14~~**16**) "Nationally Certified Exam" means an exam that is approved by the **b**~~B~~oard which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible and valid.

(~~15~~**17**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(~~16~~**18**) "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.

(19) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States <HPUS> (v.2021), or any supplement to any of these.

(~~17~~**20**) "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.

(~~18~~**21**) 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.

(~~19~~**22**) "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.

(~~20~~**23**) "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 **b**~~B~~oard but has not completed the specialized education program pursuant to OAR 855-025-0012.

(~~21~~**24**) “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.

(~~22~~**25**) “Practice of pharmacy” is as defined in ORS 689.005.

(~~23~~**26**) "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.

(~~24~~**27**) “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.

(~~25~~**28**) "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.

(~~26~~**29**) “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.

(~~27~~**30**) "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.

(~~28~~**31**) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as 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 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 or pharmacy technicians;

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

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

~~(29) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action.~~

~~During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.~~

(~~30~~**32**) "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.

(~~31~~**33**) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.

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

Division 7
PUBLIC HEALTH EMERGENCY

855-007-0120
Damage to a Pharmacy and Drug Integrity

(1) If a pharmacy prescription department sustains damage, whether by flood or otherwise, the entire drug inventory, including any prescriptions that are awaiting pickup, is unfit for dispensing, ~~shall~~**must** be classified as adulterated and must be destroyed unless, ~~in the pharmacist's professional judgment~~, ~~any items are~~ **the drugs are** deemed safe for dispensing **pursuant to OAR 855-041-1036**. Any incident of this nature must be reported to the **b**~~B~~oard within three working days.

(2) If a pharmacy loses power that affects temperature or humidity controls such that ~~USP standards for~~ **the** proper storage of drugs **pursuant to OAR 855-041-1036 has**~~ve~~ been violated, such drugs ~~shall~~**must** be classified as adulterated and may not be dispensed.

~~NOTE: for those drugs labeled for storage at "controlled room temperature," the acceptable range of temperature is 68° to 77°F with allowances for brief deviations between 59° to 86°F~~.

(3) Controlled substances damaged, lost or stolen ~~shall~~**must** be documented and reported to the DEA and the **b**~~B~~oard on DEA Form 41 or DEA Form 106 as appropriate.

(4) A pharmacy that is required to temporarily close or relocate due to an emergency must report this event to the **b**~~B~~oard within three working days.

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

Division 41

OPERATION OF PHARMACIES ~~(AMBULATORY AND RESIDENTIAL DRUG OUTLETS)~~

855-041-1001

Definitions

(1) "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.

(2) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U~~.~~S~~.~~C~~.~~ 262(k)(3)(A)(i) **(v. XX/XX/XXXX)**.

(3) "Drug room" is a drug storage area registered with the **b**Board which is secure and lockable.

(4) "Informational insert" is an auxiliary document containing directions for use and other prescription information that is provided to the patient in both English and the language requested.

(4**5**) "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 U~~.~~S~~.~~C~~.~~ 262(k)(4) **(v. XX/XX/XXXX)**.

(6) "Limited English proficiency" means not fluent in the English language.

(~~5~~**7**) "Reference biological product" means the biological product licensed pursuant to 42 U~~.~~S~~.~~C~~.~~ 262(a) **(v. XX/XX/XXXX)** 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.

(8) "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.

(9) "Temperature excursion" means an event in which a drug is exposed to a temperature outside of the manufacturers recommended storage conditions.

Statutory/Other Authority: ORS 689.205 & 689.522

Statutes/Other Implemented: ORS 689.155 ~~& 342 &~~ **ORS** 689.522**, & ORS 689.564**

855-041-1035

Minimum Equipment Requirements

(1) Each retail drug outlet and institutional drug outlet **must have** the following:

(~~1~~**a**) ~~The most~~ **Appropriate and** current ~~issue of at least one~~ pharmaceutical reference**s** ~~with current, properly filed supplements~~ **(e.g. pharmacology, injectables, and veterinary drugs)** ~~and updates appropriate to and~~ based on ~~the standards of practice for the setting.~~ **services offered by the outlet;**

(~~2~~**b**) **Appropriate and** ~~C~~**c**urrent ~~and properly filed~~ Oregon Revised Statutes, ~~Chapters 689, and 475; current and properly filed~~ Oregon Administrative Rules, ~~chapter 855;.~~ **United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet** and a minimum of three years of the Board of Pharmacy quarterly newsletters ~~maintained in house or other readily retrievable means~~;

~~(3) Official Poison and Exempt Narcotic Register if poisons and exempt narcotics are sold or distributed.~~

(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(4**d**) ~~Suitable refrigeration.~~ **Appropriate equipment to maintain the proper storage of drugs;**

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;

(~~5~~**f**) A sink with running hot and cold water~~.~~**;**

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up pharmacy per OAR 855-041-2100; and

(D) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-041-2340.

(~~6~~**h**) **Additional** ~~E~~**e**quipment and supplies ~~appropriate to and based on the standards of practice for the setting as~~ **that are** determined as **necessary** by the Pharmacy ~~and~~ **or** Pharmacist-in-Charge.

(~~7~~**2**) Failure to have**,** ~~and~~ use **and maintain required** equipment ~~necessary to your practice setting~~ constitutes unprofessional conduct ~~for purposes of~~ **under** ORS 689.405(1)(a)~~.~~**;**

~~(8) If an outlet files original prescriptions electronically, then the outlet must have a computer and software capable of storing and accessing electronically filed original prescriptions.~~

~~(9) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to provide notification of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency, in compliance with federal and state regulations.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.508**,** ~~&~~ ORS 689.155**, ORS 689.515, ORS 689.564 & ORS 689.686**

855-041-1036
Proper Storage of Drugs

~~(1) A pharmacy must maintain proper storage of all drugs. This includes, but is not limited to the following:~~

~~(a) All drugs must be stored according to manufacturer's published or USP guidelines.~~

~~(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.~~

~~(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.~~

~~(d) A pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.~~

~~(2) A pharmacy must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).~~

~~(a) All drug refrigeration systems must:~~

~~(A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.~~

~~(B) Utilize a centrally placed, accurate, and calibrated thermometer;~~

~~(C) Be dedicated to pharmaceuticals only; and~~

~~(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.~~

~~(b) A pharmacy must adhere to a monitoring plan, which includes, but is not limited to:~~

~~(A) Documentation of training of all personnel;~~

~~(B) Maintenance of manufacturer recommended calibration of thermometers;~~

~~(C) Maintenance of records of temperature logs for a minimum of three years;~~

~~(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;~~

~~(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination that it is safe for continued use. This documentation must include details of the information source;~~

~~(F) A written emergency action plan; and~~

~~(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment.~~

~~(3) Vaccine Drug Storage:~~

~~(a) A pharmacy that stores vaccines must comply with section two of this rule and the following:~~

~~(A) Vaccines must be stored in the temperature stable sections of the refrigerator;~~

~~(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C variance must be utilized;~~

~~(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;~~

~~(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and~~

~~(E) Must adhere to a written quality assurance process to avoid temperature excursions.~~

~~(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.~~

(1) A pharmacy must store each drug according to the manufacturer's storage requirements for temperature, light, humidity, sanitation, ventilation, and space.

(2) If the drug's manufacturer does not include a storage requirement, the drug must be stored as outlined in an official compendium, to ensure that the drug identity, strength, quality, and purity are not adversely affected.

(3) Each pharmacy must:

(a) Unless the manufacturer specifies differently, maintain drug required to be stored at controlled room temperature between 20-25 °C (68 to 77 °F); refrigerated products between 2 to 8 °C (35.6 to 46.4 °F); frozen products between -25 to -10 °C (-13 to 14 °F);

(b) Utilize continuous temperature monitoring device(s) that have a buffered probe (glycol, glass beads, or similar), are centrally located, accurate, calibrated within a plus or minus 0.5°C variance and record the temperature of each drug storage area at least every 15 minutes;

(c) Review all temperature data for the last 24 hours twice daily for proper drug storage and for temperature excursions. Date, time and identity of the reviewer must be documented;

(d) Utilize a system that notifies a pharmacist of each temperature excursion in real-time;

(e) Ensure drug storage refrigerators and freezers are dedicated to drugs and vaccines only and utilize refrigerator or freezer compartments with its own exterior door and independent thermostat control;

(f) Position drugs in refrigerators and freezers leaving space between the drugs, walls, ceiling, floor, and door to promote air circulation. If using a household grade unit, drugs may not be stored in any part of the unit that does not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in drawers, or on refrigerator door shelves;

(g) Maintain proper drug storage conditions during transfers between facilities and delivery to patients;

(h) Ensure that drugs stored outside of the manufacturer's drug storage requirements are physically separated from other drugs until the manufacturer determines that the drug is safe and effective for continued use, is safe and effective for continued use with limitations (ie. shortened expiration date), needs to be returned to the supplier, or destroyed;

(i) Ensure that the following is completed at a minimum of every 3 months:

(A) Test and document that all components of the temperature monitoring system(s) for each storage area are recording temperature accurately and issuing appropriate alerts;

(B) Review and assess temperature records for long-term trends or recurring problems. Date, time and identity of the reviewer must be documented;

(j) Establish, maintain, and enforce a written quality assurance plan to prevent, identify, and appropriately respond to temperature excursions;

(k) Establish, maintain, and enforce a written action plan to ensure proper drug storage in the event of an emergency (i.e. power outage or natural disaster) that includes identification of backup storage and a procedure for transfer of product between units or facilities;

(l) Document the training of all pharmacy personnel on use of temperature monitoring system(s), quality assurance plan and written emergency action plan to ensure proper drug storage in the event of an emergency;

(m) Recalibrate temperature monitoring device(s) at least once every 24 months or per manufacturer specifications, whichever is more frequent;

(n) Document the following for each temperature excursion:

(A) Date of temperature excursion;

(B) Start and end time;

(C) Minimum and maximum temperatures reached;

(D) List of each drug involved in the temperature excursion including the drug name, quantity, National Drug Code, lot number, expiration date, manufacturer, and the date(s) of previous temperature excursions experienced by the drug(s);

(E) Each drug involved in the temperature excursion must be clearly labeled with the date of temperature excursion and any shortened expiration date if determined by the manufacturer; and

(F) Name of person(s) involved in responding to the temperature excursion event discovery and response;

(o) Before a drug that has experienced a temperature excursion is dispensed, the following items must be documented:

(A) Drug manufacturer information utilized indicating each drug is safe for use;

(B) Name of the representative providing the information;

(C) Manufacturer contact information;

(D) Copy of information provided by manufacturer;

(E) Date and time information was obtained from manufacturer;

(F) Reference number associated with manufacturer contact;

(G) Name of the Oregon licensed pharmacist that reviewed the manufacturer data and confirmed the drug safe for continued use; and

(H) In the absence of (B) and (C), documentation of a drug manufacturer online reference that applies to the specific temperature excursion, documentation of this reference must be maintained; and

(p) Maintain all records required by OAR 855-041-1036 for a minimum of three years;

Statutory/Other Authority: ORS 689.205 & **ORS** 689.325
Statutes/Other Implemented: ORS 689.155

855-041-1040
Drug Outlet Procedures

Each drug outlet is accountable for establishing, maintaining, and enforcing their written procedures for:

(1) Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;

(2) Performing mandatory prospective drug utilization reviews; on all prescriptions both new and refilled;

(3) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;

(4) Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;

(5) Ensuring the delivery of each completed prescription to the correct party;

(6) Providing appropriate confidential professional advice concerning medications to patients or their agents;

(7) Prescribing services and maintenance of records for prescribing pharmacist;

(8) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties;

(9) Establishing and maintaining a Continuous Quality Assurance Program; ~~and~~

(10) Providing oral interpretation and translation services for any patient who is of limited English proficiency, and prescription readers for a visually impaired patient as required by OAR 855-041-1131 and OAR 855-041-1132~~.~~**; and**

(11) Ensuring drugs are stored as required by OAR 855-041-1036.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

855-041-1080

Pharmacy Registration (Both Retail and Institutional Drug Outlets)

(1) Pharmacies ~~shall~~**must** be registered as either retail drug outlets or institutional drug outlets or both.

(2) An application for registration of a new pharmacy ~~shall~~**must** be accompanied by a floor plan drawn to scale and ~~shall~~**must** be approved by the **b**~~B~~oard prior to opening.

(3) The application ~~shall~~**must** specify the location of the pharmacy and ~~shall~~**must** indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application ~~shall~~**must** indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owner, the names of the partners or persons holding the five largest interests ~~shall~~**must** be indicated on the application;

(b) If the owner is a corporation, the name filed ~~shall~~**must** be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests ~~shall~~**must** be indicated on the application.

(4) Upon request by the **b**~~B~~oard, the applicant ~~shall~~**must** furnish such information as required by the **b**~~B~~oard regarding the partners, stockholders, or other persons not named in the application.

(5) The application ~~shall~~**must** also identify any person who has incidents of ownership in the pharmacy who also has financial interest in any long-term care facility as defined in ORS 442.015.

(6) A certificate of registration will be issued upon **b**~~B~~oard approval of the application.

(7) All registration renewal applications ~~shall~~**must** be accompanied by the annual fee and ~~shall~~**must** contain the same information required in sections (3) and (4) of this rule.

(8) The initial and annual registration fee for pharmacies is set out in **OAR 855-110**~~division 110 of this chapter~~.

(9) Pharmacy registration expires March 31, annually. If the annual registration fee referred to in **OAR 855-110**~~division 110 of this Chapter~~ is not paid by March 31 of the current year, a ~~delinquent~~**late** fee as set out in **OAR 855-110**~~division 110 of this Chapter~~ ~~shall~~**must** be included with the application for registration renewal.

(10) The registration is not transferable and the registration fee cannot be prorated.

(11) A change of ownership requires the approval of the **b**~~B~~oard and new certificate of registration. Application ~~shall~~**must** be on a form supplied by the **b**~~B~~oard.

(12) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(13) Applicants for change in ownership ~~shall~~**must** provide the **b**~~B~~oard with the information required in sections (3), (4), and (5) of this rule.

(14) A change of ownership ~~shall~~**must** be reported to the **b**~~B~~oard ~~within~~ 15 days ~~of the~~**prior to** occurrence.

(15) No pharmacy ~~shall~~**must** be operated until a certificate of registration has been issued to the pharmacy by the **b**~~B~~oard.

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

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling

~~(1)~~Prescriptions must be labeled with the following information:

(~~a~~**1**) Name, address and telephone number of the pharmacy;

(~~b~~**2**) Date **of fill**

(~~c~~**3**) Identifying number;

(~~d~~**4**) Name of patient;

(~~e~~**5**) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(~~f~~**6**) Directions for use by the patient;

(~~g~~**7**) Name of practitioner;

(~~h~~**8**) Required precautionary information regarding controlled substances;

(~~i~~**9**) Such other and further accessory cautionary information as required for patient safety;

(~~j~~**10**) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container **or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier** ~~unless, in the pharmacist's professional judgment, a shorter expiration date is warranted~~. Any drug expiring before the

expected length of time for course of therapy ~~ends~~ must not be dispensed. ~~bearing an expiration date shall not be dispensed beyond the said expiration date of the drug; and~~

(~~k~~**11**) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, ~~shall~~**must** be labeled with its physical description, including any identification code that may appear on tablets and capsules.

~~(l) Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & **ORS** 689.515

855-041-1135
~~**Defines**~~ **Labeling and Container Requirements for Repackage~~d~~ Drugs**

(1) Each pharmacy record keeping system must identify all pharmacy personnel involved in repackaging including the pharmacist who verified the repackaged drug.

(~~1~~**2**) **A single oral solid d**~~D~~rug~~s~~ product~~s~~ ~~p~~repackaged by a pharmacy **into unit-dose packaging** ~~for later own use dispensing on prescription shall~~ must:

(a) **Utilize a unit-dose container–closure system that meets the testing requirements under USP <671> Containers—Performance Testing (12/01/2020) for either Class A or Class B containers and meets or exceeds the original container's specification for light resistance;** ~~in a container meeting USP standards and labeled to identify at a minimum:~~

(b) Be labeled to identify at a minimum:

(~~a~~**A**) Brand name~~,~~ or generic name ~~and manufacturer~~;

(~~b~~**B**) Strength;

(~~c~~**C**) **Manufacturer and** ~~l~~**l**ot number **or an internal pharmacy code that references manufacturer and lot number**; **and**

(~~d~~**D**) ~~Manufacturer's expiration date, or any earlier date which, in the pharmacist's professional judgment, is preferable.~~ **Expiration date. The expiration date used for the repackaged product must not exceed:**

(i) 6 months from the date of repackaging; or

(ii) The manufacturer's expiration date; or

(iii) 25% of the time between the date of repackaging and the expiration date shown on the manufacturer's bulk article container of the drug being repackaged, whichever is earlier.

(3) A single oral solid drug product repackaged by a pharmacy into multiple-unit packaging must:

(a) Utilize an equivalent container–closure system that is at least as protective as, or more protective than, the original system, complies with criteria established for equivalency and meets or exceeds the original container's specification for light resistance;

(b) Be labeled to identify at a minimum:

(A) Brand name or generic name;

(B) Strength;

(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot number; and

(D) Expiration date. The expiration date used for the repackaged product must not exceed the manufacturer's expiration date or one year from the date the drug was placed in the new container, whichever date is earlier.

(~~2~~) ~~An internal control number which references manufacturer and lot number may be utilized.~~

Statutory/Other Authority: ORS 689**.205**
Statutes/Other Implemented: **ORS 689.155**

855-041-1145
New Containers

~~In~~ ~~filling the original prescriptions, nothing but~~ **Each pharmacy must dispense a drug in a** new containers ~~may be used. A patient's original container may be refilled if clean and the label is legible and up-to-date. The container shall~~ **that** compli**es**~~y~~ with the current provisions of the ~~Federal Consumer~~ **Poison Prevention** Packaging Act in **16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX), and 16 CFR 1702 (XX/XX/XXXX)** ~~and rules or regulations adopted thereunder. It must also conform with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling~~.

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689**.205**
Statutes/Other Implemented: ORS 689.155

855-041-6270

Institutional Drug Outlet Pharmacy Prescription Labeling

(1) Each pharmacy record keeping system must identify **all pharmacy personnel involved in the repackaging** ~~and document~~ **including** the pharmacist who verifie**d**~~s~~ the **repackaged** drug.

(2) Each ~~pre-packed~~ **repackaged** drug, ~~including a unit-dosed drug,~~ prepared by the pharmacy and intended for use within the facility **must** ~~shall~~ be in an appropriate container with a label **that meets the requirements of OAR 855-041-1135 and includes**:

(a) The brand or generic name and expiration date;

(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;

(c) The strength of the drug.

(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:

(a) Name and location of patient;

(b) Name and strength of drug;

(c) Route of administration, when necessary for clarification;

(d) Manufacturer and lot number, or internal pharmacy code;

(e) Auxiliary labels as needed, and

(f) Expiration date.

(4) A drug that is ~~to be sent with~~ **provided** ~~the patient upon discharge~~ **for outpatient use must be dispensed by a retail drug outlet**. ~~labeled in accordance with ORS 689.505(5) and other rules in this Division. Drug counseling information must be provided to the patient or patient's agent.~~

~~(5) A label for an outpatient prescription must comply with ORS 689.505(5) and other rules in this Division.~~

(~~6~~**5**) ~~New bar coding or electronic label:~~ When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.

(~~7~~**6**) When~~ever~~ a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that ~~contains~~ **includes the**

(a) ~~The n~~**N**ame, quantity and concentration of the drug added and the primary solution;

(b) ~~The d~~**D**ate and time of addition;

(c) ~~The e~~**E**xpiration date;

(d) ~~The s~~**S**cheduled time for administration;

(e) ~~The i~~**I**nfusion rate, when applicable;

(f) ~~The n~~**N**ame or initials of person performing admixture;

(g) ~~The i~~**I**dentification of the pharmacy where the admixture was performed; and

(h) ~~The n~~**N**ame or initials of the verifying pharmacist.

(~~8~~**7**) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & **ORS** 689.505

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 shall**must** register with the **b**Board as a drug outlet and comply with **b**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)** ~~Chapters~~ **including:**

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

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

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

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

(e) ~~as well as~~ 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),** ~~825,~~ **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),** ~~and~~ 1229.5 **(08/01/2016)**~~.~~ **, 1231 (08/01/2018), and 1821 (05/01/2017).**

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

855-045-0220
Personnel and Responsibilities

(1) All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties.

(2) The Pharmacist-in-Charge (PIC) and the drug outlet shall**must** establish, maintain and enforce policies and procedures in accordance with the standards **required** in **OAR 855-045-0200(3)**~~USP Chapters~~ for all aspects of the compounding operation according to the type of compounding performed and shall**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 **b**Board within 10 working days in the event of a patient-level recall of a compounded drug.

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

855-045-0240
Labeling of Compounded Drugs

In addition to the labeling requirements specified in **OAR 855-**~~Division~~ 041, the label of a compounded drug dispensed or distributed must contain the following, at a minimum:

(1) The generic or official name of each active ingredient;

(2) The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation;

(3) The dosage form and route of administration;

(4) Rate of infusion, for a sterile parenteral preparation;

(5) The total quantity of the drug product;

(6) A **beyond-use date (**BUD**)**, compliant with ~~current USP~~ standards **required** in **OAR 855-045-0200(3)**; and

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

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

Division 65
WHOLESALE DRUG OUTLETS

855-065-0005
Definitions

(1) “Affiliate” means a business entity that has a relationship, or is an authorized trading partner, with a second business entity if, directly or indirectly:

(a) One business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both of the business entities.

(2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with either or both of the following:

(a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; or

(b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer no less than monthly.

(3) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession of the brokered substance.

(4) "Chain Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse and performs intra company sales or transfers of drugs to a group of chain pharmacies that have the same common ownership and control.

(5) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and exclusive group of patients and is not open for dispensing to the general patient population and cannot be registered as a wholesale distributor.

(6) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(7) "Designated Representative" means an individual designated by each wholesale distributor registered by the **b**Board who will serve as the primary contact person for the wholesale distributor with the **b**Board and who is responsible for managing the company's operations at that registered location.

(8) "Drug Sample" means a unit of a drug that is intended to promote the sale of the drug, but which is not itself for sale.

(9) “Illegitimate Product” means a product for which credible evidence shows that the product is:

(a) Counterfeit, diverted, or stolen;

(b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) The subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death.

(10) "Intra Company Transfer" means the transfer of any drug between a division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity.

(11) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(12) "Pedigree" for the purpose of this Division consists of:

(a) “Transaction History,” which means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(b) “Transaction Information,” which must include, but is not limited to:

(A) The proprietary or established name or names of the product;

(B) The strength and dosage form of the product;

(C) The National Drug Code number of the product;

(D) The container size;

(E) The number of containers;

(F) The lot number of the product;

(G) The date of the transaction;

(H) The date of the shipment, if more than 24 hours after the date of the transaction;

(I) The business name and address of the person from whom ownership is being transferred; and

(J) The business name and address of the person to whom ownership is being transferred.

(c) “Transaction Statement,” which is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with Food and Drug Administration (FDA) regulations set forth by the Drug Quality and Security Act and includes but is not limited to:

(A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain Security Act;

(B) Acknowledgement that product is received from an authorized or registered entity, as required under the Drug Supply Chain Security Act;

(C) Confirmation of receipt of transaction information and of transaction statement from the prior owner of the product, as required under the Drug Supply Chain Security Act;

(D) Verification that a suspect or illegitimate product was not knowingly shipped;

(E) Confirmation that systems and processes are in place to comply with verification requirements under the Drug Supply Chain Security Act;

(F) Confirmation that false transaction information was not knowingly provided; and

(G) Confirmation that transaction history was not knowingly altered.

(13) "Prescription Drug" means any drug required by law to be dispensed only by a prescription.

(14) “Quarantine” means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

~~(15) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacist responsible for dispensing the product to a patient.~~

~~(16) “Repackager” means a person who owns or operates an establishment that repacks and relabels a product or package for:~~

~~(a) Further sale; or~~

~~(b) Distribution without a further transaction.~~

(~~17~~**15**) “Suspect Product” means a product for which there is reason to believe that such product is:

(a) Potentially counterfeit, diverted, or stolen;

(b) Potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) Potentially the subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would result in serious adverse health consequences or death.

(~~18~~**16**) “Trading Partner” means:

(a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(~~19~~**17**) “Validate” means to verify that each transaction listed on the pedigree and other accompanying documentation has occurred and is accurately recorded.

(~~20~~**18**) "Wholesale Distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

(a) Delivery by a retail pharmacy of a prescription drug to a patient or patient's agent pursuant to the lawful order of a licensed practitioner.

(b) The sale of minimal quantities of a prescription drug by retail or institutional pharmacies to licensed practitioners for office use.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug which may include:

(A) Emergency medical reasons;

(B) Drug or devices used during a federal or state declared emergency; or

(C) The transfer of a drug by a pharmacy to another pharmacy to alleviate a temporary shortage.

(d) Intra company transfer of drugs as defined in these rules.

(e) The lawful distribution of a drug sample by a manufacturer's or a distributor's representative.

(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a non-profit affiliate of the organization to the extent permitted by law.

(g) The purchase or acquisition of a drug by a hospital or other health care entity that is a member of a group purchasing organization, for the hospital's or health care entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the organization or under common control.

(h) The transfer of a prescription drug between pharmacies pursuant to a shared pharmacy service agreement as defined in OAR 855-006-0005.

(i) The distribution by a manufacturer, as part of a prescription assistance program, of a drug intended for a specific patient, to a person authorized to prescribe, administer or dispense prescription drugs.

(j) The sale, purchase, or trade of blood and blood components intended for transfusion.

(k) Drug returns, when conducted in accordance with state and federal laws and regulations. A drug return includes the sale or transfer from a dispenser, retail pharmacy, or chain pharmacy warehouse of expired, damaged, returned or recalled drugs to the original manufacturer, wholesale distributor, or to a reverse wholesaler, and the returns of saleable drugs to the original manufacturer or wholesaler.

(l) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy.

(m) The distribution of drugs by a manufacturer registered under **OAR 855-065** division ~~65~~ of this chapter of rules of its own products to a person other than a patient.

(~~21~~**19**) "Wholesale Distributor" means any entity engaged in the wholesale distribution of drugs. The term "Wholesale Distributor" includes but is not limited to, own-label distributors; private-label distributors; warehouses, including manufacturers' and distributors' warehouses; drug wholesalers or distributors; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

(~~22~~**20**) "Wholesaler" means any wholesale distributor:

(a) "Class I Wholesaler" for the purpose of these rules means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which prescription drugs, including controlled drugs, devices containing prescription drugs, medicinal chemicals, or poisons are sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally licensed drug outlets or persons and is required to comply with all pedigree requirements;

(b) "Class II Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any non-prescription drugs are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer.

(c) “Class III Wholesaler” means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any of the products in paragraphs (A)-(F) below are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer and is exempted from Federal recordkeeping requirements:

(A) Drugs distributed exclusively for veterinary use. If any prescription drugs not intended for veterinary use are offered for sale, the wholesaler must register as a Class I wholesaler;

(B) Prescription devices that do not contain a prescription drug;

(C) Drugs or devices possessed by a state or local government agency, or non-profit relief organization approved by the **b**Board;

(D) Oxygen USP and medical gases;

(E) Intravenous drugs; by which formulation, are intended for the replenishment of fluids, electrolytes or calories;

(F) Medical convenience kits which includes any non controlled drug product or biological product, assembled in kit form.

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

Division 006/007/041/045/065– Definitions/Public Health Emergency/Operation of Pharmacies /Pharmacy Drug Compounding/Wholesale Drug Outlets (USP/Drug Storage/Labeling/Repackaging)

Need for Rules: The proposed revisions are to clarify the date of incorporated standards of reference, as discussed in with the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019).

Each year the board will adopt the updated USP-NF standards and USCs. The board is tasked with verifying that every USP-NF standard and USC is current and referenced appropriately.

Fiscal Impact:
Related to 855-041-1080 New Containers- None anticipated.

Documents Relied Upon:
United States Pharmacopeia -National Formulary <NF> (USP 43-NF38 v. 2021) https://www.uspnf.com/

Homeopathic Pharmacopoeia of the United States (HPUS) (v. 2021): https://www.hpus.com/
Related Federal Statutes/Rules:

Poison Prevention Packaging Act: 16 CFR 1700 (XX/XX/XXXX) Poison Prevention Packaging, 16 CFR 1701 (XX/XX/XXXX) Statements of Policy and Interpretation, and 16 CFR 1702 (XX/XX/XXXX) Petitions for Exemptions from Poison Preventing Packaging Act Requirements; Petition Procedures and Requirements

21 USC 351 (XX/XX/XXXX) Adulterated drugs and devices, 21 USC 352 (XX/XX/XXXX) Misbranded drugs and devices

42 USC 262 (XX/XX/XXXX) Regulation of biological products

Rules Summary:
Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Note: If language changes are made to OAR 855-006-0005, OAR 855-041-1001, 855-041-1035, or 855-041-1145 in other rule packages, this rule will be updated to reflect the same language in the other rule packages.

1

Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).

(~~1~~**2**) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(~~2~~**3**) "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 **b**~~B~~oard 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 pharmacy technicians.

(~~3~~**4**) "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.

(~~4~~**5**) "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.

(~~5~~**6**) "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.

(~~6~~**7**) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(~~7~~**8**) "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.

(~~8~~**9**) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(~~9~~**10**) "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.

(~~10~~**11**) "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.

(~~11~~**12**) "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.

(13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).

(~~12~~**14**) "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~~**must** not be construed to prohibit monitoring by practitioners or their agents.

(~~13~~**15**) "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.

(~~14~~**16**) "Nationally Certified Exam" means an exam that is approved by the **b**~~B~~oard which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible and valid.

(~~15~~**17**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(~~16~~**18**) "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.

(19) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States <HPUS> (v.2021), or any supplement to any of these.

(~~17~~**20**) "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.

(~~18~~**21**) 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.

(~~19~~**22**) "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.

(~~20~~**23**) "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 **b**~~B~~oard but has not completed the specialized education program pursuant to OAR 855-025-0012.

(~~21~~**24**) “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.

(~~22~~**25**) “Practice of pharmacy” is as defined in ORS 689.005.

(~~23~~**26**) "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.

(~~24~~**27**) “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.

(~~25~~**28**) "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.

(~~26~~**29**) “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.

(~~27~~**30**) "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.

(~~28~~**31**) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as 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 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 or pharmacy technicians;

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

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

~~(29) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action.~~

~~During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.~~

(~~30~~**32**) "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.

(~~31~~**33**) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.

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

Division 7
PUBLIC HEALTH EMERGENCY

855-007-0120
Damage to a Pharmacy and Drug Integrity

(1) If a pharmacy prescription department sustains damage, whether by flood or otherwise, the entire drug inventory, including any prescriptions that are awaiting pickup, is unfit for dispensing, ~~shall~~**must** be classified as adulterated and must be destroyed unless, ~~in the pharmacist's professional judgment~~, ~~any items are~~ **the drugs are** deemed safe for dispensing **pursuant to OAR 855-041-1036**. Any incident of this nature must be reported to the **b**~~B~~oard within three working days.

(2) If a pharmacy loses power that affects temperature or humidity controls such that ~~USP standards for~~ **the** proper storage of drugs **pursuant to OAR 855-041-1036 has**~~ve~~ been violated, such drugs ~~shall~~**must** be classified as adulterated and may not be dispensed.

~~NOTE: for those drugs labeled for storage at "controlled room temperature," the acceptable range of temperature is 68° to 77°F with allowances for brief deviations between 59° to 86°F~~.

(3) Controlled substances damaged, lost or stolen ~~shall~~**must** be documented and reported to the DEA and the **b**~~B~~oard on DEA Form 41 or DEA Form 106 as appropriate.

(4) A pharmacy that is required to temporarily close or relocate due to an emergency must report this event to the **b**~~B~~oard within three working days.

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

Division 41

OPERATION OF PHARMACIES ~~(AMBULATORY AND RESIDENTIAL DRUG OUTLETS)~~

~~855-041-1001~~

Definitions

(1) "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.

(2) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U~~.~~S~~.~~C~~.~~ 262(k)(3)(A)(i) **(v. XX/XX/XXXX)**.

(3) "Drug room" is a drug storage area registered with the **b**~~B~~oard which is secure and lockable.

(4) "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 U~~.~~S~~.~~C~~.~~ 262(k)(4) **(v. XX/XX/XXXX)**.

(5) "Reference biological product" means the biological product licensed pursuant to 42 U~~.~~S~~.~~C~~.~~ 262(a) **(v. XX/XX/XXXX)** 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.

(6) "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.

Statutory/Other Authority: ORS 689.205 & 689.522
Statutes/Other Implemented: ORS 689.155 ~~& 342 &~~ **ORS** 689.522

855-041-1035

Minimum Equipment Requirements

(1) Each retail drug outlet and institutional drug outlet **must have** the following:

(~~1~~**a**) ~~The most~~ **Appropriate and** current ~~issue of at least one~~ pharmaceutical reference**s** ~~with current, properly filed supplements~~ **(e.g. pharmacology, injectables, and veterinary drugs)** ~~and updates appropriate to and~~ based on ~~the standards of practice for the setting.~~ **services offered by the outlet;**

(~~2~~**b**) **Appropriate and** ~~C~~**c**urrent ~~and properly filed~~ Oregon Revised Statutes, ~~Chapters 689, and 475; current and properly filed~~ Oregon Administrative Rules, ~~chapter 855;.~~ **United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet** and a minimum of three years of the Board of Pharmacy quarterly newsletters ~~maintained in house or other readily retrievable means~~;

~~(3) Official Poison and Exempt Narcotic Register if poisons and exempt narcotics are sold or distributed.~~

(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(4**d**) ~~Suitable refrigeration.~~ **Appropriate equipment to maintain the proper storage of drugs;**

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;

(~~5~~**f**) A sink with running hot and cold water~~.~~**;**

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up pharmacy per OAR 855-041-2100; and

(D) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-041-2340.

(~~6~~**h**) **Additional** ~~E~~**e**quipment and supplies ~~appropriate to and based on the standards of practice for the setting as~~ **that are** determined as **necessary** by the Pharmacy ~~and~~ **or** Pharmacist-in-Charge.

(~~7~~**2**) Failure to have**,** ~~and~~ use **and maintain required** equipment ~~necessary to your practice setting~~ constitutes unprofessional conduct ~~for purposes of~~ **under** ORS 689.405(1)(a)~~.~~**;**

~~(8) If an outlet files original prescriptions electronically, then the outlet must have a computer and software capable of storing and accessing electronically filed original prescriptions.~~

~~(9) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to provide notification of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency, in compliance with federal and state regulations.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.508**,** ~~&~~ ORS 689.155**, ORS 689.515, ORS 689.564 & ORS 689.686**

855-041-1040
Drug Outlet Procedures

Each drug outlet is accountable for establishing, maintaining, and enforcing their written procedures for:

(1) Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;

(2) Performing mandatory prospective drug utilization reviews; on all prescriptions both new and refilled;

(3) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;

(4) Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;

(5) Ensuring the delivery of each completed prescription to the correct party;

(6) Providing appropriate confidential professional advice concerning medications to patients or their agents;

(7) Prescribing services and maintenance of records for prescribing pharmacist;

(8) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties;

(9) Establishing and maintaining a Continuous Quality Assurance Program; ~~and~~

(10) Providing oral interpretation and translation services for any patient who is of limited English proficiency, and prescription readers for a visually impaired patient as required by OAR 855-041-1131 and OAR 855-041-1132~~.~~**; and**

(11) Ensuring drugs are stored as required by OAR 855-041-1036.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

855-041-1080

Pharmacy Registration (Both Retail and Institutional Drug Outlets)

(1) Pharmacies ~~shall~~**must** be registered as either retail drug outlets or institutional drug outlets or both.

(2) An application for registration of a new pharmacy ~~shall~~**must** be accompanied by a floor plan drawn to scale and ~~shall~~**must** be approved by the **b**~~B~~oard prior to opening.

(3) The application ~~shall~~**must** specify the location of the pharmacy and ~~shall~~**must** indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application ~~shall~~**must** indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owner, the names of the partners or persons holding the five largest interests ~~shall~~**must** be indicated on the application;

(b) If the owner is a corporation, the name filed ~~shall~~**must** be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests ~~shall~~**must** be indicated on the application.

(4) Upon request by the **b**~~B~~oard, the applicant ~~shall~~**must** furnish such information as required by the **b**~~B~~oard regarding the partners, stockholders, or other persons not named in the application.

(5) The application ~~shall~~**must** also identify any person who has incidents of ownership in the pharmacy who also has financial interest in any long-term care facility as defined in ORS 442.015.

(6) A certificate of registration will be issued upon **b**~~B~~oard approval of the application.

(7) All registration renewal applications ~~shall~~**must** be accompanied by the annual fee and ~~shall~~**must** contain the same information required in sections (3) and (4) of this rule.

(8) The initial and annual registration fee for pharmacies is set out in **OAR 855-110**~~division 110 of this chapter~~.

(9) Pharmacy registration expires March 31, annually. If the annual registration fee referred to in **OAR 855-110**~~division 110 of this Chapter~~ is not paid by March 31 of the current year, a ~~delinquent~~**late** fee as set out in **OAR 855-110**~~division 110 of this Chapter~~ ~~shall~~**must** be included with the application for registration renewal.

(10) The registration is not transferable and the registration fee cannot be prorated.

(11) A change of ownership requires the approval of the **b**~~B~~oard and new certificate of registration. Application ~~shall~~**must** be on a form supplied by the **b**~~B~~oard.

(12) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(13) Applicants for change in ownership ~~shall~~**must** provide the **b**~~B~~oard with the information required in sections (3), (4), and (5) of this rule.

(14) A change of ownership ~~shall~~**must** be reported to the **b**~~B~~oard ~~within~~ 15 days ~~of the~~**prior to** occurrence.

(15) No pharmacy ~~shall~~**must** be operated until a certificate of registration has been issued to the pharmacy by the **b**~~B~~oard.

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

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling

~~(1)~~Prescriptions must be labeled with the following information:

(~~a~~**1**) Name, address and telephone number of the pharmacy;

(~~b~~**2**) Date **of fill**

(~~c~~**3**) Identifying number;

(~~d~~**4**) Name of patient;

(~~e~~**5**) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(~~f~~**6**) Directions for use by the patient;

(~~g~~**7**) Name of practitioner;

(~~h~~**8**) Required precautionary information regarding controlled substances;

(~~i~~**9**) Such other and further accessory cautionary information as required for patient safety;

(~~j~~**10**) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container **or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier** ~~unless, in the pharmacist's professional judgment, a shorter expiration date is warranted~~. Any drug expiring before the **expected length of time for** course of therapy ~~ends~~ must not be dispensed. ~~bearing an expiration date shall not be dispensed beyond the said expiration date of the drug; and~~

(k**11**) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall**must** be labeled with its physical description, including any identification code that may appear on tablets and capsules.

(l) Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & **ORS** 689.515

855-041-1135
Defines Labeling and Container Requirements for Repackaged Drugs

(1) Each pharmacy record keeping system must identify all pharmacy personnel involved in repackaging including the pharmacist who verified the repackaged drug.

(1**2**) **A single oral solid d**Drugs products prepackaged by a pharmacy **into unit-dose packaging** for later own use dispensing on prescription shall must:

(a) **Utilize a unit-dose container–closure system that meets the testing requirements under USP <671> Containers—Performance Testing (12/01/2020) for either Class A or Class B containers and meets or exceeds the original container's specification for light resistance;** in a container meeting USP standards and labeled to identify at a minimum:

(b) Be labeled to identify at a minimum:

(a**A**) Brand name, or generic name and manufacturer;

(b**B**) Strength;

(c**C**) **Manufacturer and l**lot number **or an internal pharmacy code that references manufacturer and lot number**; **and**

(d**D**) Manufacturer's expiration date, or any earlier date which, in the pharmacist's professional judgment, is preferable. **Expiration date. The expiration date used for the repackaged product must not exceed:**

(i) 6 months from the date of repackaging; or

(ii) The manufacturer's expiration date; or

(iii) 25% of the time between the date of repackaging and the expiration date shown on the manufacturer's bulk article container of the drug being repackaged, whichever is earlier.

(3) A single oral solid drug product repackaged by a pharmacy into multiple-unit packaging must:

(a) Utilize an equivalent container–closure system that is at least as protective as, or more protective than, the original system, complies with criteria established for equivalency and meets or exceeds the original container's specification for light resistance;

(b) Be labeled to identify at a minimum:

(A) Brand name or generic name;

(B) Strength;

(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot number; and

(D) Expiration date. The expiration date used for the repackaged product must not exceed the manufacturer's expiration date or one year from the date the drug was placed in the new container, whichever date is earlier.

(~~2~~) ~~An internal control number which references manufacturer and lot number may be utilized.~~

Statutory/Other Authority: ORS 689**.205**
Statutes/Other Implemented: **ORS 689.155**

855-041-1145
New Containers

~~In filling the original prescriptions, nothing but~~ **Each pharmacy must dispense a drug in a** new containers ~~may be used. A patient's original container may be refilled if clean and the label is legible and up-to-date. The container shall~~ **that** compli**es**~~y~~ with the current provisions of the ~~Federal Consumer~~ **Poison Prevention** Packaging Act in **16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX), and 16 CFR 1702 (XX/XX/XXXX)** ~~and rules or regulations adopted thereunder. It must also conform with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling~~.

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689**.205**
Statutes/Other Implemented: ORS 689.155

855-041-6270

Institutional Drug Outlet Pharmacy Prescription Labeling

(1) Each pharmacy record keeping system must identify **all pharmacy personnel involved in the repackaging** ~~and document~~ **including** the pharmacist who verifie**d**~~s~~ the **repackaged** drug.

(2) Each ~~pre-packed~~ **repackaged** drug, ~~including a unit-dosed drug,~~ prepared by the pharmacy and intended for use within the facility **must** ~~shall~~ be in an appropriate container with a label **that meets the requirements of OAR 855-041-1135 and includes**:

(a) The brand or generic name and expiration date;

(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;

(c) The strength of the drug.

(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:

(a) Name and location of patient;

(b) Name and strength of drug;

(c) Route of administration, when necessary for clarification;

(d) Manufacturer and lot number, or internal pharmacy code;

(e) Auxiliary labels as needed, and

(f) Expiration date.

(4) A drug that is ~~to be sent with~~ **provided** ~~the patient upon discharge~~ **for outpatient use must be dispensed by a retail drug outlet**. ~~labeled in accordance with ORS 689.505(5) and other rules in this Division. Drug counseling information must be provided to the patient or patient's agent.~~

~~(5) A label for an outpatient prescription must comply with ORS 689.505(5) and other rules in this Division.~~

(~~6~~**5**) ~~New bar coding or electronic label:~~ When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.

(~~7~~**6**) When~~ever~~ a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that ~~contains~~ **includes the**

(a) ~~The n~~**N**ame, quantity and concentration of the drug added and the primary solution;

(b) ~~The d~~**D**ate and time of addition;

(c) ~~The e~~**E**xpiration date;

(d) ~~The s~~**S**cheduled time for administration;

(e) ~~The i~~**I**nfusion rate, when applicable;

(f) ~~The n~~**N**ame or initials of person performing admixture;

(g) ~~The i~~**I**dentification of the pharmacy where the admixture was performed; and

(h) ~~The n~~**N**ame or initials of the verifying pharmacist.

(~~8~~**7**) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & **ORS** 689.505

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 shall**must** register with the **b**Board as a drug outlet and comply with **b**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)** ~~Chapters~~ **including:**

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

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

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

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

(e) ~~as well as~~ 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),** ~~825,~~ **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),** ~~and~~ 1229.5 **(08/01/2016)**~~.~~ **, 1231 (08/01/2018), and 1821 (05/01/2017).**

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

855-045-0220
Personnel and Responsibilities

(1) All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties.

(2) The Pharmacist-in-Charge (PIC) and the drug outlet shall**must** establish, maintain and enforce policies and procedures in accordance with the standards **required** in **OAR 855-045-0200(3)**~~USP Chapters~~ for all aspects of the compounding operation according to the type of compounding performed and shall**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 **b**Board within 10 working days in the event of a patient-level recall of a compounded drug.

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

855-045-0240
Labeling of Compounded Drugs

In addition to the labeling requirements specified in **OAR 855-**~~Division~~ 041, the label of a compounded drug dispensed or distributed must contain the following, at a minimum:

(1) The generic or official name of each active ingredient;

(2) The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation;

(3) The dosage form and route of administration;

(4) Rate of infusion, for a sterile parenteral preparation;

(5) The total quantity of the drug product;

(6) A **beyond-use date (**BUD**)**, compliant with ~~current USP~~ standards **required** in **OAR 855-045-0200(3)**; and

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

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

Division 65
WHOLESALE DRUG OUTLETS

855-065-0005
Definitions

(1) “Affiliate” means a business entity that has a relationship, or is an authorized trading partner, with a second business entity if, directly or indirectly:

(a) One business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both of the business entities.

(2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with either or both of the following:

(a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; or

(b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer no less than monthly.

(3) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession of the brokered substance.

(4) "Chain Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse and performs intra company sales or transfers of drugs to a group of chain pharmacies that have the same common ownership and control.

(5) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and exclusive group of patients and is not open for dispensing to the general patient population and cannot be registered as a wholesale distributor.

(6) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(7) "Designated Representative" means an individual designated by each wholesale distributor registered by the **b**Board who will serve as the primary contact person for the wholesale distributor with the **b**Board and who is responsible for managing the company's operations at that registered location.

(8) "Drug Sample" means a unit of a drug that is intended to promote the sale of the drug, but which is not itself for sale.

(9) “Illegitimate Product” means a product for which credible evidence shows that the product is:

(a) Counterfeit, diverted, or stolen;

(b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) The subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death.

(10) "Intra Company Transfer" means the transfer of any drug between a division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity.

(11) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(12) "Pedigree" for the purpose of this Division consists of:

(a) “Transaction History,” which means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(b) “Transaction Information,” which must include, but is not limited to:

(A) The proprietary or established name or names of the product;

(B) The strength and dosage form of the product;

(C) The National Drug Code number of the product;

(D) The container size;

(E) The number of containers;

(F) The lot number of the product;

(G) The date of the transaction;

(H) The date of the shipment, if more than 24 hours after the date of the transaction;

(I) The business name and address of the person from whom ownership is being transferred; and

(J) The business name and address of the person to whom ownership is being transferred.

(c) “Transaction Statement,” which is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with Food and Drug Administration (FDA) regulations set forth by the Drug Quality and Security Act and includes but is not limited to:

(A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain Security Act;

(B) Acknowledgement that product is received from an authorized or registered entity, as required under the Drug Supply Chain Security Act;

(C) Confirmation of receipt of transaction information and of transaction statement from the prior owner of the product, as required under the Drug Supply Chain Security Act;

(D) Verification that a suspect or illegitimate product was not knowingly shipped;

(E) Confirmation that systems and processes are in place to comply with verification requirements under the Drug Supply Chain Security Act;

(F) Confirmation that false transaction information was not knowingly provided; and

(G) Confirmation that transaction history was not knowingly altered.

(13) "Prescription Drug" means any drug required by law to be dispensed only by a prescription.

(14) “Quarantine” means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

~~(15) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacist responsible for dispensing the product to a patient.~~

~~(16) “Repackager” means a person who owns or operates an establishment that repacks and relabels a product or package for:~~

~~(a) Further sale; or~~

~~(b) Distribution without a further transaction.~~

(~~17~~**15**) “Suspect Product” means a product for which there is reason to believe that such product is:

(a) Potentially counterfeit, diverted, or stolen;

(b) Potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) Potentially the subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would result in serious adverse health consequences or death.

(~~18~~**16**) “Trading Partner” means:

(a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(~~19~~**17**) “Validate” means to verify that each transaction listed on the pedigree and other accompanying documentation has occurred and is accurately recorded.

(~~20~~**18**) "Wholesale Distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

(a) Delivery by a retail pharmacy of a prescription drug to a patient or patient's agent pursuant to the lawful order of a licensed practitioner.

(b) The sale of minimal quantities of a prescription drug by retail or institutional pharmacies to licensed practitioners for office use.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug which may include:

(A) Emergency medical reasons;

(B) Drug or devices used during a federal or state declared emergency; or

(C) The transfer of a drug by a pharmacy to another pharmacy to alleviate a temporary shortage.

(d) Intra company transfer of drugs as defined in these rules.

(e) The lawful distribution of a drug sample by a manufacturer's or a distributor's representative.

(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a non-profit affiliate of the organization to the extent permitted by law.

(g) The purchase or acquisition of a drug by a hospital or other health care entity that is a member of a group purchasing organization, for the hospital's or health care entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the organization or under common control.

(h) The transfer of a prescription drug between pharmacies pursuant to a shared pharmacy service agreement as defined in OAR 855-006-0005.

(i) The distribution by a manufacturer, as part of a prescription assistance program, of a drug intended for a specific patient, to a person authorized to prescribe, administer or dispense prescription drugs.

(j) The sale, purchase, or trade of blood and blood components intended for transfusion.

(k) Drug returns, when conducted in accordance with state and federal laws and regulations. A drug return includes the sale or transfer from a dispenser, retail pharmacy, or chain pharmacy warehouse of expired, damaged, returned or recalled drugs to the original manufacturer, wholesale distributor, or to a reverse wholesaler, and the returns of saleable drugs to the original manufacturer or wholesaler.

(l) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy.

(m) The distribution of drugs by a manufacturer registered under **OAR 855-065** division ~~65~~ of this chapter of rules of its own products to a person other than a patient.

(~~21~~**19**) "Wholesale Distributor" means any entity engaged in the wholesale distribution of drugs. The term "Wholesale Distributor" includes but is not limited to, own-label distributors; private-label distributors; warehouses, including manufacturers' and distributors' warehouses; drug wholesalers or distributors; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

(~~22~~**20**) "Wholesaler" means any wholesale distributor:

(a) "Class I Wholesaler" for the purpose of these rules means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which prescription drugs, including controlled drugs, devices containing prescription drugs, medicinal chemicals, or poisons are sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally licensed drug outlets or persons and is required to comply with all pedigree requirements;

(b) "Class II Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any non-prescription drugs are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer.

(c) “Class III Wholesaler” means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any of the products in paragraphs (A)-(F) below are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer and is exempted from Federal recordkeeping requirements:

(A) Drugs distributed exclusively for veterinary use. If any prescription drugs not intended for veterinary use are offered for sale, the wholesaler must register as a Class I wholesaler;

(B) Prescription devices that do not contain a prescription drug;

(C) Drugs or devices possessed by a state or local government agency, or non-profit relief organization approved by the **b**Board;

(D) Oxygen USP and medical gases;

(E) Intravenous drugs; by which formulation, are intended for the replenishment of fluids, electrolytes or calories;

(F) Medical convenience kits which includes any non controlled drug product or biological product, assembled in kit form.

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

Division 010 – Board Administration and Policies (Procedural Rule Review)

Filing Caption (max 15 words):

- Proactive procedural rule review. Incorporates directives of 2021 HB 2992 modifying compensation of board members.

Need for Rules:

- 2021 HB 2992 Modifies amount of compensation paid to members of state boards. Requires state boards to pay compensation and expenses to certain members with adjusted gross income below certain threshold. Provides that members may decline to accept compensation or reimbursement.

- Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Fiscal Impact:

- 2021-2023 Biennium: Increase of $55 per member per meeting resulting in a total of a $23,555 increase in Board member and Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) member compensation. *Note: August 2021 board meeting and September 2021 PHPFAC meetings held prior to 2021 HB 2992's effective date of 9/25/2021 were paid at the rate previously adopted by the board.*

- 2023-2025 Biennium: Estimated increase to GSA rate in 2023 of 2.65% results in a total of a $25,745 for Board member and Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) member compensation.

Documents Relied Upon:

- 2021 HB 2992 Modifies amount of compensation paid to members of state boards and commissions

- ORS 292.495 Compensation and expenses of members of state boards and commissions.

- ORS 171.072 Salary of members and presiding officers; per diem allowance; expenses; tax status

Rules Summary:

- Modifies amount of compensation paid to board members and Public Health and Formulary Advisory Committee members of the Oregon Board of Pharmacy. Requires board to pay compensation and expenses to certain members with adjusted gross income below threshold outlined in ORS 292.495. Provides that members may decline to accept compensation or reimbursement. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Division 10
BOARD ADMINISTRATION AND POLICIES

~~**855-010-0001**~~
~~**Definitions**~~

~~(1) "Accredited": In these rules, accredited shall mean a school or college that is currently accredited by the Accreditation Council for Pharmacy Education (ACPE) or that is in a pre-candidate or candidate status with ACPE.~~

~~(2) "Board" means Oregon State Board of Pharmacy.~~

~~Statutory/Other Authority: ORS 475.005 & 689.205~~
~~Statutes/Other Implemented: ORS 689.115~~

855-010-0005
Meetings

(1) The ~~B~~**b**oard meetings ~~shall~~**must** be held not less than once every three months as designated by the ~~B~~**b**oard.

(2) The President of the ~~B~~**b**oard ~~shall~~**must** have 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 ~~B~~**b**oard ~~shall~~**must** hold an annual meeting each year for the election of officers, the reorganization of the ~~B~~**b**oard 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**)** ~~programs~~;

~~(b) Approval of preceptor sites;~~

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

(**c**~~d~~) Review and adopt **standards** by reference ~~the Federal list of controlled substances~~.

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

855-010-0015
Individual Commitments

(1) Board members ~~shall~~ **must** be governed by ~~B~~**b**oard action and ~~shall~~ **must** make no individual commitments or promises on matters of ~~B~~**b**oard policies.

(2) No declaration ~~shall~~ **must** be made ~~n~~or vote taken on any question, except at ~~B~~**b**oard meetings. ~~However, after due notification to each Board member, emergency votes may be taken by telephone conference or mail ballot of a majority of Board members, such vote to be confirmed at the next Board meeting.~~

Statutory/Other Authority: ORS 689; **ORS 183**
Statutes/Other Implemented: ORS 183

855-010-0016

Board Administration and Policies: Pharmacy Board Member ~~or~~ **and Public Health and Pharmacy Formulary** ~~Formal~~ Advisory Committee Member Compensation

(1) A board member ~~or member of an advisory committee~~ **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** ~~up to $100 compensation~~ when engaged in the performance of official duties for each day **or portion thereof.**~~, calculated as whichever amount is the greater of:~~

~~(a) $50 after a minimum of three hours of service; or~~

~~(b) $100 after a minimum of six hours of service.~~

(2) For the purpose of compensation, a board member or member of ~~an~~ **the Public Health and Pharmacy Formulary** ~~a~~**A**dvisory ~~c~~**C**ommittee is considered engaged in the performance of official duties when:

(a) The activity furthers the ~~B~~**b**oard'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 ~~of an official appointed advisory committee, such as the Public Health & Pharmacy Formulary Advisory Committee 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) ~~No~~ **A** board **member** or **Public Health and Pharmacy Formulary Advisory** ~~c~~**C**ommittee member ~~shall be~~ **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 29~~4~~**2**.495, ORS 689.175, ORS 689.645**,** ~~& 2017 OL Ch. 106~~ **ORS 689.649 & ORS 171.072**

855-010-0021
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 ~~B~~**b**oard 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
Board Compliance Program

The ~~B~~**b**oard's Compliance Director and ~~Pharmacy Inspectors~~ **Compliance Officers** ~~shall~~ **must** be pharmacists licensed in the State of Oregon.

Statutory/Other Authority: ORS 689**.205**
Statutes/Other Implemented: ORS 689.195

855-010-0100
State and Nationwide Criminal Background Checks for Licensure

(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 ~~B~~**b**oard, 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 ~~B~~**b**oard.

(2) "Subject individual" means a person from whom the ~~B~~**b**oard 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 ~~B~~**b**oard.

(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,** ~~to~~ **ORS** 181A.215, ORS 670.280, OR**S** 676.303, ~~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,** ~~to~~ **OAR** 125-007-0310**, and OAR 125-007-0330**.

(a) The ~~B~~**b**oard will request that the Oregon Department of State Police conduct a state and nationwide criminal records check, using fingerprint identification of subject individuals. The ~~B~~**b**oard 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 ~~to~~ **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 ~~B~~**b**oard 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 ~~B~~**b**oard 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 ~~B~~**b**oard 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 ~~B~~**b**oard ~~shall~~**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 ~~shall~~ **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 ~~to~~ **and ORS** 419A.262.

(k) Under no circumstances ~~shall~~ **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 ~~shall~~ **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 ~~B~~**b**oard 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,** ~~to~~ **and ORS 183.**470 and in accordance with OAR 855-001-0005**, OAR 855-001-0012, OAR 855-001-0016,** ~~to~~ **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 ~~B~~**b**oard, the ~~B~~**b**oard 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
State and Nationwide Criminal Background Checks for Employees, Volunteers and Employment Applicants

(1) The ~~B~~**b**oard requires a criminal records check and fitness determination for ~~B~~**b**oard employees, volunteers or applicants for employment with the ~~B~~**b**oard.

(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,** ~~to~~ **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,** ~~to~~ **and OAR** 125-007-0310.

(a) To complete the criminal records check and fitness determination, the ~~B~~**b**oard 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 ~~B~~**b**oard 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 ~~B~~**b**oard 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
Criminal Background Checks – Costs ~~Fees~~

The applicant or licensee must pay **the board** ~~a criminal records check fee for~~ the cost of acquiring and furnishing the criminal offender information. The **amount** ~~fee~~ will not exceed the cost to the ~~B~~**b**oard to obtain such information **on behalf of the applicant or licensee**, including fees charged to the ~~B~~**b**oard by the **Oregon Department of State Police** ~~OSP~~ and the **Federal Bureau of Investigation** ~~FBI~~.

Statutory/Other Authority: ORS 676.303 & ORS 689.205
Statutes/Other Implemented: ORS 676.303, ORS 181A**.195** & ORS 689.207

855-010-0130
Military Spouse or Domestic Partner

(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 or OAR 855-025.

(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 ~~B~~**b**oard 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 or pharmacy technician issued by another state;

(e) Provide to the ~~B~~**b**oard, in a manner determined by the ~~B~~**b**oard, 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 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** ~~2019 OL Ch. 142 & 2019 OL Ch. 626~~

Division 041, 043 & 044 – Operation of Pharmacies/Practitioner Dispensing/Charitable Pharmacies (LEP: Informational Inserts)

Filing Caption (15 word limit)**:** Clarifies the definition and requirements for an informational insert.

Need for Rules:

1. These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to Limited English Proficiency (LEP) patients. The requirements apply to pharmacies and dispensing drug outlets.

2. The proposed revisions are to clarify the date of incorporated standards of reference, as discussed in with the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019). Each year the Board will adopt the updated USCs. The board is tasked with verifying that every USC is current and referenced appropriately.

Fiscal Impact:

The clarification of the definition and requirements for an informational insert may have a fiscal impact to Oregon registered pharmacies and dispensing drug outlets. Additional costs for informational inserts may be included in the original estimates to comply with the directives of 2019 SB 698. The estimated costs for pharmacies to comply with the rules effective 1/1/2021 ranged from $1-5M depending on the number of locations affected.

Documents relied upon include:

ORS 689.505 Labeling requirements; rules

Related Federal Statutes/Rules: 42 USC 262 (XX/XX/XXXX)

NCPDP Script (v10.6) Implementation Document v. 1.58- 16.1.2 Directions/Sig (pg. 153)

NABP Understanding the Updated SCRIPT National E-prescribing Standard (pg. 22)

Rules Summary:

Address directives of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to LEP patients. These requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Note:

Repeal of OAR 855-043-0436 and 855-043-0002(9) related to Supervising Physician Dispensing Outlets will occur to incorporate changes to physician assistant (PA) scope set forth in 2021 HB 3036, related to dispensing prescription drugs, effective 3/31/2021.

OAR 855-041-1035 and OAR 855-139-0155 relate to Outlet: Minimum Equipment Requirements and are included here for reference as OAR 855-041-1035(1)(g)(B) and OAR 855-139-0155(1)(g)(B) include signage requirements for translated prescription labels.

Division 41
OPERATION OF PHARMACIES

855-041-1001
Definitions

(1) "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.

(2) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i) **(XX/XX/XXXX)**.

(3) "Drug room" is a drug storage area registered with the Board which is secure and lockable.

(4) "Informational insert" is an auxiliary document containing directions for use and other prescription information that is provided to the patient in both English and the language requested.

(45) "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 U.S.C. 262(k)(4) **(XX/XX/XXXX)**.

(6) "Limited English proficiency" means not fluent in the English language.

(57) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) **(XX/XX/XXXX)** 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.

(8) "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.

(9) "Temperature excursion" means an event in which a drug is exposed to a temperature outside of the manufacturers recommended storage conditions.

Statutory/Other Authority: ORS 689.205 & 689.522
Statutes/Other Implemented: ORS 689.155 ~~& 342 &~~ **ORS** 689.522**, & ORS 689.564**

855-041-1132

Limited English Proficiency and Accessibility

(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency~~, defined as a person who is not fluent in the English language~~. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide **a prescription** label~~s~~ and**, when needed, an** informational insert~~s~~ in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(**l**) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

(4) An informational insert may be used when the directions for use in English and the language requested exceed 140 characters.

(5) When an informational insert is used, the prescription label affixed to the prescription container must state in both English and the language requested by the patient that an informational insert is being used.

(6) At a minimum, the informational insert must include the:

(a) Directions for use by the patient in both English and the language requested;

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

855-041-1035
Minimum Equipment Requirements

(1) Each retail drug outlet and institutional drug outlet **must have** the following:

(~~1~~**a**) ~~The most~~ **Appropriate and** current ~~issue of at least one~~ pharmaceutical reference**s** ~~with current, properly filed supplements~~ **(e.g. pharmacology, injectables, and veterinary drugs)** ~~and updates appropriate to and~~ based on ~~the standards of practice for the setting.~~ **services offered by the outlet;**

(~~2~~**b**) **Appropriate and** ~~C~~**c**urrent ~~and properly filed~~ Oregon Revised Statutes, ~~Chapters 689, and 475; current and properly filed~~ Oregon Administrative Rules, ~~chapter 855;.~~ **United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet** and a minimum of three years of the Board of Pharmacy quarterly newsletters ~~maintained in house or other readily retrievable means~~;

~~(3) Official Poison and Exempt Narcotic Register if poisons and exempt narcotics are sold or distributed.~~

(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(~~4~~**d**) ~~Suitable refrigeration.~~ **Appropriate equipment to maintain the proper storage of drugs;**

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;

(~~5~~**f**) A sink with running hot and cold water~~.~~**;**

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up pharmacy per OAR 855-041-2100; and

(D) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-041-2340.

(~~6~~h) **Additional** ~~E~~equipment and supplies ~~appropriate to and based on the standards of practice for the setting as~~ **that are** determined as **necessary** by the Pharmacy ~~and~~ **or** Pharmacist-in-Charge.

(~~7~~2) Failure to have**,** ~~and~~ use **and maintain required** equipment ~~necessary to your practice setting~~ constitutes unprofessional conduct ~~for purposes of~~ **under** ORS 689.405(1)(a)~~.~~**;**

~~(8) If an outlet files original prescriptions electronically, then the outlet must have a computer and software capable of storing and accessing electronically filed original prescriptions.~~

~~(9) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to provide notification of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency, in compliance with federal and state regulations.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.508**,** ~~&~~ ORS 689.155**, ORS 689.515, ORS 689.564 & ORS 689.686**

Division 43
PRACTITIONER DISPENSING

855-043-0002
Definitions

In this division of rules:

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

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

(b) The patient at the direction of the practitioner.

(2) "Counseling" means an oral or other appropriate communication process between a practitioner and a patient or a patient's agent in which the practitioner obtains information from the patient or patient's agent, and, where appropriate, the patient's medical 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.

(~~2~~**3**) "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(4) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(~~3~~**5**) "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or preventative measures such as immunization or birth control approved by the Board or by the Department of Human Services (DHS).

(~~4~~**6**) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of Naturopathic Medicine and employed by or under contract with a county or district health department or DHS.

(7) "Informational insert" is an auxiliary document containing directions for use and other prescription information that is provided to the patient in both English and the language requested.

(8) "Limited English proficiency" means not fluent in the English language.

~~(5~~**9**~~) "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center, treatment center, or other establishment from which a physician assistant dispenses drugs, but that is not otherwise registered with the Board in the category of Retail Drug Outlet.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **& ORS 689.564**

855-043-0436

Supervising Physician Dispensing Outlet - Limited English Proficiency and Accessibility

(1) Upon request of a patient or a patient's agent, each drug dispensed by a drug outlet for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide **a prescription** labels ~~s~~ and**, when needed, an** informational inserts~~s~~ in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

(4) An informational insert may be used when the directions for use in English and the language requested exceed 140 characters.

(5) When an informational insert is used, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used.

(6) At a minimum, the informational insert must include the:

(a) Directions for use by the patient in both English and the language requested;

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

855-043-0541
Dispensing Practitioner Drug Outlet - Limited English Proficiency and Accessibility

(1) Upon request of a patient or a patient's agent, each drug dispensed by a drug outlet for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide **a prescription** labels and**, when needed, an** informational inserts in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;
(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

(4) An informational insert may be used when the directions for use in English and the language requested exceed 140 characters.

(5) When an informational insert is used, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used.

(6) At a minimum, the informational insert must include the:

(a) Directions for use by the patient in both English and the language requested;

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

Division 44
CHARITABLE PHARMACIES

855-044-0005
Definitions

(1) "Charitable Pharmacy" means a facility registered with the Oregon Board of Pharmacy for the purpose of receiving and distributing donated drugs.

(2) "Informational insert" is an auxiliary document containing directions for use and other prescription information that is provided to the patient in both English and the language requested.

(3) "Limited English proficiency" means not fluent in the English language.

(~~2~~**4**) "Point-of-Contact" means an individual designated by a charitable pharmacy who serves as the primary contact person for the charitable pharmacy and who is responsible for managing the charitable pharmacy at that location.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.772**, &** ~~&~~ **ORS** 689.774, **& ORS 689.564**

855-044-0061
Charitable Pharmacies - Limited English Proficiency and Accessibility

(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide **a prescription** label~~s~~ and**, when needed, an** informational insert~~s~~ in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

(4) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to provide notification of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency, in compliance with federal and state regulations.

(5) An informational insert may be used when the directions for use in English and the language requested exceed 140 characters.

(6) When an informational insert is used, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used.

(7) At a minimum, the informational insert must include the:

(a) Directions for use by the patient in both English and the language requested;

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

Division 141
REMOTE DISPENSING SITE PHARMACY

855-139-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon Retail Drug Outlet Remote Dispensing Site Pharmacy must have the following:

(a) Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary drugs) services offered by the outlet;

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;

(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(d) Appropriate equipment to maintain the proper storage of drugs;

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;

(f) A sink with running hot and cold water;

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-139-0062 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-139-0215; and

(D) Stating "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed Pharmacist from (insert name of Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and

(h) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

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

Division 019/139– Pharmacists/Operation of Pharmacies (Remote Dispensing Site Pharmacy/Telepharmacy)

Filing Caption (15 word limit)**:** 2021 SB 629 Allows use of telepharmacy to deliver pharmacy services at a remote location

Need for Rules:

Revision to Division 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location.

Fiscal Impact:

2021 SB 629 does not have a fiscal impact to the agency. If a pharmacy chooses to operate a Remote Dispensing Site Pharmacy via telepharmacy, the pharmacy will be required to apply and pay a registration fee for the Remote Dispensing Site Pharmacy.

Documents relied upon include:

2021 SB 629 and related statutes

Rules Advisory Committee- Pharmacy Technicians May 2021 minutes, August 2021 minutes, & September 2021 minutes.

United States Pharmacopeia -National Formulary <NF> (USP 43-NF38 v. 2021) https://www.uspnf.com/

Related Federal Statutes/Rules:

Poison Prevention Packaging Act: 16 CFR 1700 (XX/XX/XXXX) Poison Prevention Packaging, 16 CFR 1701 (XX/XX/XXXX) Statements of Policy and Interpretation, and 16 CFR 1702 (XX/XX/XXXX) Petitions for Exemptions from Poison Preventing Packaging Act Requirements; Petition Procedures and Requirements

42 USC 262 (XX/XX/XXXX) Regulation of biological products

21 CFR 1301.52 (XX/XX/XXXX) Modification, transfer and termination of registration

Rules Summary:

Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

Resources:

Remote dispensing sites utilizing telepharmacy technologies- Telepharm

Division 19
PHARMACISTS

855-019-0300
Duties of a Pharmacist-in-Charge

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis.

(2) In order to be a PIC, a pharmacist must have:

(a) Completed at least one year of pharmacy practice; or

(b) Completed a board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the board, this course may be employer provided and may qualify for continuing education credit.

(3) A pharmacist may not be designated PIC of more than ~~two~~ **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.

(4) The PIC must perform the following the duties and responsibilities:

(a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to the board within 15 days of the occurrence, on a form provided by the board;

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

(c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;

(e) A pharmacist designated as PIC for more than one pharmacy must personally conduct and document a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit Form provided by the board;

(f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within 30 days of receiving notice.

(g) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;

(g) Implementing a quality assurance plan for the pharmacy.

(h) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

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

Division 141
REMOTE DISPENSING SITE PHARMACY

855-139-0001
Purpose and Scope

The purpose of OAR 855-139 is to provide minimum requirements for the locations where telepharmacy services are conducted.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155

855-139-0005
Definitions

The following words and terms, when used in OAR 855-139, have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section has the definition set out in OAR 855-006.

(1) "Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon where an Oregon licensed Pharmacist provides pharmacy services through a telepharmacy system.

(2) "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.

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

(4) "Informational insert" is an auxiliary document containing directions for use and other prescription information that is provided to the patient in both English and the language requested.

(5) "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) (XX/XX/XXXX).

(6) "Limited English proficiency" means not fluent in the English language.

(7) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) (XX/XX/XXXX) 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.

(8) "Remote Dispensing Site Pharmacy" means an Oregon location registered as a Retail Drug Outlet Remote Dispensing Site Pharmacy staffed by a Certified Oregon Pharmacy Technician under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.

(9) "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.

(10) "Telepharmacy" means the delivery of pharmacy services by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician.

(11) "Telepharmacy system" means a system of telecommunications technologies that enables monitoring, documenting and recording of the delivery of pharmacy services at a remote location by an electronic method which must include the use of audio and video, still image capture, and store and forward.

(12) "Temperature excursion" means an event in which a drug is exposed to a temperature outside of the manufacturers recommended storage conditions.

(13) "Still image capture" means a specific image captured electronically from a video or other image capture device.

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

Statutory/Other Authority: ORS 689.205**, ORS** 689.522**, 2021 SB 629**
Statutes/Other Implemented: ORS 689.155, **ORS** 689.522**, ORS 689.564, 2021 SB 629**

855-139-0010
Registration: General

(1) A location in Oregon where the practice of pharmacy occurs by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician must be registered by the board in Oregon as a Retail Drug Outlet Remote Dispensing Site Pharmacy.

(2) If controlled substances are stored in the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy must have an active Controlled Substance Registration Certificate with the Board and Drug Enforcement Administration (DEA).

(3) A Retail Drug Outlet Remote Dispensing Site Pharmacy application must specify the Affiliated Pharmacy and cannot operate without an Affiliated Pharmacy that is registered by the board as a Retail Drug Outlet Pharmacy.

(4) All registration renewal applications must be accompanied by the annual fee and must contain the same information required in OAR 855-139-0011(3) and (4).

(5) The initial and annual registration fee for pharmacies is set out in OAR 855-110.

(6) Retail Drug Outlet Remote Dispensing Site Pharmacy registration expires March 31, annually. If the annual registration fee referred to in OAR 855-110 is not paid by March 31 of the current year, a late fee as set out in OAR 855-110 must be included with the application for registration renewal.

(7) The registration is not transferable and the registration fee cannot be prorated.

(8) No Remote Dispensing Site Pharmacy may be operated until a certificate of registration has been issued to the pharmacy by the Board.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, 2021 SB 629

855-139-0015
Registration: Application

(1) An application for registration of a new Remote Dispensing Site Pharmacy must be accompanied by a floor plan drawn to scale and must be approved by the Board prior to opening.

(2) The application must specify the location of the Remote Dispensing Site Pharmacy and must indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application must indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owners, the names of the partners or persons holding the five largest interests must be indicated on the application;

(b) If the owner is a corporation, the name filed must be the same as filed with the Secretary of State. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests must be indicated on the application.

(3) Upon request by the Board, the applicant must furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

(4) A certificate of registration will be issued upon Board approval of the application.

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

855-139-0020
Registration: Change of Owner, Location, or Affiliated Pharmacy

(1) A change of location of the Affiliated Pharmacy or location of the Retail Drug Outlet Remote Dispensing Site Pharmacy requires:

(a) Submission of a new Retail Drug Outlet Remote Dispensing Site Pharmacy application 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the Board; and

(d) New certificate of registration.

(2) A change in the Affiliated Pharmacy or ownership of the Retail Drug Outlet Remote Dispensing Site Pharmacy requires:

(a) Submission of a new Retail Drug Outlet Remote Dispensing Site Pharmacy application 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the Board; and

(d) New certificate of registration.

(3) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(4) A certificate of registration will be issued upon Board approval of the application.

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

855-139-0025
Registration: Change of Business Name or Closure

(1) An Affiliated Pharmacy must notify the board 15 days prior to any change of business name of a Retail Drug Outlet Remote Dispensing Site Pharmacy. The change must be reported by filing a new application for which no fee is required.

(2) An Affiliated Pharmacy must notify the board 15 days prior to discontinuing operation of a Retail Drug Outlet Remote Dispensing Site Pharmacy. Notification must include the:

(a) Final disposition of drugs stored in the Retail Drug Outlet Remote Dispensing Site Pharmacy including:

(A) Name and location where the drugs are transferred;

(B) Name and location where destruction occurred; and

(C) Name and location of the site that will store all records;

(c) Transfer all Schedule II medications on DEA 222 forms, and Schedule III, IV and V by invoice;

(d) Provide the board with:

(A) Oregon Board of Pharmacy state license(s); and

(B) Signed statement giving the effective date of closure; and

(e) Comply with the requirements of 21 CFR 1301.52 (XX/XX/XXXX).

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

855-139-0030
Non-Resident Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes an Affiliated Pharmacy located outside of Oregon and providing pharmacy services through a telepharmacy system to a Retail Drug Outlet Remote Dispensing Site Pharmacy located in Oregon.

(2) Each non-resident Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every non-resident 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 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 pharmacy. 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 Affiliated Pharmacy a minimum of 20 hours per week;

(c) Complete the annual Remote Dispensing Site Pharmacy PIC self-inspection report prior to February 1 each year; and

(d) Provide the PIC self-inspection report as requested by the Board.

(5) Every non-resident Affiliated Pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon prior to initial registration of the Remote Dispensing Site Pharmacy.

(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

855-139-0050
Personnel

(1) The Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy is responsible for all operations at the Remote Dispensing Site Pharmacy including responsibility for the telepharmacy system and enforcing policies and procedures.

(2) A Remote Dispensing Site Pharmacy may not utilize Interns, Pharmacy Technicians, or unlicensed personnel.

(3) A Certified Oregon Pharmacy Technician working at a Remote Dispensing Site Pharmacy is required to have at least one year experience working at an Oregon registered Retail Drug Outlet Pharmacy during the three years preceding the date the Certified Oregon Pharmacy Technician begins working at the Remote Dispensing Site Pharmacy.

(4) The Oregon licensed Pharmacist from the Affiliated Pharmacy who is supervising a Remote Dispensing Site Pharmacy must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided.

(5) When supervising a Certified Oregon Pharmacy Technician working at a Remote Dispensing Site Pharmacy and licensees at an Affiliated Pharmacy, the Oregon licensed Pharmacist may supervise no more than four licensees.

(6) The Affiliated Pharmacy is required to comply with the pharmacist's determination in (4) and retain records.

(7) The Remote Dispensing Site Pharmacy and Affiliated Pharmacy must ensure adequate staffing at both the Remote Dispensing Site Pharmacy and Affiliated Pharmacy.

(8) Prior to working at a Remote Dispensing Site Pharmacy, the Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the Remote Dispensing Site Pharmacy must have completed a training program on the proper use of the telepharmacy system.

(9) An Affiliated Pharmacy that terminates or allows a Board licensee to resign in lieu of termination must report the termination or resignation to the Board within 10 working days.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305

855-139-0100
Security

(1) The area in a registered Remote Dispensing Site Pharmacy where legend and/or controlled substances are stored, possessed, prepared, compounded or repackaged must be restricted in access by utilizing physical barriers to include floor to ceiling walls and a locked separate entrance to ensure the security of those drugs.

(2) The Affiliated Pharmacy, the Remote Dispensing Site Pharmacy, Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the Remote Dispensing Site Pharmacy is responsible for the security of the prescription area including provisions for adequate safeguards against loss, theft or diversion of prescription drugs, and records for such drugs.

(3) The Remote Dispensing Site Pharmacy must be locked and the security system armed to prevent entry when:

(a) There is no Oregon licensed Pharmacist from the Affiliated Pharmacy actively supervising the Remote Dispensing Site Pharmacy; or

(b) There is no Certified Oregon Pharmacy Technician present in the Remote Dispensing Site Pharmacy; or

(c) Any component of the telepharmacy system is not functioning.

(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the Remote Dispensing Site Pharmacy.

(5) No one may be in the prescription area of a Remote Dispensing Site Pharmacy unless authorized in real-time by an Oregon licensed Pharmacist who is supervising the Remote Dispensing Site Pharmacy and from the Affiliated Pharmacy.

(6) Minimum security methods must include a properly functioning:

(a) Alarm system with an audible alarm at the Remote Dispensing Site Pharmacy and real-time notification to a designated licensee of the Affiliated Pharmacy;

(b) Electronic keypad or other electronic entry system that records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the Remote Dispensing Site Pharmacy;

(B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the Remote Dispensing Site Pharmacy; and

(C) Date and time of each activity.

(c) Surveillance system that utilizes continuously accessible and recorded two-way audiovisual link between the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy. The system must provide a clear view of:

(A) Dispensing site entrances;

(B) Preparation areas;

(C) Drug storage areas;

(D) Pick up areas;

(E) Office areas; and

(F) Publicly accessible areas.

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

855-139-0120
Drug: Receipt

Remote Dispensing Site Pharmacy may only receive drugs from an Oregon Registered Drug Outlet (i.e. Wholesaler, Manufacturer or Pharmacy).

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

855-139-0125
Drug: Storage

(1) A pharmacy must store each drug according to the manufacturer's storage requirements for temperature, light, humidity, sanitation, ventilation, and space.

(2) If the drug's manufacturer does not include a storage requirement, the drug must be stored as outlined in an official compendium, to ensure that the drug identity, strength, quality, and purity are not adversely affected.

(3) Each pharmacy must:

(a) Unless the manufacturer specifies differently, maintain drug required to be stored at controlled room temperature between 20-25 °C (68 to 77 °F); refrigerated products between 2 to 8 °C (35.6 to 46.4 °F); frozen products between -25 to -10 °C (-13 to 14 °F);

(b) Utilize continuous temperature monitoring device(s) that have a buffered probe (glycol, glass beads, or similar), are centrally located, accurate, calibrated within a plus or minus 0.5°C variance and record the temperature of each drug storage area at least every 15 minutes;

(c) Review all temperature data for the last 24 hours twice daily for proper drug storage and for temperature excursions. Date, time and identity of the reviewer must be documented;

(d) Utilize a system that notifies a pharmacist of each temperature excursion in real-time;

(e) Ensure drug storage refrigerators and freezers are dedicated to drugs and vaccines only and utilize refrigerator or freezer compartments with its own exterior door and independent thermostat control;

(f) Position drugs in refrigerators and freezers leaving space between the drugs, walls, ceiling, floor, and door to promote air circulation. If using a household grade unit, drugs may not be stored in any part of the unit that does not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in drawers, or on refrigerator door shelves;

(g) Maintain proper drug storage conditions during transfers between facilities and delivery to patients;

(h) Ensure that drugs stored outside of the manufacturer's drug storage requirements are physically separated from other drugs until the manufacturer determines that the drug is safe and effective for continued use, is safe and effective for continued use with limitations (ie. shortened expiration date), needs to be returned to the supplier, or destroyed;

(i) Ensure that the following is completed at a minimum of every 3 months:

(A) Test and document that all components of the temperature monitoring system(s) for each storage area are recording temperature accurately and issuing appropriate alerts;

(B) Review and assess temperature records for long-term trends or recurring problems. Date, time and identity of the reviewer must be documented;

(j) Establish, maintain, and enforce a written quality assurance plan to prevent, identify, and appropriately respond to temperature excursions;

(k) Establish, maintain, and enforce a written action plan to ensure proper drug storage in the event of an emergency (i.e. power outage or natural disaster) that includes identification of backup storage and a procedure for transfer of product between units or facilities;

(l) Document the training of all pharmacy personnel on use of temperature monitoring system(s), quality assurance plan and written emergency action plan to ensure proper drug storage in the event of an emergency;

(m) Recalibrate temperature monitoring device(s) at least once every 24 months or per manufacturer specifications, whichever is more frequent;

(n) Document the following for each temperature excursion:

(A) Date of temperature excursion;

(B) Start and end time;

(C) Minimum and maximum temperatures reached;

(D) List of each drug involved in the temperature excursion including the drug name, quantity, National Drug Code, lot number, expiration date, manufacturer, and the date(s) of previous temperature excursions experienced by the drug(s);

(E) Each drug involved in the temperature excursion must be clearly labeled with the date of temperature excursion and any shortened expiration date if determined by the manufacturer; and

(F) Name of person(s) involved in responding to the temperature excursion event discovery and response;

(o) Before a drug that has experienced a temperature excursion is dispensed, the following items must be documented:

(A) Drug manufacturer information utilized indicating each drug is safe for use;

(B) Name of the representative providing the information;

(C) Manufacturer contact information;

(D) Copy of information provided by manufacturer;

(E) Date and time information was obtained from manufacturer;

(F) Reference number associated with manufacturer contact;

(G) Name of the Oregon licensed pharmacist that reviewed the manufacturer data and confirmed the drug safe for continued use; and

(H) In the absence of (B) and (C), documentation of a drug manufacturer online reference that applies to the specific temperature excursion, documentation of this reference must be maintained; and

(p) Maintain all records required by OAR 855-139-0032 for a minimum of three years.

Statutory/Other Authority: ORS 689.205, ORS 689.325
Statutes/Other Implemented: ORS 689.155

855-139-0130
Drug: Loss

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Ensure that disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices are reported to the Board immediately.

(2) Ensure that significant drug loss or suspected violation related to drug theft is reported to the board within one business day. A pharmacy must consider a controlled drug loss to be significant when:

(a) The percentage of dosage units of a specific drug exceeds 2% of monthly dispensing volume; or

(b) Fifteen or more dosage units are not accounted for.

(3) Ensure that a Report of Theft or Loss of Controlled Substances (DEA Form 106) or Report of Theft or Loss of Listed Chemicals (DEA Form 107) is sent to the Drug Enforcement Administration, a copy is sent to the Board at the same time.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0150
Outlet: Sanitation

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Ensure the Remote Dispensing Site Pharmacy is kept clean.

(2) Ensure the Certified Oregon Pharmacy Technician working in the Remote Dispensing Site Pharmacy practices appropriate infection control.

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

855-139-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon Retail Drug Outlet Remote Dispensing Site Pharmacy must have the following:

(a) Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary drugs) services offered by the outlet;

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;

(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(d) Appropriate equipment to maintain the proper storage of drugs;

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;

(f) A sink with running hot and cold water;

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-139-0062 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-139-0215; and

(D) Stating "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed Pharmacist from (insert name of Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and

(h) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

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

855-139-0200
Outlet: General Requirements

(1) An Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.

(2) An Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the Remote Dispensing Site Pharmacy.

(3) A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(a) Have the same owner; or

(b) Have a written contract that specifies:

(A) The services to be provided by each licensee and registrant;

(B) The responsibilities of each licensee and registrant; and

(C) The accountabilities of each licensee and registrant;

(c) Ensure each prescription is dispensed in compliance with OAR 855-019, OAR 855-025 and OAR 855-139;

(d) Comply with all applicable federal and state laws and rules;

(e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians authorized to access the Remote Dispensing Site Pharmacy and operate the telepharmacy system;

(f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system and Remote Dispensing Site Pharmacy;

(g) Develop, implement and enforce a continuous quality improvement program for dispensing services from a Remote Dispensing Site 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;

(h) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Oregon licensed Pharmacist from the Affiliated Pharmacy; and

(i) Develop, implement and enforce a process for an in person physical inspection of the Remote Dispensing Site Pharmacy by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy. The inspection must utilize the Remote Dispensing Site Pharmacy self-inspection form, be documented and records retained.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155, 2021 SB 629

855-139-0205
Outlet: Technology

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Utilize a shared telepharmacy system and have appropriate technology or interface to allow access to information required to process and fill a prescription drug order;

(2) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each:

(A) Source container including manufacturer, name, strength, lot, and expiration;

(B) Source ingredient including the imprint and physical characteristics if compounding;

(C) Dispensed product including the imprint and physical characteristics;

(D) Completed prescription container including the label; and

(E) Ancillary document provided to patient at the time of dispensing.

(3) Utilize barcode, radio-frequency identification or quick response code technology to record information in (2) if available;

(4) Test the telepharmacy system and document that it operates properly before providing pharmacy services; and

(5) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155, 2021 SB 629

855-139-0210
Outlet: Supervision

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Ensure prescription drugs are only dispensed at the Remote Dispensing Site Pharmacy if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician utilizing the telepharmacy system, and the telepharmacy system is fully operational;

(2) Ensure an Oregon licensed Pharmacist continuously supervises, directs and controls each Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy using audio and visual technology which must be recorded, reviewed and stored;

(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a Remote Dispensing Site Pharmacy must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;

(b) Review patient interactions within 24 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;

(c) Document the following within 24 hours of the review in (b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions pharmacist is reviewing;

(C) Date and time of licensee patient interaction pharmacist is reviewing;

(D) Date and time of pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours and the board within 10 days.

(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.

(5) Ensure all telephone audio is recorded, reviewed and stored.

POLICY DISCUSSION: Frequency of review

(6) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy.

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.305

855-139-0215
Outlet: Pharmacist Utilization

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Utilize an Oregon licensed Pharmacist from the Affiliated Pharmacy to perform the professional tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is dispensed; and

(2) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 and when requested and document the interaction.

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

855-139-0220
Outlet: Non-Prescription Drugs

If non-prescription drugs are offered for sale at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Ensure that the Certified Oregon Pharmacy Technician does not provide advice, information that requires judgment, or recommendations involving non-prescription drugs; and

(2) Ensure that an Oregon-licensed Pharmacist is immediately available to provide counseling or recommendations involving non-prescription drugs.

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

855-139-0225
Outlet: Controlled Substances

If controlled substances are at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Comply with controlled substance regulations;

(2) Store all controlled substances in a secure locked cabinet;

(3) Maintain an accurate controlled substance perpetual inventory; and

(4) Ensure an Oregon licensed Pharmacist conducts a monthly controlled substance inventory and reconciles all discrepancies at the time of in person physical inspection.

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

855-139-0230
Outlet: Non-Sterile Compounding

If non-sterile preparations are compounded at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Adhere to the requirements of OAR 855-045;

(2) Ensure an Oregon licensed Pharmacist:

(a) Supervises via a real-time audio-visual connection all steps of the compounding; and

(b) Documents and visually verifies each item required in OAR 855-139-0041.

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

855-139-0300
Prescription: General Requirements

(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization. When a prescription is transmitted orally, it must be transmitted to the Oregon licensed Pharmacist from the Affiliated Pharmacy and both the receiving

pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.

(2) Each pharmacy must document the following information for each prescription:

(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal.

(b) If for an animal, the name of the patient, name the owner and the species of the animal.

(c) The full name, address, and contact phone number of the practitioner. If for a controlled substance, the Drug Enforcement Administration registration number of the practitioner and other number as authorized under rules adopted by reference under rule OAR 855-080-0085;

(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

(e) The directions for use, if given by the practitioner; and

(f) The date of filling, and the total number of refills authorized by the prescribing practitioner.

(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, instruction may use any one of the following phrases or notations:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words with similar meaning.

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent must clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

(c) Such instructions must not be default values on the prescription.

(4) A pharmacy or Oregon licensed Pharmacist filling a prescription or order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;

(d) The pharmacy or Oregon licensed Pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three (3) business days of dispensing the biosimilar product; and

(5) The pharmacy must dispense prescriptions accurately and to the correct party.

Statutory/Other Authority: ORS 689.205 & ORS 689.522
Statutes/Other Implemented: ORS 689.505, 689.515 & ORS 689.522

855-139-0305
Prescription: Tamper-resistant

When the use of a tamper-resistant prescription is required by any federal or state law or rule, the term "tamper-resistant" has the meaning as defined in OAR 855-006-0015.

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

855-139-0310
Prescription: Verification of Authenticity

Alteration of a written prescription, other than by an Oregon licensed Pharmacist's or practitioner's authorization, in any manner constitutes an invalid order unless verified with the prescriber.

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

855-139-0315
Prescription: Refills

(1) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions

for controlled substances in Schedules III, IV and V are limited to five refills or six months from date of issue, whichever comes first.

(2) If the practitioner is not available and in the professional judgment of the Oregon licensed pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the pharmacist may dispense a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner must be promptly notified of the emergency refill.

(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include;

(a) The identity of the responsible Oregon licensed Pharmacist;

(b) Name of the patient;

(c) Name of the medication;

(d) Date of refill; and

(e) Quantity dispensed.

(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled substance or psychotherapeutic drug and the prescriber is notified of the change.

(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient's agent. A request specific to each prescription medication is required, unless the requested fill or refill is part of an auto-refill program and is a continuation of therapy.

(6) A prescription must be refilled in context with the approximate dosage schedule unless specifically authorized by the prescriber.

(7) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may use a program that automatically refills non-controlled prescription medications, that have existing refills available and are consistent with the patient's current medication therapy only when the following conditions are met:

(a) A patient or patient's agent must enroll each prescription medication in an auto-refill program before a pharmacy can include the prescription medication as part of the auto-refill program;

(b) The prescription is not a controlled substance;

(c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or patient's agent;

(d) Pick-up notification to a patient or patient's agent may be generated upon completion of a prescription refill; and

(e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription medication is removed from the auto-refill program for that patient.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-139-0320
Prescription: Expiration

This section of rule addresses the expiration date of the prescription and not the expiration date of the drug.

(1) After one year from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber.

(2) When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled substance means that the medication can be refilled in proper context for a period of one year.

(a) When this abbreviation is used alone as a means to authorize refills for a controlled substance, the medication can be refilled in proper context for a period of six months or five refills, whichever comes first.

(b) When this abbreviation is used in conjunction with a definite time period, or a specific number of refills, the non-controlled medication can be refilled in proper context for a period not to exceed one year.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-139-0325
Prescription: Transfers

(1) Prescriptions may be transferred between pharmacies for the purpose of refill dispensing provided that:

(a) The prescription is invalidated at the sending pharmacy; and

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.

(2) Prescriptions for controlled substances can only be transferred one time.

(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

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 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX), and 16 CFR 1702 (XX/XX/XXXX).

[Publications: Publications referenced are available from the agency.]

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

855-139-0355
Dispensing: Customized Patient Medication Packages

POLICY DISCUSSION: Customized Medication Packages

In lieu of dispensing two or more prescribed drug products in separate containers, an Oregon licensed pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (patient med pak). A patient med pak is a package prepared by a pharmacist for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms. The patient med pak is so designed for each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken:

(1) Label:

(a) The patient med pak must bear a label stating:

(A) The name of the patient;

(B) A serial number for each patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;

(C) The name, strength, physical description or identification, and total quantity of each drug product contained therein;

(D) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product therein;

(E) Any storage instructions or cautionary statements required by the official compendia;

(F) The name of the prescriber of each drug product;

(G) The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date must be no later than 60 days from the date of preparation);

(H) The name, address, and telephone number of the dispenser and the dispenser's registration number where necessary; and

(I) Any other information, statements, or warnings required for any of the drug products contained therein.

(b) If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container must bear a label identifying each of the drug products contained therein.

(2) Labeling: The patient med pak must be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the Oregon licensed pharmacist for the total patient med pak.

(3) Packaging:

(a) In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak must comply with the moisture permeation requirements for a Class B single-unit or unit-dose container. Each container must be either not reclosable or so designed as to show evidence of having been opened;

(b) There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards must be placed in an outer package that does comply, or the necessary consent of the purchaser or physician, to dispense in a container not intended to be child-resistant, must be obtained.

(4) Guidelines: It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the medications. In this regard, pharmacists are encouraged to report to USP headquarters any observed or report incompatibilities.

(5) Recordkeeping: In addition to any individual prescription filing requirements, a record of each patient med pak must be made and filed. Each record must contain, as a minimum:

(a) The name and address of the patient;

(b) The serial number of the prescription order for each drug product contained therein;

(c) The name of the manufacturer or labeler and lot number for each drug product contained therein;

(d) Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

(e) The date of preparation of the patient med pak and the beyond-use date that was assigned;

(f) Any special labeling instructions; and

(g) The name or initials of the Oregon licensed pharmacist who prepared the patient med pak.

(2) Ensure an Oregon licensed Pharmacist documents and visually verifies each item required in OAR 855-139-0041 for each individual pak.

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

855-139-0400
Labeling: General Requirements

(1) Prescriptions must be labeled with the following information:

(a) Name, address and telephone number of the pharmacy;

(b) Date;

(c) Identifying number;

(d) Name of patient;

(e) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(f) Directions for use by the patient;

(g) Name of practitioner;

(h) Required precautionary information regarding controlled substances;

(i) Such other and further accessory cautionary information as required for patient safety;

(j) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container unless, in the Oregon licensed Pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an expiration date must not be dispensed beyond the said expiration date of the drug;

(k) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules; and

(l) Address and telephone number of the Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & 689.515

855-139-0405
Labeling: Prescription Reader Accessibility

A pharmacy must notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request; a prescription reader is a device designed to audibly convey labeling information.

If a person informs the pharmacy that the person identifies as a person who is blind, the pharmacy must provide to the person a prescription reader that is available to the person for at least the duration of the prescription, must confirm it is appropriate to address the person's visual impairment, and must ensure that prescription labels are compatible with the prescription reader. This requirement does not apply to an institutional drug outlet, dispensing a drug intended for administration by a healthcare provider.

POLICY DISCUSSION: Timeframe

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.561

855-139-0410
Labeling: Limited English Proficiency and Accessibility

(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide a prescription label and, when needed, an informational insert in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

(4) An informational insert may be used when the directions for use in English and the language requested exceed 140 characters.

(5) When an informational insert is used, the prescription label affixed to the prescription container must state in both English and the language requested by the patient that an informational insert is being used.

(6) At a minimum, the informational insert must include the:

(a) Directions for use by the patient in both English and the language requested;

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

855-139-0415
Labeling: Repackaged Drugs

POLICY DISCUSSION: Prohibit Repackaging, Limit to own use

(1) Each pharmacy record keeping system must identify all pharmacy personnel involved in repackaging including the pharmacist who verified the repackaged drug.

(2) A single oral solid drug products repackaged by a pharmacy into unit-dose packaging must:

(a) Utilize a unit-dose container–closure system that meets the testing requirements under USP <671> Containers—Performance Testing (12/01/2020) for either Class A or Class B containers and meets or exceeds the original container's specification for light resistance;

(b) Be labeled to identify at a minimum:

(A) Brand name~~,~~ or generic name;

(B) Strength;

(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot number; and

(D) Expiration date. The expiration date used for the repackaged product must not exceed:

(i) 6 months from the date of repackaging; or

(ii) The manufacturer's expiration date; or

(iii) 25% of the time between the date of repackaging and the expiration date shown on the manufacturer's bulk article container of the drug being repackaged, whichever is earlier.

(3) A single oral solid drug product repackaged by a pharmacy into multiple-unit packaging must:

(a) Utilize an equivalent container–closure system that is at least as protective as, or more protective than, the original system, complies with criteria established for equivalency and meets or exceeds the original container's specification for light resistance;

(b) Be labeled to identify at a minimum:

(A) Brand name or generic name;

(B) Strength;

(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot number; and

(D) Expiration date. The expiration date used for the repackaged product must not exceed the manufacturer's expiration date or one year from the date the drug was placed in the new container, whichever date is earlier.

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

855-139-0450
Drugs and Devices: Disposal

Drugs and devices that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0455
Drug and Devices: Return

(1) A Certified Oregon Pharmacy Technician may accept the return of a drug or device as defined by ORS 689.005 once the drug or device have been dispensed from the pharmacy if they were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, or are subject of a drug or device recall only if:

(a) An Oregon licensed Pharmacist has approved the return;

(b) The drugs or devices are accepted for destruction or disposal; and

(c) An Oregon licensed Pharmacist verifies the destruction or disposal.

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

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

(1) A Remote Dispensing Site 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 Remote Dispensing Site 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 Remote Dispensing Site 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 Remote Dispensing Site 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 Remote Dispensing Site 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 (04/01/2020), 21 CFR 1317.35 (04/01/2020), 21 CFR 1317.40 (04/01/2020), 21 CFR 1317.55 (04/01/2020), 21 CFR 1317.60 (04/01/2020), 21 CFR 1317.65 (04/01/2020), 21 CFR 1317.70 (04/01/2020), 21 CFR 1317.75 (04/01/2020), 21 CFR 1317.80 (04/01/2020), and 21 CFR 1317.85 (04/01/2020); and

(d) 21 USC 822 (04/01/2021), 21 USC 822a (04/01/2021).

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

855-139-0500
Policies and Procedures

(1) The Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy and the Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the Remote Dispensing Site Pharmacy. The written policies and procedures must be maintained at the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the responsibilities of the Affiliated Pharmacy and each Remote Dispensing Site Pharmacy including;

(a) Security;

(b) Operation, testing and maintenance of the telepharmacy system;

(c) Sanitation;

(d) Storage of drugs;

(e) Dispensing;

(f) Oregon licensed Pharmacist supervision, direction and control of pharmacy technicians;

(g) Documenting the identity, function, location, date and time of the licensees engaging in telepharmacy;

(h) Drug and/or device procurement;

(i) Receiving of drugs and/or devices;

(j) Delivery of drugs and/or devices;

(k) Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling);

(l) Recordkeeping;

(m) Patient confidentiality;

(n) On-site inspection by an Oregon licensed Pharmacist;

(o) Continuous quality improvement;

(p) Plan for discontinuing and recovering services if telepharmacy system disruption occurs;

(q) Training: initial and ongoing; and

(r) Interpretation, translation and prescription reader services.

(3) If non-prescription drugs are offered for sale at the Remote Dispensing Site Pharmacy, the policies and procedures must outline the process for the Oregon licensed Pharmacist counseling and advice.

(4) If non-sterile preparations are compounded at the Remote Dispensing Site Pharmacy, the policies and procedures must meet the requirements of OAR 855-045.

(5) If controlled substances are stored at the Remote Dispensing Site Pharmacy, the policies and procedures must include the following processes:

(a) Reviewing of controlled substance prescriptions for unauthorized alterations and inspected for legitimacy by the Oregon licensed Pharmacist during inspection visits;

(b) Maintaining an accurate controlled substance perpetual inventory for all controlled substances that are stocked at the Remote Dispensing Site Pharmacy; and

(c) Conducting and reconciling the controlled substance inventory.

(6) An Affiliated Pharmacy that provides remote pharmacy services through a telepharmacy system at a Remote Dispensing Site Pharmacy must review its written policies and procedures every 12 months, revise them if necessary, and document the review.

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

855-139-0550
Records: General Requirements

(1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The Remote Dispensing Site Pharmacy must maintain all required records unless these records are maintained in the Affiliated Pharmacy.

(3) Records retained by the Drug Outlet must include, but are not limited to:

(a) Patient profiles and records;

(b) Date, time and identification of each individual and activity or function performed;

(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(d) Controlled substance inventory and reconciliation;

(e) Oregon licensed Pharmacist physical inspection of Remote Dispensing Site Pharmacy;

(f) Audio and visual connection testing and individual training on use of the audio and visual connection;

(g) Data, telephone audio, audio and video, still image capture, store and forward images, security and surveillance data. This must be retained according to (1); and

(h) Any errors or irregularities identified by the quality improvement program.

(4) All data, telephone audio, audio and video, still image capture and store and forward images collected by the telepharmacy, security and surveillance systems must be retained according to (1).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508

855-139-0555
Records: Patient

A patient record system must be maintained by pharmacies for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing Oregon licensed pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing. The pharmacist must make a reasonable effort to obtain, record, and maintain the following information:

(1) Full name of the patient for whom the drug is intended;

(2) Address and telephone number of the patient;

(3) Patient's age or date of birth;

(4) Patient's gender;

(5) Chronic medical conditions;

(6) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(7) Known allergies, drug reactions, and drug idiosyncrasies; and

(8) If deemed relevant in the Oregon licensed Pharmacist's professional judgment:

(a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet Remote Dispensing Site Pharmacy may not:

(1) Allow a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;

(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the Board pursuant to ORS 689.305.

(3) Deliver a prescription;

(4) Provide non-prescription or prescription drugs when the Remote Dispensing Site Pharmacy is closed; or

(5) Compound sterile preparations.

Statutory/Other Authority: ORS 475.035, , ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0602
Prohibited Practices: Disclosure of Patient Information

(1) Allow a licensee or registrant of the Board who obtains any patient information to disclose that information to a third party without the consent of the patient except as provided in (2) of this rule

(2) A licensee may disclose patient information:

(a) To the Board;

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

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

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

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

(3) Allow a licensee or registrant of the Board to access or obtain any patient information unless it is accessed or obtained for the purpose of patient care.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0650
Grounds for Discipline

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

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

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:

(a) Is false, fraudulent, deceptive, or misleading; or

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.

(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with an Oregon licensed Pharmacist's ability to practice with reasonable competency and safety.

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

(c) Adequate time for an Oregon licensed Pharmacist to complete professional duties and responsibilities including, but not limited to:

(A) Drug Utilization Review;

(B) Verification of the accuracy of a prescription;

(C) Counseling; and

(D) All other duties and responsibilities of an Oregon licensed Pharmacist as specified in OAR 855-019.

(4) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.

(5) Incenting or inducing the transfer of a prescription absent professional rationale.

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

855-139-0710
Service: Epinephrine- Definitions

The following words and terms, when used in OAR 855-139-0210 through OAR 855-139-0211 have the following meanings, unless the context clearly indicates otherwise.

(1) "Allergic reaction" means a medical condition caused by exposure to an allergen, with physical symptoms that may be life threatening, ranging from localized itching to severe anaphylactic shock and death.

(2) "Authorization to Obtain Epinephrine" means a certificate that contains the name, signature, and license number of the supervising professional authorizing the dispensing of epinephrine to the individual whose name appears on the certificate. Additionally, the certificate contains a record of the number of epinephrine orders filled to date.

(3) "Statement of Completion" means a certificate that states the specific type of emergency the trainee was trained to respond to, the trainee's name and address, the name of the authorized trainer and the date that the training was completed.

(4) "Trainee" means an individual who has attended and successfully completed the formal training pursuant to the protocols and criteria established by the Oregon Health Authority, Public Health Division.

Statutory/Other Authority: ORS 689.205 & ORS 689.681
Statutes/Other Implemented: ORS 689.155 & ORS 689.681

855-139-0715
Service: Epinephrine- General Requirements

(1) An Oregon licensed Pharmacist may fill an order for epinephrine to be used by trainees to treat an anaphylactic reaction. Trainees must be 18 years of age or older and must have responsibility for or contact with at least one (1) other person as a result of the trainee's occupation or volunteer status, such as, but not limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide or chaperone.

(2) Individuals must successfully complete a training program approved by the Oregon Health Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:

(a) Statement of Completion; and

(b) Authorization to Obtain Epinephrine.

(3) Acquisition of epinephrine from a pharmacy to be used for the treatment of allergic emergencies may occur in the following manners:

(a) An Oregon licensed Pharmacist may dispense epinephrine to a trainee upon presentation of the Statement of Completion and Authorization to Obtain Epinephrine certificate to a pharmacy when:

(A) An Oregon licensed Pharmacist may generate a prescription for and dispense an emergency supply of epinephrine for not more than one adult and one child dose package, as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Epinephrine certificate.

(B) The Oregon licensed Pharmacist who generates the hardcopy prescription for epinephrine in this manner must reduce the prescription to writing and file the prescription in a manner appropriate for a non-controlled substance.

(C) Once the Oregon licensed Pharmacist generates the epinephrine prescription, the pharmacist must write in the appropriate space provided on the Authorization to Obtain Epinephrine certificate the date and the number of doses dispensed and return the certificate to the trainee.

(D) The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used to obtain epinephrine up to four (4) times within three (3) years from the date of the initial training.

(E) Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire three (3) years from the date of the trainee's last Oregon Health Authority approved allergy response training.

(F) Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.

(b) An Oregon licensed Pharmacist may dispense epinephrine to an entity when:

(A) The epinephrine is acquired by a valid prescription presented to the pharmacy;

(B) The prescription identifies the entity as the patient for the purpose of prescribing and labeling the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 433.825

855-139-0720
Service: Naloxone- General Requirements

Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:

(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction;

(2) Documentation and recordkeeping: and

(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682

855-139-0725
Service: Expedited Partner Therapy (EPT)- Purpose

(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.

(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.

(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

855-139-0730
Service: Expedited Partner Therapy (EPT) - Procedures

(1) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(2) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule govern.

(3) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon Health Authority (OHA) to be appropriately used for EPT.

Prescription

(4) An EPT treatment protocol must conform to the following:

(a) It must include a prescription for each named or unnamed partner of the patient;

(b) It must contain a handwritten or electronic signature of the prescribing practitioner;

(c) The practitioner must identify the prescription in the following manner:

(A) Write "for EPT," or a similar notation, on the face of the prescription;

(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;

(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe – Partner 1" or by labeling the prescription as "EPT Partner"

(d) An EPT Prescription expires 30 days after the date written;

(e) An EPT Prescription may not be refilled;

(f) If any component of the prescription is missing, the Oregon licensed Pharmacist must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.

(5) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may give all prescriptions to one pharmacy and then give the dispensed drugs to each unnamed partner.

Labeling

(6) The Certified Oregon Pharmacy Technician must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the pharmacy may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.

(7) The Oregon licensed Pharmacist must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling

(8) The Oregon licensed Pharmacist is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the pharmacist must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The Oregon licensed Pharmacist should advise the patient to encourage each partner to call the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records

(9) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the Board upon request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

Division 019/139– Pharmacists/Operation of Pharmacies (Remote Dispensing Site Pharmacy/Telepharmacy)

Filing Caption (15 word limit)**:** 2021 SB 629 Allows use of telepharmacy to deliver pharmacy services at a remote location

Need for Rules:

Revision to Division 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location.

Fiscal Impact:

2021 SB 629 does not have a fiscal impact to the agency. If a pharmacy chooses to operate a Remote Dispensing Site Pharmacy via telepharmacy, the pharmacy will be required to apply and pay a registration fee for the Remote Dispensing Site Pharmacy.

Documents relied upon include:

2021 SB 629 and related statutes

Rules Advisory Committee- Pharmacy Technicians May 2021 minutes, August 2021 minutes, & September 2021 minutes.

United States Pharmacopeia -National Formulary <NF> (USP 43-NF38 v. 2021) https://www.uspnf.com/

Related Federal Statutes/Rules:

Poison Prevention Packaging Act: 16 CFR 1700 (XX/XX/XXXX) Poison Prevention Packaging, 16 CFR 1701 (XX/XX/XXXX) Statements of Policy and Interpretation, and 16 CFR 1702 (XX/XX/XXXX) Petitions for Exemptions from Poison Preventing Packaging Act Requirements; Petition Procedures and Requirements

42 USC 262 (XX/XX/XXXX) Regulation of biological products

21 CFR 1301.52 (XX/XX/XXXX) Modification, transfer and termination of registration

Rules Summary:

Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

Resources:

Remote dispensing sites utilizing telepharmacy technologies- Telepharm

Division 19
PHARMACISTS

855-019-0300
Duties of a Pharmacist-in-Charge

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis.

(2) In order to be a PIC, a pharmacist must have:

(a) Completed at least one year of pharmacy practice; or

(b) Completed a board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the board, this course may be employer provided and may qualify for continuing education credit.

(3) A pharmacist may not be designated PIC of more than ~~two~~ **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.

(4) The PIC must perform the following the duties and responsibilities:

(a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to the board within 15 days of the occurrence, on a form provided by the board;

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

(c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;

(e) A pharmacist designated as PIC for more than one pharmacy must personally conduct and document a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit Form provided by the board;

(f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within 30 days of receiving notice.

(g) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;

(g) Implementing a quality assurance plan for the pharmacy.

(h) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

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

Division 141
REMOTE DISPENSING SITE PHARMACY

855-139-0001
Purpose and Scope

The purpose of OAR 855-139 is to provide minimum requirements for the locations where telepharmacy services are conducted.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155

855-139-0005
Definitions

The following words and terms, when used in OAR 855-139, have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section has the definition set out in OAR 855-006.

(1) "Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon where an Oregon licensed Pharmacist provides pharmacy services through a telepharmacy system.

(2) "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.

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

(4) "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) (XX/XX/XXXX).

(5) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) (XX/XX/XXXX) 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.

(7) "Remote Dispensing Site Pharmacy" means an Oregon location registered as a Retail Drug Outlet Remote Dispensing Site Pharmacy staffed by a Certified Oregon Pharmacy Technician under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.

(8) "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.

(9) "Telepharmacy" means the delivery of pharmacy services by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician.

(10) "Telepharmacy system" means a system of telecommunications technologies that enables monitoring, documenting and recording of the delivery of pharmacy services at a remote location by an electronic method which must include the use of audio and video, still image capture, and store and forward.

(11) "Still image capture" means a specific image captured electronically from a video or other image capture device.

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

Statutory/Other Authority: ORS 689.205**, ORS** 689.522**, 2021 SB 629**
Statutes/Other Implemented: ORS 689.155, **ORS** 689.522**, ORS 689.564, 2021 SB 629**

855-139-0010
Registration: General

(1) A location in Oregon where the practice of pharmacy occurs by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician must be registered by the board in Oregon as a Retail Drug Outlet Remote Dispensing Site Pharmacy.

(2) If controlled substances are stored in the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy must have an active Controlled Substance Registration Certificate with the board and Drug Enforcement Administration (DEA).

(3) A Retail Drug Outlet Remote Dispensing Site Pharmacy application must specify the Affiliated Pharmacy and cannot operate without an Affiliated Pharmacy that is registered by the board as a Retail Drug Outlet Pharmacy.

(4) All registration renewal applications must be accompanied by the annual fee and must contain the same information required in OAR 855-139-0011(3) and (4).

(5) The initial and annual registration fee for pharmacies is set out in OAR 855-110.

(6) Retail Drug Outlet Remote Dispensing Site Pharmacy registration expires March 31, annually. If the annual registration fee referred to in OAR 855-110 is not paid by March 31 of the current year, a late fee as set out in OAR 855-110 must be included with the application for registration renewal.

(7) The registration is not transferable and the registration fee cannot be prorated.

(8) No Remote Dispensing Site Pharmacy may be operated until a certificate of registration has been issued to the pharmacy by the board.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, 2021 SB 629

855-139-0015
Registration: Application

(1) An application for registration of a new Remote Dispensing Site Pharmacy must be accompanied by a floor plan drawn to scale and must be approved by the board prior to opening.

(2) The application must specify the location of the Remote Dispensing Site Pharmacy and must indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application must indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owners, the names of the partners or persons holding the five largest interests must be indicated on the application;

(b) If the owner is a corporation, the name filed must be the same as filed with the Secretary of State. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests must be indicated on the application.

(3) Upon request by the board, the applicant must furnish such information as required by the board regarding the partners, stockholders, or other persons not named in the application.

(4) A certificate of registration will be issued upon board approval of the application.

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

855-139-0020
Registration: Change of Owner, Location, or Affiliated Pharmacy

(1) A change of location of the Affiliated Pharmacy or location of the Retail Drug Outlet Remote Dispensing Site Pharmacy requires:

(a) Submission of a new Retail Drug Outlet Remote Dispensing Site Pharmacy application 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the board; and

(d) New certificate of registration.

(2) A change in the Affiliated Pharmacy or ownership of the Retail Drug Outlet Remote Dispensing Site Pharmacy requires:

(a) Submission of a new Retail Drug Outlet Remote Dispensing Site Pharmacy application 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the board; and

(d) New certificate of registration.

(3) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(4) A certificate of registration will be issued upon board approval of the application.

Statutory/Other Authority: ORS 475.035, ORS 689.205

Statutes/Other Implemented: ORS 689.155

855-139-0025
Registration: Change of Business Name or Closure

(1) An Affiliated Pharmacy must notify the board 15 days prior to any change of business name of a Retail Drug Outlet Remote Dispensing Site Pharmacy. The change must be reported by filing a new application for which no fee is required.

(2) An Affiliated Pharmacy must notify the board 15 days prior to discontinuing operation of a Retail Drug Outlet Remote Dispensing Site Pharmacy. Notification must include the:

(a) Final disposition of drugs stored in the Retail Drug Outlet Remote Dispensing Site Pharmacy including:

(A) Name and location where the drugs are transferred;

(B) Name and location where destruction occurred; and

(C) Name and location of the site that will store all records;

(c) Transfer all Schedule II medications on DEA 222 forms, and Schedule III, IV and V by invoice;

(d) Provide the board with:

(A) Oregon Board of Pharmacy state license(s); and

(B) Signed statement giving the effective date of closure; and

(e) Comply with the requirements of 21 CFR 1301.52 (XX/XX/XXXX).

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

855-139-0030
Non-Resident Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes an Affiliated Pharmacy located outside of Oregon and providing pharmacy services through a telepharmacy system to a Retail Drug Outlet Remote Dispensing Site Pharmacy located in Oregon.

(2) Each non-resident Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every non-resident 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 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 Remote Dispensing Site Pharmacy. 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 Affiliated Pharmacy a minimum of 20 hours per week;

(c) Complete the annual Remote Dispensing Site Pharmacy PIC self-inspection report prior to February 1 each year; and

(d) Provide the PIC self-inspection report as requested by the board.

(5) Every non-resident Affiliated Pharmacy will have a Pharmacist-in-Charge (PIC) who is licensed in Oregon prior to initial registration of the Remote Dispensing Site Pharmacy.

(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

855-139-0050
Personnel

(1) The Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy is responsible for all operations at the Remote Dispensing Site Pharmacy including responsibility for the telepharmacy system and enforcing policies and procedures.

(2) A Remote Dispensing Site Pharmacy may not utilize Interns, Pharmacy Technicians, or unlicensed personnel.

(3) A Certified Oregon Pharmacy Technician working at a Remote Dispensing Site Pharmacy is required to have at least one year experience working at an Oregon registered Retail Drug Outlet Pharmacy during the three years preceding the date the Certified Oregon Pharmacy Technician begins working at the Remote Dispensing Site Pharmacy.

(4) The Oregon licensed Pharmacist from the Affiliated Pharmacy who is supervising a Remote Dispensing Site Pharmacy must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided.

(5) When supervising a Certified Oregon Pharmacy Technician working at a Remote Dispensing Site Pharmacy, the Oregon licensed Pharmacist may supervise no more than four licensed pharmacy technicians among all locations, including the Affiliated Pharmacy.

(6) The Affiliated Pharmacy is required to comply with the pharmacist's determination in (4) and retain records.

(7) The Remote Dispensing Site Pharmacy and Affiliated Pharmacy must ensure adequate staffing at both the Remote Dispensing Site Pharmacy and Affiliated Pharmacy.

(8) Prior to working at a Remote Dispensing Site Pharmacy, the Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the Remote Dispensing Site Pharmacy must have completed a training program on the proper use of the telepharmacy system.

(9) An Affiliated Pharmacy that terminates or allows a board licensee to resign in lieu of termination must report the termination or resignation to the board within 10 working days.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305

855-139-0100
Security

(1) The area in a registered Remote Dispensing Site Pharmacy where legend and/or controlled substances are stored, possessed, prepared, compounded or repackaged must be restricted in access by utilizing physical barriers to include floor to ceiling walls and a locked separate entrance to ensure the security of those drugs.

(2) The Affiliated Pharmacy, the Remote Dispensing Site Pharmacy, Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the Remote Dispensing Site Pharmacy is responsible for the security of the prescription area including provisions for adequate safeguards against loss, theft or diversion of prescription drugs, and records for such drugs.

(3) The Remote Dispensing Site Pharmacy must be locked and the security system armed to prevent entry when:

(a) There is no Oregon licensed Pharmacist from the Affiliated Pharmacy actively supervising the Remote Dispensing Site Pharmacy; or

(b) There is no Certified Oregon Pharmacy Technician present in the Remote Dispensing Site Pharmacy; or

(c) Any component of the telepharmacy system is not functioning.

(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the Remote Dispensing Site Pharmacy.

(5) No one may be in the prescription area of a Remote Dispensing Site Pharmacy unless authorized in real-time by an Oregon licensed Pharmacist who is supervising the Remote Dispensing Site Pharmacy and from the Affiliated Pharmacy.

(6) Minimum security methods must include a properly functioning:

(a) Alarm system with an audible alarm at the Remote Dispensing Site Pharmacy and real-time notification to a designated licensee of the Affiliated Pharmacy;

(b) Electronic keypad or other electronic entry system that records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the Remote Dispensing Site Pharmacy;

(B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the Remote Dispensing Site Pharmacy; and

(C) Date and time of each activity.

(c) Surveillance system that utilizes continuously accessible and recorded two-way audiovisual link between the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy. The system must provide a clear view of:

(A) Dispensing site entrances;

(B) Preparation areas;

(C) Drug storage areas;

(D) Pick up areas;

(E) Office areas; and

(F) Publicly accessible areas.

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

855-139-0120
Drug: Receipt

Remote Dispensing Site Pharmacy may only receive drugs from an Oregon Registered Drug Outlet (i.e. Wholesaler, Manufacturer or Pharmacy).

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

855-139-0125
Drug: Storage

(1) A Remote Dispensing Site Pharmacy must maintain proper storage of all drugs. This includes, but is not limited to the following:

(a) All drugs must be stored according to manufacturer's published or USP guidelines.

(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.

(d) A Remote Dispensing Site Pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.

(2) A Remote Dispensing Site Pharmacy must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).

(a) All drug refrigeration systems must:

(A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.

(B) Utilize a centrally placed, accurate, and calibrated thermometer;

(C) Be dedicated to pharmaceuticals only;

(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.

(b) A Remote Dispensing Site Pharmacy must adhere to a monitoring plan, which includes, but is not limited to:

(A) Documentation of training of all personnel;

(B) Maintenance of manufacturer recommended calibration of thermometers;

(C) Maintenance of records of temperature logs for a minimum of three years;

(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;

(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination by an Oregon licensed Pharmacist that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan;

(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment; and

(H) Documentation and review of temperature recordings at least once every 28 days by the Oregon licensed Pharmacist at the time of in person physical inspection.

(3) Vaccine Drug Storage:

(a) A Remote Dispensing Site Pharmacy that stores vaccines must comply with section two of this rule and the following:

(A) Vaccines must be stored in the temperature stable sections of the refrigerator;

(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C variance must be utilized;

(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;

(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and

(E) Must adhere to a written quality assurance process to avoid temperature excursions.

(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.

Statutory/Other Authority: ORS 689.205, ORS 689.325
Statutes/Other Implemented: ORS 689.155

855-139-0130
Drug: Loss

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Ensure that disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices are reported to the board immediately.

(2) Ensure that confirmed significant drug loss or any loss related to suspected drug theft of a controlled substance is reported to the board within one business day.

(3) Ensure that a Report of Theft or Loss of Controlled Substances (DEA Form 106) or Report of Theft or Loss of Listed Chemicals (DEA Form 107) is sent to the Drug Enforcement Administration, a copy is sent to the board at the same time.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0150
Outlet: Sanitation

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Ensure the Remote Dispensing Site Pharmacy is kept clean.

(2) Ensure the Certified Oregon Pharmacy Technician working in the Remote Dispensing Site Pharmacy practices appropriate infection control.

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

855-139-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon Retail Drug Outlet Remote Dispensing Site Pharmacy must have the following:

(a) Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary drugs) services offered by the outlet;

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;

(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(d) Appropriate equipment to maintain the proper storage of drugs;

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;

(f) A sink with running hot and cold water;

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-139-0062 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-139-0215; and

(D) Stating "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed Pharmacist from (insert name of Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and

(h) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

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

855-139-0200
Outlet: General Requirements

(1) An Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.

(2) An Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the Remote Dispensing Site Pharmacy.

(3) A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(a) Have the same owner; or

(b) Have a written contract that specifies:

(A) The services to be provided by each licensee and registrant;

(B) The responsibilities of each licensee and registrant; and

(C) The accountabilities of each licensee and registrant;

(c) Ensure each prescription is dispensed in compliance with OAR 855-019, OAR 855-025 and OAR 855-139;

(d) Comply with all applicable federal and state laws and rules;

(e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians authorized to access the Remote Dispensing Site Pharmacy and operate the telepharmacy system;

(f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system and Remote Dispensing Site Pharmacy;

(g) Develop, implement and enforce a continuous quality improvement program for dispensing services from a Remote Dispensing Site 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;

(h) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Oregon licensed Pharmacist from the Affiliated Pharmacy; and

(i) Develop, implement and enforce a process for an in person physical inspection of the Remote Dispensing Site Pharmacy by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy. The inspection must utilize the Remote Dispensing Site Pharmacy self-inspection form, be documented and records retained.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155, 2021 SB 629

855-139-0205
Outlet: Technology

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Utilize a shared telepharmacy system and have appropriate technology or interface to allow access to information required to process and fill a prescription drug order;

(2) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Affiliated Pharmacy can visually identify each:

(a) Source container including manufacturer, name, strength, lot, and expiration;

(b) Source ingredient including the imprint and physical characteristics if compounding;

(c) Dispensed product including the imprint and physical characteristics;

(d) Completed prescription container including the label; and

(e) Ancillary document provided to patient at the time of dispensing.

(3) Utilize barcode, radio-frequency identification or quick response code technology to record information in (2) if available;

(4) Test the telepharmacy system and document that it operates properly before providing pharmacy services; and

(5) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155, 2021 SB 629

855-139-0210
Outlet: Supervision

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Ensure prescription drugs are only dispensed at the Remote Dispensing Site Pharmacy if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician utilizing the telepharmacy system, and the telepharmacy system is fully operational;

(2) Ensure an Oregon licensed Pharmacist continuously supervises, directs and controls each Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy using audio and visual technology which must be recorded, reviewed and stored;

(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a Remote Dispensing Site Pharmacy must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;

(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;

(c) Document the following within 24 hours of the review in (3)(b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions pharmacist is reviewing;

(C) Date and time of licensee patient interaction pharmacist is reviewing;

(D) Date and time of pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

(d) Report any violation of OAR 855 to the Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.

(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.

(5) Ensure all telephone audio is recorded, reviewed and stored.

POLICY DISCUSSION: Frequency of review

(6) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy.

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.305

855-139-0215
Outlet: Pharmacist Utilization

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Utilize an Oregon licensed Pharmacist from the Affiliated Pharmacy to perform the professional tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is dispensed; and

(2) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 and when requested and document the interaction.

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

855-139-0220
Outlet: Non-Prescription Drugs

If non-prescription drugs are offered for sale at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Ensure that the Certified Oregon Pharmacy Technician does not provide advice, information that requires judgment, or recommendations involving non-prescription drugs; and

(2) Ensure that an Oregon-licensed Pharmacist is immediately available to provide counseling or recommendations involving non-prescription drugs.

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

855-139-0225
Outlet: Controlled Substances

If controlled substances are at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Comply with controlled substance regulations;

(2) Store all controlled substances in a secure locked cabinet;

(3) Maintain an accurate controlled substance perpetual inventory; and

(4) Ensure an Oregon licensed Pharmacist conducts a controlled substance inventory at least once every 28 days and reconciles all discrepancies at the time of in person physical inspection.

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

855-139-0230
Outlet: Non-Sterile Compounding

If non-sterile preparations are compounded at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Adhere to the requirements of OAR 855-045;

(2) Ensure an Oregon licensed Pharmacist:

(a) Supervises via a real-time audio-visual connection all steps of the compounding; and

(b) Documents and visually verifies each item required in OAR 855-139-0041.

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

855-139-0300
Prescription: General Requirements

(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization. When a prescription is transmitted orally, it must be transmitted to the Oregon licensed Pharmacist from the Affiliated Pharmacy and both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.

(2) Each Remote Dispensing Site Pharmacy must document the following information for each prescription:

(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal.

(b) If for an animal, the name of the patient, name the owner and the species of the animal.

(c) The full name, address, and contact phone number of the practitioner. If for a controlled substance, the Drug Enforcement Administration registration number of the practitioner and other number as authorized under rules adopted by reference under rule OAR 855-080-0085;

(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

(e) The directions for use, if given by the practitioner; and

(f) The date of filling, and the total number of refills authorized by the prescribing practitioner.

(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, instruction may use any one of the following phrases or notations:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words with similar meaning.

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent must clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

(c) Such instructions must not be default values on the prescription.

(4) A Remote Dispensing Site Pharmacy or Oregon licensed Pharmacist filling a prescription or order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;

(d) The Remote Dispensing Site Pharmacy or Oregon licensed Pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three (3) business days of dispensing the biosimilar product; and

(5) The Remote Dispensing Site Pharmacy must dispense prescriptions accurately and to the correct party.

Statutory/Other Authority: ORS 689.205 & ORS 689.522
Statutes/Other Implemented: ORS 689.505, 689.515 & ORS 689.522

855-139-0305
Prescription: Tamper-resistant

When the use of a tamper-resistant prescription is required by any federal or state law or rule, the term "tamper-resistant" has the meaning as defined in OAR 855-006-0015.

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

855-139-0310
Prescription: Verification of Authenticity

Alteration of a written prescription, other than by an Oregon licensed Pharmacist's or practitioner's authorization, in any manner constitutes an invalid order unless verified with the prescriber.

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

855-139-0315
Prescription: Refills

(1) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III, IV and V are limited to five refills or six months from date of issue, whichever comes first.

(2) If the practitioner is not available and in the professional judgment of the Oregon licensed Pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the Oregon licensed Pharmacist may authorize the Certified Oregon Pharmacy Technician to prepare for pharmacist verification a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner must be promptly notified of the emergency refill.

(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include;

(a) The identity of the Certified Oregon Pharmacy Technician and responsible Oregon licensed Pharmacist;

(b) Name of the patient;

(c) Name of the medication;

(d) Date of refill; and

(e) Quantity dispensed.

(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled substance or psychotherapeutic drug and the prescriber is notified of the change.

(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient's agent. A request specific to each prescription medication is required, unless the requested fill or refill is part of an auto-refill program and is a continuation of therapy.

(6) A prescription must be refilled in context with the approximate dosage schedule unless specifically authorized by the prescriber.

(7) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may use a program that automatically refills non-controlled prescription medications, that have existing refills available and are consistent with the patient's current medication therapy only when the following conditions are met:

(a) A patient or patient's agent must enroll each prescription medication in an auto-refill program before a pharmacy can include the prescription medication as part of the auto-refill program;

(b) The prescription is not a controlled substance;

(c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or patient's agent;

(d) Pick-up notification to a patient or patient's agent may be generated upon completion of a prescription refill; and

(e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription medication is removed from the auto-refill program for that patient.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-139-0320
Prescription: Expiration

This section of rule addresses the expiration date of the prescription and not the expiration date of the drug.

(1) After one year from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber.

(2) When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled substance means that the medication can be refilled in proper context for a period of one year.

(a) When this abbreviation is used alone as a means to authorize refills for a controlled substance, the medication can be refilled in proper context for a period of six months or five refills, whichever comes first.

(b) When this abbreviation is used in conjunction with a definite time period, or a specific number of refills, the non-controlled medication can be refilled in proper context for a period not to exceed one year.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-139-0325
Prescription: Transfers

(1) Prescriptions may be transferred between pharmacies for the purpose of refill dispensing provided that:

(a) The prescription is invalidated at the sending pharmacy; and

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.

(2) Prescriptions for controlled substances can only be transferred one time.

(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.

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

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 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX), and 16 CFR 1702 (XX/XX/XXXX).

[Publications: Publications referenced are available from the agency.]

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

855-139-0355
Dispensing: Customized Patient Medication Packages

POLICY DISCUSSION: Customized Medication Packages

In lieu of dispensing two or more prescribed drug products in separate containers, an Oregon licensed Pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (patient med pak). A patient med pak is a package prepared by a Certified Oregon Pharmacy Technician and verified by a pharmacist for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms. The patient med pak is so designed for each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken:

(1) Label:

(a) The patient med pak must bear a label stating:

(A) The name of the patient;

(B) A serial number for each patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;

(C) The name, strength, physical description or identification, and total quantity of each drug product contained therein;

(D) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product therein;

(E) Any storage instructions or cautionary statements required by the official compendia;

(F) The name of the prescriber of each drug product;

(G) The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date must be no later than 60 days from the date of preparation);

(H) The name, address, and telephone number of the dispenser and the dispenser's registration number where necessary; and

(I) Any other information, statements, or warnings required for any of the drug products contained therein.

(b) If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container must bear a label identifying each of the drug products contained therein.

(2) Labeling: The patient med pak must be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the Oregon licensed Pharmacist for the total patient med pak.

(3) Packaging:

(a) In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak must comply with the moisture permeation requirements for a Class B single-unit or unit-dose container. Each container must be either not reclosable or so designed as to show evidence of having been opened;

(b) There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards must be placed in an outer package that does comply, or the necessary consent of the purchaser or physician, to dispense in a container not intended to be child-resistant, must be obtained.

(4) Guidelines: It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the medications. In this regard, pharmacists are encouraged to report to USP headquarters any observed or report incompatibilities.

(5) Recordkeeping: In addition to any individual prescription filing requirements, a record of each patient med pak must be made and filed. Each record must contain, as a minimum:

(a) The name and address of the patient;

(b) The serial number of the prescription order for each drug product contained therein;

(c) The name of the manufacturer or labeler and lot number for each drug product contained therein;

(d) Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

(e) The date of preparation of the patient med pak and the beyond-use date that was assigned;

(f) Any special labeling instructions; and

(g) The name or initials of the Certified Oregon Pharmacy Technician who prepared the med pak and the Oregon licensed Pharmacist who verified the patient med pak.

(6) Ensure an Oregon licensed Pharmacist visually verifies and documents each item required in OAR 855-139-0041 for each individual dosage unit in the med pak.

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

855-139-0400
Labeling: General Requirements

(1) Prescriptions must be labeled with the following information:

(a) Name, address and telephone number of the Remote Dispensing Site Pharmacy;

(b) Date;

(c) Identifying number;

(d) Name of patient;

(e) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(f) Directions for use by the patient;

(g) Name of practitioner;

(h) Required precautionary information regarding controlled substances;

(i) Such other and further accessory cautionary information as required for patient safety;

(j) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container unless, in the Oregon licensed Pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an expiration date must not be dispensed beyond the said expiration date of the drug;

(k) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules; and

(l) Address and telephone number of the Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & 689.515

855-139-0405
Labeling: Prescription Reader Accessibility

(1) A pharmacy must notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request; a prescription reader is a device designed to audibly convey labeling information.

(2) If a person informs the pharmacy that the person identifies as a person who is blind, the pharmacy must provide to the person a prescription reader that is available to the person for at least the duration of the prescription, must confirm it is appropriate to address the person's visual impairment, and must ensure that prescription labels are compatible with the prescription reader. This requirement does not apply to an institutional drug outlet, dispensing a drug intended for administration by a healthcare provider.

(3) Ensure an Oregon licensed Pharmacist verifies and documents that the correct electronic label was placed on each prescription container and that the audio information produced by the prescription reader is accurate prior to dispensing the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.561

855-139-0410
Labeling: Limited English Proficiency and Accessibility

(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide labels and informational inserts in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

855-139-0450
Drugs and Devices: Disposal

Drugs and devices that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0455
Drug and Devices: Return

(1) A Certified Oregon Pharmacy Technician may accept the return of a drug or device as defined by ORS 689.005 once the drug or device have been dispensed from the pharmacy if they were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, or are subject of a drug or device recall only if:

(a) An Oregon licensed Pharmacist has approved the return;

(b) The drugs or devices are accepted for destruction or disposal; and

(c) An Oregon licensed Pharmacist verifies the destruction or disposal.

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

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

(1) A Remote Dispensing Site 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 Remote Dispensing Site 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 Remote Dispensing Site 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 Remote Dispensing Site 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 Remote Dispensing Site 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 (04/01/2020), 21 CFR 1317.35 (04/01/2020), 21 CFR 1317.40 (04/01/2020), 21 CFR 1317.55 (04/01/2020), 21 CFR 1317.60 (04/01/2020), 21 CFR 1317.65 (04/01/2020), 21 CFR 1317.70 (04/01/2020), 21 CFR 1317.75 (04/01/2020), 21 CFR 1317.80 (04/01/2020), and 21 CFR 1317.85 (04/01/2020); and

(d) 21 USC 822 (04/01/2021), 21 USC 822a (04/01/2021).

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

855-139-0500
Policies and Procedures

(1) The Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy and the Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the Remote Dispensing Site Pharmacy. The written policies and procedures must be maintained at the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the responsibilities of the Affiliated Pharmacy and each Remote Dispensing Site Pharmacy including;

(a) Security;

(b) Operation, testing and maintenance of the telepharmacy system;

(c) Sanitation;

(d) Storage of drugs;

(e) Dispensing;

(f) Oregon licensed Pharmacist supervision, direction and control of pharmacy technicians;

(g) Documenting the identity, function, location, date and time of the licensees engaging in telepharmacy;

(h) Drug and/or device procurement;

(i) Receiving of drugs and/or devices;

(j) Delivery of drugs and/or devices;

(k) Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling);

(l) Recordkeeping;

(m) Patient confidentiality;

(n) On-site inspection by an Oregon licensed Pharmacist;

(o) Continuous quality improvement;

(p) Plan for discontinuing and recovering services if telepharmacy system disruption occurs;

(q) Training: initial and ongoing; and

(r) Interpretation, translation and prescription reader services.

(3) If non-prescription drugs are offered for sale at the Remote Dispensing Site Pharmacy, the policies and procedures must outline the process for the Oregon licensed Pharmacist counseling and advice.

(4) If non-sterile preparations are compounded at the Remote Dispensing Site Pharmacy, the policies and procedures must meet the requirements of OAR 855-045.

(5) If controlled substances are stored at the Remote Dispensing Site Pharmacy, the policies and procedures must include the following processes:

(a) Reviewing of controlled substance prescriptions for unauthorized alterations and inspected for legitimacy by the Oregon licensed Pharmacist during inspection visits;

(b) Maintaining an accurate controlled substance perpetual inventory for all controlled substances that are stocked at the Remote Dispensing Site Pharmacy; and

(c) Conducting and reconciling the controlled substance inventory.

(6) An Affiliated Pharmacy that provides remote pharmacy services through a telepharmacy system at a Remote Dispensing Site Pharmacy must review its written policies and procedures every 12 months, revise them if necessary, and document the review.

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

855-139-0550
Records: General Requirements

(1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The Remote Dispensing Site Pharmacy must maintain all required records unless these records are maintained in the Affiliated Pharmacy.

(3) Records retained by the Drug Outlet must include, but are not limited to:

(a) Patient profiles and records;

(b) Date, time and identification of each individual and activity or function performed;

(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(d) Controlled substance inventory and reconciliation;

(e) Oregon licensed Pharmacist physical inspection of Remote Dispensing Site Pharmacy;

(f) Audio and visual connection testing and individual training on use of the audio and visual connection;

(g) Data, telephone audio, audio and video, still image capture, store and forward images, security and surveillance data. This must be retained according to (1); and

(h) Any errors or irregularities identified by the quality improvement program.

(4) All data, telephone audio, audio and video, still image capture and store and forward images collected by the telepharmacy, security and surveillance systems must be retained according to (1).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508

855-139-0555
Records: Patient

A patient record system must be maintained by pharmacies for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing Oregon licensed Pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing. The pharmacist must make a reasonable effort to obtain, record, and maintain the following information:

(1) Full name of the patient for whom the drug is intended;

(2) Address and telephone number of the patient;

(3) Patient's age or date of birth;

(4) Patient's gender;

(5) Chronic medical conditions;

(6) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(7) Known allergies, drug reactions, and drug idiosyncrasies; and

(8) If deemed relevant in the Oregon licensed Pharmacist's professional judgment:

(a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet Remote Dispensing Site Pharmacy may not:

(1) Allow a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;

(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the board pursuant to ORS 689.305.

(3) Deliver a prescription;

(4) Provide non-prescription or prescription drugs when the Remote Dispensing Site Pharmacy is closed;

(5) Compound sterile preparations; or

(6) Repackage drugs.

Statutory/Other Authority: ORS 475.035, , ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0602
Prohibited Practices: Disclosure of Patient Information

(1) Allow a licensee or registrant of the board who obtains any patient information to disclose that information to a third party without the consent of the patient except as provided in (2) of this rule

(2) A licensee may disclose patient information:

(a) To the board;

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

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

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

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

(3) Allow a licensee or registrant of the board to access or obtain any patient information unless it is accessed or obtained for the purpose of patient care.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0650
Grounds for Discipline

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

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

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:

(a) Is false, fraudulent, deceptive, or misleading; or

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.

(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with an Oregon licensed Pharmacist's ability to practice with reasonable competency and safety.

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

(c) Adequate time for an Oregon licensed Pharmacist to complete professional duties and responsibilities including, but not limited to:

(A) Drug Utilization Review;

(B) Verification of the accuracy of a prescription;

(C) Counseling; and

(D) All other duties and responsibilities of an Oregon licensed Pharmacist as specified in OAR 855-019.

(4) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.

(5) Incenting or inducing the transfer of a prescription absent professional rationale.

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

855-139-0710
Service: Epinephrine- Definitions

The following words and terms, when used in OAR 855-139-0210 through OAR 855-139-0211 have the following meanings, unless the context clearly indicates otherwise.

(1) "Allergic reaction" means a medical condition caused by exposure to an allergen, with physical symptoms that may be life threatening, ranging from localized itching to severe anaphylactic shock and death.

(2) "Authorization to Obtain Epinephrine" means a certificate that contains the name, signature, and license number of the supervising professional authorizing the dispensing of epinephrine to the individual whose name appears on the certificate. Additionally, the certificate contains a record of the number of epinephrine orders filled to date.

(3) "Statement of Completion" means a certificate that states the specific type of emergency the trainee was trained to respond to, the trainee's name and address, the name of the authorized trainer and the date that the training was completed.

(4) "Trainee" means an individual who has attended and successfully completed the formal training pursuant to the protocols and criteria established by the Oregon Health Authority, Public Health Division.

Statutory/Other Authority: ORS 689.205 & ORS 689.681
Statutes/Other Implemented: ORS 689.155 & ORS 689.681

855-139-0715
Service: Epinephrine- General Requirements

(1) A Certified Oregon Pharmacy Technician may prepare for Oregon licensed Pharmacist verification an order for epinephrine to be used by trainees to treat an anaphylactic reaction. Trainees must be 18 years of age or older and must have responsibility for or contact with at least one (1) other person as a result of the trainee's occupation or volunteer status, such as, but not limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide or chaperone.

(2) Individuals must successfully complete a training program approved by the Oregon Health Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:

(a) Statement of Completion; and

(b) Authorization to Obtain Epinephrine.

(3) Acquisition of epinephrine from a pharmacy to be used for the treatment of allergic emergencies may occur in the following manners:

(a) An Oregon licensed Pharmacist may dispense epinephrine to a trainee upon presentation of the Statement of Completion and Authorization to Obtain Epinephrine certificate to a pharmacy when:

(A) An Oregon licensed Pharmacist may generate a prescription for and dispense an emergency supply of epinephrine for not more than one adult and one child dose package, as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Epinephrine certificate.

(B) The Oregon licensed Pharmacist who generates the hardcopy prescription for epinephrine in this manner must reduce the prescription to writing and file the prescription in a manner appropriate for a non-controlled substance.

(C) Once the Oregon licensed Pharmacist generates the epinephrine prescription, the Certified Oregon Pharmacy Technician must write in the appropriate space provided on the Authorization to Obtain Epinephrine certificate the date and the number of doses dispensed, the Oregon licensed Pharmacist must verify the accuracy of data written on the certificate and the Certified Oregon Pharmacy Technician must return the completed certificate to the trainee.

(D) The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used to obtain epinephrine up to four (4) times within three (3) years from the date of the initial training.

(E) Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire three (3) years from the date of the trainee's last Oregon Health Authority approved allergy response training.

(F) Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.

(b) A Certified Oregon Pharmacy Technician may prepare for Oregon licensed Pharmacist verification epinephrine to be dispensed to an entity when:

(A) The epinephrine is acquired by a valid prescription presented to the pharmacy;

(B) The prescription identifies the entity as the patient for the purpose of prescribing and labeling the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 433.825

855-139-0720
Service: Naloxone- General Requirements

Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:

(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction;

(2) Documentation and recordkeeping: and

(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682

855-139-0725
Service: Expedited Partner Therapy (EPT)- Purpose

(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.

(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.

(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

855-139-0730

Service: Expedited Partner Therapy (EPT) - Procedures

(1) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(2) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule govern.

(3) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon Health Authority (OHA) to be appropriately used for EPT.

Prescription

(4) An EPT treatment protocol must conform to the following:

(a) It must include a prescription for each named or unnamed partner of the patient;

(b) It must contain a handwritten or electronic signature of the prescribing practitioner;

(c) The practitioner must identify the prescription in the following manner:

(A) Write "for EPT," or a similar notation, on the face of the prescription;

(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;

(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe – Partner 1" or by labeling the prescription as "EPT Partner"

(d) An EPT Prescription expires 30 days after the date written;

(e) An EPT Prescription may not be refilled;

(f) If any component of the prescription is missing, the Oregon licensed Pharmacist must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.

(5) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may give all prescriptions to one pharmacy and then give the dispensed drugs to each unnamed partner.

Labeling

(6) The Certified Oregon Pharmacy Technician must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when

either the patient or partner is unnamed, the pharmacy may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.

(7) The Oregon licensed Pharmacist must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling

(8) The Oregon licensed Pharmacist is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the Oregon licensed Pharmacist must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The Oregon licensed Pharmacist should advise the patient to encourage each partner to call the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records

(9) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the board upon request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

Division 080– Controlled Substances (Pseudoephedrine/Ephedrine/Phenylpropanolamine & Procedural Rule Review)

Filing Caption (15 word limit)**:** 2021 HB 2648 Allows pharmacist or pharmacy technician to transfer pseudoephedrine or ephedrine without prescription.

Need for Rules:

1. Revisions to Division 080 are necessary to allow for the transfer of a drug containing pseudoephedrine or ephedrine without prescription to a person who is at least 18 years of age and presents person's valid government-issued photo identification pursuant to 2021 HB 2648 and effective 1/1/2022.

2. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Fiscal Impact:

No fiscal anticipated.

Documents relied upon include:

2021 HB 2648 and related statutes

ORS 475.754 Affirmative defense to unlawfully possessing pseudoephedrine

ORS 475.950(2)(f) Failure to report precursor substances transaction.

ORS 475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records.

DEA Pharmacists Manual (v.2020) pg. 90-96

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

21 CFR 1306 (XX/XX/XXXX) Prescriptions

21 CFR 1307 (XX/XX/XXXX) Miscellaneous

21 CFR 1308 (XX/XX/XXXX) Schedules of Controlled Substances

21 CFR 1314 (XX/XX/XXXX) Retail Sale of Scheduled Listed Chemical Products

Table of Exempted Prescription Products (06/26/2021) per 21 CFR 1308.32

Rules Summary:

Revisions to Division 080 are necessary to allow for the transfer of pseudoephedrine required by 2021 HB 2648. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Division 41
OPERATION OF PHARMACIES (AMBULATORY AND RESIDENTIAL DRUG OUTLETS)

855-041-1030
Reporting Drug Loss

(1) Disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices shall immediately be reported to the ~~B~~**b**oard.

(2) The outlet ~~shall~~**must** notify the ~~B~~**b**oard in the event of a significant drug loss or violation related to drug theft within one (1) business day. **A pharmacy must consider a controlled drug loss to be significant when:**

(a) The percentage of dosage units of a specific drug exceeds 2% of monthly dispensing volume; or

(b) Fifteen or more dosage units are not accounted for.

(3) At the time a Report of Theft or Loss of Controlled Substances (D~~.~~E~~.~~A~~.~~ Form 106) **or Report of Theft or Loss of Listed Chemicals (DEA Form 107)** is sent to the Drug Enforcement Administration, a copy ~~shall be~~ **is** sent to the ~~B~~**b**oard.

Statutory/Other Authority: ORS 475.035, **ORS** 689.155, **ORS** 689.205, **ORS** 689.305, **ORS** 689.315
Statutes/Other Implemented: ORS 689.155

Division 80
SCHEDULE OF CONTROLLED SUBSTANCES

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 (04/01/2020)~~; 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~~.

Statutory/Other Authority: ORS 689.205, ORS 475.973
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 (04/01/2020)**~~.~~; 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 XXX.XXX [section 2 of HB 2648 (2021)]; and

(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 2021 HB 2648;

(d) Ensure that only a Pharmacist, Pharmacy Technician or Certified Oregon 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

(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, 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) Pharmacies, Pharmacists, Certified Oregon Pharmacy Technicians and Pharmacy Technicians involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/2020), 21 CFR 1314.02 (04/01/2020), 21 CFR 1314.03

(04/01/2020), 21 CFR 1314.05 (04/01/2020), 21 CFR 1314.10 (04/01/2020), 21 CFR 1314.15 (04/01/2020), 21 CFR 1314.20 (04/01/2020), 21 CFR 1314.25, (04/01/2020); 21 CFR 1314.30 (04/01/2020), 21 CFR 1314.35 (04/01/2020), 21 CFR 1314.40 (04/01/2020), 21 CFR 1314.42 (04/01/2020), 21 CFR 1314.45 (04/01/2020); and 21 CFR 1314.50 (04/01/2020).

Statutory/Other Authority: ORS 689.205, **2021 HB 2648**
Statutes/Other Implemented: ORS 475.035, **2021 HB 2648**

855-080-0028
Excluded or Exempted Substances

(1) ~~Drugs and their generic equivalents listed~~ **The board adopts the excluded substances list found** in 21 CFR 1308.22 (04/01/2020) ~~are excluded from the schedules in OAR 855-080-0021 through 855-080-0026.~~

(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/2020).

(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (06/26/2021) pursuant to 21 CFR 1308.32 (04/01/2020).

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

OAR 855-080-0029
Acceptable Subpoenas for Law Enforcement Agencies to Obtain Pseudoephedrine or Ephedrine Log Information

(1) "Law Enforcement Agency" includes the following:

(a) County sheriffs, municipal police departments, police departments established by a university under ORS 352.121 or 353.125 and state police;

(b) Other police officers of this state or another state, including humane special agents as defined in ORS 181A.345;

(c) The Oregon Department of Justice when conducting a criminal investigation;

(d) A tribal government as defined in ORS 181A.680 that employs authorized tribal police officers as defined in ORS 181A.680; and

(e) Law enforcement agencies of the federal government.

(2) Acceptable subpoenas for a law enforcement agency to obtain information in a pseudoephedrine or ephedrine log are subpoenas lawfully issued by:

(a) A grand jury under ORS 136.563;

(b) A district attorney under ORS 136.565;

(c) The Oregon Attorney General under ORS 183.073;

(d) A law enforcement agency of a tribal government under tribal subpoena authority; and

(e) A federal law enforcement agency under federal subpoena power.

(3) Subpoenas that meet the criteria in (2) are accepted by the Board under ORS XXX.XXX [section 2, subsection 5 of HB 2648 (2021)]. The Board does not act as a decisionmaker as to a subpoena issued for pseudoephedrine or ephedrine logs under this rule. The Board is not a party to a subpoena for information contained in a pseudoephedrine or ephedrine log under this rule.

Statutory/Other Authority: ORS 689.205, **2021 HB 2648**
Statutes/Other Implemented: ORS 475.035, **2021 HB 2648**

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 (04/01/2020).

(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/2020).

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

~~855-080-0080~~
~~Special Exceptions~~

~~The board adopts the exceptions to registration found in 21 CFR 1307.11 (04/01/2020) and 21 CFR 1307.13 (04/01/2020).~~

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

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 (04/01/2020), 21 CFR 1306.02 (04/01/2020), 21 CFR 1306.03 (04/01/2020), 21 CFR 1306.04 (04/01/2020), 21 CFR 1306.05 (04/01/2020), 21 CFR 1306.06 (04/01/2020), 21 CFR 1306.07 (04/01/2020), 21 CFR 1306.08 (04/01/2020), 21 CFR 1306.09 (04/01/2020); 21 CFR 1306.11 (04/01/2020), 21 CFR 1306.12 (04/01/2020), 21 CFR 1306.13 (04/01/2020), 21 CFR 1306.14 (04/01/2020), 21 CFR 1306.15 (04/01/2020); 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25 (04/01/2020), ~~21 CFR 1306.26 (04/01/2020),~~ 21 CFR 1306.27 (04/01/2020); and 21 CFR 1304.03(d) (04/01/2020).

(2) Controlled substances listed in 21 CFR 1308.15 (XX/XX/XXXX) as schedule V are prescription drugs.

(3) Pseudoephedrine, ephedrine and phenylpropanolamine may be:

(a) Provided to a patient without a prescription under ORS XXX.XXX [section 2 of HB 2648 (2021)].

(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25 (04/01/2020), and 21 CFR 1306.27 (04/01/2020).

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

Division 080– Controlled Substances (Pseudoephedrine/Ephedrine/Phenylpropanolamine & Procedural Rule Review)

Filing Caption (15 word limit)**:** 2021 HB 2648 Allows pharmacist or pharmacy technician to transfer pseudoephedrine or ephedrine without prescription.

Need for Rules:

1. Revisions to Division 080 are necessary to allow for the transfer of a drug containing pseudoephedrine or ephedrine without prescription to a person who is at least 18 years of age and presents person's valid government-issued photo identification pursuant to 2021 HB 2648 and effective 1/1/2022.

2. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Fiscal Impact:

No fiscal anticipated.

Documents relied upon include:

2021 HB 2648 and related statutes

ORS 475.754 Affirmative defense to unlawfully possessing pseudoephedrine

ORS 475.950(2)(f) Failure to report precursor substances transaction.

ORS 475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records.

DEA Pharmacists Manual (v.2020) pg. 90-96

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

21 CFR 1306 (XX/XX/XXXX) Prescriptions

21 CFR 1307 (XX/XX/XXXX) Miscellaneous

21 CFR 1308 (XX/XX/XXXX) Schedules of Controlled Substances

21 CFR 1314 (XX/XX/XXXX) Retail Sale of Scheduled Listed Chemical Products

Table of Exempted Prescription Products (06/26/2021) per 21 CFR 1308.32

Rules Summary:

Revisions to Division 080 are necessary to allow for the transfer of pseudoephedrine required by 2021 HB 2648. Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Division 41
OPERATION OF PHARMACIES (AMBULATORY AND RESIDENTIAL DRUG OUTLETS)

855-041-1030
Reporting Drug Loss

(1) Disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices shall immediately be reported to the ~~B~~**b**oard.

(2) The outlet ~~shall~~**must** **ensure that confirmed** ~~notify the Board in the event of a~~ significant drug loss or ~~violation~~ **any loss** related to **suspected** drug theft **of a controlled substance is reported to the board** within one ~~(1)~~ business day.

(3) At the time a Report of Theft or Loss of Controlled Substances (D~~.~~E~~.~~A~~.~~ Form 106) **or Report of Theft or Loss of Listed Chemicals (DEA Form 107)** is sent to the Drug Enforcement Administration, a copy ~~shall be~~ **is** sent to the ~~B~~**b**oard.

Statutory/Other Authority: ORS 475.035, **ORS** 689.155, **ORS** 689.205, **ORS** 689.305, **ORS** 689.315
Statutes/Other Implemented: ORS 689.155

Division 80
SCHEDULE OF CONTROLLED SUBSTANCES

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 (04/01/2020)~~; 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~~.

Statutory/Other Authority: ORS 689.205, ORS 475.973
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 (04/01/2020)**~~.~~; 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 XXX.XXX [section 2 of HB 2648 (2021)]; and

(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 2021 HB 2648;

(d) Ensure that only a Pharmacist, Pharmacy Technician or Certified Oregon 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

(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, 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) Pharmacies, Pharmacists, Certified Oregon Pharmacy Technicians and Pharmacy Technicians involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/2020), 21 CFR 1314.02 (04/01/2020), 21 CFR 1314.03

(04/01/2020), 21 CFR 1314.05 (04/01/2020), 21 CFR 1314.10 (04/01/2020), 21 CFR 1314.15 (04/01/2020), 21 CFR 1314.20 (04/01/2020), 21 CFR 1314.25, (04/01/2020); 21 CFR 1314.30 (04/01/2020), 21 CFR 1314.35 (04/01/2020), 21 CFR 1314.40 (04/01/2020), 21 CFR 1314.42 (04/01/2020), 21 CFR 1314.45 (04/01/2020); and 21 CFR 1314.50 (04/01/2020).

Statutory/Other Authority: ORS 689.205, **2021 HB 2648**
Statutes/Other Implemented: ORS 475.035, **2021 HB 2648**

855-080-0028
Excluded or Exempted Substances

(1) ~~Drugs and their generic equivalents listed~~ **The board adopts the excluded substances list found** in 21 CFR 1308.22 (04/01/2020) ~~are excluded from the schedules in OAR 855-080-0021 through 855-080-0026.~~

(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/2020).

(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (06/26/2021) pursuant to 21 CFR 1308.32 (04/01/2020).

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

OAR 855-080-0029
Acceptable Subpoenas for Law Enforcement Agencies to Obtain Pseudoephedrine or Ephedrine Log Information

(1) "Law Enforcement Agency" includes the following:

(a) County sheriffs, municipal police departments, police departments established by a university under ORS 352.121 or 353.125 and state police;

(b) Other police officers of this state or another state, including humane special agents as defined in ORS 181A.345;

(c) The Oregon Department of Justice when conducting a criminal investigation;

(d) A tribal government as defined in ORS 181A.680 that employs authorized tribal police officers as defined in ORS 181A.680; and

(e) Law enforcement agencies of the federal government.

(2) Acceptable subpoenas for a law enforcement agency to obtain information in a pseudoephedrine or ephedrine log are subpoenas lawfully issued by:

(a) A grand jury under ORS 136.563;

(b) A district attorney under ORS 136.565;

(c) The Oregon Attorney General under ORS 183.073;

(d) A law enforcement agency of a tribal government under tribal subpoena authority; and

(e) A federal law enforcement agency under federal subpoena power.

(3) Subpoenas that meet the criteria in (2) are accepted by the Board under ORS XXX.XXX [section 2, subsection 5 of HB 2648 (2021)]. The Board does not act as a decisionmaker as to a subpoena issued for pseudoephedrine or ephedrine logs under this rule. The Board is not a party to a subpoena for information contained in a pseudoephedrine or ephedrine log under this rule.

Statutory/Other Authority: ORS 689.205, **2021 HB 2648**
Statutes/Other Implemented: ORS 475.035, **2021 HB 2648**

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 (04/01/2020).

(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/2020).

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

~~855-080-0080~~
~~Special Exceptions~~

~~The board adopts the exceptions to registration found in 21 CFR 1307.11 (04/01/2020) and 21 CFR 1307.13 (04/01/2020).~~

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

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 (04/01/2020), 21 CFR 1306.02 (04/01/2020), 21 CFR 1306.03 (04/01/2020), 21 CFR 1306.04 (04/01/2020), 21 CFR 1306.05 (04/01/2020), 21 CFR 1306.06 (04/01/2020), 21 CFR 1306.07 (04/01/2020), 21 CFR 1306.08 (04/01/2020), 21 CFR 1306.09 (04/01/2020); 21 CFR 1306.11 (04/01/2020), 21 CFR 1306.12 (04/01/2020), 21 CFR 1306.13 (04/01/2020), 21 CFR 1306.14 (04/01/2020), 21 CFR 1306.15 (04/01/2020); 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25 (04/01/2020), ~~21 CFR 1306.26 (04/01/2020),~~ 21 CFR 1306.27 (04/01/2020); and 21 CFR 1304.03(d) (04/01/2020).

(2) Controlled substances listed in 21 CFR 1308.15 (XX/XX/XXXX) as schedule V are prescription drugs.

(3) Pseudoephedrine, ephedrine and phenylpropanolamine may be:

(a) Provided to a patient without a prescription under ORS XXX.XXX [section 2 of HB 2648 (2021)].

(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25 (04/01/2020), and 21 CFR 1306.27 (04/01/2020).

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

Division 019/021– Pharmacist (Licensing)/Continuing Education (Pain Management)

Filing Caption (15 word limit)**:** 2021 HB 2078 Modifies pain management education requirements for pharmacists.

Need for Rules: Revisions to Division 019/021 are necessary to incorporate continuing education requirement directives set forth in 2021 HB 2078, related to pain management education.

Fiscal Impact: In Oregon, it is estimated that 8,347 pharmacists will be impacted by these new requirements. There is no fee for completing this one-hour pain management course.

Documents relied upon include:

2021 HB 2078 and related statutes

OPMC Pain Management Module

Rules Summary: Revisions to Division 019/021 are necessary to incorporate continuing education requirement directives set forth in 2021 HB 2078, related to pain management education.

Division 19
PHARMACISTS

855-019-0120
Licensure

(1) Before licensure as a pharmacist, an applicant must meet the following requirements:

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

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

(c) Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) exam with a score of not less than 75. The applicant may not take the MPJE until they have graduated from a school or college of pharmacy approved by the ~~B~~**b**oard. A candidate who does not attain this score may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times. The MPJE score ~~shall be~~ **is** valid for 6 months unless extended by the ~~B~~**b**oard;

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

(e) 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.

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

Division 21
CONTINUING PHARMACY EDUCATION

855-021-0001
Definitions

(1) “Continuing Pharmacy Education” or “CPE” means classes of post graduate studies, informal study group participation, institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, planned and professional meetings, self-study courses, cassette or audio visual tape/slides or materials, and other self-instruction units applicable to the practice of pharmacy.

(2) “Contact hour” means fifty minutes of continuing pharmacy education.

(3) “Patient safety” means systems, procedures and processes that ensure that the correct patient receives the correct drug in the correct dose and is counseled appropriately.

(4) “Medication error prevention” means systems, procedures and processes to prevent and avoid adverse events and to ensure that the correct patient receives the correct drug in the correct dose.

(5) "Pain management education program" means a specific one hour web-based program developed by the Oregon Pain Commission~~, in addition to six accredited hours of continuing education in pain management, end of life care or a combination of both~~.

(6) “Cultural competence” means the lifelong process of examining the values and beliefs and developing and applying an inclusive approach to health care practice in a manner that recognizes the content and complexities of provider-patient communication and interaction and preserves the dignity of individuals, families, and communities.

(a) Cultural competence applies to all patients.

(b) Culturally competent providers do not make assumptions on the basis of an individual’s actual or perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital status, socio-economic status, veteran’s status, sexual orientation, gender identity, gender expression, gender transition status, level of formal education, physical or mental disability, medical condition or any consideration recognized under federal, state and local law.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 413.590

855-021-0005
Continuing Pharmacy Education Required for Pharmacist License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a pharmacist must have satisfactorily completed **at least** 30 hours of continuing pharmacy education. These hours must include **at least**:

(a) Two hours of continuing pharmacy education in pharmacy law;

(b) Two hours of continuing pharmacy education in patient safety or medication error prevention;

(c) Two hours of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(d) One hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority; and

(~~d~~**e**) Twenty **three** ~~four~~ additional hours of continuing pharmacy education.

~~(2) Prior to the second license renewal, a pharmacist licensed under these rules must complete seven hours of continuing education in pain management as detailed in the following sub-sections.~~

~~(a) A one-hour pain management course, specific to Oregon, provided by the Pain Management Commission of the Oregon Health Authority; and~~

~~(b) A minimum of six hours of continuing education in pain management. This requirement may be fulfilled by any combination of continuing education coursework focusing on pain management including but not limited to the treatment of terminally ill and dying patients, and those with chronic, non-malignant pain.~~

~~(c) The pain management continuing education required under this rule may count towards the required 30 continuing pharmacy education contact hours.~~

(~~3~~**2**) Section (1) does not apply to pharmacists applying for the first renewal of their license if they have not been licensed by the board for at least one year prior to July 1 of the renewal period.

(4**3**) A pharmacist must retain documentation of completed continuing pharmacy education for six years and must provide this documentation if requested by the board.

(~~5~~**4**) Continuing pharmacy education credit accumulated in excess of the required 30 contact hours for biennial license renewal cannot be carried forward.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 689.285, ORS 413.450, ORS 413.590 & **2021 HB 2078**

Division 020: Pharmacist Prescriptive Authority (Face-to-Face/ Protocols)

Filing Caption (max 15 words): Compendia and prescribing practices updated incorporating recent Public Health and Pharmacy Formulary Advisory Committee recommendations.

Need for Rules:

1. Permanently adopts the COVID-19 monoclonal antibody (mAb) therapy protocol for the treatment and post-exposure prophylaxis of COVID-19. Improving the supply of prescribers and administrators will facilitate increased accessibility to mAb therapy is in the interest of public health.

2. Adopts revisions to PEP and PrEP protocols as recommended by the committee.

3. Clarifies that face-to-face requirement only applies to physical assessment components of patient care process (collect, assess, plan, implement, and follow-up). Additional revisions are minor corrections.

Fiscal Impact: None anticipated

Documents Relied Upon:

ORS 689.645 and 689.649 state that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol, developed by the PHPFAC; and adopted by rule of the Board. A statewide protocol consists of a standardized patient assessment process and treatment care plan under which a pharmacist may assess and identify a patient's medical need, then prescribe and dispense a drug or device to the patient.

Statewide drug therapy management protocol for COVID mAb:

- Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV

- Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of REGEN-COV

Statewide drug therapy management protocol for PEP and PrEP:

- 2021 HB 2958

- CDC Pre-exposure Prophylaxis (PrEP) Care System

- AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

Rules Summary:

Permanently adopts new COVID mAb to the protocol compendia. Amends protocol versions in the protocol compendia. Clarifies that face-to-face requirement only applies to physical assessment. Other components of patient care process (collect, assess, plan, implement, and follow-up).

1 Division 20
2 PHARMACIST PRESCRIPTIVE AUTHORITY
3

855-020-0110

Prescribing Practices

(1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist ~~shall~~**may** only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.

(2) A pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services pursuant to statewide drug therapy management protocols. The policies and procedures ~~shall~~**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 pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.

(4) For each drug or device the pharmacist prescribes, the pharmacist must:

(a) Assess patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient's health history and clinical status. The pharmacist's ~~patient~~**physical** assessment ~~shall~~**must** be performed in a face-to-face, in-person interaction and not through electronic means; and

(b) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the statewide drug therapy management protocol and policies and procedures; and

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

(d) 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 Compendia drug or device.

(5) The pharmacist ~~shall~~**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) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use real-time audio-visual communication to conduct the consultation.

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

855-020-0300
Protocol Compendium

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

(1) Continuation of therapy (v. 06/2021)

(2) Conditions

(a) Cough and cold symptom management

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

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

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

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

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

(c) COVID-19 Monoclonal Antibody **(mAb)** Protocol (v. 0~~8~~**9**/2021)

(3) Preventative care

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

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

(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT Protocol (v. 06/2021);

(d) Travel Medications Protocol (v. 06/2021)

(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 0~~6~~**9**/2021); and

(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. 0~~6~~**9**/2021)

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

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

CONDITIONS

COVID Monoclonal Antibodies (REGEN-COV™) TREATMENT and POST-EXPOSURE PROPHYLAXIS

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 and administer monoclonal antibodies casirivimab and imdevimab (REGEN-COV™).

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized COVID mAb Patient Intake Form (pg. 4-5)
  - Utilize the standardized COVID mAb Assessment and Treatment Care Pathway (pg. 6-21)
  - Utilize the standardized COVID mAb Patient Informational: Fact Sheet for Patients, Parents and Caregivers: EUA of REGEN-COV™ (pg. 23-27)
  - Utilize the standardized COVID mAb Provider Notification (pg. 28)

  PHARMACIST TRAINING/EDUCATION:
  - Completion of APhA Pharmacy-Based Immunization Delivery certificate (or equivalent)
  - Ensure Pharmacist is competent in pertinent physical assessment technique (ie. respiratory rate, pulse oximetry, blood pressure) and familiar with approved subcutaneous injection sites for REGEN-COV™.
  - Review REGEN-COV™ resources for healthcare providers, available at: https://www.regencov.com/hcp/resources
  - A minimum of 1 hour of training or continuing education (CE) on COVID monoclonal antibody treatment
    - CDC 8/12/2021 Webinar: CDC Therapeutic Options to Prevent Severe COVID-19 in Immunocompromised People
    - OHA 8/26/2021 Webinar: COVID-19 Monoclonal Antibody Webinar
    - CE: COVID-19 Monoclonal Antibody Assessment & Administration
    - CE: Pharmacists on the Frontline of COVID-19: From Testing to Treatment and Prevention

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

REALD Data Collection Form

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

Legal Name_____ Preferred Name _____

1. Which of the following describes your **Racial or Ethnic identity**? Please check **ALL** that apply.

Hispanic and Latino/a/x
□ Central American
□ Mexican
□ South American
□ Other Hispanic or Latino/a/x

Native Hawaiian and Pacific Islander
□ CHamoru (Chamorro)
□ Marshallese
□ Communities of the Micronesian Region
□ Native Hawaiian
□ Samoan
□ Other Pacific Islander

White
□ Eastern European
□ Slavic
□ Western European
□ Other White

American Indian and Alaska Native
□ American Indian
□ Alaska Native
□ Canadian Inuit, Metis, or First Nation
□ Indigenous Mexican, Central American, or South American

Black and African American
□ African American
□ Afro-Caribbean
□ Ethiopian
□ Somali
□ Other African (Black)
□ Other Black

Middle Eastern/North African
□ Middle Eastern
□ North African

Asian
□ Asian Indian
□ Cambodian
□ Chinese
□ Communities of Myanmar
□ Filipino/a
□ Hmong
□ Japanese
□ Korean
□ Laotian
□ South Asian
□ Vietnamese
□ Other Asian

Other Categories
□ Other (please list)
_____
□ Don't know
□ Don't want to answer

2. If you checked **more than one** category above, is there **<u>one</u>** you think of as your **primary** racial or ethnic identity?
   □ Yes. Please circle your primary racial or ethnic identity above.
   □ I do not have just one primary racial or ethnic identity.
   □ No. I identify as Biracial or Multiracial.
   □ N/A. I only checked one category above.
   □ Don't know
   □ Don't want to answer

Language (*Interpreters are available at no charge*)

3. What language or languages do you **use at home**? _____
   → Skip to question 9 if you indicated English only

4. In what language do you want us to communicate in **person, on the phone, or virtually** with you?

5. In what language do you want us to **write** to you? _____

6. Do you need or want an **interpreter** for us to communicate with you?
   □ Yes □ No □ Don't know □ Don't want to answer

7. If you need or want an interpreter, what type of interpreter is preferred?
□ Spanish language interpreter □ Deaf Interpreter for DeafBlind, additional barriers, or both
□ American Sign Language interpreter □ Contact sign language (PSE) interpreter
□ Other (**please list**): _____

→ Skip to question 9 if you do not use a language other than English or sign language

8. How well do you speak English?
□ Very Well □ Well □ Not Well □ Not at all □ Don't know □ Don't want to answer

	Disability Your answers will help us find health and service differences among people with and without functional difficulties. Your answers are confidential.	Yes	***If yes**, at what age did this condition begin?	No	Don't know	Don't want to answer	Don't know what this question is asking
9.	Are you deaf or do you have serious difficulty hearing?						
10.	Are you blind or do you have serious difficulty seeing, even when wearing glasses?						
11.	Do you have serious difficulty walking or climbing stairs?						
12.	Because of a physical, mental or emotional condition, do you have serious difficulty concentrating, remembering or making decisions?						
13.	Do you have difficulty dressing or bathing?						
14.	Do you have serious difficulty learning how to do things most people your age can learn?						
15.	Using your usual (customary) language, do you have serious difficulty communicating (for example understanding or being understood by others)?						
16.	Because of a physical, mental or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping?						
17.	Do you have serious difficulty with the following: mood, intense feelings, controlling your behavior, or experiencing delusions or hallucinations?						

All health care providers must begin collecting and reporting REALD data in accordance with current REALD standards and Oregon Disease Reporting rules starting October 1, 2021.

COVID Monoclonal Antibodies (REGEN-COV™) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____
Which of the following describes your racial or ethnic identity? Please check **ALL** that apply.
□ Black/African American □ Hispanic and Latino/a/x □ American Indian/Alaska Native □ Asian □ Other
□ Native Hawaiian/Pacific Islander □ Middle Eastern/North African □ White □ Not specified
Are you houseless? Yes / No
Do you live in a shelter, encampment or transitional housing? Yes / No
Do you have a disability? Yes / No

Background Information:

1.	Are you under 12 years old?	□ Yes □ No
2.	Do you weigh under 88 lbs (40 kg)?	□ Yes □ No
3.	Have you had a positive COVID (SARS-CoV-2) antigen test within the past 14 days? If yes, please indicate the date of the positive test ___/___/_____.	□ Yes □ No
4.	In the past 10 days, have you experienced new or worsening of any of the following symptoms within the past 10 days? If yes, select any/all that apply: □ Fever □ Chills □ Cough □ Shortness of breath □ Difficulty breathing □ Fatigue □ Headache □ Muscle or body aches □ New loss of taste or smell □ Sore throat □ Congestion □ Runny nose □ Nausea □ Vomiting □ Diarrhea	□ Yes □ No
5.	Have you been in close contact of someone with COVID-19 disease within the last 96 hours (4 days), or living in a setting where risk of exposure is high? Note: Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (e.g., hugging or kissing), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (e.g., sneezing or coughing)	□ Yes □ No
6.	Are you fully vaccinated for COVID-19? If yes, indicate when Brand/Dose 1: _____ Brand/Dose 2: _____ Brand/Dose 3: _____	□ Yes □ No
7.	Do you have or have you had any of the following?	
	A. Age ≥65 years of age……	□ Yes □ No
	B. Cancer……	□ Yes □ No
	C. Chronic kidney disease……	□ Yes □ No
	D. Chronic lung diseases (e.g., chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)……	□ Yes □ No
	E. Dementia or other neurological conditions……	□ Yes □ No
	F. Diabetes (Type 1 or Type 2) ……	□ Yes □ No
	G. Heart conditions (such as heart failure, coronary artery disease, cardiomyopathies or hypertension) ……	□ Yes □ No
	H. HIV Infection……	□ Yes □ No
	I. Immunocompromised state (weakened immune system) ……	□ Yes □ No
	J. Liver Disease……	□ Yes □ No
	K. Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or oxygen supplementation (not related to COVID 19)……	□ Yes □ No
	L. Neurodevelopmental disorders (e.g., cerebral palsy, intellectual or developmental disabilities including down syndrome) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies)……	□ Yes □ No

COVID Monoclonal Antibodies (REGEN-COV™) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

	M. Overweight or obese……	□ Yes □ No
	N. Pregnancy……	□ Yes □ No
	O. Sickle cell disease or thalassemia……	□ Yes □ No
	P. Smoking, current or former……	□ Yes □ No
	Q. Solid organ or blood stem cell transplant……	□ Yes □ No
	R. Stroke or cerebrovascular disease, which affects blood flow to the brain……	□ Yes □ No
	S. Substance use disorders……	□ Yes □ No
8.	Do you have any other medical problems? If yes, list them here: _____ _____	□ Yes □ No
9.	Are you allergic to casirivimab, imdevimab, histidine, histidine monohydrochloride monohydrate , polysorbate 80, or sucrose? If yes, please circle allergy.	□ Yes □ No
10.	Do you have any other allergies? If yes, list them here: _____ _____	□ Yes □ No
11.	Do you take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No

Signature_____ Date ____/_____/_____

To Be Completed by a Pharmacist:

1. Weight _____ lbs. Height __ ft. ___ in. BMI _____
2. Oxygen Reading _____% SpO2, Respiratory Rate ____/min
3. Blood Pressure Reading _____/_____ mmHg, Pulse ____/min
4. Vaccination status in #6 should be confirmed via ALERT or CDC immunization card or self-reported (circle one)

If patient received therapy:

1. EUA Fact Sheet for Patients, Parents and Caregivers Provided: Version Date____/_____
2. Dose (check box and circle indication):
   - □ Casirivimab 600 mg and imdevimab 600 mg for treatment or post-exposure prophylaxis **-or-**
   - □ Casirivimab 300 mg and imdevimab 300 mg for ongoing exposure **-or-**
   - □ *Partial dose administered: Casirivimab _____mg and imdevimab _____mg due to: _____
3. Product/Lot: _____ Expiration: ___/___/_____ Product/Lot: _____ Expiration: ___/___/_____
4. Injection Sites:
   - □ R thigh □ R back of the upper arm □ Upper R quadrant of abdomen □ Lower R quadrant of abdomen
   - □ L thigh □ L back of the upper arm □ Upper L quadrant of abdomen □ Lower L quadrant of abdomen
5. Time Administration Began: ____:_____ AM/PM Time Administration Ended: ____:_____ AM/PM
6. Time Monitoring* Began: ____:_____ AM/PM Time Monitoring Ended: ____:_____ AM/PM
   *NOTE: 60 minutes of monitoring is still required even in patient received an incomplete dose.
7. Primary Care Provider (if known) contacted/notified of therapy Date _____/_____/_____
8. FDA MedWatch Report submitted (if adverse event occurred) Date _____/_____/_____

RPH Signature_____ Date ____/_____/_____

9. Follow-up with patient completed on Date ____/_____/_____

RPH Signature_____ Date ____/_____/_____

Standardized Assessment and Treatment Care Pathway
COVID Monoclonal Antibodies (REGEN-COV™)

1) COVID Monoclonal Antibody Screen (Form Qs: #1-2 and pharmacist physical assessment)

a. Age < 12 years old → **Refer to healthcare provider**
b. Weight < 88 lbs (40 kg) → **Refer to healthcare provider**
c. Clinical Factors:
    i. Oxygenation:
        i. SpO2 < 94% or if patient self-reports SpO2 is regularly 91-93% and SpO2 is lower than normal for the patient→ **Refer immediately to local Emergency Department or call 911**
        ii. If chronic oxygen supplementation required and, based on self-report, oxygen need has increased after positive COVID-19 test or exposure → **Refer to local Emergency Department or call 911**
        iii. If on oxygen supplementation due to current or previous COVID infection → **Refer for medical evaluation by a healthcare provider**
    ii. Respiratory rate >30/min → **Refer immediately to local Emergency Department or call 911**
    iii. Blood Pressure:
        i. Systolic Blood Pressure >180 mmHg or Diastolic Blood Pressure >120 mmHg → **Refer immediately to local Emergency Department or call 911**
        ii. Systolic Blood Pressure <90 mmHg or Diastolic Blood Pressure <60 mmHg → **Refer immediately to local Emergency Department or call 911**
        iii. Pulse <60 or >100 → **Refer for medical evaluation by a healthcare provider or call 911.**
    iv. Emergency warning signs:
        i. For COVID-19: Trouble breathing; persistent pain or pressure in the chest; new confusion; inability to wake or stay awake; pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone. → **Refer immediately to local Emergency Department or call 911**
        ii. For Hypoxia (<94% or <91% for those patients reporting lower baseline oxygen readings) Headache; shortness of breath; fast heartbeat; coughing; wheezing; confusion; bluish color in skin, fingernails, and lips → **Refer immediately to local Emergency Department or call 911**

The Pharmacist must document the physical assessment of the patient on the Patient Self-Screening Intake Form. The pharmacy must utilize medical grade devices for physical assessment of the patient.

If referral criteria not met, proceed to Step 2a.

2a) Treatment Screen (Form Qs: #3-4)

a. Positive SARS-CoV-2 molecular or antigen test within past 14 days associated with current symptoms?

    NOTE: Test results that are indeterminate or inconclusive results can suggest the presence of SARS-CoV2 in quantities insufficient for the molecular or antigen test to be positive. It is recommended to collect a new specimen and retest. If the results are still indeterminate or inconclusive, the patient should be referred to their healthcare provider for further evaluation.

AND

b. Onset of mild to moderate COVID-19 symptoms within past 10 days?

NOTE: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; and/or diarrhea)

If YES to BOTH questions above, proceed to Step 3.
If NO to EITHER question above, proceed to Step 2b.

2b) Post-Exposure Prophylaxis Screen (Form Qs: #5-6, 7I)

a. Has the patient been in close contact of someone with COVID-19 disease within the last 96 hours, or living in a setting where risk of exposure is high?

NOTE: Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (e.g., hugging or kissing), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (e.g., sneezing or coughing)

AND

b. Is the patient:
   i. Unvaccinated OR
   ii. Partially vaccinated OR
   iii. Vaccinated but not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications)?

NOTE: The CDC defines moderate to severe immunocompromised as the following:
- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

The pharmacist must check the ALERT Immunization Information System (IIS) to determine whether the patient is fully vaccinated. If ALERT IIS is unavailable, use available documentation and patient statement. The patient should not be vaccinated until 90 days after last receipt of COVID-19 Monoclonal Antibodies (REGEN-COV™).

NOTE: Individuals are considered to be fully vaccinated 2 weeks after their final dose of a multi-dose series, or 2 weeks after a single-dose vaccine. For additional information visit- https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

If YES to BOTH questions above, proceed to Step 3.

If NO to EITHER question above, COVID monoclonal antibody (mAb) therapy is not indicated at this time and pharmacists are not authorized to prescribe or administer COVID mAb treatment in accordance with this RPH protocol. → ***Refer*** *the patient for further evaluation and management by the patient's primary care provider. If patient has not had a SARS-CoV-2 molecular or antigen test, obtain test and repeat question #2a once results are available.*

3) Risk of Progression Screen (Form Qs: #7, demographics and REALD)

a. Does the patient have at least one of the conditions or factors met in #7 of the Self-Screening Patient Intake Form which places an individual at high risk of progression to severe COVID-19?

b. Does the patient identify as Black, African American, Latina/o/x, American Indian/Alaska Native, Asian, Asian American, or Pacific Islander on the Self-Screening Patient Intake Form which places an individual at high risk of progression to severe COVID-19?

NOTE: Other factors, such as race, ethnicity, disability or houselessness place individual patients at high risk for progression to severe COVID-19. Data indicates that:

- Patients of color or from tribal communities are most harmed by health inequities and the risk of hospitalization and death for these groups is greater than that of white patients. These patients may face higher risk than white patients, due to longstanding societal injustices including racism, discrimination, colonization, etc., which have and continue to negatively impact health outcomes. For this reason, people who identify as Black/African American, Latino/a/x, American Indian/Alaska Native, Asian or Pacific Islander are eligible for REGEN-COV™ under this protocol.
- Patients with the following disabilities might be at increased risk of becoming infected or having unrecognized illness or progression to severe disease.
  - People who have limited mobility or who cannot avoid coming into close contact with others who may be infected, such as direct support providers and family members
  - People who have trouble understanding information or practicing preventive measures, such as hand washing and social distancing
  - People who may not be able to communicate symptoms of illness

  https://www.cdc.gov/ncbddd/humandevelopment/covid-19/people-with-disabilities.html
- There is increased transmission of virus in congregate settings and outdoor settings that do not provide protection from the environment, adequate access to hygiene and sanitation facilities, or connection to services and healthcare. These settings include houselessness, sleeping outdoors or in an encampment setting.

Pharmacist must obtain patient weight, height, and calculate BMI to verify condition of overweight/obese in #7M on the Patient Intake Form.
https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

If YES to either question above, proceed to Step 4.
If NO, COVID monoclonal antibody (mAb) treatment is not indicated at this time and pharmacists are not authorized to prescribe or administer COVID mAb treatment in accordance with this RPH protocol. → ***Refer*** *the patient for further evaluation and management by the patient's primary care provider.*

4) Allergy Screen (Form Qs: 9)

a. Does the patient have a known hypersensitivity to any ingredient of REGEN-COV™?

If YES → ***Refer***
If NO, proceed to Step 5.

5) Document the Patient Education per Section X (pg. 11)

Document that you communicated to your patient or parent/caregiver, as age appropriate, information consistent with the "Fact Sheet for Patients, Parents, and Caregivers- Emergency Use Authorization (EUA) of REGEN-COV™" and provided a copy of the Fact Sheet to the patient or parent/caregiver prior to the patient receiving REGEN-COV™ (casirivimab and imdevimab), including:

a. FDA has authorized the emergency use of REGEN-COV™ (casirivimab and imdevimab) for the two indications described in this protocol (**see Indications**).
b. The patient or parent/caregiver has the option to accept or refuse REGEN-COV™.
c. The significant known and potential risks and benefits of REGEN-COV™, and the extent to which such risks and benefits are unknown.
d. Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials*.
   NOTE: **Intravenous monoclonal antibody therapy is preferred for *treatment* of COVID-19 unless it would result in a delay of therapy**. Refer to Fact sheet for Healthcare Providers- Emergency Use Authorization (EUA) of REGEN-COV™ for other alternatives. For information on clinical trials that are testing the use of REGEN-COV™ related to COVID-19, please see www.clinicaltrials.gov.
e. Patients treated with REGEN-COV™
   i. should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.
   ii. may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.

6) Administer therapy per Section VI, VII and VIII (pg. 8-10)
If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, Pharmacists must immediately discontinue administration and follow the Oregon Immunization Program's Guidelines for Managing Severe Adverse Events Following Immunization.
NOTE: Patients administered partial/incomplete therapy may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.

7) Monitor patient per Section IX (pg. 10-11) and report any witnessed or known serious advents potentially related to treatment per Section XI (pg. 11)
Ask patient to remain seated in the clinic for 60 minutes after administering therapy to decrease the risk of injury should they faint, and for the Pharmacist must monitor for visible signs of drug reactions and for anaphylaxis.
NOTE: Patients administered partial/incomplete therapy must be observed for 60 minutes.

If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, Pharmacists must follow the Oregon Immunization Program's Guidelines for Managing Severe Adverse Events Following Immunization and report to FDA Medwatch.

8) Notify primary care provider (if known) within 5 days of receipt of therapy, fax form required

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

Oregon licensed pharmacist must adhere to the EUA when prescribing/administering REGEN-COV™

Standardized Assessment and Treatment Care Pathway
COVID Monoclonal Antibodies (REGEN-COV™)

REGEN-COV™ (casirivimab and imdevimab)

I. INDICATIONS:

1. **Treatment:** The U.S. Food and Drug Administration (FDA) has issued an EUA to permit the emergency use of the unapproved product REGEN-COV™ for the treatment of mild to moderate COVID-19 within 10 days of symptom* onset in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

   *Mild or moderate COVID-19 symptoms may include: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; and/or diarrhea.

   Limitations of Authorized Use as Treatment:

   - REGEN-COV™ is not authorized for use in patients:
     - who are hospitalized due to COVID-19, OR
     - who require oxygen therapy due to COVID-19, OR
     - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related co-morbidity.

2. **Post-exposure Prophylaxis:** The FDA also issued an EUA to permit the emergency use of the unapproved product REGEN-COV™ in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:
   a. not fully vaccinated* or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications**) AND
      i. Who have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC)*** OR
      ii. Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (e.g., nursing homes, prisons)

   * Individuals are considered to be fully vaccinated 2 weeks after their final dose of a multi-dose series, or 2 weeks after a single-dose vaccine.

   **See this website for more details: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

   ***Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (e.g., hugging or kissing), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (e.g., sneezing or coughing). See this website for additional details: https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html

Limitations of Authorized Use as Post-exposure Prophylaxis:

- Post-exposure prophylaxis with REGEN-COV™ is not a substitute for vaccination against COVID-19. Patients may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.
- REGEN-COV™ is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

II. PATIENT ELIGIBILITY:

An eligible patient must meet the criteria within one of the two authorized indications. For both indications, a patient must be at high risk for progression to severe COVID-19, including hospitalization or death. Patients at high risk include, but are not limited to, individuals with at least one of the following risk factors:

- Older age (age ≥65 years of age)
- Obesity or being overweight (BMI >25 kg/m^2, or if age 12-17 years, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung disease (e.g., chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies)
- Have a medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19)

Authorization of REGEN-COV™ under the EUA is not limited to the medical conditions or factors listed above. Other factors, such as race or ethnicity may also place individual patients at high risk for progression to severe COVID-19. For example, data show that patients of color or from tribal communities are most harmed by health inequities and the risk of hospitalization and death for these groups is greater than that of white patients. These patients may face higher risk than white patients, due to longstanding societal injustices including racism, discrimination, colonization, etc., which have and continue to negatively impact health outcomes. For this reason, people who identify as Black, African American, Latina/o/x, American Indian/Alaska Native, Asian, Asian American or Pacific Islander are eligible for REGEN-COV™ under this protocol.

If a patient requesting monoclonal antibody treatment does not fall into one of the categories specified above, pharmacists should refer the patient to a medical provider for risk-benefit consideration.

For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.

III. CONTRAINDICATIONS:

REGEN-COV™ is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to REGEN-COV™.

IV. AVAILABLE DOSAGE FORMS:

REGEN-COV™ is available as:

1. A single-dose vial co-formulated in a 1:1 ratio of casirivimab and imdevimab

Antibody	Concentration
REGEN-COV™ (casirivimab and imdevimab)	600 mg/600 mg per 10 mL (60 mg/60 mg per mL)

OR

2. Individual antibody solutions in separate single-dose vials, which may be supplied in separate cartons or in a dose pack.

Antibody	Concentration
Casirivimab REGN10933	1,332 mg/11.1 mL (120 mg/mL)
	300 mg/2.5 mL (120 mg/mL)
Imdevimab REGN10987	1,332 mg/11.1 mL (120 mg/mL)
	300 mg/2.5 mL (120 mg/mL)

The REGEN-COV™ dose packs contain individual vials of casirivimab and imdevimab. Configurations of 2, 5 and 8 cartons may vary in vial size, strength, and appearance. Dose packs are sufficient to prepare up to two treatment doses:

Dose Pack Size	Dose Pack Components	Concentration
2 Cartons	1 casirivimab REGN10933	1,332 mg/11.1 mL (120 mg/mL)
	1 imdevimab REGN10987	1,332 mg/11.1 mL (120 mg/mL)
8 Cartons	4 casirivimab REGN10933	300 mg/2.5 mL (120 mg/mL)
	4 imdevimab REGN10987	300 mg/2.5 mL (120 mg/mL)
5 Cartons	1 casirivimab REGN10933	1,332 mg/11.1 mL (120 mg/mL)
	4 imdevimab REGN10987	300 mg/2.5 mL (120 mg/mL)
5 Cartons	4 casirivimab REGN10933	300 mg/2.5 mL (120 mg/mL)
	1 imdevimab REGN10987	1,332 mg/11.1 mL (120 mg/mL)

The 11.1 mL vials may be used to prepare multiple doses simultaneously as appropriate. Immediately discard any product remaining in the vial.

The vial stoppers for all dosage forms are not made with natural rubber latex.

V. STORAGE AND HANDLING:

Refrigerate unopened vials at 2 °C to 8 °C (36 °F to 46 °F) in the individual original carton to protect from light.

Remove the casirivimab and imdevimab vial(s) from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. Do not expose to direct heat. Do not shake the vials.

DO NOT FREEZE. DO NOT EXPOSE TO DIRECT LIGHT. DO NOT SHAKE. DO NOT EXPOSE TO DIRECT HEAT.

Casirivimab is preservative-free. Discard any unused portion.

Imdevimab is preservative-free. Discard any unused portion.

VI. DOSAGE:

Treatment Dosage:

Casirivimab 600 mg and imdevimab 600 mg administered together by subcutaneous injection as soon as possible after positive SARS-CoV-2 viral testing and within 10 days of mild or moderate symptom* onset.

*Mild or moderate COVID-19 symptoms may include: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; and/or diarrhea.

Post-exposure Prophylaxis Dosage:

Casirivimab 600 mg and imdevimab 600 mg administered together by subcutaneous injection as soon as possible after exposure to SARS-CoV-2. The clinical trial leading to authorization studied patients that were dosed within 96 hours of exposure.

Repeat Dosing Dosage:

The pharmacist may prescribe repeat dosing for individuals with ongoing exposure* to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination. Following the initial subcutaneous dose of casirivimab 600 mg and imdevimab 600 mg, dosing of casirivimab 300 mg and imdevimab 300 mg by subcutaneous injection is repeated once every 4 weeks for the duration of the ongoing exposure.

*Ongoing exposure is any resident in a congregate care setting with active exposure or repeated exposure to household contact with COVID.

Dosage Adjustments:

No dosage adjustment is recommended in pregnant or lactating women and in patients with renal impairment.

VII. PREPARATION OF SUBCUTANEOUS INJECTION:

Remove the casirivimab and imdevimab vial(s) from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation**. Do not expose to direct heat. Do not shake the vials**.

Inspect casirivimab and imdevimab vial(s) visually for particulate matter and discoloration prior to administration. Should either be observed, the vial must be discarded and replaced with a new vial. The solution for each vial should be clear to slightly opalescent, colorless to pale yellow.

1. Casirivimab and imdevimab should be prepared using the appropriate number of syringes (see Table 1). Obtain 3 mL or 5 mL polypropylene Luer Lock syringes with luer connection and 21-gauge 1½ inch transfer needles.
2. Withdraw the appropriate amount of solution into each syringe (see Table 1). Prepare all syringes at the same time.
3. Replace the 21-gauge transfer needle with a 25-gauge or 27-gauge needle for subcutaneous injection.
4. This product is preservative-free and therefore, the prepared syringes should be administered immediately. If immediate administration is not possible, store the prepared casirivimab and imdevimab syringes in the refrigerator between 2 °C to 8 °C (36 °F to 46 °F) for no more than 4 hours or at room temperature up to 25°C (77 °F) for no more than 4 total hours. If refrigerated, allow the syringes to equilibrate to room temperature for approximately 20 minutes prior to administration.

Preparation of 600 mg of Casirivimab and 600 mg of Imdevimab for Subcutaneous Injections.

Prepare 600 mg of Casirivimab and 600 mg of Imdevimab	Preparation of **4 Syringes**
Using Casirivimab and Imdevimab *Co-formulated Vial*	Withdraw 2.5 mL solution per syringe into FOUR separate syringes.
Using Casirivimab *individual vial* and Imdevimab *individual vial*	• Casirivimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes. • Imdevimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes. For total of 4 syringes.

Preparation of 300 mg of Casirivimab and 300 mg of Imdevimab for Subcutaneous Injections for Repeat Dosing*.

Prepare 300 mg of Casirivimab and 300 mg of Imdevimab	Preparation of **2 Syringes**
Using Casirivimab and Imdevimab *Co-formulated Vial*	Withdraw 2.5 mL solution per syringe into TWO separate syringes.
Using Casirivimab *individual vial* and Imdevimab *individual vial*	• Casirivimab: Withdraw 2.5 mL solution per syringe into ONE syringe. • Imdevimab: Withdraw 2.5 mL solution per syringe into ONE syringe. For total of 2 syringes.

* Subsequent repeat dosing every 4 weeks for the duration of ongoing exposure after the initial 600 mg casirivimab and 600 mg imdevimab doses.

VIII. ADMINISTRATION OF SUBCUTANEOUS INJECTION:

Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.

When administering the subcutaneous injections, it is recommended that providers use different quadrants of the abdomen or upper thighs or back of the upper arms to space apart each 2.5 mL subcutaneous injection of casirivimab and imdevimab. DO NOT inject into skin that is tender, damaged, bruised, or scarred.

IX. POST-TREATMENT MONITORING:

Ask patient to remain seated in the clinic for 60 minutes after administering therapy to decrease the risk of injury should they faint and for the Pharmacist to monitor for visible signs of drug reactions and for anaphylaxis.

Pharmacists must submit a report on all medication errors and any witnessed or known SERIOUS ADVERSE EVENTS potentially related to REGEN-COV™. See Section **Adverse Reactions and Medication Errors Reporting Requirements and Instructions**.

Hypersensitivity Reactions Including Anaphylaxis:

REGEN-COV™ may only be administered in settings in which pharmacists have immediate access to medications to treat severe hypersensitivity reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, Pharmacists must immediately discontinue administration and follow the Oregon Immunization Program's Guidelines for Managing Severe Adverse Events Following Immunization.

Clinical Worsening After Administration:

Clinical worsening of COVID-19 after administration of REGEN-COV™ has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia (e.g., atrial fibrillation, tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to REGEN-COV™ use or were due to progression of COVID-19.

Adverse Effects:

See Clinical Summary in Appendix 1 for a summary of adverse effects noted in clinical trials. Additional adverse events associated with REGEN-COV™, some of which may be serious, may become apparent with more widespread use.

X. PATIENT EDUCATION:

As the health care provider, you must communicate to your patient or parent/caregiver, as age appropriate, information consistent with the "Fact Sheet for Patients, Parents and Caregivers" (and provide a copy of the Fact Sheet) prior to the patient receiving REGEN-COV™ (see References), including:

- FDA has authorized the emergency use of REGEN-COV™ for the two indications described in this protocol (**see Indications**).
- The patient or parent/caregiver has the option to accept or refuse REGEN-COV™.
- The significant known and potential risks and benefits of REGEN-COV™, and the extent to which such risks and benefits are unknown.
- Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials*.

  * *NOTE:* **Intravenous monoclonal antibody therapy is preferred for *treatment* of COVID-19 unless it would result in a delay of therapy**. Refer to Fact sheet for Healthcare Providers- Emergency Use Authorization (EUA) of REGEN-COV™ for other alternatives. For information on clinical trials that are testing the use of REGEN-COV™ related to COVID-19, please see www.clinicaltrials.gov.

- Patients treated with REGEN-COV™:
  - **should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines**.
  - may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.

XI. REQUIRED DOCUMENTATION:

Pharmacists must review the Patient Self-Assessment Intake form, utilize this Patient Assessment and Treatment Care pathway and document required elements of the pathway in the patient's medical record and record that the patient/caregiver has been:

1. Given the "Fact Sheet for Patients, Parents, and Caregivers- Emergency Use Authorization (EUA) of Regen-COV™" (see References),
2. Informed of alternatives to receiving REGEN-COV™, and
3. Informed that REGEN-COV™ is an unapproved drug that is authorized for use under this Emergency Use Authorization.

XII. ADVERSE REACTIONS AND MEDICATION ERRORS REPORTING REQUIREMENTS:

The prescribing pharmacist a is responsible for mandatory reporting of all medication errors and any witnessed or known serious adverse events* potentially related to treatment within 7 calendar days from the onset of the event to both the patient's primary care provider (if known) and FDA MedWatch. The reports should include unique identifiers and the words "REGEN-COV™ use for COVID-19 under Emergency Use Authorization (EUA)" in the description section of the report.

- Submit adverse event reports to FDA MedWatch using one of the following methods:
  - Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
  - Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by:
    - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
    - Fax (1-800-FDA-0178), or
  - Call 1-800-FDA-1088 to request a reporting form
  - Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" a statement "REGEN-COV™ use for COVID-19 under Emergency Use Authorization (EUA)."

*Serious Adverse Events are defined as:

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

The prescribing pharmacist is responsible for mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of REGEN-COV™.

IMPORTANT: When reporting adverse events or medication errors to MedWatch, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient initials, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of REGEN-COV™
- Pertinent laboratory and virology information

- Outcome of the event and any additional follow-up information if it is available at the time of the MedWatch report. Subsequent reporting of follow-up information should be completed if additional details become available.

In addition, please provide a copy of all FDA MedWatch forms to:

- Regeneron Pharmaceuticals, Inc
  - Fax: 1-888-876-2736
  - E-mail: medical.information@regeneron.com
  - Or call Regeneron Pharmaceuticals at 1-844-734-6643 to report adverse events.

XIII. OTHER REPORTING REQUIREMENTS:

Healthcare facilities and providers must report therapeutics information and utilization data through HHS Protect, Teletracking or National Healthcare Safety Network (NHSN) as directed by the U.S. Department of Health and Human Services.

XIV. REFERENCES:

REGEN-COV™ (casirivimab and imdevimab) [Emergency Use Authorization Fact Sheet for Health Care Providers]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. July 2021. Available at https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

REGEN-COV™ (casirivimab and imdevimab) [Emergency Use Authorization Fact Sheet for Patients, Parents and Caregivers]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. July 2021. Available at https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-patient.pdf. Spanish edition available https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-patient-spanish.pdf.

Standardized Assessment and Treatment Care Pathway
COVID Monoclonal Antibodies (REGEN-COV™)

APPENDIX 1. Clinical Summary

Reference: REGEN-COV™ (casirivimab and imdevimab) [Emergency Use Authorization Fact Sheet for Health Care Providers]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. July 2021. Available at https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

Overall, approximately 16,000 subjects have been exposed to REGEN-COV™ (casirivimab and imdevimab) in clinical trials in hospitalized and non-hospitalized subjects. Approximately 13,500 subjects received intravenous infusions and 2,500 subjects received subcutaneous injections.

The safety of REGEN-COV™ (casirivimab and imdevimab) is based on analyses from:

- COV-2067, a Phase 1/2/3 trial of ambulatory (non-hospitalized) subjects with COVID-19;
- COV-2069, a Phase 3 post-exposure prophylaxis trial for prevention of COVID-19; and
- COV-2093, a Phase 1 trial evaluating the safety and pharmacokinetics of REGEN-COV™ repeat subcutaneous dosing every 4 weeks for 24 weeks.

COV-2067 :

This is a randomized, double-blind, placebo-controlled clinical trial (NCT04425629) in subjects with mild to moderate COVID-19. In the phase 3 portion of the trial, subjects were treated with a single intravenous infusion of 600 mg of casirivimab and 600 mg of imdevimab (n=827), or 1,200 mg of casirivimab and 1,200 mg of imdevimab (n=1,849) (unauthorized dose under EUA), or 4,000 mg of casirivimab and 4,000 mg of imdevimab (n=1,012) (unauthorized dose under EUA), or placebo (n=1,843).

At baseline, in all randomized subjects with at least one risk factor, the median age was 50 years (with 13% of subjects ages 65 years or older), 52% of the subjects were female, 84% were White, 36% were Hispanic or Latino, and only 5% were Black or African American. In subjects with available baseline symptom data, 15% had mild symptoms, 42% had moderate, 42% had severe symptoms, and 2% reported no symptoms at baseline; the median duration of symptoms was 3 days.

The primary endpoint was the proportion of subjects with ≥1 COVID-19-related hospitalization or all-cause death through Day 29. The results for subjects treated with 600 mg of casirivumab and 600 mg of imdevimab compared to placebo are outlined in **Table 1**.

Table 1. Total Events (COVID-19-related hospitalization or all-cause death) through Day 29.

	Casirivumab 600 mg and Imdevimab 600 mg (IV) (n=736)	Placebo (n=748)
COVID-19-related hospitalization or all-cause death	7 (1.0%)	24 (3.2%)
Relative Risk Reduction	70% (p=0.0024)	
Absolute Difference	2.2%, NNT = 46	

Abbreviations: IV = intravenous; NNT = number needed-to-treat to prevent one event COVID-19-related hospitalization or all-cause death.

In pooled phase 1/2/3 analysis, infusion-related reactions (adverse event assessed as causally related by the investigator) of grade 2 or higher severity have been observed in 10/4,206 (0.2%) of those who received REGEN-COV™ at the authorized dose or a higher dose. The infusion was permanently discontinued in 4 subjects who developed infusion-related reactions (urticaria, pruritus, flushing,

pyrexia, shortness of breath, chest tightness, nausea, vomiting, rash) but each received doses higher than what is authorized under EUA.

Anaphylactic reactions have been reported in subjects receiving REGEN-COV™. The events began within 1 hour of completion of the infusion, and in at least one case required treatment including epinephrine. The events resolved.

COV-2069:

This is a Phase 3, randomized, double-blind, placebo-controlled clinical trial (NCT04452318) that assessed the efficacy and safety of REGEN-COV™ (casirivimab and imdevimab) for post-exposure prophylaxis of COVID-19 in household contacts of individuals infected with SARS-CoV-2. The trial enrolled subjects who were asymptomatic and who lived in the same household with a SARS-CoV-2 infected patient. Subjects who were SARS-CoV-2 negative (PCR negative and seronegative) at baseline were enrolled and received a single dose of 600 mg of casirivimab and 600 mg of imdevimab subcutaneously (n=751) or placebo (n=752). Subjects who were SARS-CoV-2 positive at baseline were enrolled in Cohort B and received a single dose of 600 mg of casirivimab and 600 mg of imdevimab subcutaneously or placebo.

Cohort A:

At baseline, the median age was 44 years (with 9% of subjects ages 65 years or older), 54% of the subjects were female, 86% were White, 41% were Hispanic or Latino, and 9% were Black or African American. The primary efficacy endpoint was the proportion of subjects who developed PCR-confirmed COVID-19 through Day 29. The results for subjects treated with 600 mg of casirivumab and 600 mg of imdevimab compared to placebo are outlined in **Table 2**. In a post-hoc analysis in a subgroup of subjects who met the criteria for high risk for progression to severe COVID-19, there was a 76% relative risk reduction in COVID-19 with REGEN-COV™ treatment versus placebo [10/570 (2%) vs. 42/567 (7%); adjusted odds ratio 0.22; p<0.0001].

Table 2. Total PCR-confirmed Positive COVID-19 Test through Day 29.

	Casirivumab 600 mg and Imdevimab 600 mg SC (n=753)	Placebo (n=752)
PCR-confirmed Positive COVID-19 Test	11 (1.5%)	59 (7.8%)
Relative Risk Reduction	81% (Adjust OR = 0.17; p<0.0001)	
Absolute Difference	6.3%, NNT = 16	

Abbreviations: NNT = number needed-to-treat to prevent one positive COVID-19 infection; SC = subcutaneous.

Adverse events were reported in 265 subjects (20%) in the REGEN-COV™ group and 379 subjects (29%) in the placebo group. Injection site reactions (all grade 1 and 2) occurred in 55 subjects (4%) in the REGEN-COV™ group and 19 subjects (2%) in the placebo group. The most common signs and symptoms of injection site reactions which occurred in at least 1% of subjects in the REGEN-COV™ group were erythema and pruritus. Hypersensitivity reactions occurred in 2 subjects (0.2%) in the REGEN-COV™ group and all hypersensitivity reactions were grade 1 in severity. There were no cases of anaphylaxis.

Cohort B:

In a post-hoc analysis of the overall combined Cohort A and Cohort B (regardless of serology status at baseline), there was a 62% risk reduction in COVID-19 with REGEN-COV™ treatment versus placebo [46/1201 (4%) vs. 119/1177 (10%); adjusted odds ratio 0.35; p<0.0001].

Adverse events were reported in 52 subjects (34%) in the REGEN-COV™ group and 75 subjects (48%) in the placebo group. Injection site reactions, all of which were grade 1 or 2, occurred in 6 subjects (4%) in the REGEN-COV™ group and 1 subject (1%) in the placebo group. The most common signs and symptoms of injection site reactions which occurred in at least 1% of subjects in the REGEN-COV™ group were ecchymosis and erythema. There were no cases of hypersensitivity reaction or anaphylaxis.

COV-2093:

This is a randomized double-blind, placebo-controlled Phase 1 trial evaluating the safety, pharmacokinetic and immunogenicity of repeated doses of 600 mg of casirivimab and 600 mg of imdevimab administered subcutaneously in healthy adult subjects. Subjects were randomized 3:1 to REGEN-COV™ (n=729) or placebo (n=240) administered every 4 weeks for 24 weeks. Adverse events were reported in 380 subjects (52%) in the REGEN-COV™ group and 111 subjects (46%) in the placebo group. Injection site reactions occurred in 12% and 4% of subjects following single dose administration in the REGEN-COV™ and placebo groups, respectively.

With repeat dosing, injection site reactions occurred in 252 subjects (35%) in the REGEN-COV™ group and 38 subjects (16%) in the placebo group; all injection site reactions were grade 1 or 2 in severity. Hypersensitivity reactions occurred in 8 subjects (1%) in the REGEN-COV™ group; and all hypersensitivity reactions were grade 1 or 2 in severity. There were no cases of anaphylaxis.

COVID Monoclonal Antibodies (REGEN-COV™) 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: Casirivimab 600 mg and imdevimab 600 mg (REGEN-COV™) administered subcutaneously by Pharmacist for ☐ initial treatment or ☐ post-exposure prophylaxis of SARS-CoV-2.

- Sig: Inject according to protocol
- Quantity: #10mL
- Refills: none

☐ Drug: Casirivimab 300 mg and imdevimab 300 mg (REGEN-COV™) administered subcutaneously by Pharmacist for ongoing exposure to SARS-CoV-2 lasting longer than 4 weeks

- Sig: Inject according to protocol
- Quantity: #5mL
- Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV™
(casirivimab and imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given a medicine called **REGEN-COV (casirivimab and imdevimab)** for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV.

Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.

Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

WHAT IS COVID-19?

COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

WHAT ARE THE SYMPTOMS OF COVID-19?

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

WHAT IS REGEN-COV (casirivimab and imdevimab)?

REGEN-COV is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for severe COVID-19, including hospitalization or death for:

- treatment of mild to moderate symptoms of COVID-19
- post-exposure prevention of COVID-19 in persons who are:
    - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**,
    - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising

conditions, including someone who is taking immunosuppressive medications), **and**

- have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html, **or**
- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, as nursing homes, prisons,).

REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19 or to prevent COVID-19 in people who are at high risk of being exposed to someone who is infected with SARS-CoV-2. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of REGEN-COV for the treatment of COVID-19 and the post-exposure prevention of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

WHO SHOULD NOT TAKE REGEN-COV?

Do not take REGEN-COV if you have had a severe allergic reaction to REGEN-COV.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have had a severe allergic reaction including anaphylaxis to REGEN-COV previously
- Have received a COVID-19 vaccine.
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE REGEN-COV (casirivimab and imdevimab)?

- REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together at the same time through a vein (intravenous or IV) or injected in the

tissue just under the skin (subcutaneous injections). **Your healthcare provider will determine the most appropriate way for you to be given REGEN-COV.**

- Treatment: If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.
    - If your healthcare provider determines that you are unable to receive REGEN-COV as an intravenous infusion which would lead to a delay in treatment, then as an alternative, REGEN-COV can be given in the form of subcutaneous injections. If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time.
- Post-exposure prevention: If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time. If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer.
    - After the initial dose, if your healthcare provider determines that you need to receive additional doses of REGEN-COV for ongoing protection, the additional intravenous or subcutaneous doses would be administered monthly.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab and imdevimab)?

Possible side effects of REGEN-COV are:

- Allergic reactions. Allergic reactions can happen during and after infusion or injection of REGEN-COV. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These reactions may be severe or life threatening.
- Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. The side effects of getting any medicine by subcutaneous injection may include pain, bruising of the skin, soreness, swelling, and possible infection at the injection site.

These are not all the possible side effects of REGEN-COV. Not a lot of people have been given REGEN-COV. Serious and unexpected side effects may happen. REGEN-COV is still being studied so it is possible that all of the risks are not known at this time.

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV may reduce your body’s immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

WHAT OTHER TREATMENT CHOICES ARE THERE?
Like REGEN-COV (casirivimab and imdevimab), FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA that are used to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?
Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of REGEN-COV does not replace vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
There is limited experience using REGEN-COV (casirivimab and imdevimab) in pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving REGEN-COV may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH REGEN-COV (casirivimab and imdevimab)?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

HOW CAN I LEARN MORE?
- Ask your health care provider.
- Visit www.REGENCOV.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made REGEN-COV (casirivimab and imdevimab) available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

REGEN-COV has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for REGEN-COV is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

REGENERON

Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707

Revised: 07/2021

Provider Notification
COVID Monoclonal Antibodies (REGEN-COV™) Administration

Pharmacy Name:_____

Pharmacy Address:_____

Pharmacy Phone: _____ Pharmacy Fax: _____

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

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

☐ **Prescribed and administered COVID Monoclonal Antibodies** (REGEN-COV™) at our Pharmacy noted above. The prescription issued and administered consisted of:

- ☐ Treatment of COVID-19: Casirivimab 600 mg and imdevimab 600 mg (REGEN-COV™) administered subcutaneously by the Pharmacist for initial treatment of SARS-CoV-2. Prior to prescribing and administration of COVID Monoclonal Antibodies (REGEN-COV™) for treatment of COVID-19, your patient was tested for and/or indicated the following:

Test Name	Date of Test	Result
SARS-CoV-2 (molecular or antigen)	1) _____/_____/_____	□ reactive □ *indeterminate/inconclusive* □ negative
	2*) _____/_____/_____	□ reactive □ *indeterminate/inconclusive* □ negative

*2nd test only required if 1st test is *indeterminate/inconclusive*

- ☐ Post-Exposure Prophylaxis of COVID-19: Casirivimab 600 mg and imdevimab 600 mg (REGEN-COV™) administered subcutaneously by the Pharmacist as soon as possible after exposure to SARS-CoV-2.
- ☐ Ongoing Exposure: Casirivimab 300 mg and imdevimab 300 mg (REGEN-COV™) administered subcutaneously by the Pharmacist for ongoing exposure to SARS-CoV-2 lasting longer than 4 weeks.

Your patient was:

- Provided with the FDA EUA REGEN-COV™ Fact Sheet for Patients, Parents, & Caregivers https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-patient.pdf
- Informed that an office visit with you or another provider on your team is recommended after monoclonal antibody administration.
- For treatment or post-exposure prevention of COVID-19, the patient was also advised that they should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.
- For post-exposure prophylaxis, the patient was also informed that REGEN-COV™ does not replace vaccination against COVID-19 and, if applicable, they may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.

☐ **Tested for SARS-CoV-2 (molecular or antigen) twice, both results were *indeterminate or inconclusive* and therefore the patient is being referred to you for follow-up**. COVID monoclonal antibodies were not prescribed or administered to your patient.

If you have further questions: Please contact the prescribing pharmacy or call Regeneron Medical Information Department at 1-844-REGN-MID (1-844-734-6643). Clinicians can review the NIH COVID-19 Treatment Guidelines as well as the FDA EUA for the therapy.

- NIH COVID-19 Treatment Guidelines: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/hospitalized-adults--therapeutic-management/
- FDA EUA for REGEN-COV™: https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

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.

- **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 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

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

(CONFIDENTIAL-Protected Health Information)

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

Background Information:

1.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
2.	What was the date of the exposure?	___/___/___
3.	What was the approximate time of the exposure?	___:___ *AM/PM*
4.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
5.	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
6.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
7.	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
8.	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
9.	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
10.	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
11.	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:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
13.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
14.	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
15.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
16.	Are you currently pregnant?	□ Yes □ No □ Not sure
17.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
18.	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
19.	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)

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

<table>
<tr><td colspan="2">1. Is the patient less than 13 years old?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic</td><td>☐ No: Go to #2</td></tr>
<tr><td colspan="2">2. Was the patient a survivor of sexual assault?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.**</td><td>☐ No: Go to #3</td></tr>
<tr><td colspan="2">3. Is the patient known to be HIV-positive?</td><td rowspan="2">Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.</td></tr>
<tr><td>☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.</td><td>☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).</td></tr>
<tr><td colspan="2">4. What time did the exposure occur?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.</td><td>☐ ≤72 hours ago: go to #5</td></tr>
<tr><td colspan="2">5. Was the exposure from a source person known to be HIV-positive?</td><td rowspan="2"></td></tr>
<tr><td>☐ Yes: Go to #6</td><td>☐ No: Go to #7</td></tr>
<tr><td colspan="2">6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids:</td><td rowspan="2">Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.</td></tr>
<tr><td>Please check any/all that apply:
☐Blood
☐Semen
☐Vaginal secretions
☐Rectal secretions
☐Breast milk
☐Any body fluid that is visibly contaminated with blood

If any boxes are checked, go to #9.</td><td>Please check any/all that apply (Note: only applicable if not visibly contaminated with blood):
☐Urine
☐Nasal Secretions
☐Saliva
☐Sweat
☐Tears
☐None of the above

Go to #7</td></tr>
<tr><td colspan="2">7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: This type of exposure puts the patient at a high risk for HIV acquisition</td></tr>
<tr><td>☐ Yes: Go to #9</td><td>☐ No: Go to #8</td></tr>
</table>

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

<table>
<tr><td colspan="2">8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.</td></tr>
<tr><td>☐ Yes: Please check all that apply and go to #9:
☐Was the source person known to be HIV-positive?
☐Were there cuts/openings/sores/ulcers on the oral mucosa?
☐Was blood present?
☐Has this happened more than once without PEP treatment?
☐None of the above</td><td>☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.</td></tr>
<tr><td colspan="2">9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?</td><td rowspan="2">Notes: Connection to care is critical for future recommended follow-up.</td></tr>
<tr><td>☐ Yes: Go to #10</td><td>☐ No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td></tr>
<tr><td colspan="2">10. Does the patient have history of known Hepatitis B infection (latent or active)?</td><td rowspan="4">Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No. Go to #11</td></tr>
<tr><td colspan="2">11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No
Verify vaccine records or Alert-IIS. Dates:_____</td></tr>
<tr><td>☐ Yes: Go to #13</td><td>☐ No: Go to #12</td></tr>
<tr><td colspan="2">12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.
☐Vaccine administered
Lot:_____ Exp:_____ Signature:_____</td><td></td></tr>
<tr><td colspan="2">13. Does the patient have known chronic kidney disease or reduced renal function?</td><td rowspan="2">Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.</td></tr>
</table>

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

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

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

PLUS

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

Notes:

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

COUNSELING POINTS:

- Truvada®:
  - Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset.
  - Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.
- Isentress®:
  - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
  - If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress®.
- Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.
- Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.
- Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

*Oregon licensed pharmacists are mandatory reporters of child abuse, per ORS Chapter 419B. Reports shall be made to Oregon Department of Human Services @ **1-855-503-SAFE (7233)**.

PHARMACIST MANDATORY FOLLOW-UP:

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

Pharmacist Signature_____Date____/____/_____

PEP 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

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: 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: _____
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**
- 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 doctor or pharmacist.
- Truvada and Isentress don't have side effects most of the time. The most common side effects (if they do happen) are stomach upset. Taking Truvada and Isentress with food can help with stomach upset. Over-the-counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like 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. ~~The pharmacy cannot do these lab tests.~~
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 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 antigen/antibody 4th generation
   - ☐ Hepatitis B surface antigen and surface antibody
   - ☐ Hepatitis C antibody
   - ☐ Treponema pallidum antibody
   - ☐ Comprehensive metabolic panel
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:_____
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
- 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 and Isentress are both 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 at **6 weeks** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis B surface antigen and surface antibody
- ☐ Hepatitis C antibody
- ☐ Comprehensive metabolic panel
- ☐ Treponema pallidum antibody as appropriate
- ☐ Pregnancy test as appropriate
- ☐ STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis C antibody

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

PREVENTIVE CARE

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

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

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe pre-exposure prophylaxis (PrEP) drug regimen.

- **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.4-9)
  - Utilize the standardized PrEP Provider Fax (pg.11)

  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

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

(CONFIDENTIAL-Protected Health Information)

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

Background Information: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

Do you answer yes to any of the following? □ yes □ no

1. Do you sexually partner with men, women, transgender, or non-binary people?
2. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom. _____% of the time __/__/__ last sex without a condom
3. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. Do you have vaginal sex? • Receptive- you have a vagina and you use it for vaginal sex • Insertive- you have a penis and you use it for vaginal sex
5. Do you have anal sex? • Receptive- someone uses their penis to perform anal sex on you • Insertive- you use your penis to perform anal sex on someone else
6. Do you inject drugs?
7. Are you in a relationship with an HIV-positive partner?
8. Do you exchange sex for money or goods? (includes paying for sex)
9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex?

Medical History: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)?	□ yes □ no
2. Do you see a (healthcare provider) for management of Hepatitis B?	□ yes □ no
3. Have you ever received an immunization for Hepatitis B? If yes, when: • If no, would you like a Hepatitis B immunization today? □ yes □ no	□ yes □ no Date of vaccine __/__/__
4. Do you see a healthcare provider for problems with your kidneys?	□ yes □ no
5. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? • Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)	□ yes □ no
6. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no
7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	□ yes □ no

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

(CONFIDENTIAL-Protected Health Information)

Testing and Treatment:

1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription. • I may be able to have tests performed at the pharmacy. • I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks. o I brought my labs in today □ Yes □ No • I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.	□ Yes □ No
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV. • I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate.	□ Yes □ No
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.	□ Yes □ No

Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.

Please list any questions you have for the pharmacy staff:

Patient Signature: _____ **Date:** _____

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

Risk Factor:	Notes and considerations
1. Sexual partners	• MSM activity is highest risk for HIV. • Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present.
2. Estimated condom use _____% of the time __/__/__ last sex without a condom	• Condomless sex greatly increases risk of HIV and STIs. • For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP). • Condomless sex within last 14 days, repeat HIV test in one month.
3. Oral sex	• Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals. • STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex.
4. Vaginal sex	• Receptive vaginal sex can be high risk for HIV. • Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present.
5. Anal sex	• Receptive anal sex has the most risk of HIV of any sex act. • Insertive anal sex has high risk for HIV. • STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex.
6. Injection drug use	• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
7. HIV-positive partner	• People living with HIV who have undetectable viral loads will not transmit HIV. • For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP.
8. Exchanging sex for money or goods	• People who buy or sell sex are at high risk for HIV.
9. Popper and/or methamphetamine use	• Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV. • Recommend adequate lubrication in persons who use poppers for sex.

1. Is one or More Risk Factor Present: □ yes □ *no*

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Testing:

The pharmacist must verify appropriate labs are complete. *Italics* below indicate need for referral.

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen) test:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing. NOTE: HIV test must be performed within the 14 days prior to prescribing and dispensing. Order lab at initial intake and every 90 days thereafter.			
• Syphilis/Treponemal antibody:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing. Order lab at initial intake and every 90-180 days depending on risk.			
• Hepatitis B surface antigen:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician. Confirmation of being fully vaccinated for hepatitis B via ALERT or medical record may meet criteria for negative Hepatitis B surface antigen. If records of vaccination are not available, order lab at initial intake only.			
• *Hepatitis C antibody:*	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
Positive antibody indicates exposure to Hepatitis C virus. The pharmacist will refer this person for confirmatory testing and treatment. It is permissible to proceed with PrEP prescribing in this scenario. Order lab at initial intake and annually thereafter.			
• Gonorrhea/Chlamydia:	____/____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ non-reactive	Pharyngeal test result: □ *reactive* □ *indeterminate* □ non-reactive	Rectal test result: □ *reactive* □ *indeterminate* □ non-reactive	
All reactive or indeterminate chlamydia and/or gonorrhea results will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment. Order lab at initial intake and every 90-180 days depending on risk.			
• Renal function (CrCl): SCr _____mg/dL	____/____/_____	_____ mL/min □ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min*	□ *Yes*
CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy.* Order lab at initial intake and annually thereafter.			
• Signs/symptoms of STI not otherwise specified:	____/____/_____	□ *Present*	□ *Yes*
• Condomless sex in past two weeks	____/____/_____	□ *Yes*	□ *Yes*

2. Is HIV ab/ag 4th gen test complete? □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes and non-reactive: Proceed to question #3
- *If yes and reactive or indeterminate: RPH many NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

3a. If initial visit: Are required initial labs complete? □ **yes** □ ***no***

- If yes, RPH may prescribe PrEP. Proceed to next section: Medical History.
  - □ Labs required today are: HIV, Syphilis/Treponemal antibody, Gonorrhea/Chlamydia, Hepatitis B (if no documentation of full vaccination), Hepatitis C and renal function.
- If no, RPH may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

→ *See next page for follow-up visit lab requirements and sample language for reactive (indeterminate) HIV and STI tests.*

3b. If follow-up visit: Are required follow-up labs complete? □ **yes** □ ***no***

- □ Every 90 days- HIV
- □ Every 90-180 days- Syphilis/Treponemal antibody and Gonorrhea/Chlamydia,
- □ Annually - Hepatitis C and renal function.

- If yes, RPH may prescribe PrEP. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

Sample language for reactive or indeterminate tests:

Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.

Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

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

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Medical History: The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

Medical history factor	Notes and considerations
	REFERRAL CONDITIONS
1. Positive HIV test *Needs Referral:* □ *yes* □ no	• A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. • Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management.
2. Presence of Hepatitis B infection *Needs Referral:* □ *yes* □ no	• Truvada and Descovy are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare. • People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.
3. Presence of Hepatitis C exposure *Needs Referral:* □ *yes* □ no	• People with HepC exposure must be referred to primary care or other appropriate community health outreach organization (e.g. HIV Alliance, Cascade AIDS Project, Eastern Oregon Center for Independent Living). Pharmacist may proceed with prescribing PrEP.
4. Impaired kidney function (<30mL/min) *Needs Referral:* □ *yes* □ no	• Truvada is approved for patients with a CrCl >60mL/min. • Consider Descovy in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease.
5. Other medications *Needs Referral:* □ *yes* □ no	• Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density. • For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Descovy over Truvada.
	CONSIDERATIONS
6. NSAID use Precaution- Counseled on limiting use: □ yes □ no	• Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.
7. Hepatitis B vaccinated If not, would the patient like to be vaccinated? □ yes □ no	• Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP. • Counsel on risk factors for Hepatitis B and recommend vaccination. • If patient would like to be vaccinated, proceed according to OAR 855-019-0280.
8. Pregnant or breastfeeding	• Pregnancy and breastfeeding are not contraindications for PrEP. • Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence. • Truvada is preferred due to better data in these populations.

4. Are One or More Referral Condition(s) Present? □ *yes* □ no

- *If yes, HIV PrEP is recommended but pharmacists are not authorized to prescribe in accordance with this RPH protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.*
- If no, HIV PrEP is recommended and pharmacists are authorized to prescribe and dispense PrEP in accordance with this RPH protocol. Proceed to next sections: Regimen Selection and Prescription.

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Regimen Selection:

Considerations*	Preferred regimen
Cis-gender male or male to female transgender woman. • Both Truvada and Descovy are FDA approved in these populations. May prescribe based on patient preference.	May choose Truvada or Descovy
Cis-gender female or female to male transgender man. • Only Truvada is FDA approved in these populations. • If patient has low bone mineral density or renal function that would preclude Truvada use, but has risk factors for HIV, refer the patient to a specialist for PrEP management.	Truvada
NSAID use • If patient is male or a male to female transgender woman, consider Descovy	Descovy
Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist. • If patient is male or male to female transgender woman, consider Descovy	Descovy
Patient has decreased bone mineral density or on medications that affect bone mineral density. • If patient is male or male to female transgender woman, consider Descovy.	Descovy
Patient is pregnant or breastfeeding • Descovy has not been studied in these populations. Truvada is approved in these populations.	Truvada

*generic versions are acceptable in all cases if available.

PrEP 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

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 90 days, #90, 0 refills

-or-

☐ **Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets**

- 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) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

This regimen consists of the following (check one):

☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
- Take one tablet by mouth daily for 90 days

☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
- Take one tablet by mouth daily for 90 days

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*
• Syphilis/Treponemal antibody:	____/____/_____	☐ *reactive* ☐ *indeterminate* ☐ non-reactive	☐ *Yes*
• Hepatitis B surface antigen:	____/____/_____	☐ *reactive* ☐ non-reactive	☐ *Yes*
• Hepatitis C antibody:	____/____/_____	☐ *reactive* ☐ non-reactive	☐ *Yes*
• Gonorrhea/Chlamydia:	____/____/_____		☐ *Yes*
Urinalysis result: ☐ *reactive* ☐ *indeterminate* ☐ non-reactive	Pharyngeal test result: ☐ *reactive* ☐ *indeterminate* ☐ non-reactive	Rectal test result: ☐ *reactive* ☐ *indeterminate* ☐ non-reactive	
• Renal function (CrCl):	____/____/_____	_____ mL/min	☐ *Yes*
☐ CrCl >60mL/min	☐ CrCl 30mL/min - 60mL/min	☐ *CrCl <30mL/min*	
• Signs/symptoms of STI not otherwise specified:	____/____/_____	☐ *present*	☐ *Yes*
• Condomless sex in past two weeks	____/____/_____	☐ *yes*	☐ *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:

- 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.

Pharmacy monitoring of HIV PrEP:

- The pharmacy prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing 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.

Division 043– Practitioner Dispensing (SPDO/DPDO, OSBN, Procedural Rule Review)

Filing Caption (15 word limit)**:** 2021 HB 3036 Allows physician assistant to dispense prescription drugs and proactive procedural rule review.

Need for Rules: Revisions to Division 043 are necessary to:

1. Incorporate changes to physician assistant (PA) scope set forth in 2021 HB 3036, related to dispensing prescription drugs.

2. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs.

3. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

Fiscal Impact:

1. There are 52 Supervising Physician Dispensing Outlets (SPDO) and 49 Dispensing Practitioner Dispensing Outlets (DPDO) currently active. As a result of 2021 HB 3036, SPDO will be discontinued effective 3/31/2022. 6 SPDOs also have an active DPDO registration. The discontinued SPDOs may now met the requirements for registration as a "DPDO". The current SPDO registration fee is $175 / $275 with CS annually and the current DPDO registration fee is $100 annually. There are 6 locations that hold both registrations.

The transition from SPDO Registration to DPDO registration has a net biennial revenue reduction of 17,400.

2. None anticipated

3. None anticipated

Documents relied upon include:

2021 HB 3036 and related statutes

Oregon State Board of Nursing: ORS 678.390

Poison Prevention Packaging Act: 16 CFR 1700 (XX/XX/XXXX) Poison Prevention Packaging, 16 CFR 1701 (XX/XX/XXXX) Statements of Policy and Interpretation, and 16 CFR 1702 (XX/XX/XXXX) Petitions for Exemptions from Poison Preventing Packaging Act Requirements; Petition Procedures and Requirements

Rules Summary: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

Note: If language changes are made to OAR 855-043-0002, 855-043-0436 and 855-043-0541 in other rule packages, this rule will be updated to reflect the same language in the other rule packages.

Division 43
PRACTITIONER DISPENSING

855-043-0002
Definitions

In this division of rules:

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

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

(b) The patient at the direction of the practitioner.

(2) "Counseling" means an oral or other appropriate communication process between a practitioner and a patient or a patient's agent in which the practitioner obtains information from the patient or patient's agent, and, where appropriate, the patient's medical 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.

(~~2~~**3**) "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(4) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(~~3~~**5**) "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or preventative measures such as immunization or birth control approved by the ~~B~~**b**oard or by the ~~Department of Human Services (DHS)~~ **Oregon Health Authority (OHA)**.

(~~4~~**6**) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of Naturopathic Medicine and employed by or under contract with a county or district health department or ~~DHS~~**OHA**.

(7) "Informational insert" is an auxiliary document containing directions for use and other prescription information that is provided to the patient in both English and the language requested.

(8) "Limited English proficiency" means not fluent in the English language.

~~(5~~**9**~~) "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center, treatment center, or other establishment from which a physician assistant dispenses drugs, but that is not otherwise registered with the Board in the category of Retail Drug Outlet.~~

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

855-043-0003
Expedited Partner Therapy

~~(1) Expedited Partner Therapy (EPT) means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.~~

~~(2) An EPT prescription may only be dispensed for a drug and a disease that has been determined by DHS to be appropriately addressed by EPT.~~

(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.

(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.

(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

855-043-0004
Expedited Partner Therapy (EPT) - Procedures

(1) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule governs.

(2) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon Health Authority to be appropriately used for EPT.

Prescription
(3) An EPT treatment protocol must conform to the following:

(a) It must include a prescription for each named or unnamed partner of the patient;

(b) It must contain a hand written or electronic signature of the prescribing practitioner;

(c) The practitioner must identify the prescription in the following manner:

(A) Write "for EPT," or a similar notation, on the face of the prescription;

(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;

(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe – Partner 1" or by labeling the prescription as "EPT Partner"

(d) An EPT Prescription expires 30 days after the date written;

(e) An EPT Prescription may not be refilled;

(f) If any component of the prescription is missing, the DPDO must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.

(4) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may elect for a DPDO to dispense all prescriptions and then give the dispensed drugs to each unnamed partner.

Labeling
(5) The DPDO must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the DPDO may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.

(6) The DPDO must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling
(7) The DPDO is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the DPDO must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The DPDO should advise the patient to encourage each partner to call the DPDO before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records
(8) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the board upon request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

~~**855-043-0005**~~
~~**Practitioner Labeling**~~

~~All drugs dispensed by a practitioner must be labeled with the following information:~~

~~(1) Name, address and telephone number of the practitioner;~~

~~(2) Date;~~

~~(3) Name of the patient or the owner of the animal for which the drug is dispensed. If the prescription is for an animal, the species of the animal for which the drug is dispensed;~~

~~(4) Name of drug, strength, the quantity dispensed. When a generic name is used, the label must also contain the name of the manufacturer or distributor;~~

~~(5) Directions for use;~~

~~(6) Required precautionary information regarding controlled substances;~~

~~(7) Such other cautionary information as required for patient safety; and~~

~~(8) An expiration date after which the patient should not use the drug or medicine. The expiration date on a drug dispensed must be the same as that on the original container unless, in the practitioner's professional judgment, a shorter expiration date is warranted. A drug must not be dispensed after the expiration date of the drug.~~

~~(9) Not withstanding the labeling requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient or the patient's partner may be omitted from the label.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155 & ORS 689.505~~

~~855-043-0210~~
~~Oregon Nurse Practitioner Dispensing~~

~~The Oregon State Board of Nursing may grant to a certified nurse practitioner or Clinical Nurse Specialist the privilege of writing prescriptions described in the formulary under ORS 678.385. A certified nurse practitioner or Clinical Nurse Specialist may submit an application to the Oregon State Board of Nursing to dispense prescription drugs. An application for the authority to dispense prescription drugs as authorized by ORS 678.385 shall include evidence of completion of a prescription drug dispensing training program jointly developed and adopted by rule by the Oregon State Board of Nursing (851-050-0162) and the State Board of Pharmacy. The training program shall be as follows:~~

~~(1) Documented review of content regarding safe dispensing listed below:~~

~~(a) Board of Nursing handbook "Prescriptive Authority in Oregon for Nurse Practitioners and Clinical Nurse Specialists";~~

~~(b) The Drug Enforcement Administration Pharmacist's Manual (2004);~~

~~(c) OAR 851, division 56;~~

~~(d) ORS Chapter 689 and OAR chapter 855;~~

~~(e) US Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for Pharmacist's and Physicians;"~~

~~(f) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and Dose Designations" (Nov. 2006); and~~

~~(g) Information on available electronic or hard copy prescription drug references which provide information to professionals authorized to dispense prescription medications~~

~~(2) Successful self examination as provided by the Board of Nursing on these materials.~~

~~[Publications: Publications referenced are available from the agency.]~~

~~Statutory/Other Authority: ORS 678.390 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.205~~

~~855-043-0405~~
~~Supervising Physician Dispensing Outlet - Purpose and Scope~~

~~A supervising physician or supervising physician organization that supervises a physician assistant with dispensing authority must register the dispensing site with the Board as a Supervising Physician Dispensing Outlet (SPDO) and must comply with the rules in OAR chapter 855, division 43.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0410~~
~~Supervising Physician Dispensing Outlet - Registration~~

~~(1) A Supervising Physician Dispensing Outlet must register with the Board as a SPDO in the category of Retail Drug Outlet on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.~~

~~(2) The initial application must state the location of the SPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant's affiliation with the owner.~~

~~(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.~~

~~(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.~~

~~(3) Upon request by the Board, the applicant must furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.~~

~~(4) An initial application must be accompanied by the fee established in division 110 of this chapter.~~

~~(5) A certificate of registration will be issued upon Board approval of the application.~~

~~(6) All registration renewal applications must be accompanied by the annual renewal fee established in Division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.~~

~~(7) The SPDO registration expires March 31, annually. If the annual renewal fee referred to in section (5) of this rule is not paid by February 28 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this chapter with the renewal application.~~

~~(8) The registration is not transferable and the registration fee cannot be prorated.~~

~~(9) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, consultant pharmacist or supervising physician.~~

~~(10) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in division 110 of this chapter within 15 days of the change.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~**855-043-0415**~~
~~**Supervising Physician Dispensing Outlet - Consulting Pharmacist**~~

~~(1) A SPDO must retain a pharmacist licensed in Oregon for consultation purposes.~~

~~(2) The consulting pharmacist must conduct and document an annual inspection of the outlet on a form provided by the Board. The completed inspection report form must be filed in the outlet, retained on file for three years and be available to the Board for inspection.~~
~~(3) The duties of the consulting pharmacist shall be clearly defined in writing within the organization. The consulting pharmacist must:~~

~~(a) Develop policies and procedures for the outlet in collaboration with the supervising physician; and~~

~~(b) Work in consultation with the supervising physician in the development of the formulary of drugs and classes of drugs for the outlet.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0420~~
~~Supervising Physician Dispensing Outlet - Policies and Procedures~~

~~The registered SPDO must:~~

~~(1) Maintain written policies and procedures for drug management, including storage, security, integrity, access, dispensing, disposal, record keeping and accountability;~~

~~(2) Maintain all drug records required by federal and state law;~~

~~(3) Establish procedures for procurement of drugs; and~~

~~(4) Establish procedures to train physician assistants who dispense drugs and to ensure the continued competence of physician assistants who dispense drugs.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0425~~
~~Supervising Physician Dispensing Outlet - Security~~

~~(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.~~

~~(2) No drug dispensing machine may be placed in a waiting room or an area that is accessible by the public.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0430~~
~~Supervising Physician Dispensing Outlet - Storage of Drugs~~

~~All drugs, including drug samples, must be stored under conditions that ensure proper sanitation, temperature, light, ventilation, moisture control, and any other condition recommended by the manufacturer.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0435~~
~~Supervising Physician Dispensing Outlet - Labeling~~

~~(1) A prescription must be labeled with the following information:~~

~~(a) Unique identifier;~~

~~(b) Name of patient;~~

~~(c) Name of prescriber;~~

~~(d) Name, address, and phone number of the clinic;~~

~~(e) Date of dispensing;~~

~~(f) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;~~

~~(g) Quantity dispensed;~~

~~(h) Directions for use;~~

~~(i) Initials of the physician assistant or practitioner dispensing;~~

~~(j) Cautionary statements, if any, as required by law; and~~

~~(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug; and~~

~~(l) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.~~

~~(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-041-4000 through 4005, the name of the patient may be omitted.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~**855-043-0436**~~

~~**Supervising Physician Dispensing Outlet - Limited English Proficiency and Accessibility**~~

~~(1) Upon request of a patient or a patient's agent, each drug dispensed by a drug outlet for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.~~

~~(2) When dispensing a drug under (1), a drug outlet must provide labels and informational inserts in both English and one of the following languages:~~

~~(a) Spanish;~~

~~(b) Russian;~~

~~(c) Somali;~~

~~(d) Arabic;~~

~~(e) Chinese (simplified);~~

~~(f) Vietnamese;~~

~~(g) Farsi;~~

~~(h) Korean;~~

~~(i) Romanian;~~

~~(j) Swahili;~~

~~(k) Burmese;~~

~~(l) Nepali;~~

~~(m) Amharic; and~~

~~(n) Pashtu.~~

~~(3) The board must reassess and update (2) as necessary and at least every ten years.~~

~~Statutory/Other Authority: ORS 689.564~~
~~Statutes/Other Implemented: ORS 689.205~~

~~**855-043-0440**~~

~~**Supervising Physician Dispensing Outlet - Dispensing and Drug Delivery**~~

~~(1) Drugs dispensed from a SPO by a physician assistant with dispensing authority or a practitioner must be personally dispensed by the practitioner or physician assistant.~~

~~(2) Prior to dispensing a medication a drug utilization review must be performed by the physician assistant or practitioner which includes but is not limited to drug interactions, drug allergies and duplicate drug therapy.~~

~~(3) The physician assistant or practitioner must orally counsel the patient concerning all new drugs, unless circumstances would render oral counseling ineffective.~~

~~(4) When dispensed, a drug must be accompanied by written information that contains at least the following information:~~

~~(a) Drug name, class and indications;~~

~~(b) Proper use and storage;~~

~~(c) Common side effects;~~

~~(d) Precautions and contraindications; and~~

~~(e) Significant drug interactions.~~

~~(5) 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.~~

~~(6) Any other requirement of State or federal law.~~

~~(7) A SPDO must dispense a drug in a new container that complies with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.~~

~~(8) Drugs must be prepackaged by a pharmacy or manufacturer registered with the Board.~~

~~(9) A SPDO 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.~~

~~(10) 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.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0445~~
~~Supervising Physician Dispensing Outlet - Drug Dispensing Training Program~~

~~A physician assistant must complete a drug dispensing training program jointly developed by the Oregon Medical Board and the Board of Pharmacy before dispensing drugs to patients.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~
~~History:~~
~~BP 62-2020, minor correction filed 08/06/2020, effective 08/06/2020~~
~~BP 3-2012, f. & cert. ef. 6-19-12~~

~~855-043-0450~~
~~Supervising Physician Dispensing Outlet - Disposal of Drugs~~

~~Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0455~~
~~Supervising Physician Dispensing Outlet - Record Keeping~~

~~(1) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:~~

~~(a) Name of patient;~~

~~(b) Unique identifier;~~

~~(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;~~

~~(d) Directions for use;~~

~~(e) Date of dispensing; and~~

~~(f) Initials of person dispensing the prescription.~~

~~(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.~~

~~(3) Records documenting training required by OAR 855-043-0445 must be kept for three years.~~

~~(4) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.~~
~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

855-043-0505
Dispensing Practitioner Drug Outlets - Purpose
~~A practitioner's facility that engages in dispensing certain FDA-approved human prescription drug therapies greater than a 72 hours supply or any medication refill~~ **Unless subject to an exemption in OAR 855-043-0510(2), a practitioner that engages in dispensing human prescription drug therapies** must register their dispensing site ~~as a drug outlet~~ with the B**b**oard as a Dispensing Practitioner Drug Outlet (DPDO).

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

855-043-0510
Dispensing Practitioner Drug Outlets - Registration

(1) **Unless subject to an exemption in OAR 855-043-0510(2), a practitioner that engages in dispensing human prescription drug therapies** ~~A practitioner's facility that engages in dispensing FDA-approved human prescription drug therapies greater than 72 hours supply or any medication refill~~ must register the~~ir~~ dispensing site ~~as a drug outlet~~ with the ~~B~~**b**oard as a DPDO on a form ~~provided~~**prescribed** by the ~~B~~**b**oard, and must renew its registration annually on a renewal form ~~provided~~**prescribed** by the ~~B~~**b**oard.

(2) A practitioner's facility is exempt from this registration requirement if the practitioner and facility only engages in:

(A) Dispensing FDA approved drug samples; or

(B) Dispensing Medication Assistance Program (MAP) drugs; or

(C) Dispensing homeopathic products; or

(D) Dispensing natural thyroid supplemental products; or

(E) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72 hour supply; or

(F) An amount greater than a 72 hour supply if the drug is:

(i) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-inhaler or bottle of fluoride rinse; or

(ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient's best interest, such as a course of antibiotic therapy.

(3) The initial **and renewal** application**s** must state the location of the DPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing

site, the application must disclose the name and address of the owner and the applicant's affiliation with the owner.

(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.

(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.

(4) Upon request by the ~~B~~**b**oard~~,~~ the applicant must furnish such information as required by the ~~B~~**b**oard regarding the partners, stockholders, or other persons not named in the application.

(5) An initial **and renewal** application**s** must be accompanied by the fee established **OAR 855-110**~~in division 110 of this chapter~~.

(6) A certificate of registration will be issued upon ~~B~~**b**oard approval of the application.

~~(7) All registration renewal applications must be accompanied by the annual renewal fee established in division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.~~

(~~8~~**7**) The DPDO registration expires March 31, annually. If the annual renewal fee is not paid by ~~February 28~~ **March 31** of the current year, the applicant for renewal must submit the ~~delinquent~~ **late renewal** fee established in **OAR 855-110**~~in division 110 of this chapter~~ with the renewal application.

(~~9~~**8**) The registration is not transferable and the registration fee cannot be prorated.

(~~10~~**9**) The registrant must notify the ~~B~~**b**oard~~, within~~ 15 days **prior to**~~, of~~ any substantial change to the information provided on the registration application. Substantial change ~~shall~~ include**s** but **is** not ~~be~~ limited to: change of ownership; change of business name; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, **or** officers~~, or supervising practitioner~~.

(~~11~~**10**) A new registration form is required for a change of ownership or location and must be submitted to the ~~B~~**b**oard with the fees as specified in **OAR 855-110**~~in division 110 of this chapter within~~ 15 days **prior to**~~of~~ the change.

(~~12~~**11**) The ~~B~~**b**oard may grant a time-limited waiver exempting DPDO registration when a practitioner licensing board submits a request to the ~~B~~**b**oard with a plan to annually inspect the dispensing facility to the standards of the ~~B~~**b**oard.

(12) All Supervising Physician Dispensing Outlet registrations expire on March 31, 2022. Outlets that utilize dispensing Physician Assistants must apply for and be granted registration as a Dispensing Practitioner Dispensing Outlet upon the expiration of the Supervising Physician Dispensing Outlet Registration unless subject to an exemption in OAR 855-043-0510(2).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **ORS** 689.305, **ORS 475.125**

855-043-0520
Dispensing Practitioner Drug Outlets - Policies and Procedures

The registered DPDO must maintain written policies and procedures for the management of drugs intended for dispensing, to include security, acquisition, storage, dispensing and drug delivery, disposal and record keeping.

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

855-043-0525
Dispensing Practitioner Drug Outlets - Security

(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.

(2) A drug dispensing machine cannot be placed in a waiting room or an area that is accessible by the public.

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

855-043-0530
Dispensing Practitioner Drug Outlets - Drug ~~Acquisition~~ Receipt

The registered DPDO ~~must verify that all~~ **may only receive** drugs ~~are acquired~~ from a**n Oregon Registered Drug Outlet (e.g. Wholesaler, Manufacturer or Pharmacy)** ~~registrant of the Board~~.

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

855-043-0535
Dispensing Practitioner Drug Outlets - Drug Storage

All drugs must be stored according to manufacturer's published guidelines and be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

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

855-043-0540
Dispensing Practitioner Drug Outlet - Labeling

(1) A prescription must be labeled with the following information:

(a) Name of patient;

(b) Name of prescriber;

(c) Name, address, and phone number of the clinic;

(d) Date of dispensing;

(e) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(f) Quantity dispensed;

(g) Directions for use;

(h) Cautionary statements, if any, as required by law; and

(i) ~~Manufacturer's~~ **An** expiration date~~, or an earlier date if preferable,~~ after which the patient should not use the drug **or medicine**~~; and~~**. Expiration dates on prescriptions must be the same as that on the original container or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier. Any drug expiring before the expected length of time for course of therapy must not be dispensed.**

(j) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, ~~shall~~**must** be labeled with its physical description, including any identification code that may appear on tablets and capsules.

(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-**043-0004**~~041-4000 through 4005~~, the name of the patient may be omitted.

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

855-043-0541
Dispensing Practitioner Drug Outlet - Limited English Proficiency and Accessibility

(1) Upon request of a patient or a patient's agent, each drug dispensed by a drug outlet for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide **a prescription** label~~s~~ and**, when needed, an** informational insert~~s~~ in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

(4) An informational insert may be used when the directions for use in English and the language requested exceed 140 characters.

(5) When an informational insert is used, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used.

(6) At a minimum, the informational insert must include the:

(a) Directions for use by the patient in both English and the language requested;

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

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.

(~~1~~**2**) Drugs dispensed from **the** DPDO ~~by a practitioner~~ ~~shall~~**must** be dispensed in compliance with the requirements of the practitioner's licensing ~~B~~**b**oard.

(~~2~~**3**) A DPDO must comply with all requirements of State or federal law.

(~~3~~**4**) A DPDO must dispense a drug in a new container that complies with the current provisions of the ~~Federal Consumer~~ **Poison Prevention** Packaging Act **in 16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX)** ~~(Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling~~.

(~~4~~**5**) D**ispensed d**rugs must be packaged by the ~~practitioner~~**DPDO**, a pharmacy, or a manufacturer registered with the ~~B~~**b**oard.

(~~5~~**6**) A DPDO may not accept the return of drugs from a previously dispensed prescription and ~~shall~~**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.

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

855-043-0550
Dispensing Practitioner Drug Outlets - Disposal of Drugs

Drugs that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, or identified as suspect or illegitimate must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to the supplier.

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

855-043-0555
Dispensing Practitioner Drug Outlets - Records ~~Keeping~~

(1) A unique dispensing record ~~shall~~**must** be maintained, be readily retrievable, and kept for a minimum of three years. The record must show, at a minimum, the following:

(a) Name of patient;

(b) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;

(c) Directions for use;

(d) Date of dispensing; and

(e) Initials of person dispensing the prescription.

(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

~~(3) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.~~

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

(a) Must be stored on-site for 12 months and must be provided to the board immediately upon request at the time of inspection;

(b) May be stored in a secured off-site location after 12 months of on-site storage and must be provided to the board upon request within three business days; and

(c) May be in written or electronic format.

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

855-043-0560
Dispensing Practitioner Drug Outlets - Inspections

(1) The DPDO must complete the ~~B~~**b**oard Self Inspection Form by February 1, annually.

(2) Each DPDO will be inspected **per OAR 855-001-0040** on a routine basis and ~~shall~~**must** be scheduled in advance with the ~~practitioner~~**DPDO**, to occur during normal business hours.

(3) The inspection ~~shall~~**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 ~~shall~~**must** notify the practitioner's licensing ~~B~~**b**oard of any disciplinary action taken against a DPDO.

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

855-043-0705
Community Health Clinic (CHC) - Registration

(1) A Community Health Clinic Drug Outlet must register with the ~~B~~**b**oard on a form prescribed by the ~~B~~**b**oard, and must renew its registration annually on a renewal form prescribed by the ~~B~~**b**oard.

(2) An initial application and renewal application must be accompanied by the fee established in **OAR 855-110** ~~in division 110 of this Chapter~~.

(3) A certificate of registration will be issued upon ~~B~~**b**oard approval of the application.

(4) The CHC Drug Outlet registration expires March 31, annually. If the annual renewal fee is not paid by ~~February 28~~**March 31** of the current year, the applicant for renewal must submit the ~~delinquent~~ **late renewal** fee established in **OAR 855-110** ~~division 110 of this Chapter~~ with the renewal application.

(5) The registration is not transferable and the registration fee cannot be prorated.

(6) The registrant must notify the ~~B~~**b**oard, within 15 days, of any substantial change to the information provided on the registration application. A substantial change shall include but not be limited to: a change of ownership; change of business address; change of normal business hours; any disciplinary

action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or Medical Director.

(7) A new registration form is required for a change of ownership or location and must be submitted to the ~~B~~**b**oard with the fees as specified in **OAR 855-110** ~~division 110 of this Chapter~~ within 15 days of the change.

(8) A CHC Drug Outlet may be inspected by the ~~B~~**b**oard.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: 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~~ll drugs~~**CHC** ~~must be~~ dispense~~d~~ **a drug** in a new container that complies with the current provisions of the ~~Federal Consumer~~ **Poison Prevention** Packaging Act **in 16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX)** ~~and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling~~.

(7) D**ispensed d**rugs must be ~~re~~packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the ~~B~~**b**oard.

(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.

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

Division 043– Practitioner Dispensing (SPDO/DPDO, OSBN, Procedural Rule Review)

Filing Caption (15 word limit)**:** 2021 HB 3036 Allows physician assistant to dispense prescription drugs and proactive procedural rule review.

Need for Rules: Revisions to Division 043 are necessary to:

1. Incorporate changes to physician assistant (PA) scope set forth in 2021 HB 3036, related to dispensing prescription drugs.

2. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs.

3. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

Fiscal Impact:

1. There are 52 Supervising Physician Dispensing Outlets (SPDO) and 49 Dispensing Practitioner Dispensing Outlets (DPDO) currently active. As a result of 2021 HB 3036, SPDO will be discontinued effective 3/31/2022. 6 SPDOs also have an active DPDO registration. The discontinued SPDOs may now met the requirements for registration as a "DPDO". The current SPDO registration fee is $175 / $275 with CS annually and the current DPDO registration fee is $100 annually. There are 6 locations that hold both registrations.

The transition from SPDO Registration to DPDO registration has a net biennial revenue reduction of 17,400.

2. None anticipated

3. None anticipated

Documents relied upon include:

2021 HB 3036 and related statutes

Oregon State Board of Nursing: ORS 678.390

Poison Prevention Packaging Act: 16 CFR 1700 (XX/XX/XXXX) Poison Prevention Packaging, 16 CFR 1701 (XX/XX/XXXX) Statements of Policy and Interpretation, and 16 CFR 1702 (XX/XX/XXXX) Petitions for Exemptions from Poison Preventing Packaging Act Requirements; Petition Procedures and Requirements

Rules Summary: Revisions to Division 043 are necessary to incorporate changes to PA scope set forth in 2021 HB 3036, related to dispensing prescription drugs. Repeal of OAR 855-043-0405 through 855-043-0455 and 855-043-0002(9) effective 3/31/2022. Ensure rules reflect updates to statutes, including ORS 678.390 concerning the authority of a nurse practitioner and clinical nurse specialist to dispense drugs. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

Note: If language changes are made to OAR 855-043-0002, 855-043-0436 and 855-043-0541 in other rule packages, this rule will be updated to reflect the same language in the other rule packages.

Division 43
PRACTITIONER DISPENSING

855-043-0002
Definitions

In this division of rules:

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

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

(b) The patient at the direction of the practitioner.

(2) "Counseling" means an oral or other appropriate communication process between a practitioner and a patient or a patient's agent in which the practitioner obtains information from the patient or patient's agent, and, where appropriate, the patient's medical 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.

(~~2~~**3**) "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(4) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(~~3~~**5**) "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or preventative measures such as immunization or birth control approved by the ~~B~~**b**oard or by the ~~Department of Human Services (DHS)~~ **Oregon Health Authority (OHA)**.

(~~4~~**6**) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of Naturopathic Medicine and employed by or under contract with a county or district health department or ~~DHS~~**OHA**.

~~(5**7**) "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center, treatment center, or other establishment from which a physician assistant dispenses drugs, but that is not otherwise registered with the Board in the category of Retail Drug Outlet.~~

NOTE: (7) will be repealed on 3/31/2022.

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

855-043-0003
Expedited Partner Therapy

~~(1) Expedited Partner Therapy (EPT) means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.~~

~~(2) An EPT prescription may only be dispensed for a drug and a disease that has been determined by DHS to be appropriately addressed by EPT.~~

(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.

(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.

(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

855-043-0004
Expedited Partner Therapy (EPT) - Procedures

(1) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule governs.

(2) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon Health Authority to be appropriately used for EPT.

Prescription
(3) An EPT treatment protocol must conform to the following:

(a) It must include a prescription for each named or unnamed partner of the patient;

(b) It must contain a hand written or electronic signature of the prescribing practitioner;

(c) The practitioner must identify the prescription in the following manner:

(A) Write "for EPT," or a similar notation, on the face of the prescription;

(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;

(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe – Partner 1" or by labeling the prescription as "EPT Partner"

(d) An EPT Prescription expires 30 days after the date written;

(e) An EPT Prescription may not be refilled;

(f) If any component of the prescription is missing, the DPDO must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.

(4) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may elect for a DPDO to dispense all prescriptions and then give the dispensed drugs to each unnamed partner.

Labeling

(5) The DPDO must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the DPDO may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.

(6) The DPDO must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling

(7) The DPDO is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the DPDO must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The DPDO should advise the patient to encourage each partner to call the DPDO before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records

(8) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the board upon request.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.505

855-043-0005

Practitioner Labeling

All drugs dispensed by a practitioner must be labeled with the following information:

(1) Name, address and telephone number of the practitioner;

(2) Date;

(3) Name of the patient or the owner of the animal for which the drug is dispensed. If the prescription is for an animal, the species of the animal for which the drug is dispensed;

(4) Name of drug, strength, the quantity dispensed. When a generic name is used, the label must also contain the name of the manufacturer or distributor;

(5) Directions for use;

(6) Required precautionary information regarding controlled substances;

(7) Such other cautionary information as required for patient safety; and

(8) An expiration date after which the patient should not use the drug or medicine. The expiration date on a drug dispensed must be the same as that on the original container unless, in the practitioner's professional judgment, a shorter expiration date is warranted. A drug must not be dispensed after the expiration date of the drug.

(9) Not withstanding the labeling requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient or the patient's partner may be omitted from the label.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.505

855-043-0210

Oregon Nurse Practitioner Dispensing

The Oregon State Board of Nursing may grant to a certified nurse practitioner or Clinical Nurse Specialist the privilege of writing prescriptions described in the formulary under ORS 678.385. A certified nurse practitioner or Clinical Nurse Specialist may submit an application to the Oregon State Board of Nursing to dispense prescription drugs. An application for the authority to dispense prescription drugs as authorized by ORS 678.385 shall include evidence of completion of a prescription drug dispensing training program jointly developed and adopted by rule by the Oregon State Board of Nursing (851-050-0162) and the State Board of Pharmacy. The training program shall be as follows:

(1) Documented review of content regarding safe dispensing listed below:

~~(a) Board of Nursing handbook "Prescriptive Authority in Oregon for Nurse Practitioners and Clinical Nurse Specialists";~~

~~(b) The Drug Enforcement Administration Pharmacist's Manual (2004);~~

~~(c) OAR 851, division 56;~~

~~(d) ORS Chapter 689 and OAR chapter 855;~~

~~(e) US Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for Pharmacist's and Physicians;"~~

~~(f) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and Dose Designations" (Nov. 2006); and~~

~~(g) Information on available electronic or hard copy prescription drug references which provide information to professionals authorized to dispense prescription medications~~

~~(2) Successful self-examination as provided by the Board of Nursing on these materials.~~

~~[Publications: Publications referenced are available from the agency.]~~

~~Statutory/Other Authority: ORS 678.390 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.205~~

NOTE: 855-043-0405 through 855-043-0455 will be repealed on 3/31/2022.

~~855-043-0405~~
~~Supervising Physician Dispensing Outlet - Purpose and Scope~~

~~A supervising physician or supervising physician organization that supervises a physician assistant with dispensing authority must register the dispensing site with the Board as a Supervising Physician Dispensing Outlet (SPDO) and must comply with the rules in OAR chapter 855, division 43.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0410~~
~~Supervising Physician Dispensing Outlet - Registration~~

~~(1) A Supervising Physician Dispensing Outlet must register with the Board as a SPDO in the category of Retail Drug Outlet on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.~~

~~(2) The initial application must state the location of the SPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the~~

~~application must disclose the name and address of the owner and the applicant's affiliation with the owner.~~

~~(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.~~

~~(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.~~

~~(3) Upon request by the Board, the applicant must furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.~~

~~(4) An initial application must be accompanied by the fee established in division 110 of this chapter.~~

~~(5) A certificate of registration will be issued upon Board approval of the application.~~

~~(6) All registration renewal applications must be accompanied by the annual renewal fee established in Division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.~~

~~(7) The SPDO registration expires March 31, annually. If the annual renewal fee referred to in section (5) of this rule is not paid by February 28 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this chapter with the renewal application.~~

~~(8) The registration is not transferable and the registration fee cannot be prorated.~~

~~(9) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, consultant pharmacist or supervising physician.~~

~~(10) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in division 110 of this chapter within 15 days of the change.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0415~~
~~Supervising Physician Dispensing Outlet - Consulting Pharmacist~~

~~(1) A SPDO must retain a pharmacist licensed in Oregon for consultation purposes.~~

~~(2) The consulting pharmacist must conduct and document an annual inspection of the outlet on a form provided by the Board. The completed inspection report form must be filed in the outlet, retained on file for three years and be available to the Board for inspection.~~

~~(3) The duties of the consulting pharmacist shall be clearly defined in writing within the organization. The consulting pharmacist must:~~

~~(a) Develop policies and procedures for the outlet in collaboration with the supervising physician; and~~

~~(b) Work in consultation with the supervising physician in the development of the formulary of drugs and classes of drugs for the outlet.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0420~~
~~Supervising Physician Dispensing Outlet - Policies and Procedures~~

~~The registered SPDO must:~~

~~(1) Maintain written policies and procedures for drug management, including storage, security, integrity, access, dispensing, disposal, record keeping and accountability;~~

~~(2) Maintain all drug records required by federal and state law;~~

~~(3) Establish procedures for procurement of drugs; and~~

~~(4) Establish procedures to train physician assistants who dispense drugs and to ensure the continued competence of physician assistants who dispense drugs.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0425~~
~~Supervising Physician Dispensing Outlet - Security~~

~~(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.~~

~~(2) No drug dispensing machine may be placed in a waiting room or an area that is accessible by the public.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~**855-043-0430**~~

~~**Supervising Physician Dispensing Outlet - Storage of Drugs**~~

~~All drugs, including drug samples, must be stored under conditions that ensure proper sanitation, temperature, light, ventilation, moisture control, and any other condition recommended by the manufacturer.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~**855-043-0435**~~

~~**Supervising Physician Dispensing Outlet - Labeling**~~

~~(1) A prescription must be labeled with the following information:~~

~~(a) Unique identifier;~~

~~(b) Name of patient;~~

~~(c) Name of prescriber;~~

~~(d) Name, address, and phone number of the clinic;~~

~~(e) Date of dispensing;~~

~~(f) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;~~

~~(g) Quantity dispensed;~~

~~(h) Directions for use;~~

~~(i) Initials of the physician assistant or practitioner dispensing;~~

~~(j) Cautionary statements, if any, as required by law; and~~

~~(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug; and~~

~~(l) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.~~

~~(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-041-4000 through 4005, the name of the patient may be omitted.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0436~~
~~Supervising Physician Dispensing Outlet – Limited English Proficiency and Accessibility~~

~~(1) Upon request of a patient or a patient's agent, each drug dispensed by a drug outlet for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.~~

~~(2) When dispensing a drug under (1), a drug outlet must provide labels and informational inserts in both English and one of the following languages:~~

~~(a) Spanish;~~

~~(b) Russian;~~

~~(c) Somali;~~

~~(d) Arabic;~~

~~(e) Chinese (simplified);~~

~~(f) Vietnamese;~~

~~(g) Farsi;~~

~~(h) Korean;~~

~~(i) Romanian;~~

~~(j) Swahili;~~

~~(k) Burmese;~~

~~(l) Nepali;~~

~~(m) Amharic; and~~

~~(n) Pashtu.~~

~~(3) The board must reassess and update (2) as necessary and at least every ten years.~~

~~Statutory/Other Authority: ORS 689.564~~
~~Statutes/Other Implemented: ORS 689.205~~

~~855-043-0440~~

~~Supervising Physician Dispensing Outlet - Dispensing and Drug Delivery~~

~~(1) Drugs dispensed from a SPO by a physician assistant with dispensing authority or a practitioner must be personally dispensed by the practitioner or physician assistant.~~

~~(2) Prior to dispensing a medication a drug utilization review must be performed by the physician assistant or practitioner which includes but is not limited to drug interactions, drug allergies and duplicate drug therapy.~~

~~(3) The physician assistant or practitioner must orally counsel the patient concerning all new drugs, unless circumstances would render oral counseling ineffective.~~

~~(4) When dispensed, a drug must be accompanied by written information that contains at least the following information:~~

~~(a) Drug name, class and indications;~~

~~(b) Proper use and storage;~~

~~(c) Common side effects;~~

~~(d) Precautions and contraindications; and~~

~~(e) Significant drug interactions.~~

~~(5) 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.~~

~~(6) Any other requirement of State or federal law.~~

~~(7) A SPDO must dispense a drug in a new container that complies with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.~~

~~(8) Drugs must be prepackaged by a pharmacy or manufacturer registered with the Board.~~

~~(9) A SPDO 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.~~

~~(10) 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.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0445~~

~~Supervising Physician Dispensing Outlet - Drug Dispensing Training Program~~

~~A physician assistant must complete a drug dispensing training program jointly developed by the Oregon Medical Board and the Board of Pharmacy before dispensing drugs to patients.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~
~~History:~~
~~BP 62-2020, minor correction filed 08/06/2020, effective 08/06/2020~~
~~BP 3-2012, f. & cert. ef. 6-19-12~~

~~855-043-0450~~

~~Supervising Physician Dispensing Outlet - Disposal of Drugs~~

~~Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0455~~

~~Supervising Physician Dispensing Outlet - Record Keeping~~

~~(1) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:~~

~~(a) Name of patient;~~

~~(b) Unique identifier;~~

~~(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;~~

~~(d) Directions for use;~~

~~(e) Date of dispensing; and~~

~~(f) Initials of person dispensing the prescription.~~

~~(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.~~

~~(3) Records documenting training required by OAR 855-043-0445 must be kept for three years.~~

~~(4) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

855-043-0505
Dispensing Practitioner Drug Outlets - Purpose

~~A practitioner's facility that engages in dispensing certain FDA-approved human prescription drug therapies greater than a 72 hours supply or any medication refill~~ **Unless subject to an exemption in OAR 855-043-0510(2), a practitioner that engages in dispensing human prescription drug therapies** must register their dispensing site ~~as a drug outlet~~ with the B**b**oard as a Dispensing Practitioner Drug Outlet (DPDO).

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

855-043-0510
Dispensing Practitioner Drug Outlets - Registration

(1) **Unless subject to an exemption in OAR 855-043-0510(2), a practitioner that engages in dispensing human prescription drug therapies** ~~A practitioner's facility that engages in dispensing FDA-approved human prescription drug therapies greater than 72 hours supply or any medication refill~~ must register the~~ir~~ dispensing site ~~as a drug outlet~~ with the ~~B~~**b**oard as a DPDO on a form ~~provided~~**prescribed** by the ~~B~~**b**oard, and must renew its registration annually on a renewal form ~~provided~~**prescribed** by the ~~B~~**b**oard.

(2) A practitioner's facility is exempt from this registration requirement if the practitioner and facility only engages in:

(A) Dispensing FDA approved drug samples; or

(B) Dispensing Medication Assistance Program (MAP) drugs; or

(C) Dispensing homeopathic products; or

(D) Dispensing natural thyroid supplemental products; or

(E) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72 hour supply; or

(F) An amount greater than a 72 hour supply if the drug is:

(i) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-inhaler or bottle of fluoride rinse; or

(ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient's best interest, such as a course of antibiotic therapy.

(3) The initial **and renewal** application**s** must state the location of the DPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant's affiliation with the owner.

(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.

(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.

(4) Upon request by the ~~B~~**b**oard~~,~~ the applicant must furnish such information as required by the ~~B~~**b**oard regarding the partners, stockholders, or other persons not named in the application.

(5) An initial **and renewal** application**s** must be accompanied by the fee established **OAR 855-110**~~in division 110 of this chapter~~.

(6) A certificate of registration will be issued upon ~~B~~**b**oard approval of the application.

~~(7) All registration renewal applications must be accompanied by the annual renewal fee established in division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.~~

(~~8~~**7**) The DPDO registration expires March 31, annually. If the annual renewal fee is not paid by ~~February 28~~ **March 31** of the current year, the applicant for renewal must submit the ~~delinquent~~ **late renewal** fee established in **OAR 855-110**~~in division 110 of this chapter~~ with the renewal application.

(~~9~~**8**) The registration is not transferable and the registration fee cannot be prorated.

(~~10~~**9**) The registrant must notify the ~~B~~**b**oard~~, within~~ 15 days **prior to**~~, of~~ any substantial change to the information provided on the registration application. Substantial change ~~shall~~ include**s** but **is** not ~~be~~ limited to: change of ownership; change of business name; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, **or** officers~~, or supervising practitioner~~.

(~~11~~**10**) A new registration form is required for a change of ownership or location and must be submitted to the ~~B~~**b**oard with the fees as specified in **OAR 855-110**~~in division 110 of this chapter within~~ 15 days **prior to**~~of~~ the change.

(~~12~~**11**) The ~~B~~**b**oard may grant a time-limited waiver exempting DPDO registration when a practitioner licensing board submits a request to the ~~B~~**b**oard with a plan to annually inspect the dispensing facility to the standards of the ~~B~~**b**oard.

(12) All Supervising Physician Dispensing Outlet registrations expire on March 31, 2022. Outlets that utilize dispensing Physician Assistants must apply for and be granted registration as a Dispensing

Practitioner Dispensing Outlet upon the expiration of the Supervising Physician Dispensing Outlet Registration unless subject to an exemption in OAR 855-043-0510(2).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **ORS** 689.305, **ORS 475.125**

855-043-0520
Dispensing Practitioner Drug Outlets - Policies and Procedures

The registered DPDO must maintain written policies and procedures for the management of drugs intended for dispensing, to include security, acquisition, storage, dispensing and drug delivery, disposal and record keeping.

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

855-043-0525
Dispensing Practitioner Drug Outlets - Security

(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.

(2) A drug dispensing machine cannot be placed in a waiting room or an area that is accessible by the public.

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

855-043-0530
Dispensing Practitioner Drug Outlets - Drug ~~Acquisition~~ Receipt

The registered DPDO ~~must verify that all~~ **may only receive** drugs ~~are acquired~~ from a**n Oregon Registered Drug Outlet (e.g. Wholesaler, Manufacturer or Pharmacy)** ~~registrant of the Board~~.

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

855-043-0535
Dispensing Practitioner Drug Outlets - Drug Storage

All drugs must be stored according to manufacturer's published guidelines and be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, **ORS** 689.305

855-043-0540
Dispensing Practitioner Drug Outlet - Labeling

(1) A prescription must be labeled with the following information:

(a) Name of patient;

(b) Name of prescriber;

(c) Name, address, and phone number of the clinic;

(d) Date of dispensing;

(e) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(f) Quantity dispensed;

(g) Directions for use;

(h) Cautionary statements, if any, as required by law; and

(i) ~~Manufacturer's~~ **An** expiration date~~, or an earlier date if preferable,~~ after which the patient should not use the drug **or medicine**~~; and~~**. Expiration dates on prescriptions must be the same as that on the original container or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier. Any drug expiring before the expected length of time for course of therapy must not be dispensed.**

(j) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, ~~shall~~**must** be labeled with its physical description, including any identification code that may appear on tablets and capsules.

(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-**043-0004**~~041-4000 through 4005~~, the name of the patient may be omitted.

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

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.

(~~1~~**2**) Drugs dispensed from **the** DPDO ~~by a practitioner shall~~**must** be dispensed in compliance with the requirements of the practitioner's licensing ~~B~~**b**oard.

(~~2~~**3**) A DPDO must comply with all requirements of State or federal law.

(~~3~~**4**) A DPDO must dispense a drug in a new container that complies with the current provisions of the ~~Federal Consumer~~ **Poison Prevention** Packaging Act **in 16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX)** ~~(Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling~~.

(~~4~~**5**) D**ispensed d**rugs must be packaged by the ~~practitioner~~**DPDO**, a pharmacy, or a manufacturer registered with the ~~B~~**b**oard.

(~~5~~**6**) A DPDO may not accept the return of drugs from a previously dispensed prescription and ~~shall~~**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.

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

855-043-0550
Dispensing Practitioner Drug Outlets - Disposal of Drugs

Drugs that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, or identified as suspect or illegitimate must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to the supplier.

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

855-043-0555
Dispensing Practitioner Drug Outlets - Record~~s Keeping~~

(1) A unique dispensing record ~~shall~~**must** be maintained, be readily retrievable, and kept for a minimum of three years. The record must show, at a minimum, the following:

(a) Name of patient;

(b) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;

(c) Directions for use;

(d) Date of dispensing; and

(e) Initials of person dispensing the prescription.

(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

~~(3) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.~~

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

(a) Must be stored on-site for 12 months and must be provided to the board immediately upon request at the time of inspection;

(b) May be stored in a secured off-site location after 12 months of on-site storage and must be provided to the board upon request within three business days; and

(c) May be in written or electronic format.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, **ORS** 689.305

855-043-0560
Dispensing Practitioner Drug Outlets - Inspections

(1) The DPDO must complete the ~~B~~**b**oard Self Inspection Form by February 1, annually.

(2) Each DPDO will be inspected **per OAR 855-001-0040** on a routine basis and ~~shall~~**must** be scheduled in advance with the ~~practitioner~~**DPDO**, to occur during normal business hours.

(3) The inspection ~~shall~~**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 ~~shall~~**must** notify the practitioner's licensing ~~B~~**b**oard of any disciplinary action taken against a DPDO.

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

855-043-0705
Community Health Clinic (CHC) - Registration

(1) A Community Health Clinic Drug Outlet must register with the ~~B~~**b**oard on a form prescribed by the ~~B~~**b**oard, and must renew its registration annually on a renewal form prescribed by the ~~B~~**b**oard.

(2) An initial application and renewal application must be accompanied by the fee established in **OAR 855-110** ~~in division 110 of this Chapter~~.

(3) A certificate of registration will be issued upon ~~B~~**b**oard approval of the application.

(4) The CHC Drug Outlet registration expires March 31, annually. If the annual renewal fee is not paid by ~~February 28~~**March 31** of the current year, the applicant for renewal must submit the ~~delinquent~~ **late renewal** fee established in **OAR 855-110** ~~division 110 of this Chapter~~ with the renewal application.

(5) The registration is not transferable and the registration fee cannot be prorated.

(6) The registrant must notify the ~~B~~**b**oard, within 15 days, of any substantial change to the information provided on the registration application. A substantial change shall include but not be limited to: a change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or Medical Director.

(7) A new registration form is required for a change of ownership or location and must be submitted to the ~~B~~**b**oard with the fees as specified in **OAR 855-110** ~~division 110 of this Chapter~~ within 15 days of the change.

(8) A CHC Drug Outlet may be inspected by the ~~B~~**b**oard.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: 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~~ll drugs~~**CHC** ~~must be~~ dispense~~d~~ **a drug** in a new container that complies with the current provisions of the ~~Federal Consumer~~ **Poison Prevention** Packaging Act **in 16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX)** ~~and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling~~.

(7) D**ispensed d**rugs must be ~~re~~packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the ~~B~~**b**oard.

(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.

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

Division 060/110– Manufacturer/Fees (Procedural Rule Review, PDMP, DPDO)

Filing Caption (15 word limit)**:** Addresses fee changes pursuant to 2021 HB 2074 and 2021 HB 3036; Procedural rule review.

Need for Rules:

Revisions to Division 110 are necessary to:

1. Incorporate annual Prescription Drug Monitoring Program (PDMP) fee increase of $25 to $35 set forth in 2021 HB 2074.

2. Repeal all rules related to Supervising Physician Dispensing Outlets (SPDOs) as a result of 2021 HB 3036 effective 3/31/2022.

3. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

Fiscal Impact:

1. 2021 HB 2074 increases the PDMP fee from $25 to $35 annually resulting in a $20 increase in fees paid by a pharmacist at the time of biennial licensure renewal. Increasing the fee will result in increased revenue by the agency of approximately $172,200 ($10 per year or $20 x 8600 RPH renewals). 90% of the revenue is passed through to the PDMP program and 10% is retained by the agency for administrative costs, resulting in an agency revenue increase of $17,200.

2. There are 52 Supervising Physician Dispensing Outlets (SPDO) and 49 Dispensing Practitioner Dispensing Outlets (DPDO) currently active. As a result of 2021 HB 3036, SPDO will be discontinued effective 3/31/2022. 6 SPDOs also have an active DPDO registration. The discontinued SPDOs may now meet the requirements for registration as a "DPDO". The current SPDO registration fee is $175 annually and the current DPDO registration fee is $100 annually. There are 6 locations that hold both registrations.

3. The use of NABP's eProfile and eGov processes have reduced many of the manual processes and created licensing efficiencies.

a. Re-examination fees for NAPLEX. This has become an obsolete fee that is no longer assessed. With the new exam processes, applicants do not apply for licensure with the board until after they have passed the NAPLEX exam. No anticipated fiscal.

b. Score Transfer is applicable to new graduates and has similar workload to licensure via exam (NAPLEX), so the fee should be equivalent to the current NAPLEX fee. The Board receives approximately 125 Score Transfer applications in a biennium. Reducing this fee from $250 to $50 will result in a biennial revenue reduction of $25,000.

c. Reciprocity (Licensure Transfer) is applicable to applicants who are licensed as a pharmacist in another state and meet the requirements listed in ORS 689.265 and OAR 855-019-0130. There are approximately 850 Reciprocity applications received in a biennium. Reducing this fee from $250 to $100 will result in a biennial revenue reduction of $127,500.

Documents relied upon include:

2021 HB 2074 and related statutes

2021 HB 3036 and related statutes

ORS 475.125

Rules Summary:

Revisions to Division 110:

1. Incorporate annual PDMP fee increase of $25 to $35 set forth in 2021 HB 2074.

2. Repeal all rules related to Supervising Physician Dispensing Outlets (SPDOs) as a result of 2021 HB 3036 effective 3/31/2022.

3. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

Division 60
PHARMACEUTICAL MANUFACTURERS

855-060-0001
Application

No place of manufacturing, wholesaling or repackaging of drugs or medicines, as defined in ORS 689.005(20), (35), and (36) ~~shall~~ **may** be conducted or operated until it has been registered by the State Board of Pharmacy.~~, except that compounding or repackaging, as a part of a Shared Pharmacy Services agreement as defined in OAR 855-006-0005(20), does not constitute manufacturing. Manufacturing registration expires September 30th annually:~~

(1) All applications for registration of a new or relocated manufacturer shall be accompanied by the required fees as set forth in **OAR** 855-110~~-0007(3)~~.

(2) Application ~~shall~~ **must** specify the location of the manufacturer premises. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant's affiliation with the owner;

(a) If the owner is a partnership or other multiple owner, the names of the partners or person holding the five largest interests shall be indicated on the application.

(b) If the owner is a corporation, the name filed ~~shall~~ **must** be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.

(c) Upon request by the ~~B~~**b**oard, the applicant ~~shall~~ **must** furnish such information as required by the ~~B~~**b**oard regarding the partners, stockholders, or other persons not named in the application.

(3) All registration renewal applications ~~shall~~ **must** be accompanied by the annual fee and contain the same information required in subsection (2)(a), (b), and (c) of this rule.

(4) A change of ownership or location requires a new application, fee, and registration within 15 days.

(5) The registration certificate is issued to a person or firm and is non-transferable. Additions or deletions of a partner/partners ~~shall~~ **must** be considered as a change of ownership.

(6) **Manufacturing registration expires September 30th annually.** The registration cannot be prorated.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **ORS** 689.305, **ORS** 689.315 & **ORS** 689.325

Division 110
FEES

855-110-0003
General

(1) All fees paid under these rules are non-refundable.

(2) Fees cannot be prorated.

(3) Fees for initial licensure as a Pharmacist or Certified Oregon Pharmacy Technician may be reduced to one-half of a biennial rate, if the application is received ~~or the mailing date of the application is postmarked~~ within 180 days of expiration.

(4) A ~~delinquent~~ **late** fee must be paid~~:~~ **when a renewal application is received after the date specified in these rules.**

~~(a) When an application is postmarked after the date specified in these rules; or~~

~~(b) When the Board requests additional information from an applicant and this information is not provided within 30 days.~~

~~(5) A delinquent fee may be assessed when an application is submitted incomplete and the Board requests the missing information.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135

855-110-0005
Licensing Fees

(1) Pharmacist license examination (NAPLEX) ~~and re-examination~~ fee - $50.

(2) Pharmacist jurisprudence (MPJE) re-examination fee - $25.

(3) Pharmacist licensing by reciprocity fee - $~~250~~**100**.

(4) Pharmacist licensing by score transfer fee - $~~2~~50.

(5) Intern license fee. Expires November 30 every two years - $100.

(6) Pharmacist:

(a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is - $250. Late renewal fee (received after June 30) - $50.

(b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially - $~~5~~**7**0. (This is a mandatory fee, required by ORS ~~431.972~~ **431A.880** that must be paid with the pharmacist license renewal fee).

(c) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.)

(7) Certification of approved provider of continuing education course fee, none at this time.

(8) Pharmacy Technician license fee - $100.

(9) Certified Oregon Pharmacy Technician:

(a) Biennial license fee. Expires June 30 each even numbered year - $100. Late renewal fee (received after June 30) - $20.

(b) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy Technician license renewal fee.)

Statutory/Other Authority: ORS 689.205, ORS 291.055 & ORS 183.705
Statutes/Other Implemented: ORS 689.135, ORS 676.410 & ORS 431A.880

855-110-0007
Fees for Registration, Renewal, and Reinspection of Drug Outlets

(1) Community Health Clinic. Expires March 31 annually - $100. Late renewal fee (received after March 31) - $25.

(2) Drug Distribution Agent. Expires September 30 annually - $400. Late renewal fee (received after September 30) - $100.

(3) Drug Room (including ~~c~~**C**orrectional ~~f~~**F**acility). Expires March 31 annually - $100. Late renewal fee (received after March 31) - $75.

(4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually - $525. Late renewal fee (received after September 30) - $100.

(5) Medical Device, Equipment & Gas Class C. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.

(6) Nonprescription Class A. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.

(7) Nonprescription Class B. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.

(8) Nonprescription Class D. Expires January 31 annually - $100. Late renewal fee (received after January 31) - $25.

(9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - $50. Expires December 31 annually.

(10) Re-inspection fee - $100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.

(11) Retail, Institutional, or Consulting/"Drugless". Expires March 31 annually - $225. Late renewal fee (received after March 31) - $75.

(12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually - $525. Late renewal fee (received after September 30) - $100.

(13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually - $120. Due by March 31 annually.

(14) Charitable Pharmacy. Expires March 31 annually - $75. Late renewal fee (received after March 31) - $25.

(15) Home Dialysis. Expires March 31 annually - $225. Late renewal fee (received after March 31) - $75.

~~(16) Supervising Physician Dispensing Outlet. Expires March 31 annually - $175. Late renewal fee (received after March 31) - $75.~~

(~~17~~**16**) Dispensing Practitioner Drug Outlet. Expires March 31 annually - $100. Late renewal fee (received after March 31) — $25.

Statutory/Other Authority: ORS 689.205 & ORS 291.055
Statutes/Other Implemented: ORS 689.135, ORS 689.774 & ORS 689.305

855-110-0010
Fees for Registration for Controlled Substances ~~under ORS 475.095~~

(1) Animal Euthanasia controlled substance registration fee — $75 annually.

(2) Drug Distribution Agent controlled substance registration fee — $100 annually.

(3) Drug Room (including ~~c~~**C**orrectional ~~f~~**F**acility) controlled substance registration fee — $100 annually.

(4) Manufacturer controlled substance registration fee — $100 annually.

(5) Retail or Institutional Drug Outlet controlled substance registration fee — $100 annually.

(6) Schedule II Precursor registration fee — $75 annually.

(7) Wholesaler controlled substance registration fee — $100 annually.

(8) Remote Distribution Facility controlled substance registration fee — $100 annually.

Statutory/Other Authority: ORS 689.205**,** ~~&~~ ORS 291.055, **ORS 475.095**
Statutes/Other Implemented: ORS 689.135

Division 006/041– Definitions/ Operation of Pharmacies (Telework/ Remote Processing/ TCVP)

Filing Caption (15 word limit)**:** Proactive procedural rule review. Repeals outdated regulations in alignment with the board's strategic plan

Need for Rules:

1. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

2. Telework proposed rules will allow for remote work by Interns and Certified Oregon Pharmacy Technicians under the under the supervision, direction and control with verification by an Oregon-licensed pharmacist outside of a public health emergency. Proposed telework rules replace remote processing rules in OAR 855-041-3100 through OAR 855-041-3130 and provide clarify on how technicians may assist in the practice of pharmacy.

3. OAR 855-041-5100 states that a Technician Checking Validation Program is a program that uses a technician checker to check functions completed by another technician. This program does not include a step for an Oregon licensed Pharmacist to perform final verification of work completed by a Certified Oregon Pharmacy Technician. Staff proposes to repeal OAR 855-041-5100 through OAR 855-041-5170.

Fiscal Impact:

1. None anticipated.

2. To be determined.

3. Currently there are 4 institutional pharmacies utilizing TCVP. When these rules are repealed, there are potential increased personnel expenses to the registrant. OAR 855-041-5130 requires extensive training of Certified Oregon Pharmacy Technicians to participate in TCVP that will no longer be needed, but there will be an increased cost to utilize a pharmacist to perform final verification of medications.

Documents relied upon include:

21 USC 351 (XX/XX/XXXX) Adulterated drugs and devices, 21 USC 352 (XX/XX/XXXX) Misbranded drugs and devices

Rules Summary:

Procedural rule review and revisions to ensure clarity, transparency and promote patient safety. Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location.

Note: If language changes are made to OAR 855-006-0005, OAR 855-041-1001, OAR 855-041-1035, 855-041-1036 or 855-041-1145 in other rule packages, this rule will be updated to reflect the same language in the other rule packages.

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Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).

(~~1~~2) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(~~2~~3) "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 pharmacy technicians.

(~~3~~4) "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.

(~~4~~5) "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.

(~~5~~6) "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.

(~~6~~7) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(~~7~~**8**) "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.

(~~8~~**9**) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(~~9~~**10**) "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.

(~~10~~**11**) "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.

(~~11~~**12**) "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.

(13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).

(12**14**) "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.

(~~13~~**15**) "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.

(~~14~~**16**) "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.

(~~15~~**17**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(~~16~~**18**) "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.

(19) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States <HPUS> (v.2021), or any supplement to any of these.

(~~17~~**20**) "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.

(~~18~~**21**) 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.

(~~19~~**22**) "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.

(~~20~~**23**) "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.

(~~21~~**24**) “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.

(~~22~~**25**) “Practice of pharmacy” is as defined in ORS 689.005.

(~~23~~**26**) "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.

(~~24~~**27**) “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.

(~~25~~**28**) "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.

(~~26~~**29**) “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.

(~~27~~**30**) "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.

(~~28~~**31**) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as 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 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 or pharmacy technicians;

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

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

~~(29) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, “supervision by a pharmacist” means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.~~

(~~30~~**32**) "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.

(~~31~~**33**) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.

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

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.** ~~includes, but is not limited to: Retail, Institutional, Remote Processing, Central Fill, and Drugless/Consulting Drug Outlets~~.

(2) Every non-resident pharmacy that provides drugs, devices or services to a resident in this state ~~shall~~**must** be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every non-resident pharmacy ~~shall~~**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 ~~shall~~**must** designate an Oregon licensed Pharmacist-in-Charge (PIC), who ~~shall~~**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 annual non-resident PIC self-inspection report prior to February 1 each year; and

(d) Provide the PIC self-inspection report as requested by the Board.

(5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within four months of initial licensure of the pharmacy.

(6) When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the Board within ten business days and identify a contact person. The pharmacy will have an Oregon licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the pharmacy's state of residence and is responsible for the following:

(a) Supervision of pharmacy staff and ensuring compliance with laws and rules; and

(b) Responding to Board correspondence and inquiries.

(7) A new Pharmacist-in-Charge must be appointed, and communication made to the Board within 90 days, or the non-resident pharmacy will cease drug distribution and provision of pharmacy services in Oregon.

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

~~**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~~

~~**855-041-3100**~~

~~**Remote Processing - Purpose and Scope**~~

~~The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription drug processing by a pharmacy. Any facility that processes drug orders on behalf of an Oregon pharmacy shall be licensed in Oregon as a retail or institutional drug outlet. An applicant must submit its policies and procedures to the Board of Pharmacy. An applicant must submit to the Board for approval policies and procedures and a description of how using remote processing will improve patient safety.~~

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

~~**855-041-3105**~~

~~**Remote Processing - Definitions**~~

~~The following words and terms, when used in OAR 855-041-3100 through 855-041-3130, 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 OAR chapter 855, division 006.~~

~~(1) "Remote Processing Pharmacy" means an Oregon licensed pharmacy operated under the direction of a pharmacist-in-charge that processes information related to the practice of pharmacy and engages in remote prescription processing, including central processing.~~

~~(2) "Remote Processing Functions" may include, but are not limited to, data entry, prospective drug utilization reviews, refill authorizations and interventions. This does not include the filling process.~~

~~(3) "Primary Pharmacy" means an instate Oregon licensed pharmacy that receives a patient's or a prescribing practitioner's request to fill a prescription or drug order and delivers the drug or device directly to the patient or patient's agent, and maintains ownership of the prescription or drug order.~~

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

~~855-041-3110~~
~~Remote Processing - General Requirements~~

~~An Oregon licensed pharmacy may outsource prescription drug processing to a remote processing pharmacy provided both pharmacies:~~

~~(1) Have the same owner; or~~

~~(2) Have a written shared pharmacy services contract or agreement that specifies:~~

~~(a) The services to be provided by each pharmacy;~~

~~(b) The responsibilities of each pharmacy; and~~

~~(c) The accountabilities of each pharmacy.~~

~~(3) Maintain a separate Oregon pharmacy license for each location involved in providing services;~~

~~(4) Share a common electronic file or have appropriate technology or interface to allow access to information required to process and fill a prescription drug order;~~

~~(5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3115;~~

~~(6) Ensure that each prescription has been properly processed, filled and counseling has been provided to the patient;~~

~~(7) Designate 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 pharmacy's resident state if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;~~

~~(8) Allow prospective drug utilization reviews, refill authorizations, interventions, and patient counseling for an Oregon patient must be performed only by a licensed pharmacist in Oregon or in the state in which the pharmacy is located;~~

~~(9) Ensure that each technician processing an order for an Oregon patient is a Certified Oregon Pharmacy Technician and is supervised by a licensed pharmacist or is a licensed technician in the state in which the pharmacy is located and is supervised by a licensed pharmacist in the state in which the pharmacy is located;~~

~~(10) Comply with all applicable federal and state laws and rules;~~

~~(11) Conduct an annual review of the written policies and procedures and document such review.~~

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

~~855-041-3115~~
~~Remote Processing - Policies and Procedures~~

~~(1) In addition to the requirements of OAR 855-041-1040, the primary and the remote processing pharmacy is each accountable for establishing, maintaining, and enforcing its own written policies and procedures manual. The policies and procedures manual must include, but need not be limited to the following:~~

~~(a) The responsibilities of each pharmacy;~~

~~(b) The policies and procedures that protect confidentiality and ensure the integrity of patient information;~~

~~(c) Compliance with all applicable federal and state laws and rules;~~

~~(d) Records sufficient to identify by name, initials, or unique identification code, the identity and the specific activities of each pharmacist or technician who performed any processing function, and the location where each activity was performed;~~

~~(e) A continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to pursue opportunities to improve patient care, and to resolve identified problems; and~~

~~(f) Documentation of any errors or irregularities identified by the quality improvement program.~~

~~(2) The written policies and procedures manual shall be maintained at all pharmacies involved in remote processing and must be available to the Board upon request.~~

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

~~855-041-3120~~
~~Remote Processing - Records~~

~~(1) The recordkeeping requirements OAR 855-041-3100 through 855-041-3130 are in addition to the requirements of other recordkeeping rules of the Board.~~

~~(2) The remote processing pharmacy must maintain all required records unless these records are maintained in the primary pharmacy.~~

~~(3) Both recordkeeping systems must:~~

~~(a) List the name, address, telephone number, and all license and registration numbers of each pharmacy involved in remote prescription processing;~~

~~(A) Document verification of each license and registration;~~

~~(B) Document the name of the individual responsible for verification of licensure and registration status.~~

~~(b) Identify by name, initials, or unique identification code the identity and the specific activities of each pharmacist or technician who performed any part of the prescription process;~~

~~(c) Include quality improvement program documentation;~~

~~(d) Be able to produce an audit trail showing each prescription process.~~

~~(4) Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two;~~

~~(5) The primary pharmacy shall maintain records that:~~

~~(a) Indicate the date the request for processing was transmitted to the remote processing pharmacy; and~~

~~(b) Indicate the date the prescription information was received by the primary pharmacy.~~

~~(6) The remote processing pharmacy shall maintain records that:~~

~~(a) Track the prescription drug order during each step in the order entry process;~~

~~(b) Identify the name, initials, or unique identification code and the specific activity of each pharmacist or pharmacy technician who performed any activity related to processing the prescription including receipt, transmission or delivery of information.~~

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

~~855-041-3125~~
~~Remote Processing - Prescription or Drug Order Processing~~

~~A prescription or drug order for a controlled substance may be processed by a remote processing pharmacy when permitted by law and consistent with federal rules.~~

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

~~**855-041-3130**~~
~~**Remote Processing - Prohibited Practices**~~

~~A remote processing pharmacy may not process a prescription on behalf of a primary pharmacy that is not registered with the Board, if required by the laws and rules of Oregon to be registered.~~

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

855-041-3200
Telework: Purpose and Scope

The purpose of OAR 855-041-3200 through OAR 855-041-3250 is to provide minimum requirements for pharmacy services conducted via telework.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3205
Telework: Definitions

(1) "Telework" means the practice or assistance in the practice of pharmacy physically outside of a registered drug outlet in a telework site.

(2) "Telework Site" means a location that is not a registered drug outlet where an Oregon licensed Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist in the practice of pharmacy as employees of an Oregon registered drug outlet.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3210
Telework: Registration

The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of the Drug Outlet Pharmacy are responsible for all licensees engaging in the practice of pharmacy or assisting in the practice of pharmacy from Telework Sites.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3215

Telework: General Requirements

(1) Each Oregon registered Drug Outlet Pharmacy and Pharmacist-in-charge of a Drug Outlet Pharmacy must ensure that Interns and Certified Oregon Pharmacy Technicians working from a Telework Site work under the supervision, direction and control of an Oregon licensed Pharmacist.

(2) A Pharmacist that engages in the practice of pharmacy and an Intern or Certified Oregon Pharmacy Technician that assists in the practice of pharmacy from a Telework Site for any person or facility located in Oregon must:

(a) be licensed by the board; and

(b) comply with all applicable federal and state laws and rules.

(3) Drugs and devices may not be at a Telework Site.

(4) The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of a Drug Outlet Pharmacy must:

(a) Have a written agreement that includes all conditions, duties and policies governing the licensee engaged in telework activities;

(b) Maintain a continuously updated list of all licensees engaged in telework and the Telework Sites to include:

(A) Address, phone number and hours that telework is performed for each Telework Site;

(B) Functions being performed by licensees engaged in telework; and

(C) The Oregon licensed Pharmacist providing supervision, direction and control for each non-pharmacist licensee;

(c) Develop, implement and enforce a continuous quality improvement program for services provided from a Telework Site 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;

(d) Develop, implement and enforce a procedure for identifying the Oregon licensed Pharmacist, Intern and Certified Oregon Pharmacy Technician responsible for each telework function;

(e) Develop, implement and enforce a process for a virtual inspection of the Telework Site by an Oregon licensed Pharmacist at least once every 6 months or more frequently as deemed necessary by the Oregon licensed Pharmacist. The inspection must be documented and records retained; and

(f) Utilize an Oregon licensed Pharmacist and real-time audio and visual communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 or when requested and document the interaction.

POLICY DISCUSSION: A/V Requirement

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3220
Telework: Supervision Requirements

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the supervising Oregon licensed Pharmacist from the Drug Outlet must:

(1) Utilize a continuous real-time audio and visual connection that is recorded, reviewed and stored and have appropriate technology or interface to allow access to information required to complete assigned duties;

(2) Ensure all telephone audio is recorded, reviewed and stored;

(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon Pharmacy Technician and that the continuous audio/visual connection is fully operational;

(4) Ensure that an Oregon licensed Pharmacist performs random "check-ins" via the real-time audio and visual connection at least once every 2 hours to ensure compliance with federal and state laws and patient safety and document the interaction;

(5) Be readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and

(6) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction and control at all times.

(7) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy Technician at a Telework Site must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;

(b) Review patient interactions within 24 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;

(c) Document the following within 24 hours of the review in (b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions pharmacist is reviewing;

(C) Date and time of licensee patient interaction pharmacist is reviewing;

(D) Date and time of pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours and the board within 10 days.

(8) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (7)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.

POLICY DISCUSSION: Frequency of review

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3225
Telework: Confidentiality

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet Pharmacy, and the Pharmacist, Intern and Certified Oregon Pharmacy Technician from the Drug Outlet Pharmacy must:

(1) Ensure patient and prescription information is managed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, and OAR 855-041.

(2) Ensure the security and confidentiality of patient information and pharmacy records.

(3) Document and report any breach in the security of the system or breach of confidentiality. Report of the breach must be reported in writing to the board within ten days of the event.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3230
Telework: Technology

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the Pharmacist from the Drug Outlet must:

(1) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each:

(a) Source container including manufacturer, name, strength, lot, and expiration;

(b) Dispensed product including the imprint and physical characteristics;

(c) Completed prescription container including the label; and

(d) Ancillary document provided to patient at the time of dispensing.

POLICY DISCUSSION: Remote Verification

(2) Test the continuous audio and visual connection and document that it operates properly before engaging in telework.

(3) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising, directing and controlling the Intern and Certified Oregon Pharmacy Technician at the Telework Site.

(4) Ensure access to:

(a) Appropriate and current pharmaceutical references based on the services offered; and

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters.

(5) Train the Oregon licensed Pharmacists, Interns and Certified Oregon Pharmacy Technicians in the operation of continuous audio and visual connection.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3235
Telework: Personnel

(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all operations at Drug Outlet Pharmacy including responsibility for the continuous audio and visual connection and enforcing policies and procedures.

(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel at Telework Sites.

(3) An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have at least one year experience performing similar services for an Oregon registered Drug Outlet Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy Technician begins working at the Remote Dispensing Site Pharmacy.

POLICY DISCUSSION: Experience

(4) The Oregon licensed Pharmacist from the Drug Outlet Pharmacy who is supervising a licensee at a Telework Site must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided.

(5) When supervising an Intern or Certified Oregon Pharmacy Technician working at a Telework Site and licensees at a Drug Outlet Pharmacy, the Oregon licensed Pharmacist may supervise no more than four licensees.

(6) The Drug Outlet Pharmacy is required to comply with the pharmacist's determination in (4) and retain records.

(7) Prior to working at a Telework Site, the Intern or Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on the use of all equipment necessary for secure operation of the Telework Site.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3240
Telework: Environment and Security

(1) Telework Sites must be:

(a) Located in a designated area where:

(A) All equipment is stored;

(B) All work is performed; and

(C) Confidentiality is maintained such that patient information cannot be viewed or overheard by anyone other than the Pharmacist, Intern or Certified Oregon Pharmacy Technician.

(2) The Pharmacist-in-charge of the Drug Outlet Pharmacy and each Oregon licensed Pharmacist supervising a Telework Site is responsible for ensuring the Telework Site has a designated work area that is secure and has been approved and documented by an Oregon licensed Pharmacist prior to utilization.

(3) All computer equipment used at the Telework Site must:

(a) Establish and maintain a secure connection to the pharmacy and patient information;

(b) Utilize equipment that prevents unauthorized access to the pharmacy and patient information; and

(c) Be configured so that the pharmacy and patient information is not accessible when:

(A) There is no Oregon licensed Pharmacist actively supervising the Intern or Certified Oregon Pharmacy Technician who is assisting in the practice of pharmacy from a Telework Site;or

(B) There is no Pharmacist, Intern or Certified Oregon Pharmacy Technician present at the Telework Site; or

(C) Any component of the real-time audio and visual connection is not functioning; and

(d) Comply with all security and confidentiality requirements.

(4) A record must be maintained with the date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site.

(5) Interns and Certified Oregon Pharmacy Technicians may only work from a Telework Site when authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the Telework Site.

(6) All records must be stored in a secure manner that prevents access by unauthorized persons.

(7) Any breach in security or confidentiality must be documented and reported to the Board within ten days.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3245
Telework: Policies and Procedures

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the Drug Outlet Pharmacy and the Oregon licensed Pharmacist-in-charge is accountable for establishing, maintaining, and enforcing written policies and procedures for the licensees working from a Telework Site. The written policies and procedures must be maintained at the Drug Outlet Pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the services, responsibilities and accountabilities of the licensee engaging in telework including;

(a) Security;

(b) Operation, testing and maintenance of the audio and visual connection;

(c) Detailed description of work performed;

(d) Oregon licensed Pharmacist supervision, direction and control of Interns and Certified Oregon Pharmacy Technicians;

(e) Recordkeeping;

(f) Patient confidentiality;

(g) Continuous quality improvement;

(h) Plan for discontinuing and recovering services if audio and visual connection disruption occurs;

(i) Confirmation of dedicated, secure Telework Sites;

(j) Documenting the identity, function, location, date and time of the licensees engaging in telework;

(k) Written agreement with licensees engaging in telework outlining specific functions performed, conditions and policies governing the operation of the Telework Site; and

(l) Equipment.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3250
Telework: Records

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the recordkeeping requirements OAR 855-041-3205 through OAR 855-041-3250 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules must be retained for three years and made available to the board for inspection upon request. Records created at Telework Sites must be stored at the Drug Outlet for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) Records must be stored at the Telework site in a manner that prevents unauthorized access.

(3) Records must include, but are not limited to:

(a) Patient profiles and records;

(b) Patient contact and services provided;

(c) Date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site;

(d) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(e) List of employees working from Telework Sites that includes:

(A) Name;

(B) License number;

(C) Verification of each license;

(D) Address of Telework Site; and

(E) Name of the Oregon licensed Pharmacist who verified each licensure, approved licensee to telework and approved each Telework Site; Telework;

(f) Audio and visual connection testing and training;

(g) Data, telephone audio, audio and video, still image capture, store and forward images, security and surveillance data. This must be retained according to (1); and

(h) Any errors or irregularities identified by the quality improvement program.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~**855-041-5100**~~
~~**Definitions - Technician Checking Validation Program (TCVP)**~~

~~(1) "Error" in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item counts as one error.~~

~~(2) "Error" in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date. All errors in any single dose count as one error.~~

~~(3) "Line Item" is a checking unit for ADC restocking (example: one specific drug and dose, regardless of quantity).~~

~~(4) "Technician Checker" is an Oregon certified technician who has completed the TCVP validation process and is currently authorized to check another technician's work.~~

~~(5) "Technician Checking Validation Program (TCVP)" is a program that uses a technician checker to check functions completed by another technician.~~

~~(6) "Unit Dose" is the physical quantity of a drug product designed to be administered to a patient specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged, oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed IV products.~~

~~NOTE: Technician Checking Validation Program (TCVP) The TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and [ ] appropriateness of the medications ordered and on educating staff and patients. The development of individualized training programs is the responsibility of each pharmacy in order to tailor the program to the patient population and medication distribution system of the institution. Assessment questions must be tailored to the site and be changed periodically as appropriate. It is the responsibility of the pharmacist-in-charge to ensure that all training is completed and documented prior to a technician [ ] performing as a technician checker.~~

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

~~**855-041-5120**~~
~~**Technician Checking Validation Program (TCVP) - Hospital and Pharmacist in Charge Requirements**~~

~~(1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital pharmacy must meet the following requirements:~~

~~(a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be available in the pharmacy for board inspectors.~~

~~(b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can be implemented;~~

~~(c) The hospital pharmacy must have a drug distribution system that is structured to allow for one additional check of the distributed medications by a licensed nurse or other licensed health care professional with authority to administer medications after the delivery of checked medications; and~~

~~(d) The Pharmacist-in-Charge is responsible for the TCVP and will document any error, or irregularity in the quality assurance documentation records.~~

~~(2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of Pharmacy. To apply for approval, the hospital must submit the following to the Board:~~

~~(a) Copies of written training material that will be used to train technicians as technician checkers;~~

~~(b) Copies of quality assurance documentation records and forms that will be used to evaluate the technician checkers and the proposed TCVP;~~

~~(c) Copies of the policy and procedures for the proposed TCVP; and~~

~~(d) A description of how the proposed TVCP will improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.~~
~~(e) Other items as requested by the Board.~~

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

~~**855-041-5130**~~
~~**Technician Checking Validation Program (TCVP) - Technician Eligibility and Training**~~

~~(1) Only Oregon certified technicians who undergo specific training may work as technician checkers. The training must include the following:~~

~~(a) A minimum of one year of drug distribution experience;~~

~~(b) Didactic lecture or equivalent training with a self-learning packet;~~

~~(c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a pharmacist; and~~

~~(d) Initial Validation Process as described in OAR 855-041-5140(1).~~

~~(2) The practical training sessions must include:~~

~~(a) The trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning;~~

~~(b) The trainee performing the initial check with a pharmacist verifying all doses;~~

~~(c) The trainee completing the validation process with a pharmacist verifying all doses;~~

~~(d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors. Artificial errors introduced into the live environment, which are not corrected by the technician, must be removed.~~

~~(e) The pharmacist must document and notify a technician checker of any errors found during training.~~

~~(3) If at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.~~

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

~~**855-041-5140**~~

~~**Technician Checking Validation Program (TCVP) - Initial Validation Process and Quality Assurance Process**~~

~~(1) Initial Validation Process: The initial process to validate a trainee's ability to accurately check another technician's work must include:~~

~~(a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who makes more than three errors in 1500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.~~

~~(A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.~~

~~(B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.~~

~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.~~

~~(b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.~~

~~(A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.~~

~~(B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.~~

~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.~~

~~(2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of technician checkers must include:~~

~~(a) Quality checks conducted in the same manner as the applicable initial validation process described in section one of this rule, except that the quality check sample must consist of at least 300 doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.~~

~~(b) The quality checks must occur on random and unannounced dates and times.~~

~~(c) A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.~~

~~(d) The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.~~

~~(3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.~~

~~(4) A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.~~

~~(5) A description of the quality assurance process must be included in the hospital's and the pharmacy's quality assurance program and error reporting system.~~

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

~~**855-041-5150**~~
~~**Technician Checking Validation Program (TCVP) - Checking Procedure**~~
~~(1) A technician checker must use the following procedure when checking another technician's work:~~

~~(a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits.~~

~~(b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.~~

~~(c) If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction. A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker~~

~~(d) If a technician checker is not available, then all doses must be checked by a pharmacist.~~

~~(2) This checking process continues until all doses have been checked and determined to be correct.~~

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

855-041-5160
Technician Checking Validation Program (TCVP) - Eligible Specialized Functions

(1) The following specialized functions are eligible for participation in the TCVP:

(a) Cart fill;

(b) ADC batch replacement; and

(c) Non-Emergent kits and trays.

(2) Upon written request, the Board may permit additional specialized functions if to do so will further public health or safety. A waiver granted under this section shall be effective only when issued in writing and approved by the Board.

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

855-041-5170
Technician Checking Validation Program (TCVP) – Records

(1) Unless specified otherwise, all records and documentation required by these rules must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:

(a) Technician checker training documents;

(b) List of high risk medications;

(c) Documentation of any errors, irregularities and results of each initial validation check.

(d) Documentation of quality assurance and forms used to evaluate the technician checker including:

(A) Total number of doses or line item checks;

(B) Description of errors;

(C) Total number of errors; and

(D) Percent error rate.

~~(e) Documentation of the initial validation check.~~

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

Division 006/041– Definitions/ Operation of Pharmacies (Telework/ Remote Processing/ TCVP)

Filing Caption (15 word limit)**:** Proactive procedural rule review. Repeals outdated regulations in alignment with the board's strategic plan

Need for Rules:

1. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

2. Telework proposed rules will allow for remote work by Interns and Certified Oregon Pharmacy Technicians under the under the supervision, direction and control with verification by an Oregon-licensed pharmacist outside of a public health emergency. Proposed telework rules replace remote processing rules in OAR 855-041-3100 through OAR 855-041-3130 and provide clarify on how technicians may assist in the practice of pharmacy.

3. OAR 855-041-5100 states that a Technician Checking Validation Program is a program that uses a technician checker to check functions completed by another technician. This program does not include a step for an Oregon licensed Pharmacist to perform final verification of work completed by a Certified Oregon Pharmacy Technician. Staff proposes to repeal OAR 855-041-5100 through OAR 855-041-5170.

Fiscal Impact:

1. None anticipated.

2. To be determined.

3. Currently there are 4 institutional pharmacies utilizing TCVP. When these rules are repealed, there are potential increased personnel expenses to the registrant. OAR 855-041-5130 requires extensive training of Certified Oregon Pharmacy Technicians to participate in TCVP that will no longer be needed, but there will be an increased cost to utilize a pharmacist to perform final verification of medications.

Documents relied upon include:

21 USC 351 (XX/XX/XXXX) Adulterated drugs and devices, 21 USC 352 (XX/XX/XXXX) Misbranded drugs and devices

Rules Summary:

Procedural rule review and revisions to ensure clarity, transparency and promote patient safety. Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location.

Note: If language changes are made to OAR 855-006-0005, OAR 855-041-1001, OAR 855-041-1035, 855-041-1036 or 855-041-1145 in other rule packages, this rule will be updated to reflect the same language in the other rule packages.

1

Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).

(~~1~~2) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(~~2~~3) "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 pharmacy technicians.

(~~3~~4) "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.

(~~4~~5) "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.

(~~5~~6) "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.

(~~6~~7) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(~~7~~**8**) "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.

(~~8~~**9**) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(~~9~~**10**) "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.

(~~10~~**11**) "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.

(~~11~~**12**) "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.

(13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).

(12**14**) "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.

(~~13~~**15**) "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.

(~~14~~**16**) "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.

(~~15~~**17**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(~~16~~**18**) "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.

(19) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States <HPUS> (v.2021), or any supplement to any of these.

(~~17~~**20**) "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.

(~~18~~**21**) 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.

(~~19~~**22**) "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.

(~~20~~**23**) "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.

(~~21~~**24**) “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.

(~~22~~**25**) “Practice of pharmacy” is as defined in ORS 689.005.

(~~23~~**26**) "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.

(~~24~~**27**) “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.

(~~25~~**28**) "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.

(~~26~~**29**) “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.

(~~27~~**30**) "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.

(~~28~~**31**) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as 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 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 or pharmacy technicians;

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

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

~~(29) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, “supervision by a pharmacist” means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.~~

(~~30~~**32**) "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.

(~~31~~**33**) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.

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

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.** ~~includes, but is not limited to: Retail, Institutional, Remote Processing, Central Fill, and Drugless/Consulting Drug Outlets~~.

(2) Every non-resident pharmacy that provides drugs, devices or services to a resident in this state ~~shall~~**must** be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every non-resident pharmacy ~~shall~~**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 ~~shall~~**must** designate an Oregon licensed Pharmacist-in-Charge (PIC), who ~~shall~~**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 annual non-resident PIC self-inspection report prior to February 1 each year; and

(d) Provide the PIC self-inspection report as requested by the Board.

(5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within four months of initial licensure of the pharmacy.

(6) When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the Board within ten business days and identify a contact person. The pharmacy will have an Oregon licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the pharmacy's state of residence and is responsible for the following:

(a) Supervision of pharmacy staff and ensuring compliance with laws and rules; and

(b) Responding to Board correspondence and inquiries.

(7) A new Pharmacist-in-Charge must be appointed, and communication made to the Board within 90 days, or the non-resident pharmacy will cease drug distribution and provision of pharmacy services in Oregon.

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

~~**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~~

~~**855-041-3100**~~

~~**Remote Processing - Purpose and Scope**~~

~~The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription drug processing by a pharmacy. Any facility that processes drug orders on behalf of an Oregon pharmacy shall be licensed in Oregon as a retail or institutional drug outlet. An applicant must submit its policies and procedures to the Board of Pharmacy. An applicant must submit to the Board for approval policies and procedures and a description of how using remote processing will improve patient safety.~~

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

~~**855-041-3105**~~

~~**Remote Processing - Definitions**~~

~~The following words and terms, when used in OAR 855-041-3100 through 855-041-3130, 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 OAR chapter 855, division 006.~~

~~(1) "Remote Processing Pharmacy" means an Oregon licensed pharmacy operated under the direction of a pharmacist-in-charge that processes information related to the practice of pharmacy and engages in remote prescription processing, including central processing.~~

~~(2) "Remote Processing Functions" may include, but are not limited to, data entry, prospective drug utilization reviews, refill authorizations and interventions. This does not include the filling process.~~

~~(3) "Primary Pharmacy" means an instate Oregon licensed pharmacy that receives a patient's or a prescribing practitioner's request to fill a prescription or drug order and delivers the drug or device directly to the patient or patient's agent, and maintains ownership of the prescription or drug order.~~

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

~~855-041-3110~~
~~Remote Processing - General Requirements~~

~~An Oregon licensed pharmacy may outsource prescription drug processing to a remote processing pharmacy provided both pharmacies:~~

~~(1) Have the same owner; or~~

~~(2) Have a written shared pharmacy services contract or agreement that specifies:~~

~~(a) The services to be provided by each pharmacy;~~

~~(b) The responsibilities of each pharmacy; and~~

~~(c) The accountabilities of each pharmacy.~~

~~(3) Maintain a separate Oregon pharmacy license for each location involved in providing services;~~

~~(4) Share a common electronic file or have appropriate technology or interface to allow access to information required to process and fill a prescription drug order;~~

~~(5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3115;~~

~~(6) Ensure that each prescription has been properly processed, filled and counseling has been provided to the patient;~~

~~(7) Designate 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 pharmacy's resident state if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;~~

~~(8) Allow prospective drug utilization reviews, refill authorizations, interventions, and patient counseling for an Oregon patient must be performed only by a licensed pharmacist in Oregon or in the state in which the pharmacy is located;~~

~~(9) Ensure that each technician processing an order for an Oregon patient is a Certified Oregon Pharmacy Technician and is supervised by a licensed pharmacist or is a licensed technician in the state in which the pharmacy is located and is supervised by a licensed pharmacist in the state in which the pharmacy is located;~~

~~(10) Comply with all applicable federal and state laws and rules;~~

~~(11) Conduct an annual review of the written policies and procedures and document such review.~~

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

~~855-041-3115~~
~~Remote Processing - Policies and Procedures~~

~~(1) In addition to the requirements of OAR 855-041-1040, the primary and the remote processing pharmacy is each accountable for establishing, maintaining, and enforcing its own written policies and procedures manual. The policies and procedures manual must include, but need not be limited to the following:~~

~~(a) The responsibilities of each pharmacy;~~

~~(b) The policies and procedures that protect confidentiality and ensure the integrity of patient information;~~

~~(c) Compliance with all applicable federal and state laws and rules;~~

~~(d) Records sufficient to identify by name, initials, or unique identification code, the identity and the specific activities of each pharmacist or technician who performed any processing function, and the location where each activity was performed;~~

~~(e) A continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to pursue opportunities to improve patient care, and to resolve identified problems; and~~

~~(f) Documentation of any errors or irregularities identified by the quality improvement program.~~

~~(2) The written policies and procedures manual shall be maintained at all pharmacies involved in remote processing and must be available to the Board upon request.~~

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

~~855-041-3120~~
~~Remote Processing - Records~~

~~(1) The recordkeeping requirements OAR 855-041-3100 through 855-041-3130 are in addition to the requirements of other recordkeeping rules of the Board.~~

~~(2) The remote processing pharmacy must maintain all required records unless these records are maintained in the primary pharmacy.~~

~~(3) Both recordkeeping systems must:~~

~~(a) List the name, address, telephone number, and all license and registration numbers of each pharmacy involved in remote prescription processing;~~

~~(A) Document verification of each license and registration;~~

~~(B) Document the name of the individual responsible for verification of licensure and registration status.~~

~~(b) Identify by name, initials, or unique identification code the identity and the specific activities of each pharmacist or technician who performed any part of the prescription process;~~

~~(c) Include quality improvement program documentation;~~

~~(d) Be able to produce an audit trail showing each prescription process.~~

~~(4) Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two;~~

~~(5) The primary pharmacy shall maintain records that:~~

~~(a) Indicate the date the request for processing was transmitted to the remote processing pharmacy; and~~

~~(b) Indicate the date the prescription information was received by the primary pharmacy.~~

~~(6) The remote processing pharmacy shall maintain records that:~~

~~(a) Track the prescription drug order during each step in the order entry process;~~

~~(b) Identify the name, initials, or unique identification code and the specific activity of each pharmacist or pharmacy technician who performed any activity related to processing the prescription including receipt, transmission or delivery of information.~~

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

~~855-041-3125~~
~~Remote Processing - Prescription or Drug Order Processing~~

~~A prescription or drug order for a controlled substance may be processed by a remote processing pharmacy when permitted by law and consistent with federal rules.~~

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

~~**855-041-3130**~~
~~**Remote Processing - Prohibited Practices**~~

~~A remote processing pharmacy may not process a prescription on behalf of a primary pharmacy that is not registered with the Board, if required by the laws and rules of Oregon to be registered.~~

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

855-041-3200
Telework: Purpose and Scope

The purpose of OAR 855-041-3200 through OAR 855-041-3250 is to provide minimum requirements for pharmacy services conducted via telework.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3205
Telework: Definitions

(1) "Telework" means the practice or assistance in the practice of pharmacy physically outside of a registered drug outlet in a telework site.

(2) "Telework Site" means a location that is not a registered drug outlet where an Oregon licensed Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist in the practice of pharmacy as employees of an Oregon registered drug outlet.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3210
Telework: Registration

The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of the Drug Outlet Pharmacy are responsible for all licensees engaging in the practice of pharmacy or assisting in the practice of pharmacy from Telework Sites.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3215

Telework: General Requirements

(1) Each Oregon registered Drug Outlet Pharmacy and Pharmacist-in-charge of a Drug Outlet Pharmacy must ensure that Interns and Certified Oregon Pharmacy Technicians working from a Telework Site work under the supervision, direction and control of an Oregon licensed Pharmacist.

(2) A Pharmacist that engages in the practice of pharmacy and an Intern or Certified Oregon Pharmacy Technician that assists in the practice of pharmacy from a Telework Site for any person or facility located in Oregon must:

(a) Be licensed by the board; and

(b) Comply with all applicable federal and state laws and rules.

(3) Drugs and devices may not be at a Telework Site.

(4) The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of a Drug Outlet Pharmacy must:

(a) Have a written agreement that includes all conditions, duties and policies governing the licensee engaged in telework activities;

(b) Maintain a continuously updated list of all licensees engaged in telework and the Telework Sites to include:

(A) Address, phone number and hours that telework is performed for each Telework Site;

(B) Functions being performed by licensees engaged in telework; and

(C) The Oregon licensed Pharmacist providing supervision, direction and control for each non-pharmacist licensee;

(c) Develop, implement and enforce a continuous quality improvement program for services provided from a Telework Site 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;

(d) Develop, implement and enforce a procedure for identifying the Oregon licensed Pharmacist, Intern and Certified Oregon Pharmacy Technician responsible for each telework function;

(e) Develop, implement and enforce a process for a virtual inspection of the Telework Site by an Oregon licensed Pharmacist at least once every 6 months or more frequently as deemed necessary by the Oregon licensed Pharmacist. The inspection must be documented and records retained; and

(f) Utilize an Oregon licensed Pharmacist and real-time audio and visual communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 or when requested and document the interaction.

POLICY DISCUSSION: A/V Requirement

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3220
Telework: Supervision Requirements

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the supervising Oregon licensed Pharmacist from the Drug Outlet must:

(1) Utilize a continuous real-time audio and visual connection that is recorded, reviewed and stored and have appropriate technology or interface to allow access to information required to complete assigned duties;

(2) Ensure all telephone audio is recorded, reviewed and stored;

(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon Pharmacy Technician and that the continuous audio/visual connection is fully operational;

(4) Ensure that an Oregon licensed Pharmacist performs random "check-ins" via the real-time audio and visual connection at least once every 2 hours to ensure compliance with federal and state laws and patient safety and document the interaction;

(5) Be readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and

(6) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction and control at all times.

(7) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy Technician at a Telework Site must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;

(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;

(c) Document the following within 24 hours of the review in (b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions pharmacist is reviewing;

(C) Date and time of licensee patient interaction pharmacist is reviewing;

(D) Date and time of pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of discovery and to the board within 10 days.

(8) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (7)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.

POLICY DISCUSSION: Frequency of review

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3225
Telework: Confidentiality

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet Pharmacy, and the Pharmacist, Intern and Certified Oregon Pharmacy Technician from the Drug Outlet Pharmacy must:

(1) Ensure patient and prescription information is managed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, and OAR 855-041.

(2) Ensure the security and confidentiality of patient information and pharmacy records.

(3) Document and report any breach in the security of the system or breach of confidentiality. Report of the breach must be reported in writing to the board within ten days of the event.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3230
Telework: Technology

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the Pharmacist from the Drug Outlet must:

(1) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each:

(a) Source container including manufacturer, name, strength, lot, and expiration;

(b) Dispensed product including the imprint and physical characteristics;

(c) Completed prescription container including the label; and

(d) Ancillary document provided to patient at the time of dispensing.

POLICY DISCUSSION: Remote Verification

(2) Test the continuous audio and visual connection and document that it operates properly before engaging in telework.

(3) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising, directing and controlling the Intern and Certified Oregon Pharmacy Technician at the Telework Site.

(4) Ensure access to:

(a) Appropriate and current pharmaceutical references based on the services offered; and

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters.

(5) Train the Oregon licensed Pharmacists, Interns and Certified Oregon Pharmacy Technicians in the operation of continuous audio and visual connection.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3235
Telework: Personnel

(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all operations at Drug Outlet Pharmacy including responsibility for the continuous audio and visual connection and enforcing policies and procedures.

(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel at Telework Sites.

(3) An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have at least one year experience performing similar services for an Oregon registered Drug Outlet Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy Technician begins working at the Remote Dispensing Site Pharmacy.

POLICY DISCUSSION: Experience

(4) The Oregon licensed Pharmacist from the Drug Outlet Pharmacy who is supervising a licensee at a Telework Site must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided.

(5) When supervising an Intern or Certified Oregon Pharmacy Technician working at a Telework Site, the Oregon licensed Pharmacist may supervise no more than four licensees among all locations, including the Drug Outlet Pharmacy.

(6) The Drug Outlet Pharmacy is required to comply with the pharmacist's determination in (4) and retain records.

(7) Prior to working at a Telework Site, the Intern or Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on the use of all equipment necessary for secure operation of the Telework Site.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3240
Telework: Environment and Security

(1) Telework Sites must be:

(a) Located in a designated area where:

(A) All equipment is stored;

(B) All work is performed; and

(C) Confidentiality is maintained such that patient information cannot be viewed or overheard by anyone other than the Pharmacist, Intern or Certified Oregon Pharmacy Technician.

(2) The Pharmacist-in-charge of the Drug Outlet Pharmacy and each Oregon licensed Pharmacist supervising a Telework Site is responsible for ensuring the Telework Site has a designated work area that is secure and has been approved and documented by an Oregon licensed Pharmacist prior to utilization.

(3) All computer equipment used at the Telework Site must:

(a) Establish and maintain a secure connection to the pharmacy and patient information;

(b) Utilize equipment that prevents unauthorized access to the pharmacy and patient information; and

(c) Be configured so that the pharmacy and patient information is not accessible when:

(A) There is no Oregon licensed Pharmacist actively supervising the Intern or Certified Oregon Pharmacy Technician who is assisting in the practice of pharmacy from a Telework Site; or

(B) There is no Pharmacist, Intern or Certified Oregon Pharmacy Technician present at the Telework Site; or

(C) Any component of the real-time audio and visual connection is not functioning; and

(d) Comply with all security and confidentiality requirements.

(4) A record must be maintained with the date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site.

(5) Interns and Certified Oregon Pharmacy Technicians may only work from a Telework Site when authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the Telework Site.

(6) All records must be stored in a secure manner that prevents access by unauthorized persons.

(7) Any breach in security or confidentiality must be documented and reported to the Board within ten days.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3245
Telework: Policies and Procedures

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the Drug Outlet Pharmacy and the Oregon licensed Pharmacist-in-charge is accountable for establishing, maintaining, and enforcing written policies and procedures for the licensees working from a Telework Site. The written policies and procedures must be maintained at the Drug Outlet Pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the services, responsibilities and accountabilities of the licensee engaging in telework including;

(a) Security;

(b) Operation, testing and maintenance of the audio and visual connection;

(c) Detailed description of work performed;

(d) Oregon licensed Pharmacist supervision, direction and control of Interns and Certified Oregon Pharmacy Technicians;

(e) Recordkeeping;

(f) Patient confidentiality;

(g) Continuous quality improvement;

(h) Plan for discontinuing and recovering services if audio and visual connection disruption occurs;

(i) Confirmation of dedicated, secure Telework Sites;

(j) Documenting the identity, function, location, date and time of the licensees engaging in telework;

(k) Written agreement with licensees engaging in telework outlining specific functions performed, conditions and policies governing the operation of the Telework Site; and

(l) Equipment.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3250
Telework: Records

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the recordkeeping requirements OAR 855-041-3205 through OAR 855-041-3250 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules must be retained for three years and made available to the board for inspection upon request. Records created at Telework Sites must be stored at the Drug Outlet for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) Records must be stored at the Telework site in a manner that prevents unauthorized access.

(3) Records must include, but are not limited to:

(a) Patient profiles and records;

(b) Patient contact and services provided;

(c) Date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site;

(d) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(e) List of employees working from Telework Sites that includes:

(A) Name;

(B) License number;

(C) Verification of each license;

(D) Address of Telework Site; and

(E) Name of the Oregon licensed Pharmacist who verified each licensure, approved licensee to telework and approved each Telework Site; Telework;

(f) Audio and visual connection testing and training;

(g) Data, telephone audio, audio and video, still image capture, store and forward images, security and surveillance data. This must be retained according to (1); and

(h) Any errors or irregularities identified by the quality improvement program.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~**855-041-5100**~~
~~**Definitions - Technician Checking Validation Program (TCVP)**~~

~~(1) "Error" in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item counts as one error.~~

~~(2) "Error" in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date. All errors in any single dose count as one error.~~

~~(3) "Line Item" is a checking unit for ADC restocking (example: one specific drug and dose, regardless of quantity).~~

~~(4) "Technician Checker" is an Oregon certified technician who has completed the TCVP validation process and is currently authorized to check another technician's work.~~

~~(5) "Technician Checking Validation Program (TCVP)" is a program that uses a technician checker to check functions completed by another technician.~~

~~(6) "Unit Dose" is the physical quantity of a drug product designed to be administered to a patient specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged, oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed IV products.~~

~~NOTE: Technician Checking Validation Program (TCVP) The TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and [ ]SEP appropriateness of the medications ordered and on educating staff and patients. The development of individualized training programs is the responsibility of each pharmacy in order to tailor the program to the patient population and medication distribution system of the institution. Assessment questions must be tailored to the site and be changed periodically as appropriate. It is the responsibility of the pharmacist-in-charge to ensure that all training is completed and documented prior to a technician [ ]SEP performing as a technician checker.~~

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

~~**855-041-5120**~~
~~**Technician Checking Validation Program (TCVP) - Hospital and Pharmacist in Charge Requirements**~~

~~(1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital pharmacy must meet the following requirements:~~

~~(a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be available in the pharmacy for board inspectors.~~

~~(b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can be implemented;~~

~~(c) The hospital pharmacy must have a drug distribution system that is structured to allow for one additional check of the distributed medications by a licensed nurse or other licensed health care professional with authority to administer medications after the delivery of checked medications; and~~

~~(d) The Pharmacist-in-Charge is responsible for the TCVP and will document any error, or irregularity in the quality assurance documentation records.~~

~~(2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of Pharmacy. To apply for approval, the hospital must submit the following to the Board:~~

~~(a) Copies of written training material that will be used to train technicians as technician checkers;~~

~~(b) Copies of quality assurance documentation records and forms that will be used to evaluate the technician checkers and the proposed TCVP;~~

~~(c) Copies of the policy and procedures for the proposed TCVP; and~~

~~(d) A description of how the proposed TVCP will improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.~~
~~(e) Other items as requested by the Board.~~

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

~~855-041-5130~~
~~Technician Checking Validation Program (TCVP) - Technician Eligibility and Training~~

~~(1) Only Oregon certified technicians who undergo specific training may work as technician checkers. The training must include the following:~~

~~(a) A minimum of one year of drug distribution experience;~~

~~(b) Didactic lecture or equivalent training with a self-learning packet;~~

~~(c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a pharmacist; and~~

~~(d) Initial Validation Process as described in OAR 855-041-5140(1).~~

~~(2) The practical training sessions must include:~~

~~(a) The trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning;~~

~~(b) The trainee performing the initial check with a pharmacist verifying all doses;~~

~~(c) The trainee completing the validation process with a pharmacist verifying all doses;~~

~~(d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors. Artificial errors introduced into the live environment, which are not corrected by the technician, must be removed.~~

~~(e) The pharmacist must document and notify a technician checker of any errors found during training.~~

~~(3) If at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.~~

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

~~855-041-5140~~

~~Technician Checking Validation Program (TCVP) - Initial Validation Process and Quality Assurance Process~~

~~(1) Initial Validation Process: The initial process to validate a trainee's ability to accurately check another technician's work must include:~~

~~(a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who makes more than three errors in 1500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.~~

~~(A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.~~

~~(B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.~~

~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.~~

~~(b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.~~

~~(A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.~~

~~(B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.~~

~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.~~

~~(2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of technician checkers must include:~~

~~(a) Quality checks conducted in the same manner as the applicable initial validation process described in section one of this rule, except that the quality check sample must consist of at least 300 doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.~~

~~(b) The quality checks must occur on random and unannounced dates and times.~~

~~(c) A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.~~

~~(d) The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.~~

~~(3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.~~

~~(4) A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.~~

~~(5) A description of the quality assurance process must be included in the hospital's and the pharmacy's quality assurance program and error reporting system.~~

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

~~**855-041-5150**~~
~~**Technician Checking Validation Program (TCVP) - Checking Procedure**~~
~~(1) A technician checker must use the following procedure when checking another technician's work:~~

~~(a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits.~~

~~(b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.~~

~~(c) If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction. A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker~~

~~(d) If a technician checker is not available, then all doses must be checked by a pharmacist.~~

~~(2) This checking process continues until all doses have been checked and determined to be correct.~~

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

855-041-5160
Technician Checking Validation Program (TCVP) - Eligible Specialized Functions

(1) The following specialized functions are eligible for participation in the TCVP:

(a) Cart fill;

(b) ADC batch replacement; and

(c) Non-Emergent kits and trays.

(2) Upon written request, the Board may permit additional specialized functions if to do so will further public health or safety. A waiver granted under this section shall be effective only when issued in writing and approved by the Board.

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

855-041-5170
Technician Checking Validation Program (TCVP) – Records

(1) Unless specified otherwise, all records and documentation required by these rules must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:

(a) Technician checker training documents;

(b) List of high risk medications;

(c) Documentation of any errors, irregularities and results of each initial validation check.

(d) Documentation of quality assurance and forms used to evaluate the technician checker including:

(A) Total number of doses or line item checks;

(B) Description of errors;

(C) Total number of errors; and

(D) Percent error rate.

~~(e) Documentation of the initial validation check.~~

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

SBAR: Pharmacy Technician Licensure

S	Current pharmacy technician (PT) and certified Oregon pharmacy technician (COPT) rules present unintended barriers to licensure and imply certification of pharmacy technicians who do not hold pharmacy technician certification.
B	OAR 855-025-0012 requires an applicant to take and pass a national pharmacy technician certification exam and then apply for licensure as a COPT. Pharmacy Technician Certification Board (PTCB) requirements: • complete a PTCB-recognized education/training program, or; • complete at least 500 work hours and attest to fulfilling specified knowledge requirements National Healthcare Association (NHA) requires: • completion of a training program (employer-based or offered by national pharmacy association) that is recognized by the Board of Pharmacy, or; • completion of at least 1200 hours of supervised pharmacy related work experience in the health field within any 1 year in the last 3 years. With the new PTCB and existing NHA requirements: • A PT who has not recently completed the required training requirements is not eligible to take the exam • An individual who had a technician license that has been lapsed in the last 5 years: o Is not eligible for a COPT license o Is not eligible to complete a training program as a PT or work in a pharmacy to obtain the required hours Because OAR 855-025-0012 requires a national certification (active or inactive) to remain eligible for licensure, our current rules present is a barrier to licensure and employment as a Certified Oregon Pharmacy Technician in Oregon to those who have never held a national certification. OAR 855-025-0060(2) Reinstatement of a COPT License – states: A Certified Oregon Pharmacy Technician whose license **has been lapsed greater than five years must**: (a) Re-take and pass a national pharmacy technician certification examination offered by: (A) The Pharmacy Technician Certification Board (PTCB); or (B) National Healthcareer Association (NHA). o After 5 years, a COPT with a lapsed license is required to have an active national certification, but this is not required for initial licensure. **This represents a higher bar for reinstatement than for initial licensure.** (See above - OAR 855-025-0012) OAR 855-025-0005 (1) -To qualify for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician, an applicant must demonstrate that the applicant is at least 18 years of age and has obtained a high school diploma or GED. This means: • An individual who was home schooled, did not graduate from high school, or have a GED, but obtained a 2 or 4-year college or university degree is not eligible for licensure o There have been several occasions where an applicant that holds a 2 or 4-year degree has had to enroll and obtain a GED to apply for a license o There is no waiver to the rules

855-025-0001 states that 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 (COPT). These rules facilitate the initial licensure of a nationally certified Pharmacy Technician seeking licensure in Oregon.

Extensions have not been granted for the processing time of an application. Once the qualifications for a COPT license are met and an application has been received, extensions are not considered.

- Messaging is sent out with the initial license and again in February of the license expiration year with a reminder to take the exam and apply for licensure in advance of the license expiration dates.
  - Many individuals do not apply for licensure until expiration month of their PT license. In 2021, there were 27 applications that were submitted on 6/13 or later that were not able to be issued prior to the expiration of the PT license.
  - This was due to a delay in processing because of a backlog of fingerprinting processing by the Oregon State Police. Many individuals were not able to work effective 7/1 due to the expiration of their PT license.
  - This affected both the applicants and the employers. It was reported by a chain pharmacy representative that this created "undue stress on some of the pharmacies, who have already experienced staffing shortages and burnout from the COVID-19 pandemic."

Related ORS:

689.499 Pharmacy technician specialized education program; rules. (1)(a) The State Board of Pharmacy may by rule identify activities performed by a pharmacy technician for which a specialized education program may be required.

(b) If the board identifies an activity requiring specialized education under this subsection, the board shall approve no fewer than two specialized education programs to provide the specialized education.

(c) Upon receipt of evidence satisfactory to the board that a pharmacy technician has satisfactorily completed a specialized education program approved by the board, the board shall note the specialized education on the license of the pharmacy technician.

(2) The board may establish standards for renewal or revocation of a notation of specialized education under this section.

(3) As used in this section, "specialized education program" means:

(a) **A program providing education for persons desiring licensure as 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 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 or pharmacy technicians;

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

(C) A trade association recognized by the board as representing pharmacies. [2005 c.313 §16]

- The Board has no authority to renew or revoke a national certification
  - National certification is not required to be maintained to hold a COPT license
  - When certification lapses, a COPT is no longer "certified" (the board does not issue "certification")

	• National certification is not a "specialized education program" • Duties are not different for a PT vs COPT
A	• Pharmacy Technician rules require revision to remove barriers to licensure and clarify language. Current rules have affected pharmacy staffing in communities in Oregon.
R	• *Policy Discussion at October board meeting:* • *Direct staff to draft rules that resolve barriers to PT licensure* • *Provide broad policy direction (single license, education, certification, initial limitations on tasks for new technicians, specific duties vs. pharmacist discretion)* • *Continue discussion at Strategic Planning meeting*

OREGON BOARD OF PHARMACY
DELEGATION OF AUTHORITY

The following tasks and functions are delegated to the staff of the Oregon Board of Pharmacy, under the Executive Director's supervision, in accordance with ORS 689.195:

General:

1. Executive Director is responsible for all administrative matters related to the operation of the board, the agency, and board staff.

2. Executive Director is responsible for all financial matters related to the operation of the board office except for approving the board's biennial operating budget.

3. Authorize Executive Director to exercise managerial oversight of board employees, accounting, and payroll.

4. Authorize staff per Policy (AD-010) to make reasonable efforts to collect all monies owed using appropriate practices in the management and collection of accounts receivable, to include debt collection procedures for all liquidated and delinquent accounts as outlined in ORS 293 and the Oregon Accounting Manual, Chapter 35.

5. Authorize staff per Policy (AD-009) to respond to public records request. (ORS 192)

6. Authorize staff to complete surveys. [e.g. National Association of Boards of Pharmacy (NABP) Survey of Law]

7. Authorize staff to write and submit Newsletters articles to NABP.

8. Authorize Executive Director and authorized staff to accept lawfully issued subpoenas related to pseudoephedrine (PSE) logs.

9. Authorize Pharmacist Consultant, Executive Director, or a staff member directed by the Executive Director, to review and approve board approved Continuing Pharmacy Education (CPE).

Licensing:

1. To review, process, and determine if an application is complete.

2. Review, process, and verify credentials related to license or registration type

through primary source verification for all applications. Refer to the Compliance Department, as necessary.

3. Facilitate national fingerprint background checks and review results. (OAR 855-010-0100(3))

4. Review and process applications. Refer applications to the Compliance Department if a record or discipline is self-reported on the application, identified on the national fingerprint background check results, or identified on an inspection report.

5. Expire incomplete applications 6 months from the date received.

6. Approve extensions of MPJE / NAPLEX score expiration dates (OAR 855-019-0120(1)(b) & (c))

7. Approve technician license expiration date extension requests if the following conditions are met:
   - Clear Law Enforcement Data System (LEDS) background check;
   - No active disciplinary action; and
   - The extension does not exceed two years from the issue date of the license. (OAR 855-025-0010(1)(3))

8. To issue a license or registration to applicants who satisfy all requirements.

9. Conduct LEDS background check on all renewing licensees. (OAR 855-019-0122(2), OAR 855-025-0015(2)(c), OAR 855-031-0016(2))

10. Approve voluntary registration and license lapse requests not connected to any pending investigation or disciplinary action.

11. Conduct CPE audits. (OAR 855-021-0050)

12. Review and approve CPE certificates and documentation submitted by licensees or obtained through the review of the NABP CPE Monitor. Refer to Compliance if requirements set in rule are not demonstrated. (OAR 855-021-0010)

Compliance

1. Authorize Compliance staff to review, assess, and act on applicant's or licensee's reported state, US Territory or federal disciplinary action.

- Staff will present, in Case Review, discipline related to probations, surrenders, suspensions, denials, and revocations; and
- Staff to approve license or registration, or take no action for licensees, for any other self-reported discipline (e.g. civil penalties, reprimand, letter of admonishment).

2. Authorize Compliance staff to approve the issuance of a license for an applicant or licensee that discloses the following arrests, convictions, or history, that are **not** a felony:
    - Harassment, Assault 4th degree, Vandalism, Criminal mischief, Hit and run, Disorderly conduct, Corporal injury, Battery, Domestic violence, Misuse ID, Marijuana possession, Violation of restraining order, Failure to appear, MIPs, or similar charges where staff is unable to establish a nexus to the practice.
    - A history of one DUI > 5 years.
    - A history of one Theft II or lower > 5 years

3. Authorize Compliance staff to review and close case for licensees that discloses the following arrests, convictions or history, that are **not** a felony:
    - Harassment, Assault 4th degree, Vandalism, Criminal mischief, Hit and run, Disorderly conduct, Corporal injury, Battery, Domestic violence, Misuse ID, Marijuana possession, Violation of restraining order, Failure to appear, MIPs, or similar charges where staff is unable to establish a nexus to the practice.
    - A history of one DUI > 5 years.
    - A history of one Theft II or lower > 5 years

4. Authorize Compliance staff to review complaints and ensure that all complaints of alleged violations, are fully investigated and that necessary action is taken for board review. (ORS 689.155(6))

5. Authorize Executive Director and Compliance Director to issue subpoenas. (ORS 689.135(12))

6. Authorize Compliance staff to initiate a case and follow Board approved policy for licensees that are non-compliant with order sanctions.

7. For Pharmacist CPE Audit failure cases, authorize Compliance staff to close case with Board direction and issue case closure letter of education if the following parameters are met:
    - Licensee takes and passes OR MPJE; and
    - Licensee completes CPE deficient from audit.

- Board to approve at next applicable Board meeting in the Consent Agenda.

8. Authorize Compliance staff to draft and issue Notices and Orders.

9. Authorize Compliance staff to refer hearing requests to the Department of Justice General Counsel Division to initiate hearing process with the Office of Administrative Hearings.

10. Authorize Compliance Director and Executive Director to execute modified and negotiated consent orders as directed by the board, including the following:
    - Default Orders;
    - Stipulated Orders of license surrender; and
    - Orders within Board pre-specified parameters.

11. Authorize Compliance Staff to review and accept CPE to satisfy disciplinary orders and license renewal requirements. (OAR 855-021-0010)

12. Authorize Compliance staff to report discipline to the National Practitioner Databank (NPDB).

13. Authorize Compliance staff to post final orders on BOP website via license verification.

14. Authorize Compliance staff to respond to record requests for information from another government agency. (ORS 676.177 and ORS 676.175)

15. Authorize staff to provide outlet notification of registration requirements for unregistered Non-Prescription Drug Outlet (A, B, C, D, E). (OAR 855-035)

16. Authorize staff to provide notification to unauthorized outlets for advertising or using the title pharmacy, apothecary, drug store, or similar terms in their business name. (ORS 689.225(2)

17. All applicants, licensees, registrants, and unregistered or unlicensed activity that is not approved in this document, will be provided to the board for review.

PharmCon

Contraceptive Care Specialty Pharmacist CE Certificate Program

Oregon Board of Pharmacy Content Reviewer Results

10-14-2021

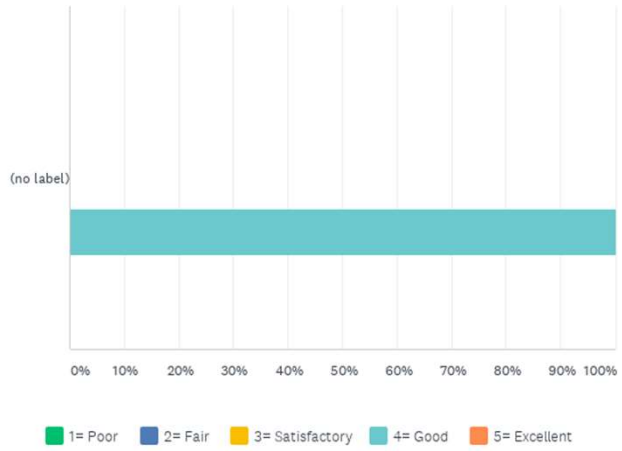
1

Content Reviewers

- Lincoln Alexander, Pharm.D., RPH
- Dr. Alison Edelman, M.D., M.P.H.
- Kayla Hensley, Pharm.D., RPH
- Fiona Karbowicz, B.Pharm., RPH

2

Q1: This program provides a thorough review of women's reproductive health.



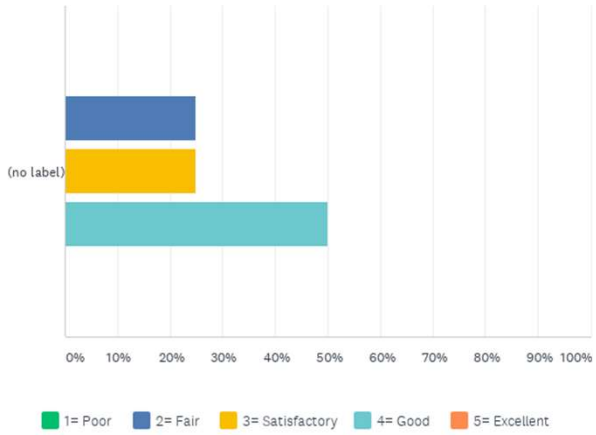
3

Q1: This program provides a thorough review of women's reproductive health.

- I will defer the clinical assessment of this program to the experts in medicine; from what I reviewed, this course is adequate.
- This program covers women's reproductive health well through Module 1.

4

Q2: This program provides a robust therapeutics and pharmacologic review.



5

Q2: This program provides a robust therapeutics and pharmacologic review.

- I will defer the clinical assessment of this program to the experts in medicine/pharmacy; from what I reviewed, this course is adequate.
- Again this part is comprehensive.
- I liked the drug review, it was a good refresher. I thought the prior OSU program did a bit better of a job with pharmacology review.
- Not clear throughout what methods are combined hormonal methods (pills, patch, ring).
- Concept of progestin 'generations' is outdated and not part of evidence-based prescribing
- Does not include estetrol in list of synthetic estrogens (granted this pill is new this year).
- Through out COCs are listed as EC - this is a historical method and no longer recommended Contraindications to many methods and obesity are listed; this also is not consistent with current guidance.

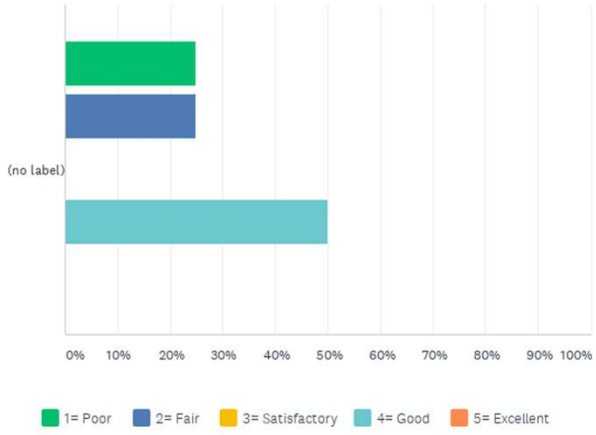
6

Q2: This program provides a robust therapeutics and pharmacologic review.

- Precautions exist but it is not contraindicated due to efficacy.
- Not clear throughout that the drosperinone only pill - is cyclic and not continuous
- Module 6 doesn't include use of referral for clients that want LARC and 'bridging' methods are not discussed if a patient does need to be referred
- Those with risk factors for DVT still have the use of a CHC listed which is also not consistent with recommendations.
- Not clear what 'tests/exams' are recommended/needed - many are listed but these again are not consistent with CDC recommendations.

7

Q3: This program comprehensively teaches the "art" of patient assessment, evaluation and contraceptive product selection.



8

Q3: This program comprehensively teaches the "art" of patient assessment, evaluation and contraceptive product selection.

- I found the example patient case not pertinent to pharmacist prescribing. I don't understand why the ONE example was a patient that was referred to a physician for a copper IUD.
- They also did not cover using the US MEC/OR MEC at all. I think pharmacists in Oregon should see the US MEC/OR MEC and understand how to use that document to select appropriate contraception for a patient.
- Additionally, in my professional opinion this training was misleading to the current guidance around the use of combined hormonal contraception options during breastfeeding and would lead a pharmacist to prescribe CHC for a patient breastfeeding without adequately addressing the risks/benefits.
- Also, the description of start methods for CHCs and the use of backup methods for 7 days is incorrect in Module 3.
- Also, they incorrectly use the term "effectiveness rates" as and example the speaker states that the "effectiveness rate" for IUDs is <1%.
- Lastly, they describe for IUDs that the strings should be "visible." Strings are not "visible" to the patient or anyone that is not looking intravaginally with a speculum.

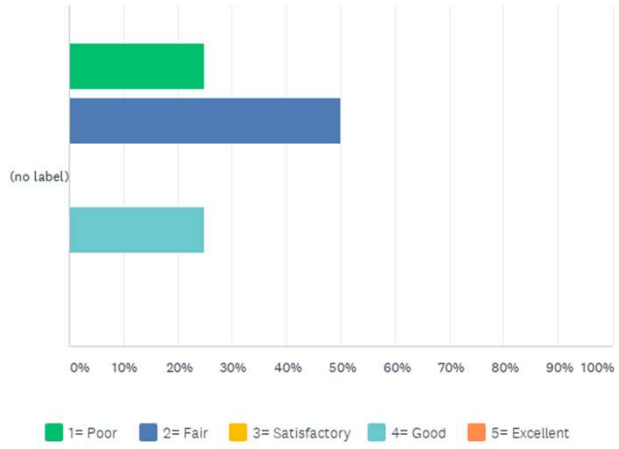
9

Q3: This program comprehensively teaches the "art" of patient assessment, evaluation and contraceptive product selection.

- The program gave a good overview of the assessment, evaluation and product selection process. The examples of patient/pharmacist interaction demonstrate some degree of interactivity.
- Modules on contraindications and evaluation contained the appropriate content but were chaotically organized. I would find it hard if I knew nothing about how to evaluate a patient to figure out how to take the knowledge and apply it to an encounter.
- I really like Oregon's training program with the checklist which is based on the CDC MEC and SPR. This training program did not reference either of those two main evidence based guidelines.
- Also there is no information on shared decision making and working with the patient around their choice. Its about what does the provider 'recommend'. I think this is extremely important in this era of social/reproductive justice and concerns regarding coercion.

10

Q4: This program prepares the pharmacist to comply with all related Oregon laws and rules.



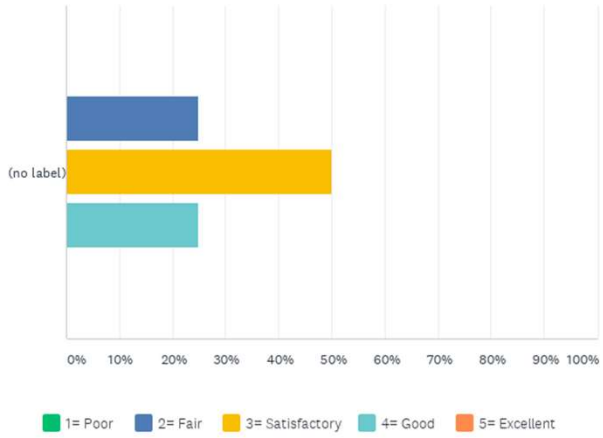
11

Q4: This program prepares the pharmacist to comply with all related Oregon laws and rules.

- In the content I reviewed, I recall a mention of "Oregon's questions" used to effectively rule out pregnancy. The reference for the questions should be the CDC. Unfortunately, this program completely misses the mark of walking a pharmacist through the use of the MEC/Questionnaire/Algorithms developed for this prescribing authority. I recommend the program create a separate module for state-specific elements; without this component, I am unsure how the board can approve this course.
- I would reiterated my concerns that this program does not cover the use of the US/OR MEC.
- Yes, but to be most compliant need to review Oregon-specific protocol on website

12

Q5: This program is interactive and incorporates effective fundamentals of adult learning.



13

Q5: This program is interactive and incorporates effective fundamentals of adult learning.

- This course is easy to follow, content is friendly and somewhat interactive.
- I think that this course should be more interactive. The quizzes are sufficient but would like to see more interaction in the presentations.
- I think this program is missing some key components in order for someone to operationalize and safely prescribe

14

Q6: Do you have any other comments, questions or concerns?

- Recommend a thorough clinical analysis of the program's "knowledge test" at the end of the course. It must be designed to provide reasonable certainty that unless a student really concentrates throughout the entire course, he/she will not be able to pass the test. A pharmacist is a postgraduate doctoral student and must be capable of passing a test designed to truly make him/her an eligible candidate for this prescribing privilege. Be sure the test isn't "too easy". Thank you for the opportunity to provide input.
- Really difficult to listen to her mispronounce "Oregon" throughout Module 5 and 6.
- Module 6 is too long and not particularly relevant to a pharmacist being able to safely prescribe hormonal contraceptives in Oregon.
- Lastly, they incorrectly say that pharmacists are not able to bill Medicaid for contraceptive services.

15

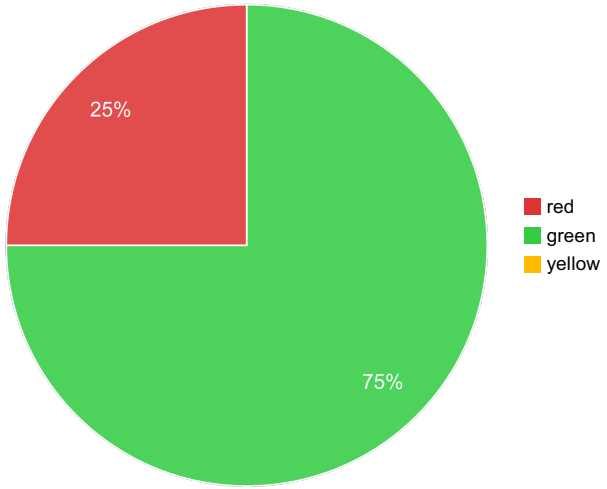
Pharmacy, Board of

Annual Performance Progress Report

Reporting Year 2021

Published: 10/1/2021 12:46:26 PM

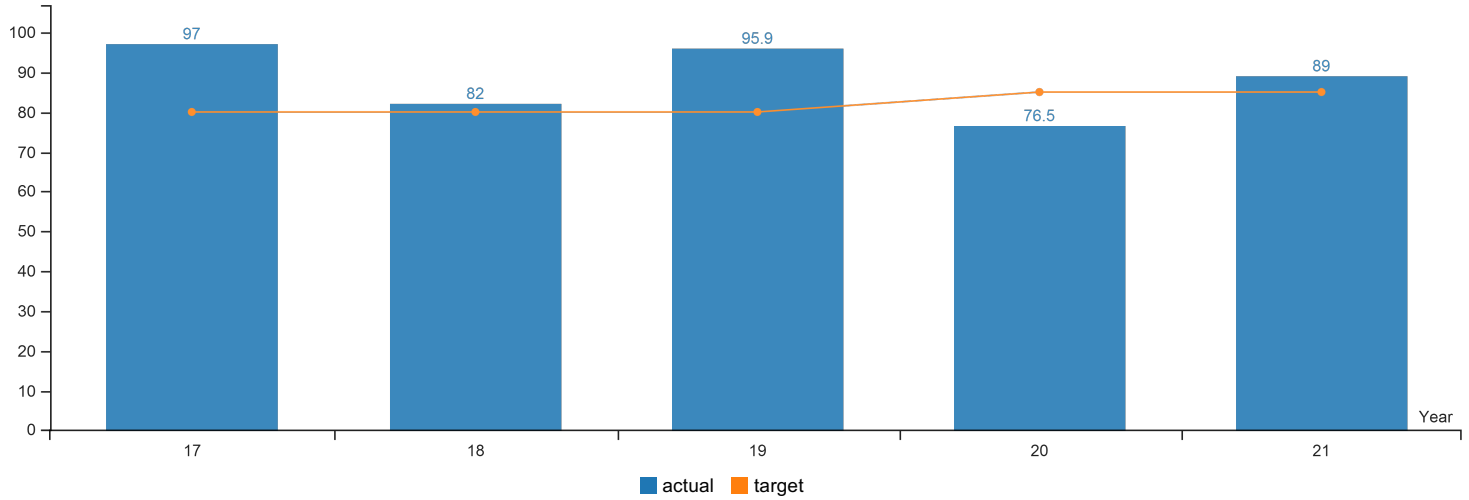
KPM #	Approved Key Performance Measures (KPMs)
1	Percent of inspected pharmacies that are in compliance annually. -
2	Percentage of individual and facility licenses that are issued within 30 days. -
3	Percent of pharmacies inspected every two years. -
4	Average number of days to complete an investigation from complaint to board presentation. -
5	CUSTOMER SERVICE - Percent of Customers Rating Their Satisfaction With the Agency's Customer Service as "Good" or "Excellent" : Overall Customer Service, Timeliness, Accuracy, Helpfulness, Expertise, and Availability of Information.
6	Board Best Practices - Percent of total best practices met by the Board.



Performance Summary	Green	Yellow	Red
	= Target to -5%	= Target -5% to -15%	= Target > -15%
Summary Stats:	75%	0%	25%

KPM #1	Percent of inspected pharmacies that are in compliance annually. -
	Data Collection Period: Feb 01 - Jan 31

** Upward Trend = positive result*



Report Year	2017	2018	2019	2020	2021
Percentage of Pharmacies that are in compliance annually.					
Actual	97%	82%	95.90%	76.50%	89%
Target	80%	80%	80%	85%	85%

How Are We Doing

From February 1, 2020 - January 31, 2021, Board Inspectors completed 74 Retail and Institutional pharmacy inspections of which 89% were in compliance. Of the 74 completed inspections, 9 passed inspection, 57 passed with notes for improvement, 4 received deficiency notifications and 4 notifications of non compliance were issued; note all notifications are reviewed by the Board to determine if disciplinary action is warranted.

23 additional non-pharmacy inspections were also completed, including 8 manufacturers that produced hand sanitizer to support the COVID-19 public health emergency.

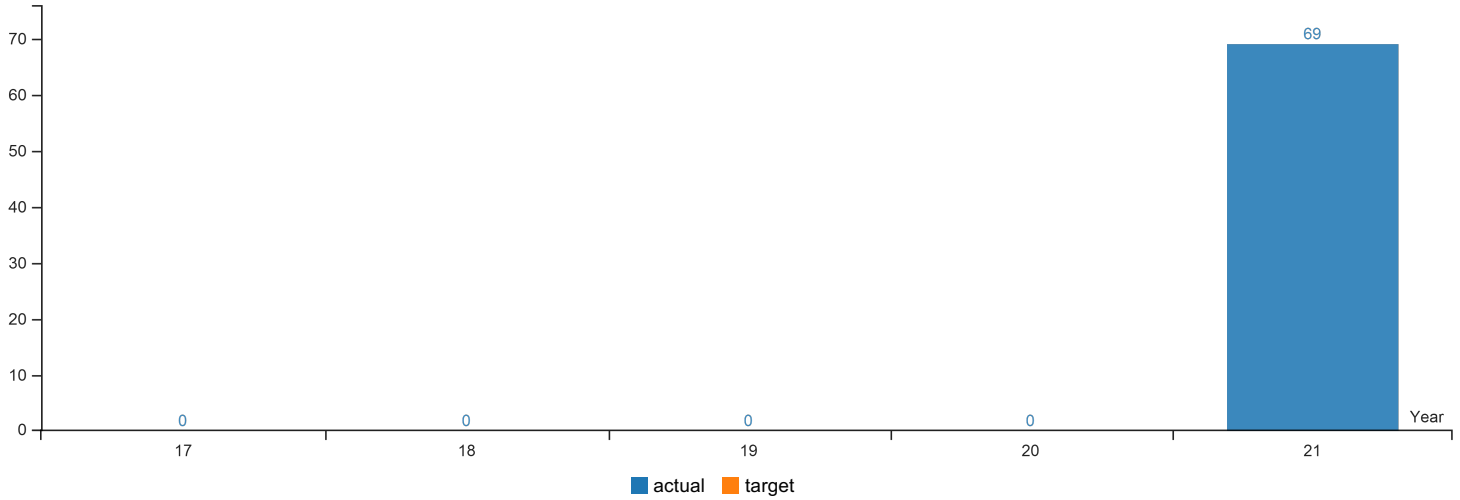
Factors Affecting Results

COVID-19 has impacted the agency's ability to conduct on-site inspections due to mandatory travel restrictions in the interest of public safety and health. Virtual inspections were implemented late spring 2021. Compliance staff' focus was on responding to COVID-19 questions and the many rule or guidance changes that impacted licensees/registrants throughout the year and continues in 2021.

KPM #3 relates to this measure and was changed to reflect the percent of pharmacies inspected every two years rather than annually effective 7/1/2021. KPM #1 and #3 relate to one another, as one is dependent on the number of inspections and the other relates to compliance upon inspection.

KPM #2	Percentage of individual and facility licenses that are issued within 30 days. -
	Data Collection Period: Jan 01 - Dec 31

** Upward Trend = positive result*



Report Year	2017	2018	2019	2020	2021
Percentage of individual and facility licenses that are issued within 30 days.					
Actual					69%
Target					

How Are We Doing

This measure is new this biennium effective 7/1/2021. It will capture the changes in volume and workflow timeframes throughout the whole licensing process, from receipt of application through investigation, including Board member deliberation and approval, when required.

In calendar year 2020, the percentage of licenses that were issued within 30 days was 69%. There were a total of 2619 licenses issued in 2020. The average number of days to issue a license was 48 days for facilities and 38 days for individuals.

Factors Affecting Results

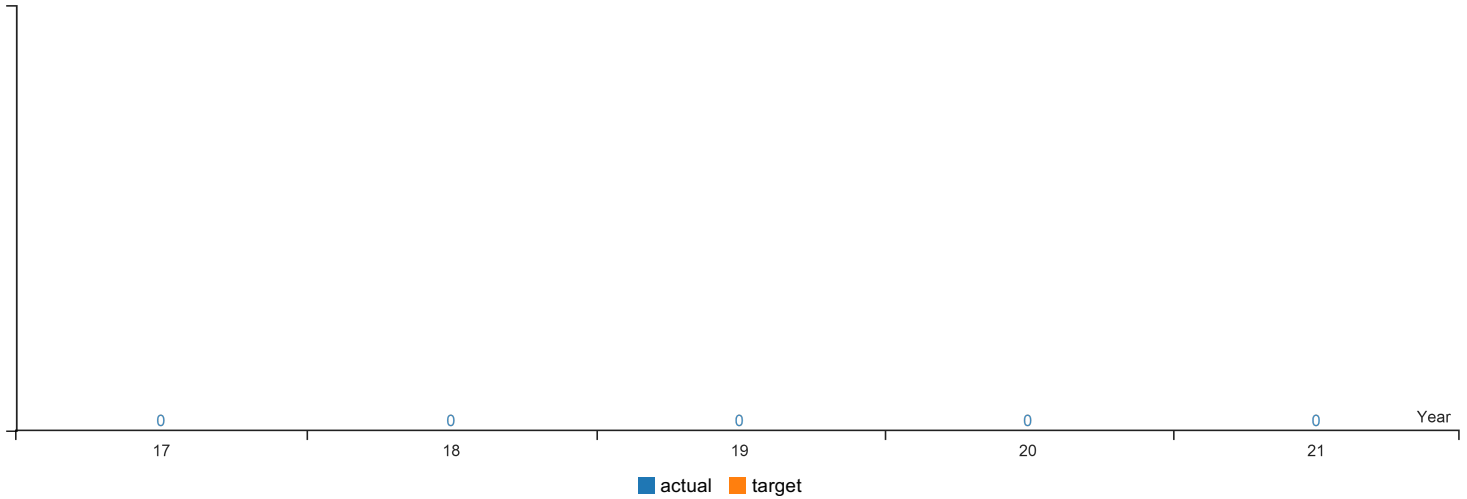
The COVID-19 public health emergency prompted many changes to the way the Board does business. There were vacancies in both the Licensing and Compliance departments which was a strain on agency resources. Recruiting and onboarding of new employees was challenging during times of social distancing and limited staff in the office. Additionally, the transition from in person processing of applications to remote processing caused delays. New workflows needed to be developed. Daily mail and application review timeframes were extended due to limited staffing physically in the office. The implementation and issuance of temporary pharmacy licenses and manufacturer licenses for the production and distribution of hand sanitizer, and the licensing of drug distribution agents for the distribution of vaccines also affected the normal processing times of facility applications as these received priority processing.

Applications that required Compliance Department and Board review were also impacted by the COVID-19 public health emergency. Much of the focus of the Compliance staff in 2020 was answering questions and following up with individuals to ensure the health, safety and welfare of patients, as well as pharmacy staff during the public health emergency. This delayed the review and approval of applications when required. Additionally, the Compliance staff is seeing that case complexity is changing, which causes increased time for investigations and Board review, which has contributed to

the increase in days to issuance or denial depending on the Board's decision.

KPM #3	Percent of pharmacies inspected every two years. -
	Data Collection Period: Feb 01 - Jan 31

** Upward Trend = positive result*



Report Year	2017	2018	2019	2020	2021
Percent of pharmacies inspected every 2 years.					
Actual					
Target					

How Are We Doing

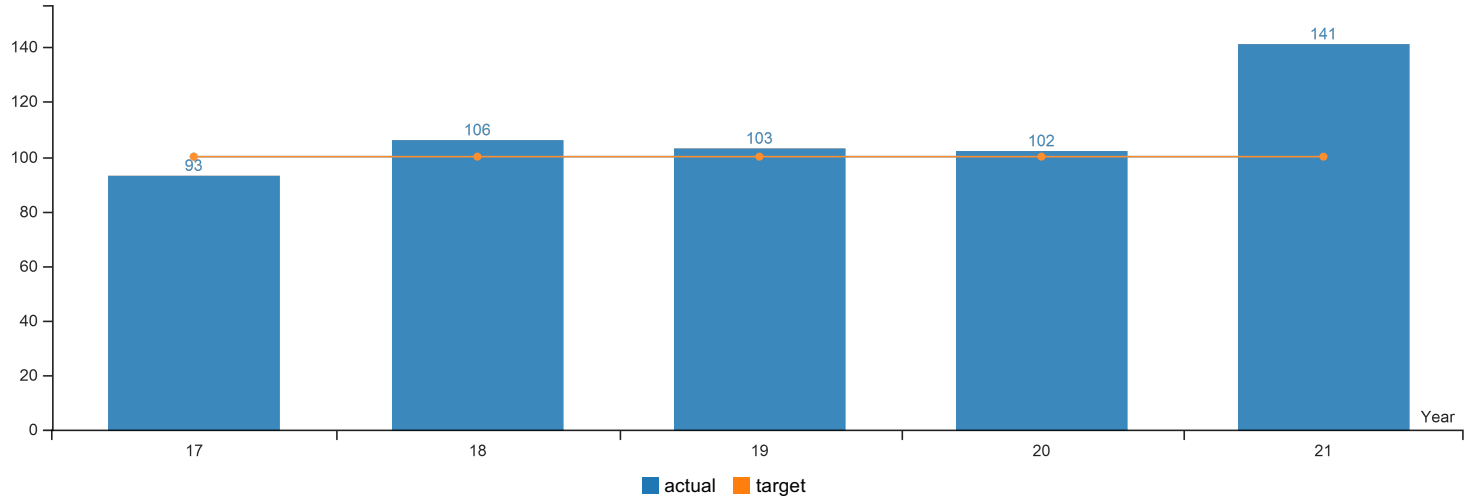
This measure was changed from annual to every two-year inspections effective 7/1/2021. Results for this measure will be reported in 2022 for calendar year 2021.

Factors Affecting Results

N/A

KPM #4	Average number of days to complete an investigation from complaint to board presentation. -
	Data Collection Period: Jan 01 - Dec 31

** Upward Trend = negative result*



Report Year	2017	2018	2019	2020	2021
Number of days to process complete investigation from complaint to Board presentation.					
Actual	93	106	103	102	141
Target	100	100	100	100	100

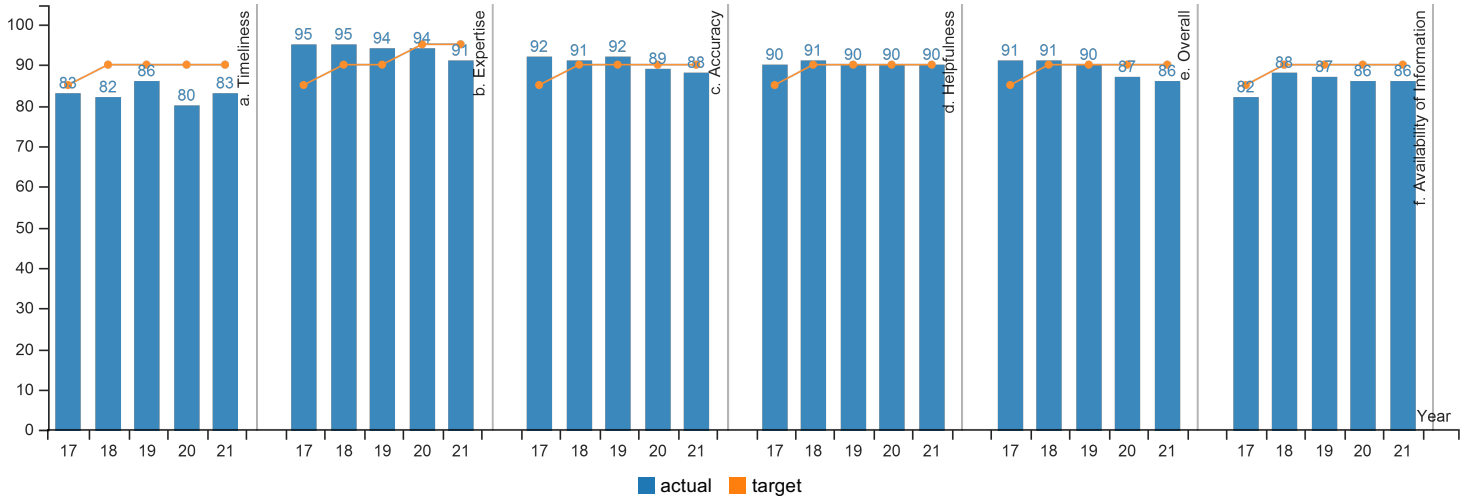
How Are We Doing

The total number of investigatory cases from January 1, 2020 - December 31, 2020 was 696, which is a decrease of 80 from 2019. This number is inclusive of all cases, which include those initiated from inspection results, licensee and registrant application cases, drug diversion and theft cases, impairment cases, unprofessional conduct cases and all consumer complaints. Cases are triaged to ensure that the public's safety is maintained which may cause delays in processing of other types of cases. On average, cases are reported and presented to the Board within 141 days. This is an increase of 39 days from 2019.

Factors Affecting Results

Onboard training of new staff, continuous quality process improvements, new regulations to enforce, resources prioritized to COVID-19 responses, and patient safety assessment case triaging all contributed to the 2020 results for this measure.

KPM #5	CUSTOMER SERVICE - Percent of Customers Rating Their Satisfaction With the Agency's Customer Service as "Good" or "Excellent" : Overall Customer Service, Timeliness, Accuracy, Helpfulness, Expertise, and Availability of Information.
	Data Collection Period: Jan 01 - Dec 31



Report Year	2017	2018	2019	2020	2021
a. Timeliness					
Actual	83%	82%	86%	80%	83%
Target	85%	90%	90%	90%	90%
b. Expertise					
Actual	95%	95%	94%	94%	91%
Target	85%	90%	90%	95%	95%
c. Accuracy					
Actual	92%	91%	92%	89%	88%
Target	85%	90%	90%	90%	90%
d. Helpfulness					
Actual	90%	91%	90%	90%	90%
Target	85%	90%	90%	90%	90%
e. Overall					
Actual	91%	91%	90%	87%	86%
Target	85%	90%	90%	90%	90%
f. Availability of Information					
Actual	82%	88%	87%	86%	86%
Target	85%	90%	90%	90%	90%

How Are We Doing

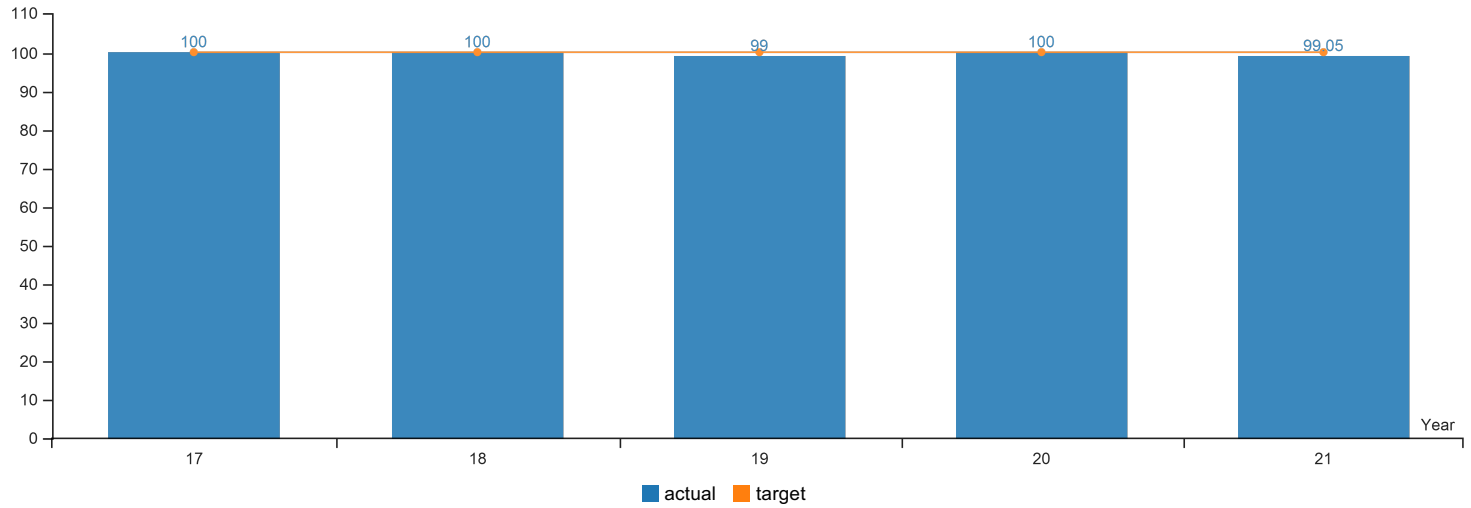
Our overall average of 87.5% is a decrease of .2% from 2019. The percentage results provided, represent the respondents who responded with a rating of either Excellent or Good. Those that responded “Don’t Know” or “N/A” were not factored into these ratings.

Factors Affecting Results

- The 2020 COVID-19 public health emergency had an impact on agency resources that affected the timely dissemination of the customer service survey distribution. The Board sent out only two emails, in June 2020 and in January of 2021 rather than monthly.
- The Board’s staff worked to address emergency issues and policies to ensure public safety.
- The Board's staff focused on implementing new online application processes to try to create efficiencies in the licensing process. In April of 2020, the Board rolled out a new online application process for all individuals, as well as online renewals for several new categories.

KPM #6	Board Best Practices - Percent of total best practices met by the Board.
	Data Collection Period: Jan 01 - Dec 31

** Upward Trend = positive result*



Report Year	2017	2018	2019	2020	2021
Is the Board following Best Practices?					
Actual	100%	100%	99%	100%	99.05%
Target	100%	100%	100%	100%	100%

How Are We Doing

The Board regularly works to follow best practices. The Executive Director provides weekly communication to the Board and meets with the President and Vice President as needed.

Factors Affecting Results

This year, seven out of nine members participated in providing feedback for this measure, two positions are vacant. There was a dissenting response on one question by one member making it impossible to achieve the 100% target. The opportunity to regularly orient the Board to best practices and answer questions is very useful. The Board has been able to meet the target most years since the measure was implemented in 2007.

SBAR: Schnebly, Eric (RPH-0007834): Approval Request – Bay Area Hospital

S	**Situation:** Approval Request – PIC of multiple pharmacy drug outlets. At the October, 2019 Board Meeting, the Board approved the request for Heather Loudon-Howley, individually, of Bay Area Hospital to be the designated PIC and oversee three pharmacies. Eric Schnebly has been appointed as the incoming interim Director of Pharmacy at Bay Area Hospital and anticipates this appointment to be 6 months or until a permanent director is hired. He is replacing Heather Loudon-Howley, RPH-0017301 as the PIC for multiple pharmacy drug outlets located at 1775 Thompson Rd, Coos Bay OR.
B	**Background:** • Regulations: o OAR 855-019-0300(3) A pharmacist may not be designated PIC of more than two 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. o OAR 855-019-0300(4)(e) The PIC must perform the following the duties and responsibilities: A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board **Description:** • In 2019, the Cancer Center registration changed from a drug room registration to a pharmacy registration, RP-0003512, prompting the need for this request. • PIC Loudon-Howley previously indicated that she conducted daily huddle meetings to discuss operations/patient care and physically is present several time a month to oversee processes and general communication with the Cancer Center. • RPH Schnebly has confirmed that all the information included in the original waiver request is still valid and fits the current practice. He understands that there is a quarterly compliance audit that must be conducted at the locations on the form provided by Board.
A	**Assessment:** Drug outlet registrations impacted are: • IP-0000616 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay) o Issue Date: 3/15/1974 • RP-0000822 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay) o Issue Date: 2/11/1981 • RP-0003512 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay) o Issue date: 9/5/19
R	**Recommendation:** Staff recommendation for approval to replace RPH Heather Loudon-Howley as the designated PIC of more than two pharmacies, with Eric Schnebly for Bay Area Hospital approval: Grant (5 year; traditional language)

Inquiry Date: 10/7/2021
Board review: October 2021 meeting

From:	Schnebly, Eric
To:	HENNIGAN Chrisy * BOP
Subject:	RE: Request for PIC of Multiple Registrants
Date:	Wednesday, October 6, 2021 2:43:01 PM

Until then, can I assume that I am able to continue to be PIC over the three licenses per the previous waiver?

From: HENNIGAN Chrisy * BOP <Chrisy.HENNIGAN@bop.oregon.gov>
Sent: Wednesday, October 6, 2021 14:41
To: Schnebly, Eric <Eric.Schnebly@bayareahospital.org>
Subject: RE: Request for PIC of Multiple Registrants

Thank you Eric,

The waiver request will be presented at the 12/9/2021 Board meeting.

Board staff often works remotely, therefore, email is the preferred and most efficient mode of communication. Thank you.

Sincerely,

Chrisy

Chrisy Hennigan
Licensing Manager
Oregon Board of Pharmacy
800 NE Oregon St, STE 150
Portland OR 97232-2142
P: (971)-673-0001 | F: (971)-673-0002
http://www.oregon.gov/Pharmacy

From: Schnebly, Eric <Eric.Schnebly@bayareahospital.org>
Sent: Wednesday, October 6, 2021 2:38 PM
To: HENNIGAN Chrisy * BOP <Chrisy.HENNIGAN@bop.oregon.gov>
Subject: RE: Request for PIC of Multiple Registrants

All the information included in the original waive request is still valid and fits the current practice. There is no additional considerations.

Thank you

Eric

From: HENNIGAN Chrisy * BOP <Chrisy.HENNIGAN@bop.oregon.gov>
Sent: Wednesday, October 6, 2021 13:13
To: Schnebly, Eric <Eric.Schnebly@bayareahospital.org>
Subject: RE: Request for PIC of Multiple Registrants

Eric,

Thank you for this information.

I have attached the information presented to the Board along with the approval letter from October of 2019. To continue the review of your request below in preparation for an upcoming Board meeting, can you please advise if any of the information has changed or there are any other items that the Board should note when reviewing this request?

Thank you.

Board staff often works remotely, therefore, email is the preferred and most efficient mode of communication. Thank you.

Sincerely,

Chrisy

Chrisy Hennigan
Licensing Manager
Oregon Board of Pharmacy
800 NE Oregon St, STE 150
Portland OR 97232-2142
P: (971)-673-0001 | F: (971)-673-0002
http://www.oregon.gov/Pharmacy

keep the contents confidential, and immediately delete the message and any attachments from your system.

From: Schnebly, Eric <Eric.Schnebly@bayareahospital.org>
Sent: Wednesday, October 6, 2021 12:58 PM
To: HENNIGAN Chrisy * BOP <Chrisy.HENNIGAN@bop.oregon.gov>
Cc: ericschnebly@gmail.com; LOOSLI Tracy * BOP <Tracy.LOOSLI@bop.oregon.gov>; HUNT Michael *BOP <Michael.HUNT@bop.oregon.gov>
Subject: RE: Request for PIC of Multiple Registrants

My understanding from Heather, is that it is active until March 2022. When I checked the status online, it is still active.

When the renewal comes up, we will evaluate the status then.

Thank you

From: HENNIGAN Chrisy * BOP <Chrisy.HENNIGAN@bop.oregon.gov>
Sent: Wednesday, October 6, 2021 12:44
To: Schnebly, Eric <Eric.Schnebly@bayareahospital.org>
Cc: ericschnebly@gmail.com; LOOSLI Tracy * BOP <Tracy.LOOSLI@bop.oregon.gov>; HUNT Michael *BOP <Michael.HUNT@bop.oregon.gov>
Subject: RE: Request for PIC of Multiple Registrants

Hi Eric,

I hope this finds you well!

We received a request from Heather Loudon-Howley to "inactivate license RP 0000822, as it is not in use. "

Can you please advise the status of RP-0000822? Thank you.

Board staff often works remotely, therefore, email is the preferred and most efficient mode of communication. Thank you.

Sincerely,

Chrisy
Chrisy Hennigan
Licensing Manager
Oregon Board of Pharmacy
800 NE Oregon St, STE 150

Portland OR 97232-2142
P: (971)-673-0001 | F: (971)-673-0002
http://www.oregon.gov/Pharmacy

From: Schnebly, Eric <Eric.Schnebly@bayareahospital.org>
Sent: Wednesday, October 6, 2021 8:39 AM
To: PHARMACY BOARD * BOP <PHARMACY.BOARD@oregon.gov>
Cc: ericschnebly@gmail.com
Subject: Request for PIC of Multiple Registrants

BOP - I am the incoming interim Director of Pharmacy at Bay Area Hospital. This hospital has three pharmacy licenses: IP-000616, RP-000822, and RP-0003512 for which I will be the PIC.

I would like to request a waiver to OAR 855-019-0300(3). This waiver was previously granted to the outgoing PIC on October 9th, 2019.

The duration of my interim role will be 6 months or until a permanent Director is hired.

Per the conditions of the previous waiver, I understand that I must personally conduct and document Quarterly PIC Compliance Audits for each license.

Thank you

Eric Schnebly
Interim Pharmacy Director
Bay Area Hospital

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Oregon
Kate Brown, Governor

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971 / 673-0001
Fax: 971 / 673-0002
E-mail: pharmacy.board@oregon.gov
Web: www.pharmacy.state.or.us

October 9, 2019

Ms. Heather Loudon-Howley, PIC
Bay Area Hospital Pharmacy
1775 Thompson Rd
Coos Bay, OR 97420

RE: Request for PIC of Multiple Registrants

Dear Ms. Loudon-Howley

At the October 2019 meeting, the Board considered your request for approval to be the PIC of more than two pharmacies per OAR 855-019-0300(3). The registered pharmacies are IP-0000616, RP-0000822 and RP-0003512.

The Board has approved your request under the following conditions:

- This approval is granted to you, individually, as PIC at these 3 locations.
- Per OAR 855-019-0300(4)(e), you must personally conduct and document a Quarterly PIC Compliance Audit form provided by the Board. The form can be found on our website.

This approval is valid until 10/9/2024 (5 years from the date of this letter). After this date, a new approval must be requested. A copy of this notification should be kept with your Pharmacist-In-Charge self inspection reports at each location.

Sincerely,

Chrisy Hennigan

Chrisy Hennigan
Licensing Manager

CC: Brianne Efremoff, Compliance Director
October 2019 Board Meeting File
IP-0000616 Licensing File
RP-0000822 Licensing File
RP-0003512 Licensing File

SBAR: Heather Loudon-Howley (RPH-0017301): Waiver Request – Bay Area Hospital

S	**Situation:** Waiver Request – PIC of multiple pharmacy drug outlets. At the June Board Meeting, the Board approved the waiver for Susanne McClelland, individually, of Bay Area Hospital to be the PIC and oversee three pharmacies. Heather Loudon-Howley has replaced Susanne McClelland as the PIC.
B	**Background:** • Regulations: o OAR 855-019-0300(3) A pharmacist may not be designated PIC of more than two 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. o OAR 855-019-0300(4)(e) The PIC must perform the following the duties and responsibilities: A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board **Description:** • Nothing has changed in the hospital's course of business and they understand that there is a quarterly compliance audit that must be conducted at both locations on the form provided by Board. • The Cancer Center registration change from a drug room registration to a pharmacy registration has been completed. The new license number is: RP-0003512. • PIC Loudon-Howley currently conducts daily huddle meetings to discuss operations/patient care and physically is present several time a month to oversee processes and general communication with the Cancer Center. •Contact information: Heather Loudon-Howley, RPH-0017301 Directory of Pharmacy Phone: 541-269-8490 Bay Area Hospital 1775 Thompson Rd Coos Bay, OR 97420
A	**Assessment:** Drug outlet registrations impacted are: • IP-0000616 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay) • RP-0000822 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay) • RP-0003512 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay) o Issue date: 9/5/19
R	**Recommendation:** Staff recommendation for approval to replace Susanne McClelland as PIC with Heather Loudon-Howley for Bay Area Hospital waiver: Grant (5 year; traditional language)

Inquiry Date: 7/26/2019
Board review: October 2019 meeting

Oregon Board of Pharmacy
800 NE Oregon St. Suite 150
Portland, OR 97232

July 26, 2019

Dear Members of the Board

In section 855-019-0300 of Pharmacist-in-Charge, section (3) states "A pharmacist may not be designated PIC of more than two 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." I am writing to formally request a waiver for the PIC at Bay Area Hospital to oversee three pharmacies. Nothing has changed in the hospital's course of business, however, we have been notified that our Cancer Center registration will need to change from a drug room over to retail drug outlet because we have a pharmacist at the center from open to close (7:00-17:30).

Currently, consulting pharmacist (Daniel Hendrickson; RPH – 0016051) along with a F/T pharmacist from the I/P side of the hospital staffs with 1.5 techs who assist with compounding, materials replenishment and inventory. We have daily huddle meetings to discuss operations/patient care and I am over there several times a month to follow up on staffing, processes and general communication with the Cancer Center. We have submitted a licensure request for Cancer Center pharmacy as the second retail drug outlet for the hospital and its' third license. On the inpatient side, we are currently registered as both an institutional drug outlet with controlled substance registration and a retail drug outlet with controlled substance registration. We understand that if the Board gives Bay Area Hospital Pharmacist in Charge a waiver that a quarterly compliance audit must be conducted at <u>both</u> locations on the form provided by Board. Thank you in advance for your time and consideration.

Respectfully,

Heather Loudon-Howley (RPH-0017301)
Bay Area Hospital Pharmacy
1775 Thompson Rd
Coos Bay, OR 97420
541-269-8490