

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**

- Roll Call
- 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)**

- Legal Advice pursuant to ORS 192.660(2)(f)
- Deliberation on Disciplinary Cases and Investigations
- 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**

- Roll Call

**II. MOTIONS RELATED TO DISCIPLINARY ACTIONS**

*Action Necessary*

**III. GENERAL ADMINISTRATION**

- Discussion Items
  - 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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971-673-0001  
pharmacy.rulemaking@bop.oregon.gov  
800 NE Oregon St., Suite 150  
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.

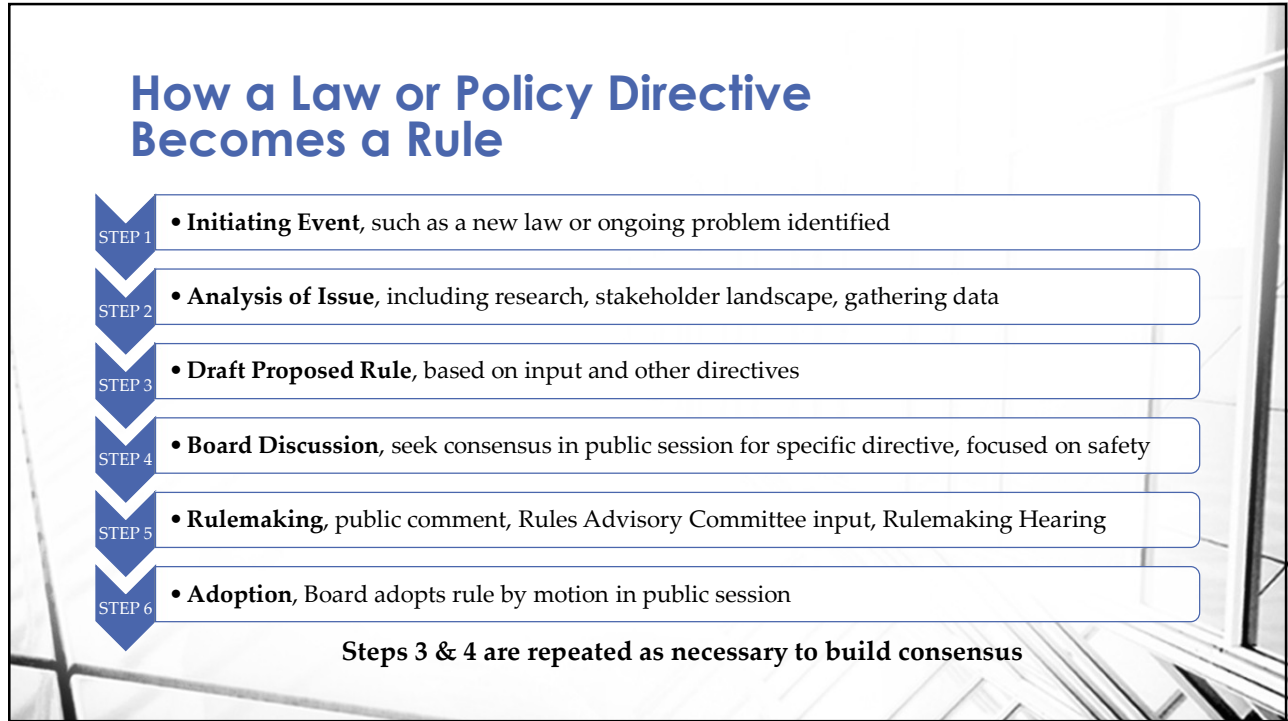
STATUTORY/OTHER AUTHORITY: ORS 689.205  
STATUTES/OTHER IMPLEMENTED: ORS 689.151



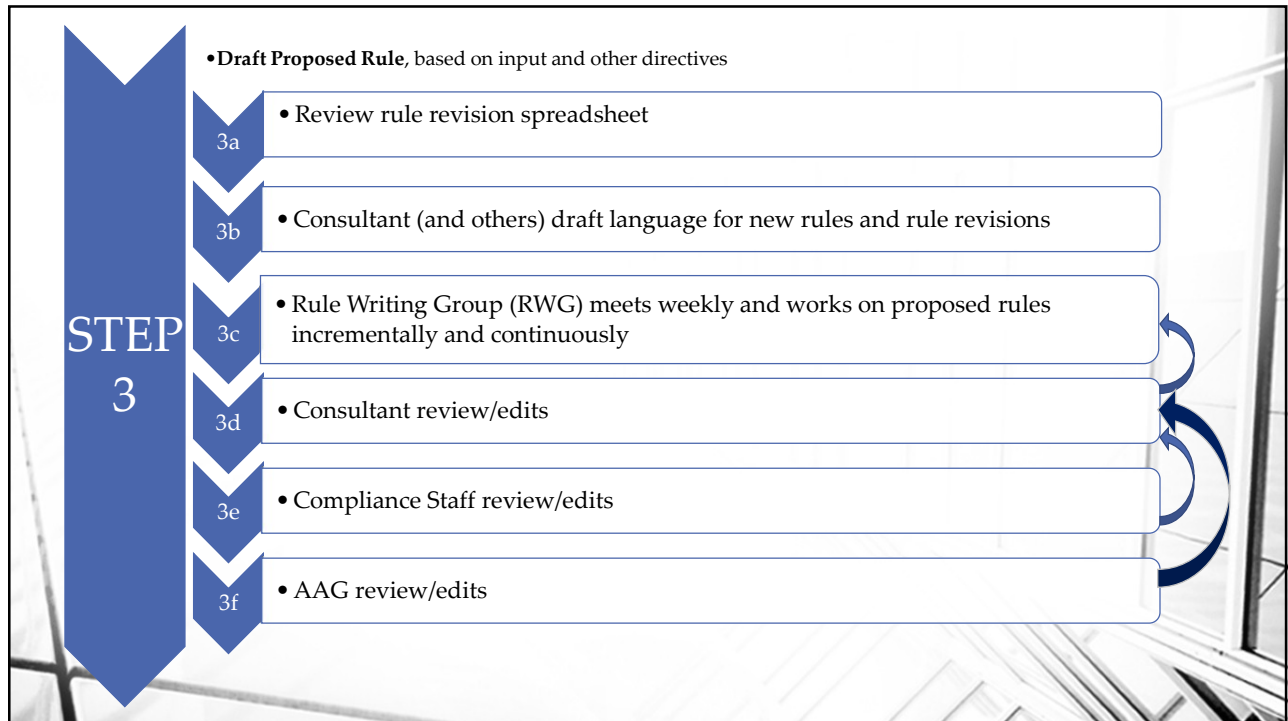
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## Objectives

- 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

6

## 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

8

## Division Vision- DRAFT

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

9

## 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 Business	325	Prescription: Transfers	605	Information
30	Non-Resident Pharmacies	350	Dispensing: Containers	650	Grounds for Discipline
50	Personnel		Dispensing: Customized Patient Medication Packages	700	Service: Non-Prescription Drugs- Double Set-Up
100	Security	355	Labeling: General Requirements	705	Service: Pharmacy Depots
120	Drug: Receipt	400	Labeling: Prescription Reader Accessibility	710	Service: Epinephrine- Definitions
125	Drug: Storage	405	Labeling: Limited English Proficiency	715	Service: Epinephrine- General Requirements
130	Drug: Loss	410	Labeling: Repackaged Drugs	720	Service: Naloxone- General Requirements
150	Outlet: Sanitation	415	Drug and Devices: Disposal		Service: Expedited Partner Therapy (EPT)- Purpose
155	Outlet: Minimum Equipment Requirements	450	Drug and Devices: Return	725	Service: Expedited Partner Therapy (EPT) - Procedures
200	Outlet: General Requirements	455	Drugs and Devices: Take-back Collection Program	730	
205	Outlet: Technology	460			
210	Outlet: Supervision				
215	Outlet: Pharmacist Utilization				
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.

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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.**

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

20

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

23

24 **Statutory/Other Authority: ORS 689.205**

25 **Statutes/Other Implemented: ORS 689.151**

26

PROPOSED

**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.

2 Division 6  
3 DEFINITIONS

4  
5 **855-006-0005**

6 **Definitions**

7  
8 As used in OAR chapter 855:

9  
10 **(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).**

11  
12 ~~(12)~~ "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the  
13 context.

14  
15 ~~(23)~~ "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy  
16 who assists the pharmacist in the practice of pharmacy pursuant to rules of the ~~h~~Board and has  
17 completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for  
18 clerical duties, such as recordkeeping, cashing, bookkeeping and delivery of medications released by  
19 the pharmacist are not considered pharmacy technicians.

20  
21 ~~(34)~~ "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a  
22 health care organization or a physician that permits the pharmacist to engage in the practice of clinical  
23 pharmacy for the benefit of the patients of the health care organization or physician.

24  
25 ~~(45)~~ "Collaborative Drug Therapy Management" means the participation by a pharmacist in the  
26 management of drug therapy pursuant to a written protocol that includes information specific to the  
27 dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and  
28 initiated upon a prescription order for an individual patient and:

29  
30 (a) Is agreed to by one pharmacist and one practitioner; or

31  
32 (b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or  
33 more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group  
34 practice, including but not limited to organized medical groups using a pharmacy and therapeutics  
35 committee.

36  
37 ~~(56)~~ "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or  
38 device:

39  
40 (a) As the result of a practitioner's prescription drug order, or initiative based on the relationship  
41 between the practitioner, the pharmacist and the patient, in the course of professional practice; or

42  
43 (b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or  
44 dispensing; or

45

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

48  
49 (~~67~~) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

50  
51 (~~78~~) "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient  
52 medication, therapy management, drug storage and management, security, education, or any other  
53 pharmaceutical service.

54  
55 (~~89~~) The "Container" is the device that holds the drug and that is or may be in direct contact with the  
56 drug.

57  
58 (~~910~~) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a  
59 lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration  
60 to or use by a patient or other individual entitled to receive the prescription drug.

61  
62 (~~1011~~) "Interpretation and evaluation of prescription orders" means the review of the order for  
63 therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug  
64 ordered, its applicability and its relationship to the other known medications used by the patient and  
65 determination of whether or not the dose and time interval of administration are within accepted limits  
66 of safety. The legal review for correctness of the prescription order includes a determination that the  
67 order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose,  
68 contains all information required by federal and state law, and is within the practitioner's scope of  
69 practice.

70  
71 (~~1112~~) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive,  
72 however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or  
73 commercially packaged legend drug or device.

74  
75 **(13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).**

76  
77 (~~1214~~) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of  
78 the therapeutic or adverse effect of medication upon a patient, including direct consultation with the  
79 patient or his agent and review of patient records, as to result and side effect, and the analysis of  
80 possible interactions with other medications that may be in the medication regimen of the patient. This  
81 section shall **must** not be construed to prohibit monitoring by practitioners or their agents.

82  
83 (~~1315~~) "Medication Therapy Management (MTM)" means a distinct service or group of services that is  
84 intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management  
85 services are independent of, but can occur in conjunction with, the provision of a medication product.

86  
87 (~~1416~~) "Nationally Certified Exam" means an exam that is approved by the **b**Board which demonstrates  
88 successful completion of a Specialized Education Program. The exam must be reliable, psychometrically  
89 sound, legally defensible and valid.



90  
91 (~~1517~~) "Non-legend drug" means a drug which does not require dispensing by prescription and which is  
92 not restricted to use by practitioners only.

93  
94 (~~1618~~) "Offering or performing of those acts, services, operations or transactions necessary in the  
95 conduct, operation, management and control of pharmacy" means, among other things:

- 96  
97 (a) The creation and retention of accurate and complete patient records;  
98  
99 (b) Assuming authority and responsibility for product selection of drugs and devices;  
100  
101 (c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the  
102 general public;  
103  
104 (d) Maintaining confidentiality of patient information.

105  
106 **(19) "Official compendium" means the official United States Pharmacopeia <USP>, official National**  
107 **Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States**  
108 **<HPUS> (v.2021), or any supplement to any of these.**

109  
110 (~~1720~~) "Oral Counseling" means an oral communication process between a pharmacist and a patient or  
111 a patient's agent in which the pharmacist obtains information from the patient (or agent) and the  
112 patient's pharmacy records, assesses that information and provides the patient (or agent) with  
113 professional advice regarding the safe and effective use of the prescription drug for the purpose of  
114 assuring therapeutic appropriateness.

115  
116 (~~1821~~) Participation in Drug Selection and Drug Utilization Review:

117  
118 (a) "Participation in drug selection" means the consultation with the practitioner in the selection of the  
119 best possible drug for a particular patient.

120  
121 (b) "Drug utilization review" means evaluating prescription drug order in light of the information  
122 currently provided to the pharmacist by the patient or the patient's agent and in light of the information  
123 contained in the patient's record for the purpose of promoting therapeutic appropriateness by  
124 identifying potential problems and consulting with the prescriber, when appropriate. Problems subject  
125 to identification during drug utilization review include, but are not limited to:

126  
127 (A) Over-utilization or under-utilization;

128  
129 (B) Therapeutic duplication;

130  
131 (C) Drug-disease contraindications;

132  
133 (D) Drug-drug interactions;

- 134  
135 (E) Incorrect drug dosage;  
136  
137 (F) Incorrect duration of treatment;  
138  
139 (G) Drug-allergy interactions; and  
140  
141 (H) Clinical drug abuse or misuse.  
142

143 ~~(1922)~~ "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of  
144 achieving definite outcomes that improve a patient's quality of life. These outcomes include:

- 145  
146 (a) Cure of a disease;  
147  
148 (b) Elimination or reduction of a patient's symptomatology;  
149  
150 (c) Arrest or slowing of a disease process; or  
151  
152 (d) Prevention of a disease or symptomatology.  
153

154 ~~(2023)~~ "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the  
155 pharmacist in the practice of pharmacy pursuant to rules of the ~~h~~Board but has not completed the  
156 specialized education program pursuant to OAR 855-025-0012.  
157

158 ~~(2124)~~ "Practice of clinical pharmacy" means:

- 159  
160 (a) The health science discipline in which, in conjunction with the patient's other practitioners, a  
161 pharmacist provides patient care to optimize medication therapy and to promote disease prevention  
162 and the patient's health and wellness;  
163  
164 (b) The provision of patient care services, including but not limited to post-diagnostic disease state  
165 management services; and  
166  
167 (c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.  
168

169 ~~(2225)~~ "Practice of pharmacy" is as defined in ORS 689.005.  
170

171 ~~(2326)~~ "Prescription released by the pharmacist" means, a prescription which has been reviewed by the  
172 pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.  
173

174 ~~(2427)~~ "Prohibited conduct" means conduct by a licensee that:

- 175  
176 (a) Constitutes a criminal act against a patient or client; or  
177

178 (b) Constitutes a criminal act that creates a risk of harm to a patient or client.  
179  
180 ~~(2528)~~ "Proper and safe storage of drugs and devices and maintenance of proper records therefore"  
181 means housing drugs and devices under conditions and circumstances that:  
182  
183 (a) Assure retention of their purity and potency;  
184  
185 (b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;  
186  
187 (c) Assure security and minimize the risk of their loss through accident or theft;  
188  
189 (d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;  
190  
191 (e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from  
192 harmful exposure to hazardous substances.  
193  
194 ~~(2629)~~ "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned  
195 and systematic process for the monitoring and evaluation of the quality and appropriateness of  
196 pharmacy services and for identifying and resolving problems.  
197  
198 ~~(2730)~~ "Responsibility for advising, when necessary or when regulated, of therapeutic values, content,  
199 hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing  
200 as required by these rules or federal regulation, of the possible therapeutic response to the medication,  
201 the names of the chemicals in the medication, the possible side effects of major importance, and the  
202 methods of use or administration of a medication.  
203  
204 ~~(2831)~~ "Specialized Education Program" means;  
205  
206 (a) A program providing education for persons desiring licensure as pharmacy technicians that is  
207 approved by the board and offered by an accredited college or university that grants a two-year degree  
208 upon successful completion of the program; or  
209  
210 (b) A structured program approved by the board and designed to educate pharmacy technicians in one  
211 or more specific issues of patient health and safety that is offered by:  
212  
213 (A) An organization recognized by the board as representing pharmacists or pharmacy technicians;  
214  
215 (B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or  
216  
217 (C) A trade association recognized by the board as representing pharmacies.  
218  
219 ~~(29)~~ "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy  
220 technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control  
221 and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action.

222 During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic,  
223 "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being  
224 supervised, coupled with the ability to control and be responsible for the technician or interns actions  
225 and for the following remote processing functions only: prescription or order entry, other data entry,  
226 and insurance processing of prescriptions and medication orders.  
227

228 (3032) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical  
229 structure for the drug product prescribed under circumstances where the prescriber has not given clear  
230 and conscious direction for substitution of the particular drug for the one which may later be ordered.  
231

232 (3133) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy  
233 and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a  
234 certified Oregon pharmacy technician.  
235

236 Statutory/Other Authority: ORS 689.205

237 Statutes/Other Implemented: ORS 689.151 & ORS 689.155

238 Division 7  
239 PUBLIC HEALTH EMERGENCY

240  
241 **855-007-0120**

242 **Damage to a Pharmacy and Drug Integrity**

243  
244 (1) If a pharmacy prescription department sustains damage, whether by flood or otherwise, the entire  
245 drug inventory, including any prescriptions that are awaiting pickup, is unfit for dispensing, ~~shall~~**must** be  
246 classified as adulterated and must be destroyed unless, ~~in the pharmacist's professional judgment, any~~  
247 ~~items are~~ **the drugs are** deemed safe for dispensing **pursuant to OAR 855-041-1036**. Any incident of this  
248 nature must be reported to the ~~b~~**B**oard within three working days.

249  
250 (2) If a pharmacy loses power that affects temperature or humidity controls such that ~~USP standards for~~  
251 ~~the~~ proper storage of drugs **pursuant to OAR 855-041-1036** ~~has~~**ve** been violated, such drugs ~~shall~~**must**  
252 be classified as adulterated and may not be dispensed.

253  
254 NOTE: for those drugs labeled for storage at "controlled room temperature," the acceptable range of  
255 temperature is 68° to 77°F with allowances for brief deviations between 59° to 86°F.

256  
257 (3) Controlled substances damaged, lost or stolen ~~shall~~**must** be documented and reported to the DEA  
258 and the ~~b~~**B**oard on DEA Form 41 or DEA Form 106 as appropriate.

259  
260 (4) A pharmacy that is required to temporarily close or relocate due to an emergency must report this  
261 event to the ~~b~~**B**oard within three working days.

262  
263 Statutory/Other Authority: ORS 689.205  
264 Statutes/Other Implemented: ORS 689.155

265 Division 41  
266 OPERATION OF PHARMACIES (~~AMBULATORY AND RESIDENTIAL DRUG OUTLETS~~)

267  
268 **855-041-1001**

269 **Definitions**  
270

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

275  
276 (2) "Biosimilar product" means a biological product licensed by the United States Food and Drug  
277 Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i) (v. XX/XX/XXXX).

278  
279 (3) "Drug room" is a drug storage area registered with the bBoard which is secure and lockable.

280  
281 **(4) "Informational insert" is an auxiliary document containing directions for use and other prescription**  
282 **information that is provided to the patient in both English and the language requested.**

283  
284 **(45) "Interchangeable" means, in reference to a biological product, that the United States Food and**  
285 **Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42**  
286 **U.S.C. 262(k)(4) (v. XX/XX/XXXX).**

287  
288 **(6) "Limited English proficiency" means not fluent in the English language.**

289  
290 **(57) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a)**  
291 **(v. XX/XX/XXXX) against which a biological product is evaluated in an application submitted to the**  
292 **United States Food and Drug Administration for licensure of a biological product as a biosimilar product**  
293 **or for determination that a biosimilar product is interchangeable.**

294  
295 **(8) "Repackage" means the act of taking a drug from the container in which it was distributed by the**  
296 **manufacturer and placing it into a different container without further manipulation of the drug.**

297  
298 **(9) "Temperature excursion" means an event in which a drug is exposed to a temperature outside of**  
299 **the manufacturers recommended storage conditions.**

300  
301 **Statutory/Other Authority:** ORS 689.205 & 689.522  
302 **Statutes/Other Implemented:** ORS 689.155 & ~~342~~ & ORS 689.522, & ORS 689.564

303  
304  
305  
306 **855-041-1035**

307 **Minimum Equipment Requirements**

308  
309 **(1) Each** retail drug outlet and institutional drug outlet **must have** the following:

310

311 ~~(1a) The most **Appropriate and** current issue of at least one pharmaceutical references with current,~~  
312 ~~properly filed supplements (**e.g. pharmacology, injectables, and veterinary drugs**) and updates~~  
313 ~~appropriate to and based on the standards of practice for the setting. **services offered by the outlet;**~~  
314

315 ~~(2b) **Appropriate and** current and properly filed Oregon Revised Statutes, Chapters 689, and 475;~~  
316 ~~current and properly filed Oregon Administrative Rules, chapter 855, **United States Code, Code of**~~  
317 ~~**Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the**~~  
318 ~~**outlet** and a minimum of three years of the Board of Pharmacy quarterly newsletters maintained in~~  
319 ~~house or other readily retrievable means;~~

320  
321 ~~(3) Official Poison and Exempt Narcotic Register if poisons and exempt narcotics are sold or distributed.~~  
322

323 ~~**(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLeX, OHA ALERT-IIS) based on**~~  
324 ~~**the services offered by the outlet;**~~  
325

326 ~~(4d) Suitable refrigeration. **Appropriate equipment to maintain the proper storage of drugs;**~~  
327

328 ~~**(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon**~~  
329 ~~**Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by**~~  
330 ~~**reference (e.g. USP) based on services offered by the outlet;**~~  
331

332 ~~(5f) A sink with running hot and cold water.;~~  
333

334 ~~**(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:**~~  
335

336 ~~**(A) Stating “This pharmacy may be able to substitute a less expensive drug which is therapeutically**~~  
337 ~~**equivalent to the one prescribed by your doctor unless you do not approve.” The printing on this sign**~~  
338 ~~**must be in block letters not less than one inch in height.**~~  
339

340 ~~**(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free,**~~  
341 ~~**competent oral interpretation and translation services, including translated prescription labels, for**~~  
342 ~~**patients who are of limited English proficiency, in compliance with federal and state regulations if the**~~  
343 ~~**pharmacy dispenses prescriptions for a patient's self-administration;**~~  
344

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

348 ~~**(D) Providing written notice in a conspicuous manner that naloxone and the necessary medical**~~  
349 ~~**supplies to administer naloxone are available at the pharmacy if naloxone services are provided by**~~  
350 ~~**the pharmacy per OAR 855-041-2340.**~~  
351

352 ~~(6h) **Additional** Equipment and supplies appropriate to and based on the standards of practice for the~~  
353 ~~setting as **that are** determined as **necessary** by the Pharmacy and **or** Pharmacist-in-Charge.~~  
354

355 ~~(72) Failure to have, and use **and maintain required** equipment necessary to your practice setting~~  
356 ~~constitutes unprofessional conduct for purposes of **under** ORS 689.405(1)(a).;~~  
357

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

360  
361 (9) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to  
362 provide notification of the right to free, competent oral interpretation and translation services for  
363 patients who are of limited English proficiency, in compliance with federal and state regulations.

364  
365 Statutory/Other Authority: ORS 689.205

366 Statutes/Other Implemented: ORS 689.508, & ORS 689.155, ORS 689.515, ORS 689.564 & ORS 689.686

367

368

369

370

371 **855-041-1036**

372 **Proper Storage of Drugs**

373

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

376

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

378

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

381

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

384

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

387

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

390

391 (a) All drug refrigeration systems must:

392

393 (A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10  
394 °C (-13 to 14 °F); or as specified by the manufacturer.

395

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

397

398 (C) Be dedicated to pharmaceuticals only; and

399

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

403

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



405  
406 (A) Documentation of training of all personnel;  
407  
408 (B) Maintenance of manufacturer recommended calibration of thermometers;  
409  
410 (C) Maintenance of records of temperature logs for a minimum of three years;  
411  
412 (D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s)  
413 involved in excursion responses;  
414  
415 (E) Documentation of action(s) taken, including decision to quarantine product for destruction, or  
416 determination that it is safe for continued use. This documentation must include details of the  
417 information source;  
418  
419 (F) A written emergency action plan; and  
420  
421 (G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring  
422 equipment.  
423  
424 (3) Vaccine Drug Storage:  
425  
426 (a) A pharmacy that stores vaccines must comply with section two of this rule and the following:  
427  
428 (A) Vaccines must be stored in the temperature stable sections of the refrigerator;  
429  
430 (B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads,  
431 calibrated within a plus or minus 0.5 °C variance must be utilized;  
432  
433 (C) Each freezer and refrigerator compartment must have its own exterior door and independent  
434 thermostat control;  
435  
436 (D) A system of continuous temperature monitoring with automated data logging and physical  
437 confirmation must be utilized. Documentation of the temperature of each active storage unit must be  
438 logged at least twice daily, data must be downloaded weekly, and system validations must be conducted  
439 quarterly; and  
440  
441 (E) Must adhere to a written quality assurance process to avoid temperature excursions.  
442  
443 (4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets  
444 all Pharmacy drug storage and security requirements.  
445  
446 **(1) A pharmacy must store each drug according to the manufacturer's storage requirements for**  
447 **temperature, light, humidity, sanitation, ventilation, and space.**  
448  
449 **(2) If the drug's manufacturer does not include a storage requirement, the drug must be stored as**  
450 **outlined in an official compendium, to ensure that the drug identity, strength, quality, and purity are**  
451 **not adversely affected.**  
452

453 **(3) Each pharmacy must:**  
454

455 **(a) Unless the manufacturer specifies differently, maintain drug required to be stored at controlled**  
456 **room temperature between 20-25 °C (68 to 77 °F); refrigerated products between 2 to 8 °C (35.6 to**  
457 **46.4 °F); frozen products between -25 to -10 °C (-13 to 14 °F);**  
458

459 **(b) Utilize continuous temperature monitoring device(s) that have a buffered probe (glycol, glass**  
460 **beads, or similar), are centrally located, accurate, calibrated within a plus or minus 0.5°C variance and**  
461 **record the temperature of each drug storage area at least every 15 minutes;**  
462

463 **(c) Review all temperature data for the last 24 hours twice daily for proper drug storage and for**  
464 **temperature excursions. Date, time and identity of the reviewer must be documented;**  
465

466 **(d) Utilize a system that notifies a pharmacist of each temperature excursion in real-time;**  
467

468 **(e) Ensure drug storage refrigerators and freezers are dedicated to drugs and vaccines only and utilize**  
469 **refrigerator or freezer compartments with its own exterior door and independent thermostat control;**  
470

471 **(f) Position drugs in refrigerators and freezers leaving space between the drugs, walls, ceiling, floor,**  
472 **and door to promote air circulation. If using a household grade unit, drugs may not be stored in any**  
473 **part of the unit that does not provide stable temperatures or sufficient air flow, such as directly under**  
474 **cooling vents, in drawers, or on refrigerator door shelves;**  
475

476 **(g) Maintain proper drug storage conditions during transfers between facilities and delivery to**  
477 **patients;**  
478

479 **(h) Ensure that drugs stored outside of the manufacturer's drug storage requirements are physically**  
480 **separated from other drugs until the manufacturer determines that the drug is safe and effective for**  
481 **continued use, is safe and effective for continued use with limitations (ie. shortened expiration date),**  
482 **needs to be returned to the supplier, or destroyed;**  
483

484 **(i) Ensure that the following is completed at a minimum of every 3 months:**  
485

486 **(A) Test and document that all components of the temperature monitoring system(s) for each storage**  
487 **area are recording temperature accurately and issuing appropriate alerts;**  
488

489 **(B) Review and assess temperature records for long-term trends or recurring problems. Date, time and**  
490 **identity of the reviewer must be documented;**  
491

492 **(j) Establish, maintain, and enforce a written quality assurance plan to prevent, identify, and**  
493 **appropriately respond to temperature excursions;**  
494

495 **(k) Establish, maintain, and enforce a written action plan to ensure proper drug storage in the event of**  
496 **an emergency (i.e. power outage or natural disaster) that includes identification of backup storage**  
497 **and a procedure for transfer of product between units or facilities;**  
498

- 499 **(l) Document the training of all pharmacy personnel on use of temperature monitoring system(s),**  
500 **quality assurance plan and written emergency action plan to ensure proper drug storage in the event**  
501 **of an emergency;**  
502
- 503 **(m) Recalibrate temperature monitoring device(s) at least once every 24 months or per manufacturer**  
504 **specifications, whichever is more frequent;**  
505
- 506 **(n) Document the following for each temperature excursion:**  
507
- 508 **(A) Date of temperature excursion;**  
509
- 510 **(B) Start and end time;**  
511
- 512 **(C) Minimum and maximum temperatures reached;**  
513
- 514 **(D) List of each drug involved in the temperature excursion including the drug name, quantity,**  
515 **National Drug Code, lot number, expiration date, manufacturer, and the date(s) of previous**  
516 **temperature excursions experienced by the drug(s);**  
517
- 518 **(E) Each drug involved in the temperature excursion must be clearly labeled with the date of**  
519 **temperature excursion and any shortened expiration date if determined by the manufacturer; and**  
520
- 521 **(F) Name of person(s) involved in responding to the temperature excursion event discovery and**  
522 **response;**  
523
- 524 **(o) Before a drug that has experienced a temperature excursion is dispensed, the following items must**  
525 **be documented:**  
526
- 527 **(A) Drug manufacturer information utilized indicating each drug is safe for use;**  
528
- 529 **(B) Name of the representative providing the information;**  
530
- 531 **(C) Manufacturer contact information;**  
532
- 533 **(D) Copy of information provided by manufacturer;**  
534
- 535 **(E) Date and time information was obtained from manufacturer;**  
536
- 537 **(F) Reference number associated with manufacturer contact;**  
538
- 539 **(G) Name of the Oregon licensed pharmacist that reviewed the manufacturer data and confirmed the**  
540 **drug safe for continued use; and**  
541
- 542 **(H) In the absence of (B) and (C), documentation of a drug manufacturer online reference that applies**  
543 **to the specific temperature excursion, documentation of this reference must be maintained; and**  
544
- 545 **(p) Maintain all records required by OAR 855-041-1036 for a minimum of three years;**  
546

547 Statutory/Other Authority: ORS 689.205 & ORS 689.325

548 Statutes/Other Implemented: ORS 689.155

549

550

551 **855-041-1040**

552 **Drug Outlet Procedures**

553

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

555

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

558

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

561

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

564

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

567

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

569

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

572

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

574

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

577

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

579

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

583

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

585

586 Statutory/Other Authority: ORS 689.205

587 Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

588

589

590

591

592 **855-041-1080**

593 **Pharmacy Registration (Both Retail and Institutional Drug Outlets)**

594

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

596

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

599

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

604

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

607

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

611

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

614

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

617

618 (6) A certificate of registration will be issued upon ~~b~~Board approval of the application.

619

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

622

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

625

626 **(9)** Pharmacy registration expires March 31, annually. If the annual registration fee referred to in **OAR**  
627 **855-110**~~division 110 of this Chapter~~ is not paid by March 31 of the current year, a ~~delinquent~~late fee as  
628 set out in **OAR 855-110**~~division 110 of this Chapter~~ ~~shall~~must be included with the application for  
629 registration renewal.

630

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

632

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

635

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

638  
639 (13) Applicants for change in ownership ~~shall~~must provide the ~~b~~Board with the information required in  
640 sections (3), (4), and (5) of this rule.

641  
642 (14) A change of ownership ~~shall~~must be reported to the ~~b~~Board ~~within 15 days of the~~prior to  
643 occurrence.

644  
645 (15) No pharmacy ~~shall~~must be operated until a certificate of registration has been issued to the  
646 pharmacy by the ~~b~~Board.

647  
648 Statutory/Other Authority: ORS 475.035 & 689.205  
649 Statutes/Other Implemented: ORS 689.155

650

651

652

653

654 **855-041-1130**

655 **Retail Drug Outlet Pharmacy Prescription Labeling**

656

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

658

659 ~~(a1)~~ Name, address and telephone number of the pharmacy;

660

661 ~~(b2)~~ Date of fill

662

663 ~~(c3)~~ Identifying number;

664

665 ~~(d4)~~ Name of patient;

666

667 ~~(e5)~~ Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also  
668 contain the identifier of the manufacturer or distributor;

669

670 ~~(f6)~~ Directions for use by the patient;

671

672 ~~(g7)~~ Name of practitioner;

673

674 ~~(h8)~~ Required precautionary information regarding controlled substances;

675

676 ~~(i9)~~ Such other and further accessory cautionary information as required for patient safety;

677

678 ~~(j10)~~ An expiration date after which the patient should not use the drug or medicine. Expiration dates on  
679 prescriptions must be the same as that on the original container **or one year from the date the drug**

680 **was originally dispensed and placed in the new container, whichever date is earlier** ~~unless, in the~~

681 ~~pharmacist's professional judgment, a shorter expiration date is warranted.~~ Any drug expiring before the

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

684

685 ~~(k11)~~ Any dispensed prescription medication, other than those in unit dose or unit of use packaging,  
686 ~~shall~~**must** be labeled with its physical description, including any identification code that may appear on  
687 tablets and capsules.

688

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

691

692 Statutory/Other Authority: ORS 689.205

693 Statutes/Other Implemented: ORS 689.505 & **ORS** 689.515

694

695

696

697 **855-041-1135**

698 **Defines Labeling and Container Requirements for Repackaged Drugs**

699

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

702

703 ~~(12)~~ **A single oral solid d**Drugs products ~~repackaged~~ by a pharmacy **into unit-dose packaging** for later  
704 own use dispensing on prescription shall must:

705

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

710

711 (b) Be labeled to identify at a minimum:

712

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

714

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

716

717 ~~(c)~~ **C** **Manufacturer and Lot number or an internal pharmacy code that references manufacturer and**  
718 **lot number; and**

719

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

723

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

725

726 **(ii) The manufacturer's expiration date; or**

727

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

730  
731 **(3) A single oral solid drug product repackaged by a pharmacy into multiple-unit packaging must:**  
732  
733 **(a) Utilize an equivalent container–closure system that is at least as protective as, or more protective**  
734 **than, the original system, complies with criteria established for equivalency and meets or exceeds the**  
735 **original container's specification for light resistance;**  
736  
737 **(b) Be labeled to identify at a minimum:**  
738  
739 **(A) Brand name or generic name;**  
740  
741 **(B) Strength;**  
742  
743 **(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot**  
744 **number; and**  
745  
746 **(D) Expiration date. The expiration date used for the repackaged product must not exceed the**  
747 **manufacturer's expiration date or one year from the date the drug was placed in the new container,**  
748 **whichever date is earlier.**  
749  
750 (2) An internal control number which references manufacturer and lot number may be utilized.

751  
752 Statutory/Other Authority: ORS 689.**205**  
753 Statutes/Other Implemented: **ORS 689.155**

754  
755 **855-041-1145**  
756 **New Containers**

757  
758 In filling the original prescriptions, nothing but **Each pharmacy must dispense a drug in a** new  
759 containers may be used. A patient's original container may be refilled if clean and the label is legible and  
760 up-to-date. The container shall **that** complies with the current provisions of the Federal Consumer  
761 **Poison Prevention** Packaging Act in **16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX), and 16 CFR**  
762 **1702 (XX/XX/XXXX)** and rules or regulations adopted thereunder. It must also conform with the current  
763 United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and  
764 labeling.

765  
766 [Publications: Publications referenced are available from the agency.]

767  
768 Statutory/Other Authority: ORS 689.**205**  
769 **Statutes/Other Implemented: ORS 689.155**

770  
771  
772  
773  
774  
775



776 **855-041-6270**

777 **Institutional Drug Outlet Pharmacy Prescription Labeling**

778

779 (1) Each pharmacy record keeping system must identify **all pharmacy personnel involved in the**  
780 **repackaging** and document **including** the pharmacist who verified ~~ds~~ the **repackaged** drug.

781

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

785

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

787

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

790

791 (c) The strength of the drug.

792

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

795

796 (a) Name and location of patient;

797

798 (b) Name and strength of drug;

799

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

801

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

803

804 (e) Auxiliary labels as needed, and

805

806 (f) Expiration date.

807

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

811

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

814

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

818

819 (~~76~~) Whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the  
820 admixture must be labeled with a distinctive supplementary label that ~~contains~~ includes the

821

822 (a) ~~The n~~Name, quantity and concentration of the drug added and the primary solution;

823

824 (b) ~~The d~~Date and time of addition;

825

826 (c) ~~The e~~Expiration date;

827

828 (d) ~~The s~~Scheduled time for administration;

829

830 (e) ~~The i~~Infusion rate, when applicable;

831

832 (f) ~~The n~~Name or initials of person performing admixture;

833

834 (g) ~~The i~~Identification of the pharmacy where the admixture was performed; and

835

836 (h) ~~The n~~Name or initials of the verifying pharmacist.

837

838 (~~87~~) The label applied at a secondary storage or remote storage area by a nurse or physician must  
839 include: the patient name or patient identifier, quantity and concentration of the drug added and the  
840 primary IV solution; the date and time of addition and the initials of the nurse or physician adding the  
841 drug.

842

843 Statutory/Other Authority: ORS 689.205

844 Statutes/Other Implemented: ORS 689.155 & ORS 689.505

845 Division 45  
846 DRUG COMPOUNDING

848 **855-045-0200**

849 **Application**

850

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

854

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

856

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

859

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

861

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

864

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

866

867 **(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging**  
868 **(12/01/2020 v. 2020); and**

869

870 **(e) as well as all Chapters of USP and USP-NF related to the compounding practices at any location. This**  
871 **includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),**  
872 **151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731**  
873 **(11/01/2020), 821 (05/01/2017), 823 (2013), 825, 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151**  
874 **(05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211**  
875 **(03/01/2019), and 1229.5 (08/01/2016), 1231 (08/01/2018), and 1821 (05/01/2017).**

876

877 Statutory/Other Authority: ORS 689.205

878 Statutes/Other Implemented: ORS 689.155

879

880

881

882 **855-045-0220**

883 **Personnel and Responsibilities**

884

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

887

888

889 (2) The Pharmacist-in-Charge (PIC) and the drug outlet shall **must** establish, maintain and enforce policies  
890 and procedures in accordance with the standards **required** in **OAR 855-045-0200(3)** ~~USP Chapters~~ for all  
891 aspects of the compounding operation according to the type of compounding performed and shall **must**  
892 include written procedures for:

- 893
- 894 (a) Personnel qualifications, to include training, evaluation and requalification;
- 895
- 896 (b) Hand hygiene;
- 897
- 898 (c) Garbing;
- 899
- 900 (d) Engineering and environmental controls, to include equipment certification and calibration, air and  
901 surface sampling, and viable particles;
- 902
- 903 (e) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and  
904 other staff responsible for cleaning;
- 905
- 906 (f) Components, to include selection, handling, and storage;
- 907
- 908 (g) Creating master formulation records, with documented pharmacist approval;
- 909
- 910 (h) Creating compounding records;
- 911
- 912 (i) Establishing beyond-use dates (BUDs);
- 913
- 914 (j) Continuous quality assurance program and quality controls, to include release testing, end-product  
915 evaluation, and quantitative/qualitative testing;
- 916
- 917 (k) Completed compounded preparations, to include handling, packaging, storage and transport;
- 918
- 919 (l) Adverse event reporting process and recall procedure. The recall procedure must include notification  
920 to the **b**Board within 10 working days in the event of a patient-level recall of a compounded drug.

921  
922 Statutory/Other Authority: ORS 689.205  
923 Statutes/Other Implemented: ORS 689.155

924  
925  
926  
927 **855-045-0240**

928 **Labeling of Compounded Drugs**

929  
930 In addition to the labeling requirements specified in **OAR 855-~~Division~~-041**, the label of a compounded  
931 drug dispensed or distributed must contain the following, at a minimum:

932

- 933 (1) The generic or official name of each active ingredient;  
934  
935 (2) The strength or concentration of each active ingredient, to include primary solution for a sterile  
936 parenteral preparation;  
937  
938 (3) The dosage form and route of administration;  
939  
940 (4) Rate of infusion, for a sterile parenteral preparation;  
941  
942 (5) The total quantity of the drug product;  
943  
944 (6) A **beyond-use date (BUD)**, compliant with ~~current USP standards~~ **required** in **OAR 855-045-0200(3)**;  
945 and  
946  
947 (7) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or  
948 appropriate for proper use and patient safety.  
949

950 Statutory/Other Authority: ORS 689.205  
951 Statutes/Other Implemented: ORS 689.155  
952

953 Division 65  
954 WHOLESale DRUG OUTLETS  
955

956 **855-065-0005**

957 **Definitions**  
958

- 959 (1) "Affiliate" means a business entity that has a relationship, or is an authorized trading partner, with a  
960 second business entity if, directly or indirectly:  
961  
962 (a) One business entity controls, or has the power to control, the other business entity; or  
963  
964 (b) A third party controls, or has the power to control, both of the business entities.  
965  
966 (2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has  
967 established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing  
968 relationship is deemed to exist between such wholesale distributor and a manufacturer when the  
969 wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section  
970 1504 of the Internal Revenue Code, complies with either or both of the following:  
971  
972 (a) The wholesale distributor has a written agreement currently in effect with the manufacturer  
973 evidencing such ongoing relationship; or  
974  
975 (b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of  
976 record, which is updated by the manufacturer no less than monthly.

- 977 (3) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale  
978 distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession  
979 of the brokered substance.  
980
- 981 (4) "Chain Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse  
982 and performs intra company sales or transfers of drugs to a group of chain pharmacies that have the  
983 same common ownership and control.  
984
- 985 (5) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and  
986 exclusive group of patients and is not open for dispensing to the general patient population and cannot  
987 be registered as a wholesale distributor.  
988
- 989 (6) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an  
990 agreement with another pharmaceutical manufacturer to engage in a business activity or occupation  
991 related to the manufacture or distribution of a prescription drug.  
992
- 993 (7) "Designated Representative" means an individual designated by each wholesale distributor  
994 registered by the bBoard who will serve as the primary contact person for the wholesale distributor with  
995 the bBoard and who is responsible for managing the company's operations at that registered location.  
996
- 997 (8) "Drug Sample" means a unit of a drug that is intended to promote the sale of the drug, but which is  
998 not itself for sale.  
999
- 1000 (9) "Illegitimate Product" means a product for which credible evidence shows that the product is:  
1001
- 1002 (a) Counterfeit, diverted, or stolen;
  - 1003
  - 1004 (b) Intentionally adulterated such that the product would result in serious adverse health consequences  
1005 or death to humans;
  - 1006
  - 1007 (c) The subject of a fraudulent transaction; or
  - 1008
  - 1009 (d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious  
1010 adverse health consequences or death.  
1011
- 1012 (10) "Intra Company Transfer" means the transfer of any drug between a division, subsidiary, parent,  
1013 and an affiliated or related company under the common ownership and control of a corporate entity.  
1014
- 1015 (11) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is  
1016 engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging,  
1017 or labeling of a drug, except when the process is part of a shared pharmacy service agreement as  
1018 defined in OAR 855-006-0005.  
1019
- 1020 (12) "Pedigree" for the purpose of this Division consists of:

1021  
1022 (a) "Transaction History," which means a statement in paper or electronic form, including the  
1023 transaction information for each prior transaction going back to the manufacturer of the product.  
1024  
1025 (b) "Transaction Information," which must include, but is not limited to:  
1026  
1027 (A) The proprietary or established name or names of the product;  
1028  
1029 (B) The strength and dosage form of the product;  
1030  
1031 (C) The National Drug Code number of the product;  
1032  
1033 (D) The container size;  
1034  
1035 (E) The number of containers;  
1036  
1037 (F) The lot number of the product;  
1038  
1039 (G) The date of the transaction;  
1040  
1041 (H) The date of the shipment, if more than 24 hours after the date of the transaction;  
1042  
1043 (I) The business name and address of the person from whom ownership is being transferred; and  
1044  
1045 (J) The business name and address of the person to whom ownership is being transferred.  
1046  
1047 (c) "Transaction Statement," which is a statement, in paper or electronic form, that the entity  
1048 transferring ownership in a transaction is compliant with Food and Drug Administration (FDA)  
1049 regulations set forth by the Drug Quality and Security Act and includes but is not limited to:  
1050  
1051 (A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain  
1052 Security Act;  
1053  
1054 (B) Acknowledgement that product is received from an authorized or registered entity, as required  
1055 under the Drug Supply Chain Security Act;  
1056  
1057 (C) Confirmation of receipt of transaction information and of transaction statement from the prior  
1058 owner of the product, as required under the Drug Supply Chain Security Act;  
1059  
1060 (D) Verification that a suspect or illegitimate product was not knowingly shipped;  
1061  
1062 (E) Confirmation that systems and processes are in place to comply with verification requirements under  
1063 the Drug Supply Chain Security Act;  
1064

1065 (F) Confirmation that false transaction information was not knowingly provided; and  
1066  
1067 (G) Confirmation that transaction history was not knowingly altered.  
1068  
1069 (13) "Prescription Drug" means any drug required by law to be dispensed only by a prescription.  
1070  
1071 (14) "Quarantine" means the storage or identification of a product, to prevent distribution or transfer of  
1072 the product, in a physically separate area clearly identified for such use or through other procedures.  
1073  
1074 ~~(15) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to~~  
1075 ~~further the distribution of a prescription drug excluding that completed by the pharmacist responsible~~  
1076 ~~for dispensing the product to a patient.~~  
1077  
1078 ~~(16) "Repackager" means a person who owns or operates an establishment that repacks and relabels a~~  
1079 ~~product or package for:~~  
1080  
1081 ~~(a) Further sale; or~~  
1082  
1083 ~~(b) Distribution without a further transaction.~~  
1084  
1085 ~~(17)~~ 15 "Suspect Product" means a product for which there is reason to believe that such product is:  
1086  
1087 (a) Potentially counterfeit, diverted, or stolen;  
1088  
1089 (b) Potentially intentionally adulterated such that the product would result in serious adverse health  
1090 consequences or death to humans;  
1091  
1092 (c) Potentially the subject of a fraudulent transaction; or  
1093  
1094 (d) Otherwise unfit for distribution such that the product would result in serious adverse health  
1095 consequences or death.  
1096  
1097 ~~(18)~~ 16 "Trading Partner" means:  
1098  
1099 (a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer,  
1100 repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a  
1101 manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product;  
1102 or  
1103  
1104 (b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or  
1105 dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale  
1106 distributor, or dispenser transfers direct possession of a product.  
1107



1108 (~~1917~~) "Validate" means to verify that each transaction listed on the pedigree and other accompanying  
1109 documentation has occurred and is accurately recorded.  
1110  
1111 (~~2018~~) "Wholesale Distribution" means distribution of a drug to a person other than a consumer or  
1112 patient, but does not include:  
1113  
1114 (a) Delivery by a retail pharmacy of a prescription drug to a patient or patient's agent pursuant to the  
1115 lawful order of a licensed practitioner.  
1116  
1117 (b) The sale of minimal quantities of a prescription drug by retail or institutional pharmacies to licensed  
1118 practitioners for office use.  
1119  
1120 (c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug which may include:  
1121  
1122 (A) Emergency medical reasons;  
1123  
1124 (B) Drug or devices used during a federal or state declared emergency; or  
1125  
1126 (C) The transfer of a drug by a pharmacy to another pharmacy to alleviate a temporary shortage.  
1127  
1128 (d) Intra company transfer of drugs as defined in these rules.  
1129  
1130 (e) The lawful distribution of a drug sample by a manufacturer's or a distributor's representative.  
1131  
1132 (f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a non-profit  
1133 affiliate of the organization to the extent permitted by law.  
1134  
1135 (g) The purchase or acquisition of a drug by a hospital or other health care entity that is a member of a  
1136 group purchasing organization, for the hospital's or health care entity's own use, from the group  
1137 purchasing organization or from other hospitals or health care entities that are members of the  
1138 organization or under common control.  
1139  
1140 (h) The transfer of a prescription drug between pharmacies pursuant to a shared pharmacy service  
1141 agreement as defined in OAR 855-006-0005.  
1142  
1143 (i) The distribution by a manufacturer, as part of a prescription assistance program, of a drug intended  
1144 for a specific patient, to a person authorized to prescribe, administer or dispense prescription drugs.  
1145  
1146 (j) The sale, purchase, or trade of blood and blood components intended for transfusion.  
1147  
1148 (k) Drug returns, when conducted in accordance with state and federal laws and regulations. A drug  
1149 return includes the sale or transfer from a dispenser, retail pharmacy, or chain pharmacy warehouse of  
1150 expired, damaged, returned or recalled drugs to the original manufacturer, wholesale distributor, or to a  
1151 reverse wholesaler, and the returns of saleable drugs to the original manufacturer or wholesaler.

1152  
1153 (l) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with  
1154 another pharmacy.  
1155  
1156 (m) The distribution of drugs by a manufacturer registered under OAR 855-065 division ~~65~~ of this  
1157 chapter of rules of its own products to a person other than a patient.  
1158  
1159 (~~2119~~) "Wholesale Distributor" means any entity engaged in the wholesale distribution of drugs. The  
1160 term "Wholesale Distributor" includes but is not limited to, own-label distributors; private-label  
1161 distributors; warehouses, including manufacturers' and distributors' warehouses; drug wholesalers or  
1162 distributors; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses  
1163 that conduct wholesale distribution.  
1164  
1165 (~~2220~~) "Wholesaler" means any wholesale distributor:  
1166  
1167 (a) "Class I Wholesaler" for the purpose of these rules means any person operating or maintaining a  
1168 wholesale distribution center, wholesale business or any other business in which prescription drugs,  
1169 including controlled drugs, devices containing prescription drugs, medicinal chemicals, or poisons are  
1170 sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally  
1171 licensed drug outlets or persons and is required to comply with all pedigree requirements;  
1172  
1173 (b) "Class II Wholesaler" means any person operating or maintaining a wholesale distribution center,  
1174 wholesale business or any other business in which any non-prescription drugs are stored, or offered for  
1175 sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute,  
1176 dispense or administer.  
1177  
1178 (c) "Class III Wholesaler" means any person operating or maintaining a wholesale distribution center,  
1179 wholesale business or any other business in which any of the products in paragraphs (A)-(F) below are  
1180 stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized  
1181 to resell, distribute, dispense or administer and is exempted from Federal recordkeeping requirements:  
1182  
1183 (A) Drugs distributed exclusively for veterinary use. If any prescription drugs not intended for veterinary  
1184 use are offered for sale, the wholesaler must register as a Class I wholesaler;  
1185  
1186 (B) Prescription devices that do not contain a prescription drug;  
1187  
1188 (C) Drugs or devices possessed by a state or local government agency, or non-profit relief organization  
1189 approved by the bBoard;  
1190  
1191 (D) Oxygen USP and medical gases;  
1192  
1193 (E) Intravenous drugs; by which formulation, are intended for the replenishment of fluids, electrolytes or  
1194 calories;  
1195

1196 (F) Medical convenience kits which includes any non controlled drug product or biological product,  
1197 assembled in kit form.  
1198  
1199 Statutory/Other Authority: ORS 689.205  
1200 Statutes/Other Implemented: ORS 689.155

PROPOSED

**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.

2 Division 6  
3 DEFINITIONS

4  
5 **855-006-0005**

6 **Definitions**

7  
8 As used in OAR chapter 855:

9  
10 **(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).**

11  
12 ~~(12)~~ "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the  
13 context.

14  
15 ~~(23)~~ "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy  
16 who assists the pharmacist in the practice of pharmacy pursuant to rules of the ~~l~~Board and has  
17 completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for  
18 clerical duties, such as recordkeeping, cashing, bookkeeping and delivery of medications released by  
19 the pharmacist are not considered pharmacy technicians.

20  
21 ~~(34)~~ "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a  
22 health care organization or a physician that permits the pharmacist to engage in the practice of clinical  
23 pharmacy for the benefit of the patients of the health care organization or physician.

24  
25 ~~(45)~~ "Collaborative Drug Therapy Management" means the participation by a pharmacist in the  
26 management of drug therapy pursuant to a written protocol that includes information specific to the  
27 dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and  
28 initiated upon a prescription order for an individual patient and:

29  
30 (a) Is agreed to by one pharmacist and one practitioner; or

31  
32 (b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or  
33 more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group  
34 practice, including but not limited to organized medical groups using a pharmacy and therapeutics  
35 committee.

36  
37 ~~(56)~~ "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or  
38 device:

39  
40 (a) As the result of a practitioner's prescription drug order, or initiative based on the relationship  
41 between the practitioner, the pharmacist and the patient, in the course of professional practice; or

42  
43 (b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or  
44 dispensing; or

45

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

48  
49 ~~(67)~~ "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

50  
51 ~~(78)~~ "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient  
52 medication, therapy management, drug storage and management, security, education, or any other  
53 pharmaceutical service.

54  
55 ~~(89)~~ The "Container" is the device that holds the drug and that is or may be in direct contact with the  
56 drug.

57  
58 ~~(910)~~ "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a  
59 lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration  
60 to or use by a patient or other individual entitled to receive the prescription drug.

61  
62 ~~(1011)~~ "Interpretation and evaluation of prescription orders" means the review of the order for  
63 therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug  
64 ordered, its applicability and its relationship to the other known medications used by the patient and  
65 determination of whether or not the dose and time interval of administration are within accepted limits  
66 of safety. The legal review for correctness of the prescription order includes a determination that the  
67 order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose,  
68 contains all information required by federal and state law, and is within the practitioner's scope of  
69 practice.

70  
71 ~~(1112)~~ "Labeling" means the process of preparing and affixing of a label to any drug container exclusive,  
72 however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or  
73 commercially packaged legend drug or device.

74  
75 **(13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).**

76  
77 ~~(1214)~~ "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of  
78 the therapeutic or adverse effect of medication upon a patient, including direct consultation with the  
79 patient or his agent and review of patient records, as to result and side effect, and the analysis of  
80 possible interactions with other medications that may be in the medication regimen of the patient. This  
81 section shall **must** not be construed to prohibit monitoring by practitioners or their agents.

82  
83 ~~(1315)~~ "Medication Therapy Management (MTM)" means a distinct service or group of services that is  
84 intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management  
85 services are independent of, but can occur in conjunction with, the provision of a medication product.

86  
87 ~~(1416)~~ "Nationally Certified Exam" means an exam that is approved by the **b**Board which demonstrates  
88 successful completion of a Specialized Education Program. The exam must be reliable, psychometrically  
89 sound, legally defensible and valid.

90  
91 (~~1517~~) "Non-legend drug" means a drug which does not require dispensing by prescription and which is  
92 not restricted to use by practitioners only.

93  
94 (~~1618~~) "Offering or performing of those acts, services, operations or transactions necessary in the  
95 conduct, operation, management and control of pharmacy" means, among other things:

- 96  
97 (a) The creation and retention of accurate and complete patient records;  
98  
99 (b) Assuming authority and responsibility for product selection of drugs and devices;  
100  
101 (c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the  
102 general public;  
103  
104 (d) Maintaining confidentiality of patient information.

105  
106 **(19) "Official compendium" means the official United States Pharmacopeia <USP>, official National**  
107 **Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States**  
108 **<HPUS> (v.2021), or any supplement to any of these.**

109  
110 (~~1720~~) "Oral Counseling" means an oral communication process between a pharmacist and a patient or  
111 a patient's agent in which the pharmacist obtains information from the patient (or agent) and the  
112 patient's pharmacy records, assesses that information and provides the patient (or agent) with  
113 professional advice regarding the safe and effective use of the prescription drug for the purpose of  
114 assuring therapeutic appropriateness.

115  
116 (~~1821~~) Participation in Drug Selection and Drug Utilization Review:

117  
118 (a) "Participation in drug selection" means the consultation with the practitioner in the selection of the  
119 best possible drug for a particular patient.

120  
121 (b) "Drug utilization review" means evaluating prescription drug order in light of the information  
122 currently provided to the pharmacist by the patient or the patient's agent and in light of the information  
123 contained in the patient's record for the purpose of promoting therapeutic appropriateness by  
124 identifying potential problems and consulting with the prescriber, when appropriate. Problems subject  
125 to identification during drug utilization review include, but are not limited to:

- 126  
127 (A) Over-utilization or under-utilization;  
128  
129 (B) Therapeutic duplication;  
130  
131 (C) Drug-disease contraindications;  
132  
133 (D) Drug-drug interactions;

- 134  
135 (E) Incorrect drug dosage;  
136  
137 (F) Incorrect duration of treatment;  
138  
139 (G) Drug-allergy interactions; and  
140  
141 (H) Clinical drug abuse or misuse.  
142

143 (~~1922~~) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of  
144 achieving definite outcomes that improve a patient's quality of life. These outcomes include:

- 145  
146 (a) Cure of a disease;  
147  
148 (b) Elimination or reduction of a patient's symptomatology;  
149  
150 (c) Arrest or slowing of a disease process; or  
151  
152 (d) Prevention of a disease or symptomatology.  
153

154 (~~2023~~) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the  
155 pharmacist in the practice of pharmacy pursuant to rules of the ~~h~~Board but has not completed the  
156 specialized education program pursuant to OAR 855-025-0012.

157  
158 (~~2124~~) "Practice of clinical pharmacy" means:

- 159  
160 (a) The health science discipline in which, in conjunction with the patient's other practitioners, a  
161 pharmacist provides patient care to optimize medication therapy and to promote disease prevention  
162 and the patient's health and wellness;  
163  
164 (b) The provision of patient care services, including but not limited to post-diagnostic disease state  
165 management services; and  
166  
167 (c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.  
168

169 (~~2225~~) "Practice of pharmacy" is as defined in ORS 689.005.  
170

171 (~~2326~~) "Prescription released by the pharmacist" means, a prescription which has been reviewed by the  
172 pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.  
173

174 (~~2427~~) "Prohibited conduct" means conduct by a licensee that:

- 175  
176 (a) Constitutes a criminal act against a patient or client; or  
177



178 (b) Constitutes a criminal act that creates a risk of harm to a patient or client.  
179  
180 ~~(2528)~~ "Proper and safe storage of drugs and devices and maintenance of proper records therefore"  
181 means housing drugs and devices under conditions and circumstances that:  
182  
183 (a) Assure retention of their purity and potency;  
184  
185 (b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;  
186  
187 (c) Assure security and minimize the risk of their loss through accident or theft;  
188  
189 (d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;  
190  
191 (e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from  
192 harmful exposure to hazardous substances.  
193  
194 ~~(2629)~~ "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned  
195 and systematic process for the monitoring and evaluation of the quality and appropriateness of  
196 pharmacy services and for identifying and resolving problems.  
197  
198 ~~(2730)~~ "Responsibility for advising, when necessary or when regulated, of therapeutic values, content,  
199 hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing  
200 as required by these rules or federal regulation, of the possible therapeutic response to the medication,  
201 the names of the chemicals in the medication, the possible side effects of major importance, and the  
202 methods of use or administration of a medication.  
203  
204 ~~(2831)~~ "Specialized Education Program" means;  
205  
206 (a) A program providing education for persons desiring licensure as pharmacy technicians that is  
207 approved by the board and offered by an accredited college or university that grants a two-year degree  
208 upon successful completion of the program; or  
209  
210 (b) A structured program approved by the board and designed to educate pharmacy technicians in one  
211 or more specific issues of patient health and safety that is offered by:  
212  
213 (A) An organization recognized by the board as representing pharmacists or pharmacy technicians;  
214  
215 (B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or  
216  
217 (C) A trade association recognized by the board as representing pharmacies.  
218  
219 ~~(29)~~ "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy  
220 technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control  
221 and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action.

222 During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic,  
223 "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being  
224 supervised, coupled with the ability to control and be responsible for the technician or interns actions  
225 and for the following remote processing functions only: prescription or order entry, other data entry,  
226 and insurance processing of prescriptions and medication orders.  
227

228 (3032) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical  
229 structure for the drug product prescribed under circumstances where the prescriber has not given clear  
230 and conscious direction for substitution of the particular drug for the one which may later be ordered.  
231

232 (3133) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy  
233 and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a  
234 certified Oregon pharmacy technician.  
235

236 Statutory/Other Authority: ORS 689.205

237 Statutes/Other Implemented: ORS 689.151 & ORS 689.155

238 Division 7  
239 PUBLIC HEALTH EMERGENCY

240  
241 **855-007-0120**

242 **Damage to a Pharmacy and Drug Integrity**

243  
244 (1) If a pharmacy prescription department sustains damage, whether by flood or otherwise, the entire  
245 drug inventory, including any prescriptions that are awaiting pickup, is unfit for dispensing, ~~shall~~**must** be  
246 classified as adulterated and must be destroyed unless, ~~in the pharmacist's professional judgment, any~~  
247 ~~items are~~ **the drugs are** deemed safe for dispensing **pursuant to OAR 855-041-1036**. Any incident of this  
248 nature must be reported to the ~~b~~**B**oard within three working days.

249  
250 (2) If a pharmacy loses power that affects temperature or humidity controls such that ~~USP standards for~~  
251 ~~the~~ proper storage of drugs **pursuant to OAR 855-041-1036** ~~has~~**ve** been violated, such drugs ~~shall~~**must**  
252 be classified as adulterated and may not be dispensed.

253  
254 NOTE: for those drugs labeled for storage at "controlled room temperature," the acceptable range of  
255 temperature is 68° to 77°F with allowances for brief deviations between 59° to 86°F.

256  
257 (3) Controlled substances damaged, lost or stolen ~~shall~~**must** be documented and reported to the DEA  
258 and the ~~b~~**B**oard on DEA Form 41 or DEA Form 106 as appropriate.

259  
260 (4) A pharmacy that is required to temporarily close or relocate due to an emergency must report this  
261 event to the ~~b~~**B**oard within three working days.

262  
263 Statutory/Other Authority: ORS 689.205  
264 Statutes/Other Implemented: ORS 689.155

265 Division 41  
266 OPERATION OF PHARMACIES (~~AMBULATORY AND RESIDENTIAL DRUG OUTLETS~~)

267  
268 **855-041-1001**

269 **Definitions**  
270

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

275  
276 (2) "Biosimilar product" means a biological product licensed by the United States Food and Drug  
277 Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i) (v. XX/XX/XXXX).

278  
279 (3) "Drug room" is a drug storage area registered with the ~~b~~Board which is secure and lockable.

280  
281 (4) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug  
282 Administration has determined that a biosimilar product meets the safety standards set forth in 42  
283 U.S.C. 262(k)(4) (v. XX/XX/XXXX).

284  
285 (5) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) (v.  
286 XX/XX/XXXX) against which a biological product is evaluated in an application submitted to the United  
287 States Food and Drug Administration for licensure of a biological product as a biosimilar product or for  
288 determination that a biosimilar product is interchangeable.

289  
290 **(6) "Repackage" means the act of taking a drug from the container in which it was distributed by the**  
291 **manufacturer and placing it into a different container in which it was distributed by the**

292  
293 **Statutory/Other Authority:** ORS 689.205 & 689.522  
294 **Statutes/Other Implemented:** ORS 689.155 & 342 & ORS 689.522

295  
296  
297  
298 **855-041-1035**

299 **Minimum Equipment Requirements**

300  
301 **(1) Each** retail drug outlet and institutional drug outlet **must have** the following:

302  
303 ~~(1a) The most **Appropriate and** current issue of at least one pharmaceutical references with current,~~  
304 ~~properly filed supplements **(e.g. pharmacology, injectables, and veterinary drugs)** and updates~~  
305 ~~appropriate to and based on the standards of practice for the setting. **services offered by the outlet;**~~

306  
307 ~~(2b) **Appropriate and** current and properly filed Oregon Revised Statutes, Chapters 689, and 475;~~  
308 ~~current and properly filed Oregon Administrative Rules, chapter 855, **United States Code, Code of**~~  
309 ~~**Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the**~~  
310 ~~**outlet** and a minimum of three years of the Board of Pharmacy quarterly newsletters maintained in~~  
311 ~~house or other readily retrievable means;~~

312  
313 ~~(3) Official Poison and Exempt Narcotic Register if poisons and exempt narcotics are sold or distributed.~~

314  
315 **(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLeX, OHA ALERT-IIS) based on**  
316 **the services offered by the outlet;**

317  
318 ~~(4d) Suitable refrigeration.~~ **Appropriate equipment to maintain the proper storage of drugs;**

319  
320 **(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon**  
321 **Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by**  
322 **reference (e.g. USP) based on services offered by the outlet;**

323  
324 ~~(5f) A sink with running hot and cold water.;~~

325  
326 **(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:**

327  
328 **(A) Stating “This pharmacy may be able to substitute a less expensive drug which is therapeutically**  
329 **equivalent to the one prescribed by your doctor unless you do not approve.” The printing on this sign**  
330 **must be in block letters not less than one inch in height.**

331  
332 **(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free,**  
333 **competent oral interpretation and translation services, including translated prescription labels, for**  
334 **patients who are of limited English proficiency, in compliance with federal and state regulations if the**  
335 **pharmacy dispenses prescriptions for a patient's self-administration;**

336  
337 **(C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's**  
338 **operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up**  
339 **pharmacy per OAR 855-041-2100; and**

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

343  
344 ~~(6h) Additional equipment and supplies appropriate to and based on the standards of practice for the~~  
345 ~~setting as that are determined as necessary by the Pharmacy and or Pharmacist-in-Charge.~~

346  
347 ~~(7) Failure to have, and use **and maintain required** equipment necessary to your practice setting~~  
348 ~~constitutes unprofessional conduct for purposes of under ORS 689.405(1)(a).;~~

349  
350 ~~(8) If an outlet files original prescriptions electronically, then the outlet must have a computer and~~  
351 ~~software capable of storing and accessing electronically filed original prescriptions.~~

352  
353 ~~(9) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to~~  
354 ~~provide notification of the right to free, competent oral interpretation and translation services for~~  
355 ~~patients who are of limited English proficiency, in compliance with federal and state regulations.~~

356  
357 Statutory/Other Authority: ORS 689.205

358 Statutes/Other Implemented: ORS 689.508, & ORS 689.155, **ORS 689.515, ORS 689.564 & ORS 689.686**

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**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

403 **855-041-1080**

404 **Pharmacy Registration (Both Retail and Institutional Drug Outlets)**

405

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

407

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

410

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

415

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

418

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

422

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

425

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

428

429 (6) A certificate of registration will be issued upon ~~b~~Board approval of the application.

430

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

433

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

436

437 **(9)** Pharmacy registration expires March 31, annually. If the annual registration fee referred to in **OAR**  
438 **855-110**~~division 110 of this Chapter~~ is not paid by March 31 of the current year, a ~~delinquent~~late fee as  
439 set out in **OAR 855-110**~~division 110 of this Chapter~~ ~~shall~~must be included with the application for  
440 registration renewal.

441

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

443

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

446

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

449  
450 (13) Applicants for change in ownership ~~shall~~must provide the ~~b~~BBoard with the information required in  
451 sections (3), (4), and (5) of this rule.

452  
453 (14) A change of ownership ~~shall~~must be reported to the ~~b~~BBoard ~~within 15 days of the~~prior to  
454 occurrence.

455  
456 (15) No pharmacy ~~shall~~must be operated until a certificate of registration has been issued to the  
457 pharmacy by the ~~b~~BBoard.

458  
459 Statutory/Other Authority: ORS 475.035 & 689.205  
460 Statutes/Other Implemented: ORS 689.155

461

462

463

464 **855-041-1130**

465 **Retail Drug Outlet Pharmacy Prescription Labeling**

466

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

468

469 (a1) Name, address and telephone number of the pharmacy;

470

471 (b2) Date of fill

472

473 (c3) Identifying number;

474

475 (d4) Name of patient;

476

477 (e5) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also  
478 contain the identifier of the manufacturer or distributor;

479

480 (f6) Directions for use by the patient;

481

482 (g7) Name of practitioner;

483

484 (h8) Required precautionary information regarding controlled substances;

485

486 (i9) Such other and further accessory cautionary information as required for patient safety;

487

488 (j10) An expiration date after which the patient should not use the drug or medicine. Expiration dates on  
489 prescriptions must be the same as that on the original container or one year from the date the drug  
490 was originally dispensed and placed in the new container, whichever date is earlier unless, in the  
491 pharmacist's professional judgment, a shorter expiration date is warranted. Any drug expiring before the  
492 expected length of time for course of therapy ends must not be dispensed. ~~bearing an expiration date~~  
493 ~~shall not be dispensed beyond the said expiration date of the drug; and~~



494  
495 (~~k~~**11**) Any dispensed prescription medication, other than those in unit dose or unit of use packaging,  
496 ~~shall~~**must** be labeled with its physical description, including any identification code that may appear on  
497 tablets and capsules.

498  
499 (~~l~~) Upon written request and for good cause, the Board may waive any of the requirements of this rule.  
500 A waiver granted under this section shall only be effective when it is issued by the Board in writing.

501  
502 Statutory/Other Authority: ORS 689.205  
503 Statutes/Other Implemented: ORS 689.505 & ORS 689.515

504  
505  
506  
507 **855-041-1135**

508 **Defines Labeling and Container Requirements for Repackaged Drugs**

509  
510 **(1) Each pharmacy record keeping system must identify all pharmacy personnel involved in**  
511 **repackaging including the pharmacist who verified the repackaged drug.**

512  
513 (~~12~~) **A single oral solid drug** products repackaged by a pharmacy **into unit-dose packaging** for later  
514 own use dispensing on prescription shall must:

515  
516 (a) **Utilize a unit-dose container-closure system that meets the testing requirements under USP <671>**  
517 **Containers—Performance Testing (12/01/2020) for either Class A or Class B containers and meets or**  
518 **exceeds the original container's specification for light resistance;** in a container meeting USP standards  
519 and labeled to identify at a minimum:

520  
521 (b) Be labeled to identify at a minimum:

522  
523 (~~a~~**A**) Brand name, or generic name and manufacturer;

524  
525 (~~b~~**B**) Strength;

526  
527 (~~c~~**C**) **Manufacturer and lot number or an internal pharmacy code that references manufacturer and**  
528 **lot number; and**

529  
530 (~~d~~**D**) **Manufacturer's expiration date, or any earlier date which, in the pharmacist's professional**  
531 **judgment, is preferable. Expiration date. The expiration date used for the repackaged product must**  
532 **not exceed:**

533  
534 **(i) 6 months from the date of repackaging; or**

535  
536 **(ii) The manufacturer's expiration date; or**

537  
538 **(iii) 25% of the time between the date of repackaging and the expiration date shown on the**  
539 **manufacturer's bulk article container of the drug being repackaged, whichever is earlier.**

540  
541 **(3) A single oral solid drug product repackaged by a pharmacy into multiple-unit packaging must:**

542  
543 **(a) Utilize an equivalent container–closure system that is at least as protective as, or more protective**  
544 **than, the original system, complies with criteria established for equivalency and meets or exceeds the**  
545 **original container's specification for light resistance;**

546  
547 **(b) Be labeled to identify at a minimum:**

548  
549 **(A) Brand name or generic name;**

550  
551 **(B) Strength;**

552  
553 **(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot**  
554 **number; and**

555  
556 **(D) Expiration date. The expiration date used for the repackaged product must not exceed the**  
557 **manufacturer's expiration date or one year from the date the drug was placed in the new container,**  
558 **whichever date is earlier.**

559  
560 (2) An internal control number which references manufacturer and lot number may be utilized.

561  
562 Statutory/Other Authority: ORS 689.**205**

563 Statutes/Other Implemented: **ORS 689.155**

564  
565 **855-041-1145**

566 **New Containers**

567  
568 **In** filling the original prescriptions, nothing but **Each pharmacy must dispense a drug in a new**  
569 **containers may be used. A patient's original container may be refilled if clean and the label is legible and**  
570 **up to date. The container shall that complies with the current provisions of the Federal Consumer**  
571 **Poison Prevention Packaging Act in 16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX), and 16 CFR**  
572 **1702 (XX/XX/XXXX) and rules or regulations adopted thereunder. It must also conform with the current**  
573 **United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and**  
574 **labeling.**

575  
576 [Publications: Publications referenced are available from the agency.]

577  
578 Statutory/Other Authority: ORS 689.**205**

579 **Statutes/Other Implemented: ORS 689.155**

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588 **855-041-6270**

589 **Institutional Drug Outlet Pharmacy Prescription Labeling**

590

591 (1) Each pharmacy record keeping system must identify **all pharmacy personnel involved in the**  
592 **repackaging** and document **including** the pharmacist who verified ~~ds~~ the **repackaged** drug.

593

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

597

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

599

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

602

603 (c) The strength of the drug.

604

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

607

608 (a) Name and location of patient;

609

610 (b) Name and strength of drug;

611

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

613

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

615

616 (e) Auxiliary labels as needed, and

617

618 (f) Expiration date.

619

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

623

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

626

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

630

631 (~~76~~) Whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the  
632 admixture must be labeled with a distinctive supplementary label that ~~contains~~ includes the

633

634 (a) ~~The n~~Name, quantity and concentration of the drug added and the primary solution;

635

636 (b) ~~The d~~Date and time of addition;

637

638 (c) ~~The e~~Expiration date;

639

640 (d) ~~The s~~Scheduled time for administration;

641

642 (e) ~~The i~~Infusion rate, when applicable;

643

644 (f) ~~The n~~Name or initials of person performing admixture;

645

646 (g) ~~The i~~Identification of the pharmacy where the admixture was performed; and

647

648 (h) ~~The n~~Name or initials of the verifying pharmacist.

649

650 (~~87~~) The label applied at a secondary storage or remote storage area by a nurse or physician must  
651 include: the patient name or patient identifier, quantity and concentration of the drug added and the  
652 primary IV solution; the date and time of addition and the initials of the nurse or physician adding the  
653 drug.

654

655 Statutory/Other Authority: ORS 689.205

656 Statutes/Other Implemented: ORS 689.155 & ORS 689.505

657 Division 45  
658 DRUG COMPOUNDING

660 **855-045-0200**

661 **Application**

662

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

666

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

668

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

671

672 **(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (USP <795> 05/01/2020 v.**  
673 **2014);**

674

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

677

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

679

680 **(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging**  
681 **(12/01/2020 v. 2020); and**

682

683 **(e) as well as all Chapters of USP and USP-NF related to the compounding practices at any location. This**  
684 **includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),**  
685 **151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731**  
686 **(11/01/2020), 821 (05/01/2017), 823 (2013), 825, 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151**  
687 **(05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211**  
688 **(03/01/2019), and 1229.5 (08/01/2016), 1231 (08/01/2018), and 1821 (05/01/2017).**

689

690 Statutory/Other Authority: ORS 689.205

691 Statutes/Other Implemented: ORS 689.155

692

693

694

695 **855-045-0220**

696 **Personnel and Responsibilities**

697

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

700

701 (2) The Pharmacist-in-Charge (PIC) and the drug outlet shall **must** establish, maintain and enforce policies  
702 and procedures in accordance with the standards **required** in **OAR 855-045-0200(3)** ~~USP Chapters~~ for all  
703 aspects of the compounding operation according to the type of compounding performed and shall **must**  
704 include written procedures for:

705

706 (a) Personnel qualifications, to include training, evaluation and requalification;

707

708 (b) Hand hygiene;

709

710 (c) Garbing;

711

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

714

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

717

718 (f) Components, to include selection, handling, and storage;

719

720 (g) Creating master formulation records, with documented pharmacist approval;

721

722 (h) Creating compounding records;

723

724 (i) Establishing beyond-use dates (BUDs);

725

726 (j) Continuous quality assurance program and quality controls, to include release testing, end-product  
727 evaluation, and quantitative/qualitative testing;

728

729 (k) Completed compounded preparations, to include handling, packaging, storage and transport;

730

731 (l) Adverse event reporting process and recall procedure. The recall procedure must include notification  
732 to the **b**Board within 10 working days in the event of a patient-level recall of a compounded drug.

733

734 Statutory/Other Authority: ORS 689.205

735 Statutes/Other Implemented: ORS 689.155

736

737

738

739 **855-045-0240**

740 **Labeling of Compounded Drugs**

741

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

744

- 745 (1) The generic or official name of each active ingredient;  
746  
747 (2) The strength or concentration of each active ingredient, to include primary solution for a sterile  
748 parenteral preparation;  
749  
750 (3) The dosage form and route of administration;  
751  
752 (4) Rate of infusion, for a sterile parenteral preparation;  
753  
754 (5) The total quantity of the drug product;  
755  
756 (6) A **beyond-use date (BUD)**, compliant with ~~current USP standards~~ **required** in **OAR 855-045-0200(3)**;  
757 and  
758  
759 (7) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or  
760 appropriate for proper use and patient safety.  
761  
762 Statutory/Other Authority: ORS 689.205  
763 Statutes/Other Implemented: ORS 689.155  
764  
765

766 Division 65  
767 WHOLESale DRUG OUTLETS

768  
769 **855-065-0005**

770 **Definitions**

771

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

774

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

776

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

778

779 (2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has  
780 established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing  
781 relationship is deemed to exist between such wholesale distributor and a manufacturer when the  
782 wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section  
783 1504 of the Internal Revenue Code, complies with either or both of the following:

784

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

787

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

790

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

793

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

797

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

801

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

805

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

809



810 (8) "Drug Sample" means a unit of a drug that is intended to promote the sale of the drug, but which is  
811 not itself for sale.  
812

813 (9) "Illegitimate Product" means a product for which credible evidence shows that the product is:  
814  
815 (a) Counterfeit, diverted, or stolen;  
816  
817 (b) Intentionally adulterated such that the product would result in serious adverse health consequences  
818 or death to humans;  
819  
820 (c) The subject of a fraudulent transaction; or  
821  
822 (d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious  
823 adverse health consequences or death.  
824

825 (10) "Intra Company Transfer" means the transfer of any drug between a division, subsidiary, parent,  
826 and an affiliated or related company under the common ownership and control of a corporate entity.  
827

828 (11) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is  
829 engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging,  
830 or labeling of a drug, except when the process is part of a shared pharmacy service agreement as  
831 defined in OAR 855-006-0005.  
832

833 (12) "Pedigree" for the purpose of this Division consists of:  
834  
835 (a) "Transaction History," which means a statement in paper or electronic form, including the  
836 transaction information for each prior transaction going back to the manufacturer of the product.  
837  
838 (b) "Transaction Information," which must include, but is not limited to:  
839  
840 (A) The proprietary or established name or names of the product;  
841  
842 (B) The strength and dosage form of the product;  
843  
844 (C) The National Drug Code number of the product;  
845  
846 (D) The container size;  
847  
848 (E) The number of containers;  
849  
850 (F) The lot number of the product;  
851  
852 (G) The date of the transaction;  
853

- 854 (H) The date of the shipment, if more than 24 hours after the date of the transaction;  
855
- 856 (I) The business name and address of the person from whom ownership is being transferred; and  
857
- 858 (J) The business name and address of the person to whom ownership is being transferred.  
859
- 860 (c) "Transaction Statement," which is a statement, in paper or electronic form, that the entity  
861 transferring ownership in a transaction is compliant with Food and Drug Administration (FDA)  
862 regulations set forth by the Drug Quality and Security Act and includes but is not limited to:  
863
- 864 (A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain  
865 Security Act;  
866
- 867 (B) Acknowledgement that product is received from an authorized or registered entity, as required  
868 under the Drug Supply Chain Security Act;  
869
- 870 (C) Confirmation of receipt of transaction information and of transaction statement from the prior  
871 owner of the product, as required under the Drug Supply Chain Security Act;  
872
- 873 (D) Verification that a suspect or illegitimate product was not knowingly shipped;  
874
- 875 (E) Confirmation that systems and processes are in place to comply with verification requirements under  
876 the Drug Supply Chain Security Act;  
877
- 878 (F) Confirmation that false transaction information was not knowingly provided; and  
879
- 880 (G) Confirmation that transaction history was not knowingly altered.  
881
- 882 (13) "Prescription Drug" means any drug required by law to be dispensed only by a prescription.  
883
- 884 (14) "Quarantine" means the storage or identification of a product, to prevent distribution or transfer of  
885 the product, in a physically separate area clearly identified for such use or through other procedures.  
886
- 887 ~~(15) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to  
888 further the distribution of a prescription drug excluding that completed by the pharmacist responsible  
889 for dispensing the product to a patient.~~
- 890
- 891 ~~(16) "Repackager" means a person who owns or operates an establishment that repacks and relabels a  
892 product or package for:~~
- 893
- 894 ~~(a) Further sale; or~~
- 895
- 896 ~~(b) Distribution without a further transaction.~~  
897

898 ~~(1715)~~ "Suspect Product" means a product for which there is reason to believe that such product is:

899

900 (a) Potentially counterfeit, diverted, or stolen;

901

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

904

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

906

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

909

910 ~~(1816)~~ "Trading Partner" means:

911

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

916

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

920

921 ~~(1917)~~ "Validate" means to verify that each transaction listed on the pedigree and other accompanying  
922 documentation has occurred and is accurately recorded.

923

924 ~~(2018)~~ "Wholesale Distribution" means distribution of a drug to a person other than a consumer or  
925 patient, but does not include:

926

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

929

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

932

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

934

935 (A) Emergency medical reasons;

936

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

938

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

940

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

- 942
- 943 (e) The lawful distribution of a drug sample by a manufacturer's or a distributor's representative.
- 944
- 945 (f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a non-profit
- 946 affiliate of the organization to the extent permitted by law.
- 947
- 948 (g) The purchase or acquisition of a drug by a hospital or other health care entity that is a member of a
- 949 group purchasing organization, for the hospital's or health care entity's own use, from the group
- 950 purchasing organization or from other hospitals or health care entities that are members of the
- 951 organization or under common control.
- 952
- 953 (h) The transfer of a prescription drug between pharmacies pursuant to a shared pharmacy service
- 954 agreement as defined in OAR 855-006-0005.
- 955
- 956 (i) The distribution by a manufacturer, as part of a prescription assistance program, of a drug intended
- 957 for a specific patient, to a person authorized to prescribe, administer or dispense prescription drugs.
- 958
- 959 (j) The sale, purchase, or trade of blood and blood components intended for transfusion.
- 960
- 961 (k) Drug returns, when conducted in accordance with state and federal laws and regulations. A drug
- 962 return includes the sale or transfer from a dispenser, retail pharmacy, or chain pharmacy warehouse of
- 963 expired, damaged, returned or recalled drugs to the original manufacturer, wholesale distributor, or to a
- 964 reverse wholesaler, and the returns of saleable drugs to the original manufacturer or wholesaler.
- 965
- 966 (l) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with
- 967 another pharmacy.
- 968
- 969 (m) The distribution of drugs by a manufacturer registered under OAR 855-065 division ~~65~~ of this
- 970 chapter of rules of its own products to a person other than a patient.
- 971
- 972 (~~21~~19) "Wholesale Distributor" means any entity engaged in the wholesale distribution of drugs. The
- 973 term "Wholesale Distributor" includes but is not limited to, own-label distributors; private-label
- 974 distributors; warehouses, including manufacturers' and distributors' warehouses; drug wholesalers or
- 975 distributors; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses
- 976 that conduct wholesale distribution.
- 977
- 978 (~~22~~20) "Wholesaler" means any wholesale distributor:
- 979
- 980 (a) "Class I Wholesaler" for the purpose of these rules means any person operating or maintaining a
- 981 wholesale distribution center, wholesale business or any other business in which prescription drugs,
- 982 including controlled drugs, devices containing prescription drugs, medicinal chemicals, or poisons are
- 983 sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally
- 984 licensed drug outlets or persons and is required to comply with all pedigree requirements;
- 985

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

990

991 (c) "Class III Wholesaler" means any person operating or maintaining a wholesale distribution center,  
992 wholesale business or any other business in which any of the products in paragraphs (A)-(F) below are  
993 stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized  
994 to resell, distribute, dispense or administer and is exempted from Federal recordkeeping requirements:  
995

996

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

998

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

1000

1001 (C) Drugs or devices possessed by a state or local government agency, or non-profit relief organization  
1002 approved by the bBoard;

1003

1004 (D) Oxygen USP and medical gases;

1005

1006 (E) Intravenous drugs; by which formulation, are intended for the replenishment of fluids, electrolytes or  
1007 calories;

1008

1009 (F) Medical convenience kits which includes any non controlled drug product or biological product,  
1010 assembled in kit form.

1011

1012 Statutory/Other Authority: ORS 689.205

1013 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.

1 Division 10  
2 BOARD ADMINISTRATION AND POLICIES

3  
4 **855-010-0001**

5 **Definitions**

6  
7 (1) "Accredited": In these rules, accredited shall mean a school or college that is currently accredited by  
8 the Accreditation Council for Pharmacy Education (ACPE) or that is in a pre-candidate or candidate  
9 status with ACPE.

10  
11 (2) "Board" means Oregon State Board of Pharmacy.

12  
13 Statutory/Other Authority: ORS 475.005 & 689.205  
14 Statutes/Other Implemented: ORS 689.115

15  
16  
17 **855-010-0005**  
18 **Meetings**

19  
20 (1) The ~~B~~board meetings ~~shall~~**must** be held not less than once every three months as designated by the  
21 ~~B~~board.

22  
23 (2) The President of the ~~B~~board ~~shall~~**must** have power to call special meetings, subject to ORS 689.185,  
24 when it may be deemed necessary or upon request of a majority of members.

25  
26 (3) The ~~B~~board ~~shall~~**must** hold an annual meeting each year for the election of officers, the  
27 reorganization of the ~~B~~board and the transaction of other business, which may include but is not limited  
28 to:

29  
30 (a) Approval of **providers of continuing pharmacy education accredited by the** Accreditation Council for  
31 Pharmacy Education (ACPE) programs;

32  
33 (b) Approval of preceptor sites;

34  
35 (be) Approval of ACPE-accredited schools and colleges of pharmacy **accredited, accredited with**  
36 **probation, pre-candidate or candidate status by ACPE;**

37  
38 (ce) Review and adopt **standards** by reference the Federal list of controlled substances.

39  
40 Statutory/Other Authority: ORS 689.205  
41 Statutes/Other Implemented: ORS 689.135, **ORS** 689.151, **ORS** 689.185 & **ORS** 689.255

42  
43  
44 **855-010-0015**  
45 **Individual Commitments**

46  
47 (1) Board members ~~shall~~**must** be governed by ~~B~~board action and ~~shall~~**must** make no individual  
48 commitments or promises on matters of ~~B~~board policies.

49  
50 (2) No declaration ~~shall~~**must** be made nor vote taken on any question, except at ~~B~~board meetings.  
51 ~~However, after due notification to each Board member, emergency votes may be taken by telephone~~  
52 ~~conference or mail ballot of a majority of Board members, such vote to be confirmed at the next Board~~  
53 ~~meeting.~~

54  
55 Statutory/Other Authority: ORS 689; **ORS 183**  
56 **Statutes/Other Implemented: ORS 183**

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**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** Advisory ~~e~~Committee is considered engaged in the performance of official duties when:

(a) The activity furthers the ~~B~~board's mission, such as attending a board meeting;

(b) Engaged in an activity at the request of the board chair or authorized by a vote of the board in advance of the activity; or

(c) Attending an **authorized** meeting ~~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 e**Committee 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 294.495, ORS 689.175, ORS 689.645, & 2017 OL Ch. 106~~ **ORS 689.649 & ORS 171.072**



104 **855-010-0021**  
105 **Adoption by Reference**

107 **(1) The board adopts standards and other publications by reference, as necessary, through**  
108 **administrative rule. When a matter is included in a referenced publication that is in conflict with**  
109 **Oregon Revised Statutes or Oregon Administrative Rules, the statute or rule applies and the standard**  
110 **provision does not. All remaining parts or application of the standard remain in effect.**

111  
112 **(2) All outside standards, statutes, rules and publications referred to in any rules adopted by the Bboard**  
113 **are by those references made a part of those rules as though fully set forth. Copies are available for**  
114 **inspection** in the office of the Board of Pharmacy.

115  
116 Statutory/Other Authority: ORS 689.**205**  
117 **Statutes/Other Implemented: ORS 689.205**

118  
119  
120 **855-010-0035**  
121 **Board Compliance Program**

122  
123 The Bboard's Compliance Director and Pharmacy Inspectors **Compliance Officers** shall ~~shall~~ **must** be  
124 pharmacists licensed in the State of Oregon.

125  
126 Statutory/Other Authority: ORS 689.**205**  
127 **Statutes/Other Implemented: ORS 689.195**

128  
129  
130 **855-010-0100**  
131 **State and Nationwide Criminal Background Checks for Licensure**

132  
133 (1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure;  
134 directors, officers and designated representatives of drug outlets applying for registration; and  
135 individuals subject to investigation by the Bboard, in order to determine if they have a history of  
136 criminal behavior such that they are not fit to be granted or retain a license or registration issued by the  
137 **Bboard**.

138  
139 (2) "Subject individual" means a person from whom the Bboard may require legible fingerprints for the  
140 purpose of a state or nationwide criminal records check and fitness determination. In this rule, subject  
141 individual means: applicants for licensure or renewal of a license; directors, officers and designated  
142 representatives of drug outlets applying for registration or renewal of a registration; and individuals  
143 subject to an investigation by the Bboard.

144  
145 (3) Criminal records checks and fitness determinations are conducted according to ORS 181A.170, **ORS**  
146 **181A.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205**  
147 **ORS 181A.210, ~~to~~ ORS 181A.215, ORS 670.280, ORS 676.303, and OAR 125-007-0200, OAR 125-007-**  
148 **0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-**  
149 **0300, ~~to~~ OAR 125-007-0310, and OAR 125-007-0330.**

150

151 (a) The Bboard will request that the Oregon Department of State Police conduct a state and nationwide  
152 criminal records check, using fingerprint identification of subject individuals. The Bboard may conduct  
153 state criminal records checks on subject individuals and any licensee through the Law Enforcement Data  
154 System maintained by the Oregon Department of State Police in accordance with rules adopted, and  
155 procedures established, by the Oregon Department of State Police. Criminal history information  
156 obtained from the Law Enforcement Data System must be handled in accordance with ORS Chapter  
157 181A, OAR 257-010 ~~to~~ and OAR 257-015 and applicable Oregon Department of State Police procedures.

158  
159 (b) The applicant or licensee must disclose all arrests, charges, and convictions regardless of the  
160 outcome or date of occurrence. Disclosure includes any military or criminal records.

161  
162 (c) The Bboard may require additional information from the applicant or licensee, such as, but not  
163 limited to, proof of identity, previous names, residential history or additional criminal, judicial or other  
164 background information.

165  
166 (4) In making licensing fitness determinations subject to the requirements of ORS 670.280, the Bboard  
167 will consider the following:

168  
169 (a) The nature of any criminal record that reflects:

170  
171 (A) Drug or alcohol offense;

172  
173 (B) Felony;

174  
175 (C) Misdemeanor;

176  
177 (D) U.S. military or international crime;

178  
179 (E) Offense involving fraud, theft, identity theft or other instance of dishonesty;

180  
181 (F) Offense involving violation of federal importation or customs laws or rules;

182  
183 (G) Offense requiring registration as a sex offender;

184  
185 (H) Condition of parole, probation, or diversion program, or

186  
187 (I) Unresolved arrest, charge, pending indictment or outstanding warrant.

188  
189 (b) Intervening circumstances relevant to the responsibilities and circumstances of the license or  
190 registration. Intervening circumstances include but are not limited to:

191  
192 (A) The passage of time since the commission of the crime;

193  
194 (B) The age of the subject individual at the time of the crime;

195  
196 (C) The likelihood of a repetition of offenses or of the commission of another crime;

197

- 198 (D) The subsequent commission of another relevant crime;  
199  
200 (E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and  
201  
202 (F) A recommendation of an employer.  
203  
204 (c) The facts that support the conviction or indictment, or that indicate the making of a false statement;  
205  
206 (d) The relevancy, if any, of the crime or the false statement to the specific requirements of the subject  
207 individual's license or registration; and  
208  
209 (e) Any false statement or omission made to the **B**board regarding the individual's criminal history.  
210  
211 (f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint  
212 identification;  
213  
214 (g) Any other pertinent information obtained as part of an investigation.  
215  
216 (h) The **B**board ~~shall~~**must** evaluate a crime or offense on the basis of the law of the jurisdiction in which  
217 the crime or offense occurred.  
218  
219 (i) The following are examples of crimes likely to result in denial unless there are significant mitigating  
220 circumstances:  
221  
222 (A) Aggravated murder;  
223  
224 (B) Murder;  
225  
226 (C) Rape I;  
227  
228 (D) Sodomy I;  
229  
230 (E) Unlawful sexual penetration I;  
231  
232 (F) Sexual abuse I  
233  
234 (j) Under no circumstances ~~shall~~**must** an applicant be denied under these rules because of a juvenile  
235 record that has been expunged or set aside pursuant to ORS 419A.260 ~~to~~**and ORS** 419A.262.  
236  
237 (k) Under no circumstances ~~shall~~**must** an applicant be denied under these rules due to the existence or  
238 contents of an adult record that has been set aside pursuant to ORS 137.225.  
239  
240 (5) Criminal offender information is confidential. Dissemination of information received under this rule  
241 may only be made to people with a demonstrated and legitimate need to know the information. When  
242 the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS  
243 676.175. Any fingerprint cards used to conduct a check ~~shall~~**must** be destroyed by either the Federal  
244 Bureau of Investigation or the **Oregon** Department of State Police as specified in ORS 181A.195.

245  
246 (6) The Bboard will permit the subject individual for whom a fingerprint-based criminal records check  
247 was conducted to inspect the individual's own state and national criminal offender records and, if  
248 requested by the subject individual, provide the individual with a copy of the individual's own state and  
249 national criminal offender records.

250  
251 (7) If an applicant, licensee or registrant is denied a license, they are entitled to a contested case hearing  
252 pursuant to ORS 183.413, ORS 183.415, ORS 183.417, ORS 183.425, ORS 183.430, ORS 183.435, ORS  
253 183.440, ORS 183.445, ORS 183.450, ORS 183.452, ORS 183.453, ORS 183.457, ORS 183.458, ORS  
254 183.459, ORS 183.460, ORS 183.462, ORS 183.464, ~~and~~ ORS 183.470 and in accordance with OAR  
255 855-001-0005, OAR 855-001-0012, OAR 855-001-0016, ~~and~~ OAR 855-001-0017.

256  
257 (8) A challenge to the accuracy or completeness of information provided by the Oregon Department of  
258 State Police, Federal Bureau of Investigation and agencies reporting information must be made through  
259 the Oregon Department of State Police, Federal Bureau of Investigation or reporting agency and not  
260 through the contested case process.

261  
262 (9) Request for re-evaluation following correction. If the subject individual successfully contests the  
263 accuracy or completeness of information provided by the Oregon Department of State Police, the  
264 Federal Bureau of Investigation or other agency reporting information to the Bboard, the Bboard will  
265 conduct a new criminal history check and re-evaluate the criminal history upon submission of a new  
266 criminal history request form.

267  
268 (10) The applicant or licensee must pay a criminal records check fee for the actual cost of acquiring and  
269 furnishing the criminal offender information.

270  
271 Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195  
272 Statutes/Other Implemented: ORS 676.303, ORS 181A.195, ORS 181A.170, ORS 181A.215 & ORS 676.175

273  
274  
275 **855-010-0110**  
276 **State and Nationwide Criminal Background Checks for Employees, Volunteers and Employment**  
277 **Applicants**

278  
279 (1) The Bboard requires a criminal records check and fitness determination for Bboard employees,  
280 volunteers or applicants for employment with the Bboard.

281  
282 (2) Criminal records checks and fitness determinations are conducted pursuant to ORS 181A.170, ORS  
283 181A.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205  
284 ORS 181A.210, ~~and~~ ORS 125-181A.215 and OAR 125-007-0200, OAR 125-007-0210, OAR 125-007-0220,  
285 OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, ~~and~~ OAR 125-007-  
286 0310.

287  
288 (a) To complete the criminal records check and fitness determination, the Bboard may require additional  
289 information from the employee, volunteer or applicant, such as, but not limited to, proof of identity or  
290 additional criminal, judicial or other background information.

292 (b) If the employee, volunteer or applicant has potentially disqualifying criminal offender information,  
293 the **B**board will consider factors listed in ORS 181A.195 before making a fitness determination.

294  
295 (c) An approved fitness determination does not guarantee employment.

296  
297 (d) An incomplete fitness determination does not entitle the employee, volunteer or applicant the right  
298 to appeal under OAR 125-007-0300.

299  
300 (3) Pursuant to ORS 181A.195, and OAR 125-007-0310, information obtained in the criminal records  
301 check is confidential and will not be disseminated by the **B**board except to persons with a demonstrated  
302 and legitimate need to know the information.

303  
304 Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195

305 Statutes/Other Implemented: ORS 181A.195, ORS 181A.170, ORS 181A.215 & ORS 676.303

306

307

308 **855-010-0120**

309 **Criminal Background Checks – Costs Fees**

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

314

315 Statutory/Other Authority: ORS 676.303 & ORS 689.205

316 Statutes/Other Implemented: ORS 676.303, ORS 181A.195 & ORS 689.207

317

318

319 **855-010-0130**

320 **Military Spouse or Domestic Partner**

321

322 (1) “Military spouse or domestic partner” means a spouse or domestic partner of an active member of  
323 the Armed Forces of the United States who is the subject of a military transfer to Oregon.

324

325 (2) To qualify for licensure under this rule, the military spouse or domestic partner must meet the  
326 following requirements:

327

328 (a) Meet the qualifications for licensure as stated in OAR Division 855-019 or OAR 855-025.

329

330 (b) Be married to, or in a domestic partnership with, a member of the Armed Forces of the United States  
331 who is assigned to a duty station located in Oregon by official active duty military order;

332

333 (c) Applicant must complete an application for licensure, provide the **B**board with a valid email address,  
334 and complete and pass a national fingerprint-based criminal background check;

335

336 (d) Provide evidence of current licensure as a pharmacist or pharmacy technician issued by another  
337 state;

338 (e) Provide to the ~~B~~board, in a manner determined by the ~~B~~board, sufficient proof that the person is in  
339 good standing with the issuing out-of-state professional licensing board; and  
340

341 (f) Demonstrate competency as a pharmacist or pharmacy technician by having at least one year of  
342 active practice during the three years immediately preceding the application.  
343

344 (3) A temporary authorization under this section is valid until the earliest of the following:  
345

346 (a) Two years after the date of issuance;  
347

348 (b) The date the spouse or domestic partner of the person to whom the authorization was issued  
349 completes the spouse's term of service in this state; or  
350

351 (c) The date the person's authorization issued by the other state expires.  
352

353 (4) A temporary authorization issued under this section is not renewable.  
354

355 Statutory/Other Authority: ORS 689.205

356 Statutes/Other Implemented: ORS 689.151, ORS 689.265, ORS 670.400 & ORS 670.403 2019 OL Ch. 142  
357 & ~~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.

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

4 Division 41  
5 OPERATION OF PHARMACIES

6 **855-041-1001**

7 **Definitions**

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

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

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

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

17 (4) "Interchangeable" means, in reference to a biological product, that the United States Food and  
18 Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42  
19 U.S.C. 262(k)(4) (XX/XX/XXXX).

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

21 (5) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a)  
22 (XX/XX/XXXX) against which a biological product is evaluated in an application submitted to the United  
23 States Food and Drug Administration for licensure of a biological product as a biosimilar product or for  
24 determination that a biosimilar product is interchangeable.

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

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

29 **Statutory/Other Authority:** ORS 689.205 & 689.522

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



43 **855-041-1132**

44 **Limited English Proficiency and Accessibility**

45

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

51

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

54

55 (a) Spanish;

56

57 (b) Russian;

58

59 (c) Somali;

60

61 (d) Arabic;

62

63 (e) Chinese (simplified);

64

65 (f) Vietnamese;

66

67 (g) Farsi;

68

69 (h) Korean;

70

71 (i) Romanian;

72

73 (j) Swahili;

74

75 (k) Burmese;

76

77 (l) Nepali;

78

79 (m) Amharic; and

80

81 (n) Pashtu.

82

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

84

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

87

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

91  
92 **(6) At a minimum, the informational insert must include the:**

93  
94 **(a) Directions for use by the patient in both English and the language requested;**

95  
96 **(b) Identifying number;**

97  
98 **(c) Name of patient;**

99  
100 **(d) Name of drug and strength; and**

101  
102 **(e) Date of fill.**

103  
104 **Statutory/Other Authority:** ORS 689.564

105 **Statutes/Other Implemented:** ORS 689.205

106

107

108

109 **855-041-1035**

110 **Minimum Equipment Requirements**

111

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

113

114 ~~(1a) The most **Appropriate and** current issue of at least one pharmaceutical references with current,~~  
115 ~~properly filed supplements **(e.g. pharmacology, injectables, and veterinary drugs)** and updates~~  
116 ~~appropriate to and based on the standards of practice for the setting. **services offered by the outlet;**~~

117

118 ~~(2b) **Appropriate and** Current and properly filed Oregon Revised Statutes, Chapters 689, and 475;~~  
119 ~~current and properly filed Oregon Administrative Rules, chapter 855;. **United States Code, Code of**~~  
120 ~~**Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the**~~  
121 ~~**outlet** and a minimum of three years of the Board of Pharmacy quarterly newsletters maintained in~~  
122 ~~house or other readily retrievable means;~~

123

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

125

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

128

129 ~~(4d) Suitable refrigeration. **Appropriate equipment to maintain the proper storage of drugs;**~~

130

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

134

135 ~~(5f) A sink with running hot and cold water;~~

136

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

138

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

142  
143 (B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free,  
144 competent oral interpretation and translation services, including translated prescription labels, for  
145 patients who are of limited English proficiency, in compliance with federal and state regulations if the  
146 pharmacy dispenses prescriptions for a patient's self-administration;

147  
148 (C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's  
149 operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up  
150 pharmacy per OAR 855-041-2100; and

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

154  
155 ~~(6h) Additional~~ Equipment and supplies appropriate to and based on the standards of practice for the  
156 setting as **that are** determined as **necessary** by the Pharmacy and **or** Pharmacist-in-Charge.

157  
158 ~~(7i) Failure to have, and use~~ **and maintain required** equipment necessary to your practice setting  
159 constitutes unprofessional conduct for purposes of **under** ORS 689.405(1)(a)-i;

160  
161 ~~(8) If an outlet files original prescriptions electronically, then the outlet must have a computer and~~  
162 ~~software capable of storing and accessing electronically filed original prescriptions.~~

163  
164 ~~(9) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to~~  
165 ~~provide notification of the right to free, competent oral interpretation and translation services for~~  
166 ~~patients who are of limited English proficiency, in compliance with federal and state regulations.~~

167  
168 Statutory/Other Authority: ORS 689.205

169 Statutes/Other Implemented: ORS 689.508, & ORS 689.155, ORS 689.515, ORS 689.564 & ORS 689.686

170 Division 43  
171 PRACTITIONER DISPENSING

172  
173 **855-043-0002**

174 **Definitions**

175  
176 In this division of rules:

177  
178 (1) "Administer" means the direct application of a drug or device whether by injection, inhalation,  
179 ingestion, or any other means, to the body of a patient by:

180  
181 (a) A practitioner or the practitioner's authorized agent; or

182  
183 (b) The patient at the direction of the practitioner.

184  
185 **(2) "Counseling" means an oral or other appropriate communication process between a practitioner**  
186 **and a patient or a patient's agent in which the practitioner obtains information from the patient or**  
187 **patient's agent, and, where appropriate, the patient's medical records, assesses that information and**  
188 **provides the patient or patient's agent with professional advice regarding the safe and effective use of**  
189 **the drug or device for the purpose of assuring therapeutic appropriateness.**

190  
191 ~~(23)~~ "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a  
192 lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration  
193 to or use by a patient or other individual entitled to receive the prescription drug.

194  
195 **(4) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic**  
196 **drug for the treatment of a sexually transmitted disease to the partner of a patient without first**  
197 **examining that partner.**

198  
199 ~~(35)~~ "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or  
200 preventative measures such as immunization or birth control approved by the Board or by the  
201 Department of Human Services (DHS).

202  
203 ~~(46)~~ "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of  
204 Naturopathic Medicine and employed by or under contract with a county or district health department  
205 or DHS.

206  
207 **(7) "Informational insert" is an auxiliary document containing directions for use and other prescription**  
208 **information that is provided to the patient in both English and the language requested.**

209  
210 **(8) "Limited English proficiency" means not fluent in the English language.**

211  
212 ~~(59)~~ "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center,  
213 treatment center, or other establishment from which a physician assistant dispenses drugs, but that is  
214 not otherwise registered with the Board in the category of Retail Drug Outlet.

215  
216 **Statutory/Other Authority:** ORS 689.205  
217 **Statutes/Other Implemented:** ORS 689.155, **& ORS 689.564**

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**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 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.**

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

267

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

269

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

271

272 **(b) Identifying number;**

273

274 **(c) Name of patient;**

275

276 **(d) Name of drug and strength; and**

277

278 **(e) Date of fill.**

279

280 **Statutory/Other Authority:** ORS 689.564

281 **Statutes/Other Implemented:** ORS 689.205

282

283

284

285 **855-043-0541**

286 **Dispensing Practitioner Drug Outlet - Limited English Proficiency and Accessibility**

287

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

292

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

295

296 (a) Spanish;

297

298 (b) Russian;

299

300 (c) Somali;

301

302 (d) Arabic;

303 (e) Chinese (simplified);

304

305 (f) Vietnamese;

306

307 (g) Farsi;

308

309 (h) Korean;

310

311 (i) Romanian;

312

- 313 (j) Swahili;  
314  
315 (k) Burmese;  
316  
317 (l) Nepali;  
318  
319 (m) Amharic; and  
320  
321 (n) Pashtu.  
322

323 (3) The board must reassess and update (2) as necessary and at least every ten years.  
324

325 **(4) An informational insert may be used when the directions for use in English and the language**  
326 **requested exceed 140 characters.**  
327

328 **(5) When an informational insert is used, the prescription label affixed to the prescription container**  
329 **must state in the language requested by the patient that an informational insert is being used.**  
330

331 **(6) At a minimum, the informational insert must include the:**  
332

333 **(a) Directions for use by the patient in both English and the language requested;**  
334

335 **(b) Identifying number;**  
336

337 **(c) Name of patient;**  
338

339 **(d) Name of drug and strength; and**  
340

341 **(e) Date of fill.**  
342

343 **Statutory/Other Authority: ORS 689.564**

344 **Statutes/Other Implemented: ORS 689.205**

345 Division 44  
346 CHARITABLE PHARMACIES

347  
348 **855-044-0005**

349 **Definitions**

350

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

353

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

356

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

358

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

362

363 **Statutory/Other Authority:** ORS 689.205

364 **Statutes/Other Implemented:** ORS 689.772, ~~ORS 689.774~~, **ORS 689.564**

365

366

367

368 **855-044-0061**

369 **Charitable Pharmacies - Limited English Proficiency and Accessibility**

370

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

376

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

379

380 (a) Spanish;

381

382 (b) Russian;

383

384 (c) Somali;

385

386 (d) Arabic;

387

388 (e) Chinese (simplified);

389

390 (f) Vietnamese;

391

392 (g) Farsi;



- 393 (h) Korean;  
394  
395 (i) Romanian;  
396  
397 (j) Swahili;  
398  
399 (k) Burmese;  
400  
401 (l) Nepali;  
402  
403 (m) Amharic; and  
404  
405 (n) Pashtu.

406  
407 (3) The board must reassess and update (2) as necessary and at least every ten years.

408  
409 (4) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to  
410 provide notification of the right to free, competent oral interpretation and translation services for  
411 patients who are of limited English proficiency, in compliance with federal and state regulations.

412  
413 **(5) An informational insert may be used when the directions for use in English and the language**  
414 **requested exceed 140 characters.**

415  
416 **(6) When an informational insert is used, the prescription label affixed to the prescription container**  
417 **must state in the language requested by the patient that an informational insert is being used.**

418  
419 **(7) At a minimum, the informational insert must include the:**

420  
421 **(a) Directions for use by the patient in both English and the language requested;**

422  
423 **(b) Identifying number;**

424  
425 **(c) Name of patient;**

426  
427 **(d) Name of drug and strength; and**

428  
429 **(e) Date of fill.**

430  
431 **Statutory/Other Authority: ORS 689.564**

432 **Statutes/Other Implemented: ORS 689.205**

433

434

435

436 **Division 141**  
437 **REMOTE DISPENSING SITE PHARMACY**

438  
439 **855-139-0155**

440 **Outlet: Minimum Equipment Requirements**

441  
442 **(1) Each Oregon Retail Drug Outlet Remote Dispensing Site Pharmacy must have the following:**

443  
444 **(a) Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary**  
445 **drugs) services offered by the outlet;**

446  
447 **(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States**  
448 **Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services**  
449 **offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;**

450  
451 **(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on**  
452 **the services offered by the outlet;**

453  
454 **(d) Appropriate equipment to maintain the proper storage of drugs;**

455  
456 **(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon**  
457 **Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by**  
458 **reference (e.g. USP) based on services offered by the outlet;**

459  
460 **(f) A sink with running hot and cold water;**

461  
462 **(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:**

463  
464 **(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically**  
465 **equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign**  
466 **must be in block letters not less than one inch in height.**

467  
468 **(B) Providing notification in each of the languages required in OAR 855-139-0062 of the right to free,**  
469 **competent oral interpretation and translation services, including translated prescription labels, for**  
470 **patients who are of limited English proficiency, in compliance with federal and state regulations if the**  
471 **pharmacy dispenses prescriptions for a patient's self-administration;**

472  
473 **(C) Providing written notice in a conspicuous manner that naloxone and the necessary medical**  
474 **supplies to administer naloxone are available at the pharmacy if naloxone services are provided by**  
475 **the pharmacy per OAR 855-139-0215; and**

476  
477 **(D) Stating "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed**  
478 **Pharmacist from (insert name of Affiliated Pharmacy, address, and telephone number)." The printing**  
479 **on the sign must be in block letters not less than one inch in height; and**

480  
481 **(h) Additional equipment and supplies that are determined as necessary by the Pharmacy or**  
482 **Pharmacist-in-Charge.**

483

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

486

487 **Statutory/Other Authority: ORS 689.205**

488 **Statutes/Other Implemented: ORS 689.155**

489

PROPOSED

**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](#)

- 1 Division 19
- 2 PHARMACISTS
- 3
- 4 855-019-0300
- 5 Duties of a Pharmacist-in-Charge
- 6
- 7 (1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one
- 8 Pharmacist-in-Charge (PIC) employed on a regular basis.

9

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

11

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

13

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

17

18 (3) A pharmacist may not be designated PIC of more than ~~two~~ three pharmacies without prior written  
19 approval by the board. If such approval is given, the pharmacist must comply with the requirements in  
20 sub-section (4)(e) of this rule.

21

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

23

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

26

27 (b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of  
28 becoming PIC;

29

30 (c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy,  
31 except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as  
32 specified in OAR 855-041-0120;

33

34 (d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor  
35 who has been designated to have access to the pharmacy department in the absence of a pharmacist;

36

37 (e) A pharmacist designated as PIC for more than one pharmacy must personally conduct and document  
38 a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit  
39 Form provided by the board;

40

41 (f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within 30  
42 days of receiving notice.

43

44 (g) The records and forms required by this section must be filed in the pharmacy, made available to the  
45 board for inspection upon request, and must be retained for three years.

46

47 (5) The PIC is responsible for ensuring that the following activities are correctly completed:

48

49 (a) An inventory of all controlled substances must be taken within 15 days before or after the effective  
50 date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained  
51 in the pharmacy for three years and in accordance with all federal laws and regulations;

52

53 (b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all  
54 pharmacy personnel who are required to be licensed by the board;

55

- 56 (c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided  
57 by the board, by February 1 each year. The completed self-inspection forms must be signed and dated  
58 by the PIC and maintained for three years from the date of completion;  
59  
60 (d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;  
61  
62 (e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.  
63  
64 (f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training  
65 should include an annual review of the PIC Self-Inspection Report;  
66  
67 (g) Implementing a quality assurance plan for the pharmacy.  
68  
69 (h) The records and forms required by this section must be filed in the pharmacy, made available to the  
70 board for inspection upon request, and must be retained for three years.  
71  
72 (6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in  
73 compliance with all state and federal laws and rules governing the practice of pharmacy and that all  
74 controlled substance records and inventories are maintained in accordance with all state and federal  
75 laws and rules.

76  
77 Statutory/Other Authority: ORS 689.205  
78 Statutes/Other Implemented: ORS 689.151 & ORS 689.155  
79  
80

81 **Division 141**  
82 **REMOTE DISPENSING SITE PHARMACY**  
83

84  
85 **855-139-0001**  
86 **Purpose and Scope**  
87

88 **The purpose of OAR 855-139 is to provide minimum requirements for the locations where**  
89 **telepharmacy services are conducted.**  
90

91 **Statutory/Other Authority: ORS 689.205, 2021 SB 629**  
92 **Statutes/Other Implemented: ORS 689.155**  
93  
94  
95

96 **855-139-0005**  
97 **Definitions**  
98

99 **The following words and terms, when used in OAR 855-139, have the following meanings, unless the**  
100 **context clearly indicates otherwise. Any term not defined in this section has the definition set out in**  
101 **OAR 855-006.**  
102

103 **(1) “Affiliated Pharmacy” means a Retail Drug Outlet Pharmacy registered in Oregon where an Oregon**  
104 **licensed Pharmacist provides pharmacy services through a telepharmacy system.**

105  
106 **(2) “Biological product” means, with respect to the prevention, treatment or cure of a disease or**  
107 **condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood**  
108 **component, blood derivative, allergenic product, protein other than a chemically synthesized**  
109 **polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.**

110  
111 **(3) “Biosimilar product” means a biological product licensed by the United States Food and Drug**  
112 **Administration pursuant to 42 USC 262(k)(3)(A)(i) (XX/XX/XXXX).**

113  
114 **(4) “Informational insert” is an auxiliary document containing directions for use and other prescription**  
115 **information that is provided to the patient in both English and the language requested.**

116  
117 **(5) “Interchangeable” means, in reference to a biological product, that the United States Food and**  
118 **Drug Administration has determined that a biosimilar product meets the safety standards set forth in**  
119 **42 USC-262(k)(4) (XX/XX/XXXX).**

120  
121 **(6) “Limited English proficiency” means not fluent in the English language.**

122  
123 **(7) “Reference biological product” means the biological product licensed pursuant to 42 U.S.C. 262(a)**  
124 **(XX/XX/XXXX) against which a biological product is evaluated in an application submitted to the**  
125 **United States Food and Drug Administration for licensure of a biological product as a biosimilar**  
126 **product or for determination that a biosimilar product is interchangeable.**

127  
128 **(8) “Remote Dispensing Site Pharmacy” means an Oregon location registered as a Retail Drug Outlet**  
129 **Remote Dispensing Site Pharmacy staffed by a Certified Oregon Pharmacy Technician under the**  
130 **supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.**

131  
132 **(9) “Repackage” means the act of taking a drug from the container in which it was distributed by the**  
133 **manufacturer and placing it into a different container without further manipulation of the drug.**

134  
135 **(10) “Telepharmacy” means the delivery of pharmacy services by an Oregon licensed Pharmacist**  
136 **through the use of a telepharmacy system to a patient at a remote location staffed by a Certified**  
137 **Oregon Pharmacy Technician.**

138  
139 **(11) “Telepharmacy system” means a system of telecommunications technologies that enables**  
140 **monitoring, documenting and recording of the delivery of pharmacy services at a remote location by**  
141 **an electronic method which must include the use of audio and video, still image capture, and store**  
142 **and forward.**

143  
144 **(12) “Temperature excursion” means an event in which a drug is exposed to a temperature outside of**  
145 **the manufacturers recommended storage conditions.**

146  
147 **(13) “Still image capture” means a specific image captured electronically from a video or other image**  
148 **capture device.**

149

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

152

153 **Statutory/Other Authority:** ORS 689.205, ORS 689.522, 2021 SB 629

154 **Statutes/Other Implemented:** ORS 689.155, ORS 689.522, ORS 689.564, 2021 SB 629

155

156

157

158 **855-139-0010**

159 **Registration: General**

160

161 **(1) A location in Oregon where the practice of pharmacy occurs by an Oregon licensed Pharmacist**  
162 **through the use of a telepharmacy system to a patient at a remote location staffed by a Certified**  
163 **Oregon Pharmacy Technician must be registered by the board in Oregon as a Retail Drug Outlet**  
164 **Remote Dispensing Site Pharmacy.**

165

166 **(2) If controlled substances are stored in the Remote Dispensing Site Pharmacy, the Remote**  
167 **Dispensing Site Pharmacy must have an active Controlled Substance Registration Certificate with the**  
168 **Board and Drug Enforcement Administration (DEA).**

169

170 **(3) A Retail Drug Outlet Remote Dispensing Site Pharmacy application must specify the Affiliated**  
171 **Pharmacy and cannot operate without an Affiliated Pharmacy that is registered by the board as a**  
172 **Retail Drug Outlet Pharmacy.**

173

174 **(4) All registration renewal applications must be accompanied by the annual fee and must contain the**  
175 **same information required in OAR 855-139-0011(3) and (4).**

176

177 **(5) The initial and annual registration fee for pharmacies is set out in OAR 855-110.**

178

179 **(6) Retail Drug Outlet Remote Dispensing Site Pharmacy registration expires March 31, annually. If the**  
180 **annual registration fee referred to in OAR 855-110 is not paid by March 31 of the current year, a late**  
181 **fee as set out in OAR 855-110 must be included with the application for registration renewal.**

182

183 **(7) The registration is not transferable and the registration fee cannot be prorated.**

184

185 **(8) No Remote Dispensing Site Pharmacy may be operated until a certificate of registration has been**  
186 **issued to the pharmacy by the Board.**

187

188 **Statutory/Other Authority:** ORS 689.205, 2021 SB 629

189 **Statutes/Other Implemented:** ORS 689.151, ORS 689.155, ORS 689.225, 2021 SB 629

190

191

192

193 **855-139-0015**

194 **Registration: Application**

195

196 **(1) An application for registration of a new Remote Dispensing Site Pharmacy must be accompanied**  
197 **by a floor plan drawn to scale and must be approved by the Board prior to opening.**



198 **(2) The application must specify the location of the Remote Dispensing Site Pharmacy and must**  
199 **indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant**  
200 **is not the owner of the pharmacy, the application must indicate the owner and the applicant's**  
201 **affiliation with the owner:**

202  
203 **(a) If the owner is a partnership or other multiple owners, the names of the partners or persons**  
204 **holding the five largest interests must be indicated on the application;**

205  
206 **(b) If the owner is a corporation, the name filed must be the same as filed with the Secretary of State.**  
207 **The name of the corporation, the names of the corporation officers and the names of the stockholders**  
208 **who own the five largest interests must be indicated on the application.**

209  
210 **(3) Upon request by the Board, the applicant must furnish such information as required by the Board**  
211 **regarding the partners, stockholders, or other persons not named in the application.**

212  
213 **(4) A certificate of registration will be issued upon Board approval of the application.**

214  
215 **Statutory/Other Authority: ORS 475.035, ORS 689.205**

216 **Statutes/Other Implemented: ORS 689.155**

217  
218  
219  
220 **855-139-0020**

221 **Registration: Change of Owner, Location, or Affiliated Pharmacy**

222  
223 **(1) A change of location of the Affiliated Pharmacy or location of the Retail Drug Outlet Remote**  
224 **Dispensing Site Pharmacy requires:**

225  
226 **(a) Submission of a new Retail Drug Outlet Remote Dispensing Site Pharmacy application 15 days prior**  
227 **to occurrence;**

228  
229 **(b) Registration fee;**

230  
231 **(c) Approval of the Board; and**

232  
233 **(d) New certificate of registration.**

234  
235 **(2) A change in the Affiliated Pharmacy or ownership of the Retail Drug Outlet Remote Dispensing Site**  
236 **Pharmacy requires:**

237  
238 **(a) Submission of a new Retail Drug Outlet Remote Dispensing Site Pharmacy application 15 days prior**  
239 **to occurrence;**

240  
241 **(b) Registration fee;**

242  
243 **(c) Approval of the Board; and**

244  
245 **(d) New certificate of registration.**

246  
247 **(3) A change of ownership includes any change in the legal form of the business including additions or**  
248 **deletions of partners.**

249  
250 **(4) A certificate of registration will be issued upon Board approval of the application.**

251  
252  
253 **Statutory/Other Authority: ORS 475.035, ORS 689.205**  
254 **Statutes/Other Implemented: ORS 689.155**

255  
256  
257  
258 **855-139-0025**  
259 **Registration: Change of Business Name or Closure**

260  
261 **(1) An Affiliated Pharmacy must notify the board 15 days prior to any change of business name of a**  
262 **Retail Drug Outlet Remote Dispensing Site Pharmacy. The change must be reported by filing a new**  
263 **application for which no fee is required.**

264  
265 **(2) An Affiliated Pharmacy must notify the board 15 days prior to discontinuing operation of a Retail**  
266 **Drug Outlet Remote Dispensing Site Pharmacy. Notification must include the:**

267  
268 **(a) Final disposition of drugs stored in the Retail Drug Outlet Remote Dispensing Site Pharmacy**  
269 **including:**

270  
271 **(A) Name and location where the drugs are transferred;**

272  
273 **(B) Name and location where destruction occurred; and**

274  
275 **(C) Name and location of the site that will store all records;**

276  
277 **(c) Transfer all Schedule II medications on DEA 222 forms, and Schedule III, IV and V by invoice;**

278  
279 **(d) Provide the board with:**

280  
281 **(A) Oregon Board of Pharmacy state license(s); and**

282  
283 **(B) Signed statement giving the effective date of closure; and**

284  
285 **(e) Comply with the requirements of 21 CFR 1301.52 (XX/XX/XXXX).**

286  
287 **Statutory/Other Authority: ORS 475.035, ORS 689.205**  
288 **Statutes/Other Implemented: ORS 689.155**

289  
290  
291 **855-139-0030**  
292 **Non-Resident Pharmacies**

293

294 **(1) For the purpose of these rules, a non-resident pharmacy includes an Affiliated Pharmacy located**  
295 **outside of Oregon and providing pharmacy services through a telepharmacy system to a Retail Drug**  
296 **Outlet Remote Dispensing Site Pharmacy located in Oregon.**

297  
298 **(2) Each non-resident Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy.**

299  
300 **(3) To qualify for registration under these rules, every non-resident Affiliated Pharmacy must be**  
301 **registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.**

302  
303 **(4) Each out-of-state non-resident Affiliated Pharmacy must designate an Oregon licensed Pharmacist-**  
304 **in-Charge (PIC), who is responsible for all pharmacy services and to provide supervision and control of**  
305 **the pharmacy. To qualify for this designation, the person must:**

306  
307 **(a) Hold a license to practice pharmacy in the resident state;**

308  
309 **(b) Be normally working for the Affiliated Pharmacy a minimum of 20 hours per week;**

310  
311 **(c) Complete the annual Remote Dispensing Site Pharmacy PIC self-inspection report prior to February**  
312 **1 each year; and**

313  
314 **(d) Provide the PIC self-inspection report as requested by the Board.**

315  
316 **(5) Every non-resident Affiliated Pharmacy will have a pharmacist-in-charge (PIC) who is licensed in**  
317 **Oregon prior to initial registration of the Remote Dispensing Site Pharmacy.**

318  
319 **(6) The PIC must comply with the requirements of OAR 855-019-0300.**

320  
321 **Statutory/Other Authority: ORS 689.205**

322 **Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225**

323  
324  
325  
326 **855-139-0050**

327 **Personnel**

328  
329 **(1) The Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy is responsible for all**  
330 **operations at the Remote Dispensing Site Pharmacy including responsibility for the telepharmacy**  
331 **system and enforcing policies and procedures.**

332  
333 **(2) A Remote Dispensing Site Pharmacy may not utilize Interns, Pharmacy Technicians, or unlicensed**  
334 **personnel.**

335  
336 **(3) A Certified Oregon Pharmacy Technician working at a Remote Dispensing Site Pharmacy is required**  
337 **to have at least one year experience working at an Oregon registered Retail Drug Outlet Pharmacy**  
338 **during the three years preceding the date the Certified Oregon Pharmacy Technician begins working**  
339 **at the Remote Dispensing Site Pharmacy.**

340

341 **(4) The Oregon licensed Pharmacist from the Affiliated Pharmacy who is supervising a Remote**  
342 **Dispensing Site Pharmacy must determine and document how many licensed individuals the**  
343 **pharmacist is capable of supervising, directing and controlling based on the services being provided.**  
344

345 **(5) When supervising a Certified Oregon Pharmacy Technician working at a Remote Dispensing Site**  
346 **Pharmacy and licensees at an Affiliated Pharmacy, the Oregon licensed Pharmacist may supervise no**  
347 **more than four licensees.**  
348

349 **(6) The Affiliated Pharmacy is required to comply with the pharmacist's determination in (4) and**  
350 **retain records.**  
351

352 **(7) The Remote Dispensing Site Pharmacy and Affiliated Pharmacy must ensure adequate staffing at**  
353 **both the Remote Dispensing Site Pharmacy and Affiliated Pharmacy.**  
354

355 **(8) Prior to working at a Remote Dispensing Site Pharmacy, the Certified Oregon Pharmacy Technician**  
356 **and the Oregon licensed Pharmacist supervising the Remote Dispensing Site Pharmacy must have**  
357 **completed a training program on the proper use of the telepharmacy system.**  
358

359 **(9) An Affiliated Pharmacy that terminates or allows a Board licensee to resign in lieu of termination**  
360 **must report the termination or resignation to the Board within 10 working days.**  
361

362 **Statutory/Other Authority: ORS 689.205**

363 **Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305**

364

365

366 **855-139-0100**

367 **Security**

368

369 **(1) The area in a registered Remote Dispensing Site Pharmacy where legend and/or controlled**  
370 **substances are stored, possessed, prepared, compounded or repackaged must be restricted in access**  
371 **by utilizing physical barriers to include floor to ceiling walls and a locked separate entrance to ensure**  
372 **the security of those drugs.**  
373

374 **(2) The Affiliated Pharmacy, the Remote Dispensing Site Pharmacy, Oregon licensed Pharmacist-in-**  
375 **charge of the Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the Remote**  
376 **Dispensing Site Pharmacy is responsible for the security of the prescription area including provisions**  
377 **for adequate safeguards against loss, theft or diversion of prescription drugs, and records for such**  
378 **drugs.**  
379

380 **(3) The Remote Dispensing Site Pharmacy must be locked and the security system armed to prevent**  
381 **entry when:**  
382

383 **(a) There is no Oregon licensed Pharmacist from the Affiliated Pharmacy actively supervising the**  
384 **Remote Dispensing Site Pharmacy; or**  
385

386 **(b) There is no Certified Oregon Pharmacy Technician present in the Remote Dispensing Site**  
387 **Pharmacy; or**  
388

389 **(c) Any component of the telepharmacy system is not functioning.**  
390  
391 **(4) A record must be maintained with the name and license number of each person entering the**  
392 **pharmacy area of the Remote Dispensing Site Pharmacy.**  
393  
394 **(5) No one may be in the prescription area of a Remote Dispensing Site Pharmacy unless authorized in**  
395 **real-time by an Oregon licensed Pharmacist who is supervising the Remote Dispensing Site Pharmacy**  
396 **and from the Affiliated Pharmacy.**  
397  
398 **(6) Minimum security methods must include a properly functioning:**  
399  
400 **(a) Alarm system with an audible alarm at the Remote Dispensing Site Pharmacy and real-time**  
401 **notification to a designated licensee of the Affiliated Pharmacy;**  
402  
403 **(b) Electronic keypad or other electronic entry system that records the:**  
404  
405 **(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the Remote**  
406 **Dispensing Site Pharmacy;**  
407  
408 **(B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the Remote**  
409 **Dispensing Site Pharmacy; and**  
410  
411 **(C) Date and time of each activity.**  
412  
413 **(c) Surveillance system that utilizes continuously accessible and recorded two-way audiovisual link**  
414 **between the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy. The system must provide**  
415 **a clear view of:**  
416  
417 **(A) Dispensing site entrances;**  
418  
419 **(B) Preparation areas;**  
420  
421 **(C) Drug storage areas;**  
422  
423 **(D) Pick up areas;**  
424  
425 **(E) Office areas; and**  
426  
427 **(F) Publicly accessible areas.**  
428  
429 **Statutory/Other Authority: ORS 475.035, ORS 689.205**  
430 **Statutes/Other Implemented: ORS 689.155**  
431  
432 **855-139-0120**  
433 **Drug: Receipt**  
434  
435 **Remote Dispensing Site Pharmacy may only receive drugs from an Oregon Registered Drug Outlet (i.e.**  
436 **Wholesaler, Manufacturer or Pharmacy).**

437 **Statutory/Other Authority: ORS 475.035, ORS 689.205**

438 **Statutes/Other Implemented: ORS 689.155**

439

440

441 **855-139-0125**

442 **Drug: Storage**

443

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

446

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

450

451 **(3) Each pharmacy must:**

452

453 **(a) Unless the manufacturer specifies differently, maintain drug required to be stored at controlled**  
454 **room temperature between 20-25 °C (68 to 77 °F); refrigerated products between 2 to 8 °C (35.6 to**  
455 **46.4 °F); frozen products between -25 to -10 °C (-13 to 14 °F);**

456

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

460

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

463

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

465

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

468

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

473

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

476

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

481

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

483

- 484 **(A) Test and document that all components of the temperature monitoring system(s) for each storage**  
485 **area are recording temperature accurately and issuing appropriate alerts;**  
486
- 487 **(B) Review and assess temperature records for long-term trends or recurring problems. Date, time and**  
488 **identity of the reviewer must be documented;**  
489
- 490 **(j) Establish, maintain, and enforce a written quality assurance plan to prevent, identify, and**  
491 **appropriately respond to temperature excursions;**  
492
- 493 **(k) Establish, maintain, and enforce a written action plan to ensure proper drug storage in the event of**  
494 **an emergency (i.e. power outage or natural disaster) that includes identification of backup storage**  
495 **and a procedure for transfer of product between units or facilities;**  
496
- 497 **(l) Document the training of all pharmacy personnel on use of temperature monitoring system(s),**  
498 **quality assurance plan and written emergency action plan to ensure proper drug storage in the event**  
499 **of an emergency;**  
500
- 501 **(m) Recalibrate temperature monitoring device(s) at least once every 24 months or per manufacturer**  
502 **specifications, whichever is more frequent;**  
503
- 504 **(n) Document the following for each temperature excursion:**  
505
- 506 **(A) Date of temperature excursion;**  
507
- 508 **(B) Start and end time;**  
509
- 510 **(C) Minimum and maximum temperatures reached;**  
511
- 512 **(D) List of each drug involved in the temperature excursion including the drug name, quantity,**  
513 **National Drug Code, lot number, expiration date, manufacturer, and the date(s) of previous**  
514 **temperature excursions experienced by the drug(s);**  
515
- 516 **(E) Each drug involved in the temperature excursion must be clearly labeled with the date of**  
517 **temperature excursion and any shortened expiration date if determined by the manufacturer; and**  
518
- 519 **(F) Name of person(s) involved in responding to the temperature excursion event discovery and**  
520 **response;**  
521
- 522 **(o) Before a drug that has experienced a temperature excursion is dispensed, the following items must**  
523 **be documented:**  
524
- 525 **(A) Drug manufacturer information utilized indicating each drug is safe for use;**  
526
- 527 **(B) Name of the representative providing the information;**  
528
- 529 **(C) Manufacturer contact information;**  
530
- 531 **(D) Copy of information provided by manufacturer;**

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**(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.**



580  
581 **(2) Ensure the Certified Oregon Pharmacy Technician working in the Remote Dispensing Site Pharmacy**  
582 **practices appropriate infection control.**

583  
584 **Statutory/Other Authority: ORS 689.305**  
585 **Statutes/Other Implemented: ORS 689.305**

586  
587  
588 **855-139-0155**  
589 **Outlet: Minimum Equipment Requirements**

590  
591 **(1) Each Oregon Retail Drug Outlet Remote Dispensing Site Pharmacy must have the following:**

592  
593 **(a) Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary**  
594 **drugs) services offered by the outlet;**

595  
596 **(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States**  
597 **Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services**  
598 **offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;**

599  
600 **(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on**  
601 **the services offered by the outlet;**

602  
603 **(d) Appropriate equipment to maintain the proper storage of drugs;**

604  
605 **(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon**  
606 **Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by**  
607 **reference (e.g. USP) based on services offered by the outlet;**

608  
609 **(f) A sink with running hot and cold water;**

610  
611 **(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:**

612  
613 **(A) Stating “This pharmacy may be able to substitute a less expensive drug which is therapeutically**  
614 **equivalent to the one prescribed by your doctor unless you do not approve.” The printing on this sign**  
615 **must be in block letters not less than one inch in height.**

616  
617 **(B) Providing notification in each of the languages required in OAR 855-139-0062 of the right to free,**  
618 **competent oral interpretation and translation services, including translated prescription labels, for**  
619 **patients who are of limited English proficiency, in compliance with federal and state regulations if the**  
620 **pharmacy dispenses prescriptions for a patient's self-administration;**

621  
622 **(C) Providing written notice in a conspicuous manner that naloxone and the necessary medical**  
623 **supplies to administer naloxone are available at the pharmacy if naloxone services are provided by**  
624 **the pharmacy per OAR 855-139-0215; and**

625

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

629  
630 **(h) Additional equipment and supplies that are determined as necessary by the Pharmacy or**  
631 **Pharmacist-in-Charge.**

632  
633 **(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under**  
634 **ORS 689.405(1)(a).**

635  
636 **Statutory/Other Authority: ORS 689.205**  
637 **Statutes/Other Implemented: ORS 689.155**

638  
639  
640 **855-139-0200**

641 **Outlet: General Requirements**

642  
643 **(1) An Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site**  
644 **Pharmacies.**

645  
646 **(2) An Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from**  
647 **the Remote Dispensing Site Pharmacy.**

648  
649 **(3) A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

650  
651 **(a) Have the same owner; or**

652  
653 **(b) Have a written contract that specifies:**

654  
655 **(A) The services to be provided by each licensee and registrant;**

656  
657 **(B) The responsibilities of each licensee and registrant; and**

658  
659 **(C) The accountabilities of each licensee and registrant;**

660  
661 **(c) Ensure each prescription is dispensed in compliance with OAR 855-019, OAR 855-025 and OAR 855-**  
662 **139;**

663  
664 **(d) Comply with all applicable federal and state laws and rules;**

665  
666 **(e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians**  
667 **authorized to access the Remote Dispensing Site Pharmacy and operate the telepharmacy system;**

668  
669 **(f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians in the operation**  
670 **of the telepharmacy system and Remote Dispensing Site Pharmacy;**

671  
672 **(g) Develop, implement and enforce a continuous quality improvement program for dispensing**  
673 **services from a Remote Dispensing Site Pharmacy designed to objectively and systematically;**

- 674 **(A) Monitor, evaluate, document the quality and appropriateness of patient care;**  
675  
676 **(B) Improve patient care; and**  
677  
678 **(C) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their**  
679 **reoccurrence;**  
680  
681 **(h) Provide a telephone number that a patient, patient’s agent or prescriber may use to contact the**  
682 **Oregon licensed Pharmacist from the Affiliated Pharmacy; and**  
683  
684 **(i) Develop, implement and enforce a process for an in person physical inspection of the Remote**  
685 **Dispensing Site Pharmacy by an Oregon licensed Pharmacist at least once every 28 days or more**  
686 **frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the Affiliated**  
687 **Pharmacy. The inspection must utilize the Remote Dispensing Site Pharmacy self-inspection form, be**  
688 **documented and records retained.**  
689  
690 **Statutory/Other Authority: ORS 689.205, 2021 SB 629**  
691 **Statutes/Other Implemented: ORS 689.155, 2021 SB 629**  
692  
693  
694  
695 **855-139-0205**  
696 **Outlet: Technology**  
697  
698 **A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:**  
699  
700 **(1) Utilize a shared telepharmacy system and have appropriate technology or interface to allow access**  
701 **to information required to process and fill a prescription drug order;**  
702  
703 **(2) Use still image capture or store and forward for verification of prescriptions with a camera that is**  
704 **of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered**  
705 **Drug Outlet Pharmacy can visually identify each:**  
706  
707 **(A) Source container including manufacturer, name, strength, lot, and expiration;**  
708  
709 **(B) Source ingredient including the imprint and physical characteristics if compounding;**  
710  
711 **(C) Dispensed product including the imprint and physical characteristics;**  
712  
713 **(D) Completed prescription container including the label; and**  
714  
715 **(E) Ancillary document provided to patient at the time of dispensing.**  
716  
717 **(3) Utilize barcode, radio-frequency identification or quick response code technology to record**  
718 **information in (2) if available;**  
719  
720 **(4) Test the telepharmacy system and document that it operates properly before providing pharmacy**  
721 **services; and**

722 **(5) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system.**

723

724 **Statutory/Other Authority: ORS 689.205, 2021 SB 629**

725 **Statutes/Other Implemented: ORS 689.155, 2021 SB 629**

726

727

728

729 **855-139-0210**

730 **Outlet: Supervision**

731

732 **A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

733

734 **(1) Ensure prescription drugs are only dispensed at the Remote Dispensing Site Pharmacy if an Oregon**  
735 **licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician utilizing the**  
736 **telepharmacy system, and the telepharmacy system is fully operational;**

737

738 **(2) Ensure an Oregon licensed Pharmacist continuously supervises, directs and controls each Certified**  
739 **Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy using audio and visual**  
740 **technology which must be recorded, reviewed and stored;**

741

742 **(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a**  
743 **Remote Dispensing Site Pharmacy must:**

744

745 **(a) Using professional judgment, determine the percentage of patient interactions for each licensee**  
746 **that must be reviewed to ensure public health and safety with a minimum of 25% of patient**  
747 **interactions reviewed;**

748

749 **(b) Review patient interactions within 24 hours of the patient interaction to ensure that each licensee**  
750 **is acting within the authority permitted under their license and patients are connected with a**  
751 **pharmacist upon request;**

752

753 **(c) Document the following within 24 hours of the review in (b):**

754

755 **(A) Number of each licensee's patient interactions;**

756

757 **(B) Number of each licensee's patient interactions pharmacist is reviewing;**

758

759 **(C) Date and time of licensee patient interaction pharmacist is reviewing;**

760

761 **(D) Date and time of pharmacist review of licensee's patient interaction; and**

762

763 **(E) Pharmacist notes of each interaction reviewed; and**

764

765 **(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours**  
766 **and the board within 10 days.**

767

768 **(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist’s determination in**  
769 **(3)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain**  
770 **records.**

771  
772 **(5) Ensure all telephone audio is recorded, reviewed and stored.**

773 **POLICY DISCUSSION:** Frequency of review

774  
775  
776 **(6) Develop, implement and enforce a plan for responding to and recovering from an interruption of**  
777 **service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy**  
778 **Technician at the Remote Dispensing Site Pharmacy.**

779  
780 **Statutory/Other Authority: ORS 689.205, ORS 689.225**

781 **Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.305**

782  
783  
784  
785 **855-139-0215**

786 **Outlet: Pharmacist Utilization**

787  
788 **A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

789  
790 **(1) Utilize an Oregon licensed Pharmacist from the Affiliated Pharmacy to perform the professional**  
791 **tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is**  
792 **dispensed; and**

793  
794 **(2) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication to provide**  
795 **counseling or accept the refusal of counseling from the patient or the patient’s agent for each**  
796 **prescription being dispensed when counseling is required under OAR 855-019-0230 and when**  
797 **requested and document the interaction.**

798  
799 **Statutory/Other Authority: ORS 689.205**

800 **Statutes/Other Implemented: ORS 689.155**

801  
802  
803  
804 **855-139-0220**

805 **Outlet: Non-Prescription Drugs**

806  
807 **If non-prescription drugs are offered for sale at the Remote Dispensing Site Pharmacy, the Remote**  
808 **Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

809  
810 **(1) Ensure that the Certified Oregon Pharmacy Technician does not provide advice, information that**  
811 **requires judgment, or recommendations involving non-prescription drugs; and**

812  
813 **(2) Ensure that an Oregon-licensed Pharmacist is immediately available to provide counseling or**  
814 **recommendations involving non-prescription drugs.**

815

816 **Statutory/Other Authority: ORS 689.205**  
817 **Statutes/Other Implemented: ORS 689.155**

818  
819  
820 **855-139-0225**

821 **Outlet: Controlled Substances**

822  
823 **If controlled substances are at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site**  
824 **Pharmacy and its Affiliated Pharmacy must:**

825  
826 **(1) Comply with controlled substance regulations;**

827  
828 **(2) Store all controlled substances in a secure locked cabinet;**

829  
830 **(3) Maintain an accurate controlled substance perpetual inventory; and**

831  
832 **(4) Ensure an Oregon licensed Pharmacist conducts a monthly controlled substance inventory and**  
833 **reconciles all discrepancies at the time of in person physical inspection.**

834  
835 **Statutory/Other Authority: ORS 689.205**  
836 **Statutes/Other Implemented: ORS 689.155**

837  
838  
839  
840 **855-139-0230**

841 **Outlet: Non-Sterile Compounding**

842  
843 **If non-sterile preparations are compounded at the Remote Dispensing Site Pharmacy, the Remote**  
844 **Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

845  
846 **(1) Adhere to the requirements of OAR 855-045;**

847  
848 **(2) Ensure an Oregon licensed Pharmacist:**

849  
850 **(a) Supervises via a real-time audio-visual connection all steps of the compounding; and**

851  
852 **(b) Documents and visually verifies each item required in OAR 855-139-0041.**

853  
854 **Statutory/Other Authority: ORS 689.205**  
855 **Statutes/Other Implemented: ORS 689.155**

856  
857  
858 **855-139-0300**

859 **Prescription: General Requirements**

860  
861 **(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with**  
862 **the prescribing practitioner's authorization. When a prescription is transmitted orally, it must be**  
863 **transmitted to the Oregon licensed Pharmacist from the Affiliated Pharmacy and both the receiving**

864 pharmacist's name or initials and the name of the person transmitting must be noted on the  
865 prescription.

866

867 **(2) Each pharmacy must document the following information for each prescription:**

868

869 **(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal.**

870

871 **(b) If for an animal, the name of the patient, name the owner and the species of the animal.**

872

873 **(c) The full name, address, and contact phone number of the practitioner. If for a controlled**  
874 **substance, the Drug Enforcement Administration registration number of the practitioner and other**  
875 **number as authorized under rules adopted by reference under rule OAR 855-080-0085;**

876

877 **(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the**  
878 **quantity prescribed, the quantity dispensed;**

879

880 **(e) The directions for use, if given by the practitioner; and**

881

882 **(f) The date of filling, and the total number of refills authorized by the prescribing practitioner.**

883

884 **(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic**  
885 **communication or by electronic transmission that there may be no substitution for the specified**  
886 **brand name drug in a prescription.**

887

888 **(a) For a hard copy prescription issued in writing or a prescription orally communicated over the**  
889 **telephone, instruction may use any one of the following phrases or notations:**

890

891 **(A) No substitution;**

892

893 **(B) N.S.;**

894

895 **(C) Brand medically necessary;**

896

897 **(D) Brand necessary;**

898

899 **(E) Medically necessary;**

900

901 **(F) D.A.W. (Dispense As Written); or**

902

903 **(G) Words with similar meaning.**

904

905 **(b) For an electronically transmitted prescription, the prescriber or prescriber's agent must clearly**  
906 **indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or**  
907 **words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic**  
908 **indicators sent as part of the electronic prescription transmission.**

909

910 **(c) Such instructions must not be default values on the prescription.**

911

912 **(4) A pharmacy or Oregon licensed Pharmacist filling a prescription or order for a biological product**  
913 **may not substitute a biosimilar product for the prescribed biological product unless:**

914  
915 **(a) The biosimilar product has been determined by the United States Food and Drug Administration to**  
916 **be interchangeable with the prescribed biological product;**

917  
918 **(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;**

919  
920 **(c) The patient for whom the biological product is prescribed is informed of the substitution prior to**  
921 **dispensing the biosimilar product;**

922  
923 **(d) The pharmacy or Oregon licensed Pharmacist provides written, electronic or telephonic**  
924 **notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff**  
925 **within three (3) business days of dispensing the biosimilar product; and**

926  
927 **(5) The pharmacy must dispense prescriptions accurately and to the correct party.**

928  
929 **Statutory/Other Authority: ORS 689.205 & ORS 689.522**  
930 **Statutes/Other Implemented: ORS 689.505, 689.515 & ORS 689.522**

931  
932  
933  
934 **855-139-0305**

935 **Prescription: Tamper-resistant**

936  
937 **When the use of a tamper-resistant prescription is required by any federal or state law or rule, the**  
938 **term "tamper-resistant" has the meaning as defined in OAR 855-006-0015.**

939  
940 **Statutory/Other Authority: ORS 689.205**  
941 **Statutes/Other Implemented: ORS 689.155**

942  
943  
944 **855-139-0310**

945 **Prescription: Verification of Authenticity**

946  
947 **Alteration of a written prescription, other than by an Oregon licensed Pharmacist's or practitioner's**  
948 **authorization, in any manner constitutes an invalid order unless verified with the prescriber.**

949  
950 **Statutory/Other Authority: ORS 689.205**  
951 **Statutes/Other Implemented: ORS 689.151, ORS 689.155**

952  
953  
954 **855-139-0315**

955 **Prescription: Refills**

956  
957 **(1) Where refill authority is given other than by the original prescription, documentation that such**  
958 **refill authorization was given, the date of authorization, and name of the authorizing prescriber or the**  
959 **prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions**



960 for controlled substances in Schedules III, IV and V are limited to five refills or six months from date of  
961 issue, whichever comes first.

962

963 **(2) If the practitioner is not available and in the professional judgment of the Oregon licensed**  
964 **pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the**  
965 **pharmacist may dispense a sufficient quantity of the drug consistent with the dosage regimen,**  
966 **provided it is not a controlled substance, to last until a practitioner can be contacted for**  
967 **authorization, but not to exceed a 72-hour supply. The practitioner must be promptly notified of the**  
968 **emergency refill.**

969

970 **(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly**  
971 **maintained for three years. This record must include;**

972

973 **(a) The identity of the responsible Oregon licensed Pharmacist;**

974

975 **(b) Name of the patient;**

976

977 **(c) Name of the medication;**

978

979 **(d) Date of refill; and**

980

981 **(e) Quantity dispensed.**

982

983 **(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled**  
984 **substance or psychotherapeutic drug and the prescriber is notified of the change.**

985

986 **(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient's**  
987 **agent. A request specific to each prescription medication is required, unless the requested fill or refill**  
988 **is part of an auto-refill program and is a continuation of therapy.**

989

990 **(6) A prescription must be refilled in context with the approximate dosage schedule unless specifically**  
991 **authorized by the prescriber.**

992

993 **(7) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may**  
994 **use a program that automatically refills non-controlled prescription medications, that have existing**  
995 **refills available and are consistent with the patient's current medication therapy only when the**  
996 **following conditions are met:**

997

998 **(a) A patient or patient's agent must enroll each prescription medication in an auto-refill program**  
999 **before a pharmacy can include the prescription medication as part of the auto-refill program;**

1000

1001 **(b) The prescription is not a controlled substance;**

1002

1003 **(c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or**  
1004 **patient's agent;**

1005

1006 **(d) Pick-up notification to a patient or patient's agent may be generated upon completion of a**  
1007 **prescription refill; and**

1008 (e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription  
1009 medication is removed from the auto-refill program for that patient.

1010  
1011 Statutory/Other Authority: ORS 689.205

1012 Statutes/Other Implemented: ORS 689.505 & ORS 689.515

1013

1014

1015 855-139-0320

1016 Prescription: Expiration

1017

1018 This section of rule addresses the expiration date of the prescription and not the expiration date of  
1019 the drug.

1020

1021 (1) After one year from date of issue, a prescription for a non-controlled substance becomes invalid  
1022 and must be re-authorized by the prescriber.

1023

1024 (2) When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled  
1025 substance means that the medication can be refilled in proper context for a period of one year.

1026

1027 (a) When this abbreviation is used alone as a means to authorize refills for a controlled substance, the  
1028 medication can be refilled in proper context for a period of six months or five refills, whichever comes  
1029 first.

1030

1031 (b) When this abbreviation is used in conjunction with a definite time period, or a specific number of  
1032 refills, the non-controlled medication can be refilled in proper context for a period not to exceed one  
1033 year.

1034

1035 Statutory/Other Authority: ORS 689.205

1036 Statutes/Other Implemented: ORS 689.505 & ORS 689.515

1037

1038

1039 855-139-0325

1040 Prescription: Transfers

1041

1042 (1) Prescriptions may be transferred between pharmacies for the purpose of refill dispensing provided  
1043 that:

1044

1045 (a) The prescription is invalidated at the sending pharmacy; and

1046

1047 (b) The receiving pharmacy obtains all the information constituting the prescription and its relevant  
1048 refill history in a manner that ensures accuracy and accountability.

1049

1050 (2) Prescriptions for controlled substances can only be transferred one time.

1051

1052 (3) Pharmacies using the same electronic prescription database are not required to transfer  
1053 prescriptions for dispensing purposes.

1054

1055 Statutory/Other Authority: ORS 689.205

1056 Statutes/Other Implemented: ORS 689.155

1057

1058 855-139-0350

1059 Dispensing: Containers

1060

1061 **Each pharmacy must dispense a drug in a new container that complies with the current provisions of**  
1062 **the Poison Prevention Packaging Act in 16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX), and 16**  
1063 **CFR 1702 (XX/XX/XXXX).**

1064

1065 [Publications: Publications referenced are available from the agency.]

1066

1067 Statutory/Other Authority: ORS 689.205

1068 Statutes/Other Implemented: ORS 689.155

1069

1070

1071 855-139-0355

1072 Dispensing: Customized Patient Medication Packages

1073

1074 **POLICY DISCUSSION:** Customized Medication Packages

1075

1076 **In lieu of dispensing two or more prescribed drug products in separate containers, an Oregon licensed**  
1077 **pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a**  
1078 **customized patient medication package (patient med pak). A patient med pak is a package prepared**  
1079 **by a pharmacist for a specific patient comprising a series of containers and containing two or more**  
1080 **prescribed solid oral dosage forms. The patient med pak is so designed for each container is so labeled**  
1081 **as to indicate the day and time, or period of time, that the contents within each container are to be**  
1082 **taken:**

1083

1084 **(1) Label:**

1085

1086 **(a) The patient med pak must bear a label stating:**

1087

1088 **(A) The name of the patient;**

1089

1090 **(B) A serial number for each patient med pak itself and a separate identifying serial number for each**  
1091 **of the prescription orders for each of the drug products contained therein;**

1092

1093 **(C) The name, strength, physical description or identification, and total quantity of each drug product**  
1094 **contained therein;**

1095

1096 **(D) The directions for use and cautionary statements, if any, contained in the prescription order for**  
1097 **each drug product therein;**

1098

1099 **(E) Any storage instructions or cautionary statements required by the official compendia;**

1100

1101 **(F) The name of the prescriber of each drug product;**

1102

1103 (G) The date of preparation of the patient med pak and the beyond-use date assigned to the patient  
1104 med pak (such beyond-use date must be no later than 60 days from the date of preparation);

1105  
1106 (H) The name, address, and telephone number of the dispenser and the dispenser’s registration  
1107 number where necessary; and

1108  
1109 (I) Any other information, statements, or warnings required for any of the drug products contained  
1110 therein.

1111  
1112 (b) If the patient med pak allows for the removal or separation of the intact containers therefrom,  
1113 each individual container must bear a label identifying each of the drug products contained therein.

1114  
1115 **(2)** Labeling: The patient med pak must be accompanied by a patient package insert, in the event that  
1116 any medication therein is required to be dispensed with such insert as accompanying labeling.  
1117 Alternatively, such required information may be incorporated into a single, overall educational insert  
1118 provided by the Oregon licensed pharmacist for the total patient med pak.

1119  
1120 **(3)** Packaging:

1121  
1122 (a) In the absence of more stringent packaging requirements for any of the drug products contained  
1123 therein, each container of the patient med pak must comply with the moisture permeation  
1124 requirements for a Class B single-unit or unit-dose container. Each container must be either not  
1125 reclosable or so designed as to show evidence of having been opened;

1126  
1127 (b) There is no special exemption for patient med paks from the requirements of the Poison  
1128 Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards  
1129 must be placed in an outer package that does comply, or the necessary consent of the purchaser or  
1130 physician, to dispense in a container not intended to be child-resistant, must be obtained.

1131  
1132 **(4)** Guidelines: It is the responsibility of the dispenser, when preparing a patient med pak, to take into  
1133 account any applicable compendia requirements or guidelines and the physical and chemical  
1134 compatibility of the dosage forms placed within each container, as well as any therapeutic  
1135 incompatibilities that may attend the simultaneous administration of the medications. In this regard,  
1136 pharmacists are encouraged to report to USP headquarters any observed or report incompatibilities.

1137  
1138 **(5)** Recordkeeping: In addition to any individual prescription filing requirements, a record of each  
1139 patient med pak must be made and filed. Each record must contain, as a minimum:

1140  
1141 (a) The name and address of the patient;

1142  
1143 (b) The serial number of the prescription order for each drug product contained therein;

1144  
1145 (c) The name of the manufacturer or labeler and lot number for each drug product contained therein;

1146  
1147 (d) Information identifying or describing the design, characteristics, or specifications of the patient  
1148 med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

1149  
1150 (e) The date of preparation of the patient med pak and the beyond-use date that was assigned;

- 1151 (f) Any special labeling instructions; and  
1152  
1153 (g) The name or initials of the Oregon licensed pharmacist who prepared the patient med pak.  
1154  
1155 **(2)** Ensure an Oregon licensed Pharmacist documents and visually verifies each item required in OAR  
1156 855-139-0041 for each individual pak.

1157  
1158 Statutory/Other Authority: ORS 689.205  
1159 Statutes/Other Implemented: ORS 689.155

1160  
1161  
1162 **855-139-0400**

1163 Labeling: General Requirements

1164  
1165 **(1)** Prescriptions must be labeled with the following information:

1166  
1167 (a) Name, address and telephone number of the pharmacy;

1168  
1169 (b) Date;

1170  
1171 (c) Identifying number;

1172  
1173 (d) Name of patient;

1174  
1175 (e) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also  
1176 contain the identifier of the manufacturer or distributor;

1177  
1178 (f) Directions for use by the patient;

1179  
1180 (g) Name of practitioner;

1181  
1182 (h) Required precautionary information regarding controlled substances;

1183  
1184 (i) Such other and further accessory cautionary information as required for patient safety;

1185  
1186 (j) An expiration date after which the patient should not use the drug or medicine. Expiration dates on  
1187 prescriptions must be the same as that on the original container unless, in the Oregon licensed  
1188 Pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an  
1189 expiration date must not be dispensed beyond the said expiration date of the drug;

1190  
1191 (k) Any dispensed prescription medication, other than those in unit dose or unit of use packaging,  
1192 must be labeled with its physical description, including any identification code that may appear on  
1193 tablets and capsules; and

1194  
1195 **(l)** Address and telephone number of the Affiliated Pharmacy.

1196  
1197 Statutory/Other Authority: ORS 689.205  
1198 Statutes/Other Implemented: ORS 689.505 & 689.515

1199 **855-139-0405**

1200 **Labeling: Prescription Reader Accessibility**

1201

1202 **A pharmacy must notify each person to whom a prescription drug is dispensed that a prescription**  
1203 **reader is available to the person upon request; a prescription reader is a device designed to audibly**  
1204 **convey labeling information.**

1205

1206 **If a person informs the pharmacy that the person identifies as a person who is blind, the pharmacy**  
1207 **must provide to the person a prescription reader that is available to the person for at least the**  
1208 **duration of the prescription, must confirm it is appropriate to address the person’s visual impairment,**  
1209 **and must ensure that prescription labels are compatible with the prescription reader. This**  
1210 **requirement does not apply to an institutional drug outlet, dispensing a drug intended for**  
1211 **administration by a healthcare provider.**

1212

1213 **POLICY DISCUSSION:** Timeframe

1214

1215 **Statutory/Other Authority: ORS 689.205**

1216 **Statutes/Other Implemented: ORS 689.561**

1217

1218

1219 **855-139-0410**

1220 **Labeling: Limited English Proficiency and Accessibility**

1221

1222 **(1) Upon request of a prescriber, patient or a patient’s agent, each drug dispensed by a pharmacy for a**  
1223 **patient’s self-administration must bear a label in both English and the language requested for an**  
1224 **individual with limited English proficiency. This does not apply to a drug outlet dispensing a drug**  
1225 **intended for administration by a healthcare worker.**

1226

1227 **(2) When dispensing a drug under (1), a pharmacy must provide a prescription label and, when**  
1228 **needed, an informational insert in both English and one of the following languages:**

1229

1230 **(a) Spanish;**

1231

1232 **(b) Russian;**

1233

1234 **(c) Somali;**

1235

1236 **(d) Arabic;**

1237

1238 **(e) Chinese (simplified);**

1239

1240 **(f) Vietnamese;**

1241

1242 **(g) Farsi;**

1243

1244 **(h) Korean;**

1245

1246 **(i) Romanian;**

1247  
1248 **(j) Swahili;**  
1249  
1250 **(k) Burmese;**  
1251  
1252 **(l) Nepali;**  
1253  
1254 **(m) Amharic; and**  
1255  
1256 **(n) Pashtu.**  
1257  
1258 **(3) The board must reassess and update (2) as necessary and at least every ten years.**  
1259  
1260 **(4) An informational insert may be used when the directions for use in English and the language**  
1261 **requested exceed 140 characters.**  
1262  
1263 **(5) When an informational insert is used, the prescription label affixed to the prescription container**  
1264 **must state in both English and the language requested by the patient that an informational insert is**  
1265 **being used.**  
1266  
1267 **(6) At a minimum, the informational insert must include the:**  
1268  
1269 **(a) Directions for use by the patient in both English and the language requested;**  
1270  
1271 **(b) Identifying number;**  
1272  
1273 **(c) Name of patient;**  
1274  
1275 **(d) Name of drug and strength; and**  
1276  
1277 **(e) Date of fill.**  
1278  
1279 **Statutory/Other Authority: ORS 689.564**  
1280 **Statutes/Other Implemented: ORS 689.205**  
1281  
1282  
1283 **855-139-0415**  
1284 **Labeling: Repackaged Drugs**  
1285  
1286 **POLICY DISCUSSION:** Prohibit Repackaging, Limit to own use  
1287  
1288 **(1) Each pharmacy record keeping system must identify all pharmacy personnel involved in**  
1289 **repackaging including the pharmacist who verified the repackaged drug.**  
1290  
1291 **(2) A single oral solid drug products repackaged by a pharmacy into unit-dose packaging must:**  
1292

1293 **(a) Utilize a unit-dose container–closure system that meets the testing requirements under USP <671>**  
1294 **Containers—Performance Testing (12/01/2020) for either Class A or Class B containers and meets or**  
1295 **exceeds the original container's specification for light resistance;**

1296  
1297 **(b) Be labeled to identify at a minimum:**

1298  
1299 **(A) Brand name, or generic name;**

1300  
1301 **(B) Strength;**

1302  
1303 **(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot**  
1304 **number; and**

1305  
1306 **(D) Expiration date. The expiration date used for the repackaged product must not exceed:**

1307  
1308 **(i) 6 months from the date of repackaging; or**

1309  
1310 **(ii) The manufacturer's expiration date; or**

1311  
1312 **(iii) 25% of the time between the date of repackaging and the expiration date shown on the**  
1313 **manufacturer's bulk article container of the drug being repackaged, whichever is earlier.**

1314  
1315 **(3) A single oral solid drug product repackaged by a pharmacy into multiple-unit packaging must:**

1316  
1317 **(a) Utilize an equivalent container–closure system that is at least as protective as, or more protective**  
1318 **than, the original system, complies with criteria established for equivalency and meets or exceeds the**  
1319 **original container's specification for light resistance;**

1320  
1321 **(b) Be labeled to identify at a minimum:**

1322  
1323 **(A) Brand name or generic name;**

1324  
1325 **(B) Strength;**

1326  
1327 **(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot**  
1328 **number; and**

1329  
1330 **(D) Expiration date. The expiration date used for the repackaged product must not exceed the**  
1331 **manufacturer's expiration date or one year from the date the drug was placed in the new container,**  
1332 **whichever date is earlier.**

1333  
1334 **Statutory/Other Authority: ORS 689.205**

1335 **Statutes/Other Implemented: ORS 689.155**

1336  
1337  
1338 **855-139-0450**

1339 **Drugs and Devices: Disposal**

1340



1341 **Drugs** and devices that are outdated, damaged, deteriorated, misbranded, or adulterated must be  
1342 **quarantined and physically separated from other drugs until they are destroyed or returned to their**  
1343 **supplier.**

1344  
1345 **Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315**

1346 **Statutes/Other Implemented: ORS 689.155**

1347

1348

1349 **855-139-0455**

1350 **Drug and Devices: Return**

1351

1352 **(1) A Certified Oregon Pharmacy Technician may accept the return of a drug or device as defined by**  
1353 **ORS 689.005 once the drug or device have been dispensed from the pharmacy if they were dispensed**  
1354 **in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, or are**  
1355 **subject of a drug or device recall only if:**

1356

1357 **(a) An Oregon licensed Pharmacist has approved the return;**

1358

1359 **(b) The drugs or devices are accepted for destruction or disposal; and**

1360

1361 **(c) An Oregon licensed Pharmacist verifies the destruction or disposal.**

1362

1363 **Statutory/Other Authority: ORS 689.205**

1364 **Statutes/Other Implemented: ORS 689.305**

1365

1366

1367 **855-139-0460**

1368 **Drugs and Devices: Take-back Program**

1369

1370 **(1) A Remote Dispensing Site Pharmacy that operates a drug take-back collection program or that**  
1371 **participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized**  
1372 **collector must be registered with the DEA as an authorized collector to collect controlled and non-**  
1373 **controlled drugs for destruction.**

1374

1375 **(2) A Remote Dispensing Site Pharmacy that operates as a Drug Enforcement Agency (DEA) authorized**  
1376 **collector must notify the board within 30 days of initiating or terminating the program and must**  
1377 **establish and enforce policies and procedures, including but not limited to:**

1378

1379 **(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is**  
1380 **accessible to the public, within view of the pharmacy counter and must not be located behind the**  
1381 **pharmacy counter; and**

1382

1383 **(b) Provision of adequate security measures, including proper installation and maintenance of the**  
1384 **collection receptacle, tracking of liners, documentation and key accountability; and**

1385

1386 **(c) Personnel training and accountability.**

1387

1388 **(3) A Remote Dispensing Site Pharmacy must inform consumers to directly deposit drugs into the**  
1389 **collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs**  
1390 **collected.**

1391  
1392 **(4) A Remote Dispensing Site Pharmacy must not dispose of drugs from pharmacy stock in a collection**  
1393 **receptacle.**

1394  
1395 **(5) The liner must be inserted and removed from a locked collection receptacle only by or under the**  
1396 **supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed,**  
1397 **and the pharmacy employees must document their participation in the insertion and removal of each**  
1398 **liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed or penetrated**  
1399 **at any time by the pharmacy or pharmacy personnel.**

1400  
1401 **(6) Liners that have been removed from a collection receptacle and immediately sealed must be**  
1402 **directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer**  
1403 **than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution**  
1404 **agent (such as registered UPS, FedEx or USPS) or a reverse wholesaler registered with the DEA and the**  
1405 **board.**

1406  
1407 **(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to**  
1408 **the board in writing within one day of discovery.**

1409  
1410 **(8) A Remote Dispensing Site Pharmacy must maintain all drug disposal records for a minimum of 3**  
1411 **years.**

1412  
1413 **(9) Authorized collectors are required to comply with the following federal and state laws:**

1414  
1415 **(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS**  
1416 **459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236,**  
1417 **ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS**  
1418 **459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;**

1419  
1420 **(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370,**  
1421 **and OAR 340-098-0390;**

1422  
1423 **(c) 21 CFR 1317.30 (04/01/2020), 21 CFR 1317.35 (04/01/2020), 21 CFR 1317.40 (04/01/2020), 21 CFR**  
1424 **1317.55 (04/01/2020), 21 CFR 1317.60 (04/01/2020), 21 CFR 1317.65 (04/01/2020), 21 CFR 1317.70**  
1425 **(04/01/2020), 21 CFR 1317.75 (04/01/2020), 21 CFR 1317.80 (04/01/2020), and 21 CFR 1317.85**  
1426 **(04/01/2020); and**

1427  
1428 **(d) 21 USC 822 (04/01/2021), 21 USC 822a (04/01/2021).**

1429  
1430 **Statutory/Other Authority: ORS 689.205 & ORS 459A.266**  
1431 **Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215 & ORS 495A.218**

1432  
1433  
1434

1435 **855-139-0500**

1436 **Policies and Procedures**

1437

1438 **(1) The Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy and the Affiliated Pharmacy**  
1439 **drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures**  
1440 **for the Remote Dispensing Site Pharmacy. The written policies and procedures must be maintained at**  
1441 **the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy and must be available to the board**  
1442 **upon request.**

1443

1444 **(2) The written policies and procedures must include at a minimum the responsibilities of the**  
1445 **Affiliated Pharmacy and each Remote Dispensing Site Pharmacy including;**

1446

1447 **(a) Security;**

1448

1449 **(b) Operation, testing and maintenance of the telepharmacy system;**

1450

1451 **(c) Sanitation;**

1452

1453 **(d) Storage of drugs;**

1454

1455 **(e) Dispensing;**

1456

1457 **(f) Oregon licensed Pharmacist supervision, direction and control of pharmacy technicians;**

1458

1459 **(g) Documenting the identity, function, location, date and time of the licensees engaging in**  
1460 **telepharmacy;**

1461

1462 **(h) Drug and/or device procurement;**

1463

1464 **(i) Receiving of drugs and/or devices;**

1465

1466 **(j) Delivery of drugs and/or devices;**

1467

1468 **(k) Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling);**

1469

1470 **(l) Recordkeeping;**

1471

1472 **(m) Patient confidentiality;**

1473

1474 **(n) On-site inspection by an Oregon licensed Pharmacist;**

1475

1476 **(o) Continuous quality improvement;**

1477

1478 **(p) Plan for discontinuing and recovering services if telepharmacy system disruption occurs;**

1479

1480 **(q) Training: initial and ongoing; and**

1481

1482 **(r) Interpretation, translation and prescription reader services.**

1483 **(3) If non-prescription drugs are offered for sale at the Remote Dispensing Site Pharmacy, the policies**  
1484 **and procedures must outline the process for the Oregon licensed Pharmacist counseling and advice.**

1485  
1486 **(4) If non-sterile preparations are compounded at the Remote Dispensing Site Pharmacy, the policies**  
1487 **and procedures must meet the requirements of OAR 855-045.**

1488  
1489 **(5) If controlled substances are stored at the Remote Dispensing Site Pharmacy, the policies and**  
1490 **procedures must include the following processes:**

1491  
1492 **(a) Reviewing of controlled substance prescriptions for unauthorized alterations and inspected for**  
1493 **legitimacy by the Oregon licensed Pharmacist during inspection visits;**

1494  
1495 **(b) Maintaining an accurate controlled substance perpetual inventory for all controlled substances**  
1496 **that are stocked at the Remote Dispensing Site Pharmacy; and**

1497  
1498 **(c) Conducting and reconciling the controlled substance inventory.**

1499  
1500 **(6) An Affiliated Pharmacy that provides remote pharmacy services through a telepharmacy system at**  
1501 **a Remote Dispensing Site Pharmacy must review its written policies and procedures every 12 months,**  
1502 **revise them if necessary, and document the review.**

1503  
1504 **Statutory/Other Authority: ORS 689.205**  
1505 **Statutes/Other Implemented: ORS 689.155**

1506  
1507  
1508 **855-139-0550**

1509 **Records: General Requirements**

1510  
1511 **(1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other**  
1512 **recordkeeping rules of the board. Unless otherwise specified, all records and documentation required**  
1513 **by these rules, must be retained for three years and made available to the board for inspection upon**  
1514 **request. Records must be stored onsite for at least one year and may be stored, after one year, in a**  
1515 **secured off-site location if retrievable within three business days. Records and documentation may be**  
1516 **written, electronic or a combination of the two.**

1517  
1518 **(2) The Remote Dispensing Site Pharmacy must maintain all required records unless these records are**  
1519 **maintained in the Affiliated Pharmacy.**

1520  
1521 **(3) Records retained by the Drug Outlet must include, but are not limited to:**

1522  
1523 **(a) Patient profiles and records;**

1524  
1525 **(b) Date, time and identification of each individual and activity or function performed;**

1526  
1527 **(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or**  
1528 **function of the person performing each step in the dispensing process;**

1529  
1530 **(d) Controlled substance inventory and reconciliation;**

- 1531 **(e) Oregon licensed Pharmacist physical inspection of Remote Dispensing Site Pharmacy;**  
1532  
1533 **(f) Audio and visual connection testing and individual training on use of the audio and visual**  
1534 **connection;**  
1535  
1536 **(g) Data, telephone audio, audio and video, still image capture, store and forward images, security**  
1537 **and surveillance data. This must be retained according to (1); and**  
1538  
1539 **(h) Any errors or irregularities identified by the quality improvement program.**

1540  
1541 **(4) All data, telephone audio, audio and video, still image capture and store and forward images**  
1542 **collected by the telepharmacy, security and surveillance systems must be retained according to (1).**  
1543

1544 **Statutory/Other Authority: ORS 689.205**  
1545 **Statutes/Other Implemented: ORS 689.155, ORS 689.508**  
1546

1547  
1548 **855-139-0555**  
1549 **Records: Patient**  
1550

1551 **A patient record system must be maintained by pharmacies for all patients for whom a prescription**  
1552 **drug is dispensed. The patient record system must provide information necessary for the dispensing**  
1553 **Oregon licensed pharmacist to identify previously dispensed drugs at the time a prescription is**  
1554 **presented for dispensing. The pharmacist must make a reasonable effort to obtain, record, and**  
1555 **maintain the following information:**  
1556

1557 **(1) Full name of the patient for whom the drug is intended;**  
1558

1559 **(2) Address and telephone number of the patient;**  
1560

1561 **(3) Patient's age or date of birth;**  
1562

1563 **(4) Patient's gender;**  
1564

1565 **(5) Chronic medical conditions;**  
1566

1567 **(6) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the**  
1568 **patient record showing the name of the drug or device, prescription number, name and strength of**  
1569 **the drug, the quantity and date received, and the name of the prescriber;**  
1570

1571 **(7) Known allergies, drug reactions, and drug idiosyncrasies; and**  
1572

1573 **(8) If deemed relevant in the Oregon licensed Pharmacist's professional judgment:**  
1574

1575 **(a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any**  
1576 **other information peculiar to the specific patient or drug; and**  
1577

1578 **(b) Additional information such as chronic conditions or disease states of the patient, the patient's**  
1579 **current weight, and the identity of any other drugs, including over-the-counter drugs, or devices**  
1580 **currently being used by the patient which may relate to prospective drug review.**

1581

1582 **Statutory/Other Authority: ORS 689.205**

1583 **Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508**

1584

1585

1586

1587 **855-139-0600**

1588 **Prohibited Practices: General**

1589

1590 **A Retail Drug Outlet Remote Dispensing Site Pharmacy may not:**

1591

1592 **(1) Allow a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent**  
1593 **which screen and/or limit interaction with the Oregon licensed Pharmacist;**

1594

1595 **(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide**  
1596 **pharmacy services unless the person is registered with the Board pursuant to ORS 689.305.**

1597

1598 **(3) Deliver a prescription;**

1599

1600 **(4) Provide non-prescription or prescription drugs when the Remote Dispensing Site Pharmacy is**  
1601 **closed; or**

1602

1603 **(5) Compound sterile preparations.**

1604

1605 **Statutory/Other Authority: ORS 475.035, , ORS 689.205, ORS 689.305, ORS 689.315**

1606 **Statutes/Other Implemented: ORS 689.155**

1607

1608

1609 **855-139-0602**

1610 **Prohibited Practices: Disclosure of Patient Information**

1611

1612 **(1) Allow a licensee or registrant of the Board who obtains any patient information to disclose that**  
1613 **information to a third party without the consent of the patient except as provided in (2) of this rule**

1614

1615 **(2) A licensee may disclose patient information:**

1616

1617 **(a) To the Board;**

1618

1619 **(b) To a practitioner, Oregon licensed Pharmacist, Intern, Pharmacy Technician, or Certified Oregon**  
1620 **Pharmacy Technician, if disclosure is authorized by an Oregon-licensed Pharmacist who reasonably**  
1621 **believes that disclosure is necessary to protect the patient's health or well-being; or**

1622

1623 **(c) To a third-party when disclosure is authorized or required by law; or**

1624

1625 **(d) As permitted pursuant to federal and state patient confidentiality laws; or**

1626  
1627 **(e) To the patient or to persons as authorized by the patient.**

1628  
1629 **(3) Allow a licensee or registrant of the Board to access or obtain any patient information unless it is**  
1630 **accessed or obtained for the purpose of patient care.**

1631  
1632 **Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315**  
1633 **Statutes/Other Implemented: ORS 689.155**

1634  
1635  
1636 **855-139-0650**  
1637 **Grounds for Discipline**

1638  
1639 **The State Board of Pharmacy may impose one or more of the following penalties which includes:**  
1640 **suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet**  
1641 **upon the following grounds:**

1642  
1643 **(1) Unprofessional conduct as defined in OAR 855-006-0020;**

1644  
1645 **(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including,**  
1646 **but not be limited to, advertising or soliciting that:**

1647  
1648 **(a) Is false, fraudulent, deceptive, or misleading; or**

1649  
1650 **(b) Makes any claim regarding a professional service or product or the cost or price thereof which**  
1651 **cannot be substantiated by the licensee.**

1652  
1653 **(3) Failure to provide a working environment that protects the health, safety and welfare of a patient**  
1654 **which includes but is not limited to:**

1655  
1656 **(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with an**  
1657 **Oregon licensed Pharmacist's ability to practice with reasonable competency and safety.**

1658  
1659 **(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.**

1660  
1661 **(c) Adequate time for an Oregon licensed Pharmacist to complete professional duties and**  
1662 **responsibilities including, but not limited to:**

1663  
1664 **(A) Drug Utilization Review;**

1665  
1666 **(B) Verification of the accuracy of a prescription;**

1667  
1668 **(C) Counseling; and**

1669  
1670 **(D) All other duties and responsibilities of an Oregon licensed Pharmacist as specified in OAR 855-019.**

1671  
1672 **(4) Introducing external factors such as productivity or production quotas or other programs to the**  
1673 **extent that they interfere with the ability to provide appropriate professional services to the public.**

1674 **(5) Incenting or inducing the transfer of a prescription absent professional rationale.**

1675

1676 **Statutory/Other Authority: ORS 689.151, ORS 689.155, ORS 689.205, ORS 689.225**

1677 **Statutes/Other Implemented: ORS 689.155**

1678

1679

1680 **855-139-0710**

1681 **Service: Epinephrine- Definitions**

1682

1683 **The following words and terms, when used in OAR 855-139-0210 through OAR 855-139-0211 have the**  
1684 **following meanings, unless the context clearly indicates otherwise.**

1685

1686 **(1) "Allergic reaction" means a medical condition caused by exposure to an allergen, with physical**  
1687 **symptoms that may be life threatening, ranging from localized itching to severe anaphylactic shock**  
1688 **and death.**

1689

1690 **(2) "Authorization to Obtain Epinephrine" means a certificate that contains the name, signature, and**  
1691 **license number of the supervising professional authorizing the dispensing of epinephrine to the**  
1692 **individual whose name appears on the certificate. Additionally, the certificate contains a record of the**  
1693 **number of epinephrine orders filled to date.**

1694

1695 **(3) "Statement of Completion" means a certificate that states the specific type of emergency the**  
1696 **trainee was trained to respond to, the trainee's name and address, the name of the authorized trainer**  
1697 **and the date that the training was completed.**

1698

1699 **(4) "Trainee" means an individual who has attended and successfully completed the formal training**  
1700 **pursuant to the protocols and criteria established by the Oregon Health Authority, Public Health**  
1701 **Division.**

1702

1703 **Statutory/Other Authority: ORS 689.205 & ORS 689.681**

1704 **Statutes/Other Implemented: ORS 689.155 & ORS 689.681**

1705

1706

1707 **855-139-0715**

1708 **Service: Epinephrine- General Requirements**

1709

1710 **(1) An Oregon licensed Pharmacist may fill an order for epinephrine to be used by trainees to treat an**  
1711 **anaphylactic reaction. Trainees must be 18 years of age or older and must have responsibility for or**  
1712 **contact with at least one (1) other person as a result of the trainee's occupation or volunteer status,**  
1713 **such as, but not limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide**  
1714 **or chaperone.**

1715

1716 **(2) Individuals must successfully complete a training program approved by the Oregon Health**  
1717 **Authority, Public Health Division. Upon successful completion, the trainee will receive the following**  
1718 **certificates:**

1719

1720 **(a) Statement of Completion; and**

1721



1722 **(b) Authorization to Obtain Epinephrine.**

1723

1724 **(3) Acquisition of epinephrine from a pharmacy to be used for the treatment of allergic emergencies**  
1725 **may occur in the following manners:**

1726

1727 **(a) An Oregon licensed Pharmacist may dispense epinephrine to a trainee upon presentation of the**  
1728 **Statement of Completion and Authorization to Obtain Epinephrine certificate to a pharmacy when:**

1729

1730 **(A) An Oregon licensed Pharmacist may generate a prescription for and dispense an emergency supply**  
1731 **of epinephrine for not more than one adult and one child dose package, as specified by the**  
1732 **supervising professional whose name, signature, and license number appear on the Authorization to**  
1733 **Obtain Epinephrine certificate.**

1734

1735 **(B) The Oregon licensed Pharmacist who generates the hardcopy prescription for epinephrine in this**  
1736 **manner must reduce the prescription to writing and file the prescription in a manner appropriate for a**  
1737 **non-controlled substance.**

1738

1739 **(C) Once the Oregon licensed Pharmacist generates the epinephrine prescription, the pharmacist must**  
1740 **write in the appropriate space provided on the Authorization to Obtain Epinephrine certificate the**  
1741 **date and the number of doses dispensed and return the certificate to the trainee.**

1742

1743 **(D) The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used**  
1744 **to obtain epinephrine up to four (4) times within three (3) years from the date of the initial training.**

1745

1746 **(E) Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire**  
1747 **three (3) years from the date of the trainee's last Oregon Health Authority approved allergy response**  
1748 **training.**

1749

1750 **(F) Upon completion of the training, the trainee will receive a new Statement of Completion and**  
1751 **Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.**

1752

1753 **(b) An Oregon licensed Pharmacist may dispense epinephrine to an entity when:**

1754

1755 **(A) The epinephrine is acquired by a valid prescription presented to the pharmacy;**

1756

1757 **(B) The prescription identifies the entity as the patient for the purpose of prescribing and labeling the**  
1758 **prescription.**

1759

1760 **Statutory/Other Authority: ORS 689.205**

1761 **Statutes/Other Implemented: ORS 689.155 & ORS 433.825**

1762

1763

1764 **855-139-0720**

1765 **Service: Naloxone- General Requirements**

1766

1767 **Pharmacies providing naloxone services must establish, maintain and enforce written procedures**  
1768 **including, but not limited to:**

1769

1770 **(1) Providing a workflow process and physical location that maintains confidentiality and is not**  
1771 **susceptible to distraction;**

1772  
1773 **(2) Documentation and recordkeeping: and**

1774  
1775 **(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies**  
1776 **to administer naloxone are available at the pharmacy.**

1777  
1778 **Statutory/Other Authority: ORS 689.205**  
1779 **Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682**

1780  
1781  
1782 **855-139-0725**  
1783 **Service: Expedited Partner Therapy (EPT)- Purpose**

1784  
1785 **(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases**  
1786 **can be reduced by treating all sexual partners for the disease, even when the treating clinician has not**  
1787 **examined those partners. This practice is known as Expedited Partner Therapy.**

1788  
1789 **(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022**  
1790 **authorizing this practice. This law permits health professional regulatory boards to adopt rules**  
1791 **permitting practitioners to practice Expedited Partner Therapy.**

1792  
1793 **(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid,**  
1794 **even if the name of the patient the prescription is intended for is not on the prescription.**

1795  
1796 **Statutory/Other Authority: ORS 689.205**  
1797 **Statutes/Other Implemented: ORS 689.505**

1798  
1799  
1800 **855-139-0730**  
1801 **Service: Expedited Partner Therapy (EPT) - Procedures**

1802  
1803 **(1) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic**  
1804 **drug for the treatment of a sexually transmitted disease to the partner of a patient without first**  
1805 **examining that partner.**

1806  
1807 **(2) Notwithstanding any other rules in this division that mandate requirements for a valid prescription**  
1808 **and for labeling, when a prescription is marked EPT or a similar notation by the prescribing**  
1809 **practitioner, this rule govern.**

1810  
1811 **(3) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon**  
1812 **Health Authority (OHA) to be appropriately used for EPT.**

1813  
1814 **Prescription**

1815  
1816 **(4) An EPT treatment protocol must conform to the following:**

1817

- 1818 (a) It must include a prescription for each named or unnamed partner of the patient;  
1819  
1820 (b) It must contain a handwritten or electronic signature of the prescribing practitioner;  
1821  
1822 (c) The practitioner must identify the prescription in the following manner:  
1823  
1824 (A) Write “for EPT,” or a similar notation, on the face of the prescription;  
1825  
1826 (B) For a verbal order, the practitioner must identify the prescription as an “EPT Prescription,” or  
1827 similar identification;  
1828  
1829 (C) The practitioner must identify the prescription for each partner either by including the name of the  
1830 patient, such as “John Doe – Partner 1” or by labeling the prescription as “EPT Partner”  
1831  
1832 (d) An EPT Prescription expires 30 days after the date written;  
1833  
1834 (e) An EPT Prescription may not be refilled;  
1835  
1836 (f) If any component of the prescription is missing, the Oregon licensed Pharmacist must contact the  
1837 prescriber or the prescriber’s agent and must record the additional information on the prescription.  
1838  
1839 (5) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy  
1840 of their choice; or the patient may give all prescriptions to one pharmacy and then give the dispensed  
1841 drugs to each unnamed partner.

1842  
1843 **Labeling**  
1844

- 1845 (6) The Certified Oregon Pharmacy Technician must label the drug for the named patient in  
1846 accordance with normal procedures as specified in the other rules of this division, however when  
1847 either the patient or partner is unnamed, the pharmacy may create a unique identifier and use that  
1848 instead of a name for both labeling and record keeping purposes.  
1849  
1850 (7) The Oregon licensed Pharmacist must assign a separate and unique identifier to each prescription  
1851 and clearly identify this number on each corresponding prescription label.  
1852

1853 **Counseling**  
1854

- 1855 (8) The Oregon licensed Pharmacist is not required to obtain an EPT patient’s or partner’s name,  
1856 address, or demographics; however, the pharmacist must:  
1857  
1858 (a) Provide counseling in the form of written patient information to accompany each prescription for  
1859 each partner and ask the patient about any known allergies or other drugs being taken by each  
1860 partner. The Oregon licensed Pharmacist should advise the patient to encourage each partner to call  
1861 the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the  
1862 past or if they are taking other drugs;

- 1863  
1864 (b) Document counseling.  
1865

1866 **Records**

1867

1868 **(9) All documentation required by this rule must be attached to the prescription and must be**  
1869 **referenced to each partner’s prescription. Such documentation must be retained in accordance with**  
1870 **the other rules in this division and must be made available to the Board upon request.**

1871

1872 **Statutory/Other Authority: ORS 689.205**

1873 **Statutes/Other Implemented: ORS 689.505**

PROPOSED

**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](#)

- 1 Division 19
- 2 PHARMACISTS
- 3
- 4 855-019-0300
- 5 Duties of a Pharmacist-in-Charge
- 6
- 7 (1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one
- 8 Pharmacist-in-Charge (PIC) employed on a regular basis.

9

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

11

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

13

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

17

18 (3) A pharmacist may not be designated PIC of more than ~~two~~three pharmacies without prior written  
19 approval by the board. If such approval is given, the pharmacist must comply with the requirements in  
20 sub-section (4)(e) of this rule.

21

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

23

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

26

27 (b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of  
28 becoming PIC;

29

30 (c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy,  
31 except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as  
32 specified in OAR 855-041-0120;

33

34 (d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor  
35 who has been designated to have access to the pharmacy department in the absence of a pharmacist;

36

37 (e) A pharmacist designated as PIC for more than one pharmacy must personally conduct and document  
38 a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit  
39 Form provided by the board;

40

41 (f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within 30  
42 days of receiving notice.

43

44 (g) The records and forms required by this section must be filed in the pharmacy, made available to the  
45 board for inspection upon request, and must be retained for three years.

46

47 (5) The PIC is responsible for ensuring that the following activities are correctly completed:

48

49 (a) An inventory of all controlled substances must be taken within 15 days before or after the effective  
50 date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained  
51 in the pharmacy for three years and in accordance with all federal laws and regulations;

52

53 (b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all  
54 pharmacy personnel who are required to be licensed by the board;

55

- 56 (c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided  
57 by the board, by February 1 each year. The completed self-inspection forms must be signed and dated  
58 by the PIC and maintained for three years from the date of completion;  
59  
60 (d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;  
61  
62 (e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.  
63  
64 (f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training  
65 should include an annual review of the PIC Self-Inspection Report;  
66  
67 (g) Implementing a quality assurance plan for the pharmacy.  
68  
69 (h) The records and forms required by this section must be filed in the pharmacy, made available to the  
70 board for inspection upon request, and must be retained for three years.  
71  
72 (6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in  
73 compliance with all state and federal laws and rules governing the practice of pharmacy and that all  
74 controlled substance records and inventories are maintained in accordance with all state and federal  
75 laws and rules.

76  
77 Statutory/Other Authority: ORS 689.205  
78 Statutes/Other Implemented: ORS 689.151 & ORS 689.155  
79  
80

81 **Division 141**  
82 **REMOTE DISPENSING SITE PHARMACY**  
83

84  
85 **855-139-0001**  
86 **Purpose and Scope**  
87

88 **The purpose of OAR 855-139 is to provide minimum requirements for the locations where**  
89 **telepharmacy services are conducted.**  
90

91 **Statutory/Other Authority: ORS 689.205, 2021 SB 629**  
92 **Statutes/Other Implemented: ORS 689.155**  
93

94  
95  
96 **855-139-0005**  
97 **Definitions**  
98

99 **The following words and terms, when used in OAR 855-139, have the following meanings, unless the**  
100 **context clearly indicates otherwise. Any term not defined in this section has the definition set out in**  
101 **OAR 855-006.**  
102

103 **(1) “Affiliated Pharmacy” means a Retail Drug Outlet Pharmacy registered in Oregon where an Oregon**  
104 **licensed Pharmacist provides pharmacy services through a telepharmacy system.**

105  
106 **(2) “Biological product” means, with respect to the prevention, treatment or cure of a disease or**  
107 **condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood**  
108 **component, blood derivative, allergenic product, protein other than a chemically synthesized**  
109 **polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.**

110  
111 **(3) “Biosimilar product” means a biological product licensed by the United States Food and Drug**  
112 **Administration pursuant to 42 USC 262(k)(3)(A)(i) (XX/XX/XXXX).**

113  
114 **(4) “Interchangeable” means, in reference to a biological product, that the United States Food and**  
115 **Drug Administration has determined that a biosimilar product meets the safety standards set forth in**  
116 **42 USC-262(k)(4) (XX/XX/XXXX).**

117  
118 **(5) “Reference biological product” means the biological product licensed pursuant to 42 U.S.C. 262(a)**  
119 **(XX/XX/XXXX) against which a biological product is evaluated in an application submitted to the**  
120 **United States Food and Drug Administration for licensure of a biological product as a biosimilar**  
121 **product or for determination that a biosimilar product is interchangeable.**

122  
123 **(7) “Remote Dispensing Site Pharmacy” means an Oregon location registered as a Retail Drug Outlet**  
124 **Remote Dispensing Site Pharmacy staffed by a Certified Oregon Pharmacy Technician under the**  
125 **supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.**

126  
127 **(8) “Repackage” means the act of taking a drug from the container in which it was distributed by the**  
128 **manufacturer and placing it into a different container without further manipulation of the drug.**

129  
130 **(9) “Telepharmacy” means the delivery of pharmacy services by an Oregon licensed Pharmacist**  
131 **through the use of a telepharmacy system to a patient at a remote location staffed by a Certified**  
132 **Oregon Pharmacy Technician.**

133  
134 **(10) “Telepharmacy system” means a system of telecommunications technologies that enables**  
135 **monitoring, documenting and recording of the delivery of pharmacy services at a remote location by**  
136 **an electronic method which must include the use of audio and video, still image capture, and store**  
137 **and forward.**

138  
139 **(11) “Still image capture” means a specific image captured electronically from a video or other image**  
140 **capture device.**

141  
142 **(12) “Store and forward” means a video or still image record which is saved electronically for future**  
143 **review.**

144  
145 **Statutory/Other Authority: ORS 689.205, ORS 689.522, 2021 SB 629**  
146 **Statutes/Other Implemented: ORS 689.155, ORS 689.522, ORS 689.564, 2021 SB 629**

147  
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150



151 **855-139-0010**  
152 **Registration: General**

153  
154 **(1) A location in Oregon where the practice of pharmacy occurs by an Oregon licensed Pharmacist**  
155 **through the use of a telepharmacy system to a patient at a remote location staffed by a Certified**  
156 **Oregon Pharmacy Technician must be registered by the board in Oregon as a Retail Drug Outlet**  
157 **Remote Dispensing Site Pharmacy.**

158  
159 **(2) If controlled substances are stored in the Remote Dispensing Site Pharmacy, the Remote**  
160 **Dispensing Site Pharmacy must have an active Controlled Substance Registration Certificate with the**  
161 **board and Drug Enforcement Administration (DEA).**

162  
163 **(3) A Retail Drug Outlet Remote Dispensing Site Pharmacy application must specify the Affiliated**  
164 **Pharmacy and cannot operate without an Affiliated Pharmacy that is registered by the board as a**  
165 **Retail Drug Outlet Pharmacy.**

166  
167 **(4) All registration renewal applications must be accompanied by the annual fee and must contain the**  
168 **same information required in OAR 855-139-0011(3) and (4).**

169  
170 **(5) The initial and annual registration fee for pharmacies is set out in OAR 855-110.**

171  
172 **(6) Retail Drug Outlet Remote Dispensing Site Pharmacy registration expires March 31, annually. If the**  
173 **annual registration fee referred to in OAR 855-110 is not paid by March 31 of the current year, a late**  
174 **fee as set out in OAR 855-110 must be included with the application for registration renewal.**

175  
176 **(7) The registration is not transferable and the registration fee cannot be prorated.**

177  
178 **(8) No Remote Dispensing Site Pharmacy may be operated until a certificate of registration has been**  
179 **issued to the pharmacy by the board.**

180  
181 **Statutory/Other Authority: ORS 689.205, 2021 SB 629**  
182 **Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, 2021 SB 629**

183  
184  
185  
186 **855-139-0015**  
187 **Registration: Application**

188  
189 **(1) An application for registration of a new Remote Dispensing Site Pharmacy must be accompanied**  
190 **by a floor plan drawn to scale and must be approved by the board prior to opening.**

191  
192 **(2) The application must specify the location of the Remote Dispensing Site Pharmacy and must**  
193 **indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant**  
194 **is not the owner of the pharmacy, the application must indicate the owner and the applicant's**  
195 **affiliation with the owner:**

196  
197 **(a) If the owner is a partnership or other multiple owners, the names of the partners or persons**  
198 **holding the five largest interests must be indicated on the application;**

199  
200 **(b) If the owner is a corporation, the name filed must be the same as filed with the Secretary of State.**  
201 **The name of the corporation, the names of the corporation officers and the names of the stockholders**  
202 **who own the five largest interests must be indicated on the application.**  
203

204 **(3) Upon request by the board, the applicant must furnish such information as required by the board**  
205 **regarding the partners, stockholders, or other persons not named in the application.**  
206

207 **(4) A certificate of registration will be issued upon board approval of the application.**  
208

209 **Statutory/Other Authority: ORS 475.035, ORS 689.205**

210 **Statutes/Other Implemented: ORS 689.155**  
211

212  
213  
214 **855-139-0020**

215 **Registration: Change of Owner, Location, or Affiliated Pharmacy**  
216

217 **(1) A change of location of the Affiliated Pharmacy or location of the Retail Drug Outlet Remote**  
218 **Dispensing Site Pharmacy requires:**  
219

220 **(a) Submission of a new Retail Drug Outlet Remote Dispensing Site Pharmacy application 15 days prior**  
221 **to occurrence;**  
222

223 **(b) Registration fee;**  
224

225 **(c) Approval of the board; and**  
226

227 **(d) New certificate of registration.**  
228

229 **(2) A change in the Affiliated Pharmacy or ownership of the Retail Drug Outlet Remote Dispensing Site**  
230 **Pharmacy requires:**  
231

232 **(a) Submission of a new Retail Drug Outlet Remote Dispensing Site Pharmacy application 15 days prior**  
233 **to occurrence;**  
234

235 **(b) Registration fee;**  
236

237 **(c) Approval of the board; and**  
238

239 **(d) New certificate of registration.**  
240

241 **(3) A change of ownership includes any change in the legal form of the business including additions or**  
242 **deletions of partners.**  
243

244 **(4) A certificate of registration will be issued upon board approval of the application.**  
245

246 **Statutory/Other Authority: ORS 475.035, ORS 689.205**

247 Statutes/Other Implemented: ORS 689.155

248

249

250

251 855-139-0025

252 Registration: Change of Business Name or Closure

253

254 **(1) An Affiliated Pharmacy must notify the board 15 days prior to any change of business name of a**  
255 **Retail Drug Outlet Remote Dispensing Site Pharmacy. The change must be reported by filing a new**  
256 **application for which no fee is required.**

257

258 **(2) An Affiliated Pharmacy must notify the board 15 days prior to discontinuing operation of a Retail**  
259 **Drug Outlet Remote Dispensing Site Pharmacy. Notification must include the:**

260

261 **(a) Final disposition of drugs stored in the Retail Drug Outlet Remote Dispensing Site Pharmacy**  
262 **including:**

263

264 **(A) Name and location where the drugs are transferred;**

265

266 **(B) Name and location where destruction occurred; and**

267

268 **(C) Name and location of the site that will store all records;**

269

270 **(c) Transfer all Schedule II medications on DEA 222 forms, and Schedule III, IV and V by invoice;**

271

272 **(d) Provide the board with:**

273

274 **(A) Oregon Board of Pharmacy state license(s); and**

275

276 **(B) Signed statement giving the effective date of closure; and**

277

278 **(e) Comply with the requirements of 21 CFR 1301.52 (XX/XX/XXXX).**

279

280 Statutory/Other Authority: ORS 475.035, ORS 689.205

281 Statutes/Other Implemented: ORS 689.155

282

283

284 855-139-0030

285 Non-Resident Pharmacies

286

287 **(1) For the purpose of these rules, a non-resident pharmacy includes an Affiliated Pharmacy located**  
288 **outside of Oregon and providing pharmacy services through a telepharmacy system to a Retail Drug**  
289 **Outlet Remote Dispensing Site Pharmacy located in Oregon.**

290

291 **(2) Each non-resident Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy.**

292

293 **(3) To qualify for registration under these rules, every non-resident Affiliated Pharmacy must be**  
294 **registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.**

295  
296 **(4) Each out-of-state non-resident Affiliated Pharmacy must designate an Oregon licensed Pharmacist-**  
297 **in-Charge (PIC), who is responsible for all pharmacy services and to provide supervision and control of**  
298 **the Remote Dispensing Site Pharmacy. To qualify for this designation, the person must:**

299  
300 **(a) Hold a license to practice pharmacy in the resident state;**

301  
302 **(b) Be normally working for the Affiliated Pharmacy a minimum of 20 hours per week;**

303  
304 **(c) Complete the annual Remote Dispensing Site Pharmacy PIC self-inspection report prior to February**  
305 **1 each year; and**

306  
307 **(d) Provide the PIC self-inspection report as requested by the board.**

308  
309 **(5) Every non-resident Affiliated Pharmacy will have a Pharmacist-in-Charge (PIC) who is licensed in**  
310 **Oregon prior to initial registration of the Remote Dispensing Site Pharmacy.**

311  
312 **(6) The PIC must comply with the requirements of OAR 855-019-0300.**

313  
314 **Statutory/Other Authority: ORS 689.205**

315 **Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225**

316  
317  
318  
319 **855-139-0050**

320 **Personnel**

321  
322 **(1) The Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy is responsible for all**  
323 **operations at the Remote Dispensing Site Pharmacy including responsibility for the telepharmacy**  
324 **system and enforcing policies and procedures.**

325  
326 **(2) A Remote Dispensing Site Pharmacy may not utilize Interns, Pharmacy Technicians, or unlicensed**  
327 **personnel.**

328  
329 **(3) A Certified Oregon Pharmacy Technician working at a Remote Dispensing Site Pharmacy is required**  
330 **to have at least one year experience working at an Oregon registered Retail Drug Outlet Pharmacy**  
331 **during the three years preceding the date the Certified Oregon Pharmacy Technician begins working**  
332 **at the Remote Dispensing Site Pharmacy.**

333  
334 **(4) The Oregon licensed Pharmacist from the Affiliated Pharmacy who is supervising a Remote**  
335 **Dispensing Site Pharmacy must determine and document how many licensed individuals the**  
336 **pharmacist is capable of supervising, directing and controlling based on the services being provided.**

337  
338 **(5) When supervising a Certified Oregon Pharmacy Technician working at a Remote Dispensing Site**  
339 **Pharmacy, the Oregon licensed Pharmacist may supervise no more than four licensed pharmacy**  
340 **technicians among all locations, including the Affiliated Pharmacy.**

341

342 **(6) The Affiliated Pharmacy is required to comply with the pharmacist's determination in (4) and**  
343 **retain records.**

344  
345 **(7) The Remote Dispensing Site Pharmacy and Affiliated Pharmacy must ensure adequate staffing at**  
346 **both the Remote Dispensing Site Pharmacy and Affiliated Pharmacy.**

347  
348 **(8) Prior to working at a Remote Dispensing Site Pharmacy, the Certified Oregon Pharmacy Technician**  
349 **and the Oregon licensed Pharmacist supervising the Remote Dispensing Site Pharmacy must have**  
350 **completed a training program on the proper use of the telepharmacy system.**

351  
352 **(9) An Affiliated Pharmacy that terminates or allows a board licensee to resign in lieu of termination**  
353 **must report the termination or resignation to the board within 10 working days.**

354  
355 **Statutory/Other Authority: ORS 689.205**  
356 **Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305**

357  
358  
359 **855-139-0100**

360 **Security**

361  
362 **(1) The area in a registered Remote Dispensing Site Pharmacy where legend and/or controlled**  
363 **substances are stored, possessed, prepared, compounded or repackaged must be restricted in access**  
364 **by utilizing physical barriers to include floor to ceiling walls and a locked separate entrance to ensure**  
365 **the security of those drugs.**

366  
367 **(2) The Affiliated Pharmacy, the Remote Dispensing Site Pharmacy, Oregon licensed Pharmacist-in-**  
368 **charge of the Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the Remote**  
369 **Dispensing Site Pharmacy is responsible for the security of the prescription area including provisions**  
370 **for adequate safeguards against loss, theft or diversion of prescription drugs, and records for such**  
371 **drugs.**

372  
373 **(3) The Remote Dispensing Site Pharmacy must be locked and the security system armed to prevent**  
374 **entry when:**

375  
376 **(a) There is no Oregon licensed Pharmacist from the Affiliated Pharmacy actively supervising the**  
377 **Remote Dispensing Site Pharmacy; or**

378  
379 **(b) There is no Certified Oregon Pharmacy Technician present in the Remote Dispensing Site**  
380 **Pharmacy; or**

381  
382 **(c) Any component of the telepharmacy system is not functioning.**

383  
384 **(4) A record must be maintained with the name and license number of each person entering the**  
385 **pharmacy area of the Remote Dispensing Site Pharmacy.**

386  
387 **(5) No one may be in the prescription area of a Remote Dispensing Site Pharmacy unless authorized in**  
388 **real-time by an Oregon licensed Pharmacist who is supervising the Remote Dispensing Site Pharmacy**  
389 **and from the Affiliated Pharmacy.**

390  
391 **(6) Minimum security methods must include a properly functioning:**  
392  
393 **(a) Alarm system with an audible alarm at the Remote Dispensing Site Pharmacy and real-time**  
394 **notification to a designated licensee of the Affiliated Pharmacy;**  
395  
396 **(b) Electronic keypad or other electronic entry system that records the:**  
397  
398 **(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the Remote**  
399 **Dispensing Site Pharmacy;**  
400  
401 **(B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the Remote**  
402 **Dispensing Site Pharmacy; and**  
403  
404 **(C) Date and time of each activity.**  
405  
406 **(c) Surveillance system that utilizes continuously accessible and recorded two-way audiovisual link**  
407 **between the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy. The system must provide**  
408 **a clear view of:**  
409  
410 **(A) Dispensing site entrances;**  
411  
412 **(B) Preparation areas;**  
413  
414 **(C) Drug storage areas;**  
415  
416 **(D) Pick up areas;**  
417  
418 **(E) Office areas; and**  
419  
420 **(F) Publicly accessible areas.**  
421  
422 **Statutory/Other Authority: ORS 475.035, ORS 689.205**  
423 **Statutes/Other Implemented: ORS 689.155**  
424  
425  
426  
427 **855-139-0120**  
428 **Drug: Receipt**  
429  
430 **Remote Dispensing Site Pharmacy may only receive drugs from an Oregon Registered Drug Outlet (i.e.**  
431 **Wholesaler, Manufacturer or Pharmacy).**  
432  
433 **Statutory/Other Authority: ORS 475.035, ORS 689.205**  
434 **Statutes/Other Implemented: ORS 689.155**  
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**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;**

485 **(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or**  
486 **determination by an Oregon licensed Pharmacist that it is safe for continued use. This documentation**  
487 **must include details of the information source;**  
488

489 **(F) A written emergency action plan;**  
490

491 **(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring**  
492 **equipment; and**  
493

494 **(H) Documentation and review of temperature recordings at least once every 28 days by the Oregon**  
495 **licensed Pharmacist at the time of in person physical inspection.**

496  
497 **(3) Vaccine Drug Storage:**  
498

499 **(a) A Remote Dispensing Site Pharmacy that stores vaccines must comply with section two of this rule**  
500 **and the following:**  
501

502 **(A) Vaccines must be stored in the temperature stable sections of the refrigerator;**  
503

504 **(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads,**  
505 **calibrated within a plus or minus 0.5 °C variance must be utilized;**  
506

507 **(C) Each freezer and refrigerator compartment must have its own exterior door and independent**  
508 **thermostat control;**  
509

510 **(D) A system of continuous temperature monitoring with automated data logging and physical**  
511 **confirmation must be utilized. Documentation of the temperature of each active storage unit must be**  
512 **logged at least twice daily, data must be downloaded weekly, and system validations must be**  
513 **conducted quarterly; and**  
514

515 **(E) Must adhere to a written quality assurance process to avoid temperature excursions.**  
516

517 **(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and**  
518 **meets all Pharmacy drug storage and security requirements.**  
519

520 **Statutory/Other Authority: ORS 689.205, ORS 689.325**

521 **Statutes/Other Implemented: ORS 689.155**  
522

523  
524 **855-139-0130**

525 **Drug: Loss**  
526

527 **A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:**  
528

529 **(1) Ensure that disasters, accidents and emergencies which may affect the strength, purity, or labeling**  
530 **of drugs or devices are reported to the board immediately.**  
531



532 **(2) Ensure that confirmed significant drug loss or any loss related to suspected drug theft of a**  
533 **controlled substance is reported to the board within one business day.**

534  
535 **(3) Ensure that a Report of Theft or Loss of Controlled Substances (DEA Form 106) or Report of Theft**  
536 **or Loss of Listed Chemicals (DEA Form 107) is sent to the Drug Enforcement Administration, a copy is**  
537 **sent to the board at the same time.**

538  
539 **Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315**

540 **Statutes/Other Implemented: ORS 689.155**

541 **855-139-0150**

542 **Outlet: Sanitation**

543

544 **A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

545

546 **(1) Ensure the Remote Dispensing Site Pharmacy is kept clean.**

547

548 **(2) Ensure the Certified Oregon Pharmacy Technician working in the Remote Dispensing Site Pharmacy**  
549 **practices appropriate infection control.**

550

551 **Statutory/Other Authority: ORS 689.305**

552 **Statutes/Other Implemented: ORS 689.305**

553

554

555 **855-139-0155**

556 **Outlet: Minimum Equipment Requirements**

557

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

559

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

562

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

566

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

569

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

571

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

575

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

577

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

579

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

583  
584 (B) Providing notification in each of the languages required in OAR 855-139-0062 of the right to free,  
585 competent oral interpretation and translation services, including translated prescription labels, for  
586 patients who are of limited English proficiency, in compliance with federal and state regulations if the  
587 pharmacy dispenses prescriptions for a patient's self-administration;

588  
589 (C) Providing written notice in a conspicuous manner that naloxone and the necessary medical  
590 supplies to administer naloxone are available at the pharmacy if naloxone services are provided by  
591 the pharmacy per OAR 855-139-0215; and

592  
593 (D) Stating "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed  
594 Pharmacist from (insert name of Affiliated Pharmacy, address, and telephone number)." The printing  
595 on the sign must be in block letters not less than one inch in height; and

596  
597 (h) Additional equipment and supplies that are determined as necessary by the Pharmacy or  
598 Pharmacist-in-Charge.

599  
600 (2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under  
601 ORS 689.405(1)(a).

602  
603 Statutory/Other Authority: ORS 689.205  
604 Statutes/Other Implemented: ORS 689.155

605  
606  
607 855-139-0200

608 Outlet: General Requirements

609  
610 (1) An Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site  
611 Pharmacies.

612  
613 (2) An Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from  
614 the Remote Dispensing Site Pharmacy.

615  
616 (3) A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

617  
618 (a) Have the same owner; or

619  
620 (b) Have a written contract that specifies:

621  
622 (A) The services to be provided by each licensee and registrant;

623  
624 (B) The responsibilities of each licensee and registrant; and

625  
626 (C) The accountabilities of each licensee and registrant;

627

628 **(c) Ensure each prescription is dispensed in compliance with OAR 855-019, OAR 855-025 and OAR 855-**  
629 **139;**

630  
631 **(d) Comply with all applicable federal and state laws and rules;**

632  
633 **(e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians**  
634 **authorized to access the Remote Dispensing Site Pharmacy and operate the telepharmacy system;**

635  
636 **(f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians in the operation**  
637 **of the telepharmacy system and Remote Dispensing Site Pharmacy;**

638  
639 **(g) Develop, implement and enforce a continuous quality improvement program for dispensing**  
640 **services from a Remote Dispensing Site Pharmacy designed to objectively and systematically;**

641 **(A) Monitor, evaluate, document the quality and appropriateness of patient care;**

642  
643 **(B) Improve patient care; and**

644  
645 **(C) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their**  
646 **reoccurrence;**

647  
648 **(h) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the**  
649 **Oregon licensed Pharmacist from the Affiliated Pharmacy; and**

650  
651 **(i) Develop, implement and enforce a process for an in person physical inspection of the Remote**  
652 **Dispensing Site Pharmacy by an Oregon licensed Pharmacist at least once every 28 days or more**  
653 **frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the Affiliated**  
654 **Pharmacy. The inspection must utilize the Remote Dispensing Site Pharmacy self-inspection form, be**  
655 **documented and records retained.**

656  
657 **Statutory/Other Authority: ORS 689.205, 2021 SB 629**  
658 **Statutes/Other Implemented: ORS 689.155, 2021 SB 629**

659  
660  
661  
662 **855-139-0205**

663 **Outlet: Technology**

664  
665 **A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

666  
667 **(1) Utilize a shared telepharmacy system and have appropriate technology or interface to allow access**  
668 **to information required to process and fill a prescription drug order;**

669  
670 **(2) Use still image capture or store and forward for verification of prescriptions with a camera that is**  
671 **of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Affiliated**  
672 **Pharmacy can visually identify each:**

673  
674 **(a) Source container including manufacturer, name, strength, lot, and expiration;**

675

676 **(b) Source ingredient including the imprint and physical characteristics if compounding;**  
677  
678 **(c) Dispensed product including the imprint and physical characteristics;**  
679  
680 **(d) Completed prescription container including the label; and**  
681  
682 **(e) Ancillary document provided to patient at the time of dispensing.**  
683  
684 **(3) Utilize barcode, radio-frequency identification or quick response code technology to record**  
685 **information in (2) if available;**  
686  
687 **(4) Test the telepharmacy system and document that it operates properly before providing pharmacy**  
688 **services; and**  
689  
690 **(5) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system.**  
691  
692 **Statutory/Other Authority: ORS 689.205, 2021 SB 629**  
693 **Statutes/Other Implemented: ORS 689.155, 2021 SB 629**  
694  
695  
696  
697 **855-139-0210**  
698 **Outlet: Supervision**  
699  
700 **A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:**  
701  
702 **(1) Ensure prescription drugs are only dispensed at the Remote Dispensing Site Pharmacy if an Oregon**  
703 **licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician utilizing the**  
704 **telepharmacy system, and the telepharmacy system is fully operational;**  
705  
706 **(2) Ensure an Oregon licensed Pharmacist continuously supervises, directs and controls each Certified**  
707 **Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy using audio and visual**  
708 **technology which must be recorded, reviewed and stored;**  
709  
710 **(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a**  
711 **Remote Dispensing Site Pharmacy must:**  
712  
713 **(a) Using professional judgment, determine the percentage of patient interactions for each licensee**  
714 **that must be reviewed to ensure public health and safety with a minimum of 25% of patient**  
715 **interactions reviewed;**  
716  
717 **(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee**  
718 **is acting within the authority permitted under their license and patients are connected with a**  
719 **pharmacist upon request;**  
720  
721 **(c) Document the following within 24 hours of the review in (3)(b):**  
722  
723 **(A) Number of each licensee's patient interactions;**

- 724  
725 **(B) Number of each licensee’s patient interactions pharmacist is reviewing;**  
726  
727 **(C) Date and time of licensee patient interaction pharmacist is reviewing;**  
728  
729 **(D) Date and time of pharmacist review of licensee’s patient interaction; and**  
730  
731 **(E) Pharmacist notes of each interaction reviewed; and**  
732  
733 **(d) Report any violation of OAR 855 to the Affiliated Pharmacy within 24 hours of discovery and to the**  
734 **board within 10 days.**

735  
736 **(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist’s determination in**  
737 **(3)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain**  
738 **records.**

739  
740 **(5) Ensure all telephone audio is recorded, reviewed and stored.**

741  
742 **POLICY DISCUSSION:** Frequency of review

743  
744 **(6) Develop, implement and enforce a plan for responding to and recovering from an interruption of**  
745 **service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy**  
746 **Technician at the Remote Dispensing Site Pharmacy.**

747  
748 **Statutory/Other Authority: ORS 689.205, ORS 689.225**

749 **Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.305**

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751  
752  
753 **855-139-0215**

754 **Outlet: Pharmacist Utilization**

755  
756 **A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

757  
758 **(1) Utilize an Oregon licensed Pharmacist from the Affiliated Pharmacy to perform the professional**  
759 **tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is**  
760 **dispensed; and**

761  
762 **(2) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication to provide**  
763 **counseling or accept the refusal of counseling from the patient or the patient’s agent for each**  
764 **prescription being dispensed when counseling is required under OAR 855-019-0230 and when**  
765 **requested and document the interaction.**

766  
767 **Statutory/Other Authority: ORS 689.205**

768 **Statutes/Other Implemented: ORS 689.155**

769  
770  
771

772 **855-139-0220**

773 **Outlet: Non-Prescription Drugs**

774

775 **If non-prescription drugs are offered for sale at the Remote Dispensing Site Pharmacy, the Remote**  
776 **Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

777

778 **(1) Ensure that the Certified Oregon Pharmacy Technician does not provide advice, information that**  
779 **requires judgment, or recommendations involving non-prescription drugs; and**

780

781 **(2) Ensure that an Oregon-licensed Pharmacist is immediately available to provide counseling or**  
782 **recommendations involving non-prescription drugs.**

783

784 **Statutory/Other Authority: ORS 689.205**

785 **Statutes/Other Implemented: ORS 689.155**

786

787

788 **855-139-0225**

789 **Outlet: Controlled Substances**

790

791 **If controlled substances are at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site**  
792 **Pharmacy and its Affiliated Pharmacy must:**

793

794 **(1) Comply with controlled substance regulations;**

795

796 **(2) Store all controlled substances in a secure locked cabinet;**

797

798 **(3) Maintain an accurate controlled substance perpetual inventory; and**

799

800 **(4) Ensure an Oregon licensed Pharmacist conducts a controlled substance inventory at least once**  
801 **every 28 days and reconciles all discrepancies at the time of in person physical inspection.**

802

803 **Statutory/Other Authority: ORS 689.205**

804 **Statutes/Other Implemented: ORS 689.155**

805

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807

808 **855-139-0230**

809 **Outlet: Non-Sterile Compounding**

810

811 **If non-sterile preparations are compounded at the Remote Dispensing Site Pharmacy, the Remote**  
812 **Dispensing Site Pharmacy and its Affiliated Pharmacy must:**

813

814 **(1) Adhere to the requirements of OAR 855-045;**

815

816 **(2) Ensure an Oregon licensed Pharmacist:**

817

818 **(a) Supervises via a real-time audio-visual connection all steps of the compounding; and**

819

820 **(b) Documents and visually verifies each item required in OAR 855-139-0041.**

821

822 **Statutory/Other Authority: ORS 689.205**

823 **Statutes/Other Implemented: ORS 689.155**

824

825

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828 **855-139-0300**

829 **Prescription: General Requirements**

830

831 **(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with**  
832 **the prescribing practitioner's authorization. When a prescription is transmitted orally, it must be**  
833 **transmitted to the Oregon licensed Pharmacist from the Affiliated Pharmacy and both the receiving**  
834 **pharmacist's name or initials and the name of the person transmitting must be noted on the**  
835 **prescription.**

836

837 **(2) Each Remote Dispensing Site Pharmacy must document the following information for each**  
838 **prescription:**

839

840 **(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal.**

841

842 **(b) If for an animal, the name of the patient, name the owner and the species of the animal.**

843

844 **(c) The full name, address, and contact phone number of the practitioner. If for a controlled**  
845 **substance, the Drug Enforcement Administration registration number of the practitioner and other**  
846 **number as authorized under rules adopted by reference under rule OAR 855-080-0085;**

847

848 **(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the**  
849 **quantity prescribed, the quantity dispensed;**

850

851 **(e) The directions for use, if given by the practitioner; and**

852

853 **(f) The date of filling, and the total number of refills authorized by the prescribing practitioner.**

854

855 **(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic**  
856 **communication or by electronic transmission that there may be no substitution for the specified**  
857 **brand name drug in a prescription.**

858

859 **(a) For a hard copy prescription issued in writing or a prescription orally communicated over the**  
860 **telephone, instruction may use any one of the following phrases or notations:**

861

862 **(A) No substitution;**

863

864 **(B) N.S.;**

865

866 **(C) Brand medically necessary;**

867

868 **(D) Brand necessary;**

869

870 **(E) Medically necessary;**

871

872 **(F) D.A.W. (Dispense As Written); or**

873

874 **(G) Words with similar meaning.**

875

876 **(b) For an electronically transmitted prescription, the prescriber or prescriber's agent must clearly**  
877 **indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or**  
878 **words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic**  
879 **indicators sent as part of the electronic prescription transmission.**

880

881 **(c) Such instructions must not be default values on the prescription.**

882

883 **(4) A Remote Dispensing Site Pharmacy or Oregon licensed Pharmacist filling a prescription or order**  
884 **for a biological product may not substitute a biosimilar product for the prescribed biological product**  
885 **unless:**

886

887 **(a) The biosimilar product has been determined by the United States Food and Drug Administration to**  
888 **be interchangeable with the prescribed biological product;**

889

890 **(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;**

891

892 **(c) The patient for whom the biological product is prescribed is informed of the substitution prior to**  
893 **dispensing the biosimilar product;**

894

895 **(d) The Remote Dispensing Site Pharmacy or Oregon licensed Pharmacist provides written, electronic**  
896 **or telephonic notification of the substitution to the prescribing practitioner or the prescribing**  
897 **practitioner's staff within three (3) business days of dispensing the biosimilar product; and**

898

899 **(5) The Remote Dispensing Site Pharmacy must dispense prescriptions accurately and to the correct**  
900 **party.**

901

902 **Statutory/Other Authority: ORS 689.205 & ORS 689.522**

903 **Statutes/Other Implemented: ORS 689.505, 689.515 & ORS 689.522**

904

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907 **855-139-0305**

908 **Prescription: Tamper-resistant**

909

910 **When the use of a tamper-resistant prescription is required by any federal or state law or rule, the**  
911 **term "tamper-resistant" has the meaning as defined in OAR 855-006-0015.**

912

913 **Statutory/Other Authority: ORS 689.205**

914 **Statutes/Other Implemented: ORS 689.155**

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**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.**

964 **(6) A prescription must be refilled in context with the approximate dosage schedule unless specifically**  
965 **authorized by the prescriber.**

966  
967 **(7) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may**  
968 **use a program that automatically refills non-controlled prescription medications, that have existing**  
969 **refills available and are consistent with the patient’s current medication therapy only when the**  
970 **following conditions are met:**

971  
972 **(a) A patient or patient’s agent must enroll each prescription medication in an auto-refill program**  
973 **before a pharmacy can include the prescription medication as part of the auto-refill program;**

974  
975 **(b) The prescription is not a controlled substance;**

976  
977 **(c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or**  
978 **patient’s agent;**

979  
980 **(d) Pick-up notification to a patient or patient’s agent may be generated upon completion of a**  
981 **prescription refill; and**

982  
983 **(e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription**  
984 **medication is removed from the auto-refill program for that patient.**

985  
986 **Statutory/Other Authority: ORS 689.205**

987 **Statutes/Other Implemented: ORS 689.505 & ORS 689.515**

988  
989  
990 **855-139-0320**

991 **Prescription: Expiration**

992  
993 **This section of rule addresses the expiration date of the prescription and not the expiration date of**  
994 **the drug.**

995  
996 **(1) After one year from date of issue, a prescription for a non-controlled substance becomes invalid**  
997 **and must be re-authorized by the prescriber.**

998  
999 **(2) When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled**  
1000 **substance means that the medication can be refilled in proper context for a period of one year.**

1001  
1002 **(a) When this abbreviation is used alone as a means to authorize refills for a controlled substance, the**  
1003 **medication can be refilled in proper context for a period of six months or five refills, whichever comes**  
1004 **first.**

1005  
1006 **(b) When this abbreviation is used in conjunction with a definite time period, or a specific number of**  
1007 **refills, the non-controlled medication can be refilled in proper context for a period not to exceed one**  
1008 **year.**

1009  
1010 **Statutory/Other Authority: ORS 689.205**

1011 **Statutes/Other Implemented: ORS 689.505 & ORS 689.515**

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**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:**

1060  
1061 **(a) The patient med pak must bear a label stating:**  
1062  
1063 **(A) The name of the patient;**  
1064  
1065 **(B) A serial number for each patient med pak itself and a separate identifying serial number for each**  
1066 **of the prescription orders for each of the drug products contained therein;**  
1067  
1068 **(C) The name, strength, physical description or identification, and total quantity of each drug product**  
1069 **contained therein;**  
1070  
1071 **(D) The directions for use and cautionary statements, if any, contained in the prescription order for**  
1072 **each drug product therein;**  
1073  
1074 **(E) Any storage instructions or cautionary statements required by the official compendia;**  
1075  
1076 **(F) The name of the prescriber of each drug product;**  
1077  
1078 **(G) The date of preparation of the patient med pak and the beyond-use date assigned to the patient**  
1079 **med pak (such beyond-use date must be no later than 60 days from the date of preparation);**  
1080  
1081 **(H) The name, address, and telephone number of the dispenser and the dispenser's registration**  
1082 **number where necessary; and**  
1083  
1084 **(I) Any other information, statements, or warnings required for any of the drug products contained**  
1085 **therein.**  
1086  
1087 **(b) If the patient med pak allows for the removal or separation of the intact containers therefrom,**  
1088 **each individual container must bear a label identifying each of the drug products contained therein.**  
1089  
1090 **(2) Labeling: The patient med pak must be accompanied by a patient package insert, in the event that**  
1091 **any medication therein is required to be dispensed with such insert as accompanying labeling.**  
1092 **Alternatively, such required information may be incorporated into a single, overall educational insert**  
1093 **provided by the Oregon licensed Pharmacist for the total patient med pak.**  
1094  
1095 **(3) Packaging:**  
1096  
1097 **(a) In the absence of more stringent packaging requirements for any of the drug products contained**  
1098 **therein, each container of the patient med pak must comply with the moisture permeation**  
1099 **requirements for a Class B single-unit or unit-dose container. Each container must be either not**  
1100 **reclosable or so designed as to show evidence of having been opened;**  
1101  
1102 **(b) There is no special exemption for patient med paks from the requirements of the Poison**  
1103 **Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards**  
1104 **must be placed in an outer package that does comply, or the necessary consent of the purchaser or**  
1105 **physician, to dispense in a container not intended to be child-resistant, must be obtained.**  
1106

1107 **(4) Guidelines: It is the responsibility of the dispenser, when preparing a patient med pak, to take into**  
1108 **account any applicable compendia requirements or guidelines and the physical and chemical**  
1109 **compatibility of the dosage forms placed within each container, as well as any therapeutic**  
1110 **incompatibilities that may attend the simultaneous administration of the medications. In this regard,**  
1111 **pharmacists are encouraged to report to USP headquarters any observed or report incompatibilities.**  
1112

1113 **(5) Recordkeeping: In addition to any individual prescription filing requirements, a record of each**  
1114 **patient med pak must be made and filed. Each record must contain, as a minimum:**  
1115

1116 **(a) The name and address of the patient;**  
1117

1118 **(b) The serial number of the prescription order for each drug product contained therein;**  
1119

1120 **(c) The name of the manufacturer or labeler and lot number for each drug product contained therein;**  
1121

1122 **(d) Information identifying or describing the design, characteristics, or specifications of the patient**  
1123 **med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;**  
1124

1125 **(e) The date of preparation of the patient med pak and the beyond-use date that was assigned;**  
1126

1127 **(f) Any special labeling instructions; and**  
1128

1129 **(g) The name or initials of the Certified Oregon Pharmacy Technician who prepared the med pak and**  
1130 **the Oregon licensed Pharmacist who verified the patient med pak.**  
1131

1132 **(6) Ensure an Oregon licensed Pharmacist visually verifies and documents each item required in OAR**  
1133 **855-139-0041 for each individual dosage unit in the med pak.**  
1134

1135 **Statutory/Other Authority: ORS 689.205**

1136 **Statutes/Other Implemented: ORS 689.155**  
1137

1138

1139 **855-139-0400**

1140 **Labeling: General Requirements**  
1141

1142 **(1) Prescriptions must be labeled with the following information:**  
1143

1144 **(a) Name, address and telephone number of the Remote Dispensing Site Pharmacy;**  
1145

1146 **(b) Date;**  
1147

1148 **(c) Identifying number;**  
1149

1150 **(d) Name of patient;**  
1151

1152 **(e) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also**  
1153 **contain the identifier of the manufacturer or distributor;**  
1154

1155 **(f) Directions for use by the patient;**  
1156  
1157 **(g) Name of practitioner;**  
1158  
1159 **(h) Required precautionary information regarding controlled substances;**  
1160  
1161 **(i) Such other and further accessory cautionary information as required for patient safety;**  
1162  
1163 **(j) An expiration date after which the patient should not use the drug or medicine. Expiration dates on**  
1164 **prescriptions must be the same as that on the original container unless, in the Oregon licensed**  
1165 **Pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an**  
1166 **expiration date must not be dispensed beyond the said expiration date of the drug;**  
1167  
1168 **(k) Any dispensed prescription medication, other than those in unit dose or unit of use packaging,**  
1169 **must be labeled with its physical description, including any identification code that may appear on**  
1170 **tablets and capsules; and**  
1171  
1172 **(l) Address and telephone number of the Affiliated Pharmacy.**  
1173  
1174 **Statutory/Other Authority: ORS 689.205**  
1175 **Statutes/Other Implemented: ORS 689.505 & 689.515**  
1176  
1177  
1178 **855-139-0405**  
1179 **Labeling: Prescription Reader Accessibility**  
1180  
1181 **(1) A pharmacy must notify each person to whom a prescription drug is dispensed that a prescription**  
1182 **reader is available to the person upon request; a prescription reader is a device designed to audibly**  
1183 **convey labeling information.**  
1184  
1185 **(2) If a person informs the pharmacy that the person identifies as a person who is blind, the pharmacy**  
1186 **must provide to the person a prescription reader that is available to the person for at least the**  
1187 **duration of the prescription, must confirm it is appropriate to address the person's visual impairment,**  
1188 **and must ensure that prescription labels are compatible with the prescription reader. This**  
1189 **requirement does not apply to an institutional drug outlet, dispensing a drug intended for**  
1190 **administration by a healthcare provider.**  
1191  
1192 **(3) Ensure an Oregon licensed Pharmacist verifies and documents that the correct electronic label was**  
1193 **placed on each prescription container and that the audio information produced by the prescription**  
1194 **reader is accurate prior to dispensing the prescription.**  
1195  
1196 **Statutory/Other Authority: ORS 689.205**  
1197 **Statutes/Other Implemented: ORS 689.561**  
1198  
1199  
1200 **855-139-0410**  
1201 **Labeling: Limited English Proficiency and Accessibility**  
1202

1203 **(1) Upon request of a prescriber, patient or a patient’s agent, each drug dispensed by a pharmacy for a**  
1204 **patient’s self-administration must bear a label in both English and the language requested for an**  
1205 **individual with limited English proficiency, defined as a person who is not fluent in the English**  
1206 **language. This does not apply to a drug outlet dispensing a drug intended for administration by a**  
1207 **healthcare worker.**

1208  
1209 **(2) When dispensing a drug under (1), a pharmacy must provide labels and informational inserts in**  
1210 **both English and one of the following languages:**

1211  
1212 **(a) Spanish;**

1213  
1214 **(b) Russian;**

1215  
1216 **(c) Somali;**

1217  
1218 **(d) Arabic;**

1219  
1220 **(e) Chinese (simplified);**

1221  
1222 **(f) Vietnamese;**

1223  
1224 **(g) Farsi;**

1225  
1226 **(h) Korean;**

1227  
1228 **(i) Romanian;**

1229  
1230 **(j) Swahili;**

1231  
1232 **(k) Burmese;**

1233  
1234 **(l) Nepali;**

1235  
1236 **(m) Amharic; and**

1237  
1238 **(n) Pashtu.**

1239  
1240 **(3) The board must reassess and update (2) as necessary and at least every ten years.**

1241  
1242 **Statutory/Other Authority: ORS 689.564**

1243 **Statutes/Other Implemented: ORS 689.205**

1244

1245

1246 **855-139-0450**

1247 **Drugs and Devices: Disposal**

1248

1249 **Drugs** and devices that are outdated, damaged, deteriorated, misbranded, or adulterated must be  
1250 **quarantined and physically separated from other drugs until they are destroyed or returned to their**  
1251 **supplier.**

1252  
1253 **Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315**

1254 **Statutes/Other Implemented: ORS 689.155**

1255

1256

1257 **855-139-0455**

1258 **Drug and Devices: Return**

1259

1260 **(1) A Certified Oregon Pharmacy Technician may accept the return of a drug or device as defined by**  
1261 **ORS 689.005 once the drug or device have been dispensed from the pharmacy if they were dispensed**  
1262 **in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, or are**  
1263 **subject of a drug or device recall only if:**

1264

1265 **(a) An Oregon licensed Pharmacist has approved the return;**

1266

1267 **(b) The drugs or devices are accepted for destruction or disposal; and**

1268

1269 **(c) An Oregon licensed Pharmacist verifies the destruction or disposal.**

1270

1271 **Statutory/Other Authority: ORS 689.205**

1272 **Statutes/Other Implemented: ORS 689.305**

1273

1274

1275 **855-139-0460**

1276 **Drugs and Devices: Take-back Program**

1277

1278 **(1) A Remote Dispensing Site Pharmacy that operates a drug take-back collection program or that**  
1279 **participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized**  
1280 **collector must be registered with the DEA as an authorized collector to collect controlled and non-**  
1281 **controlled drugs for destruction.**

1282

1283 **(2) A Remote Dispensing Site Pharmacy that operates as a Drug Enforcement Agency (DEA) authorized**  
1284 **collector must notify the board within 30 days of initiating or terminating the program and must**  
1285 **establish and enforce policies and procedures, including but not limited to:**

1286

1287 **(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is**  
1288 **accessible to the public, within view of the pharmacy counter and must not be located behind the**  
1289 **pharmacy counter; and**

1290

1291 **(b) Provision of adequate security measures, including proper installation and maintenance of the**  
1292 **collection receptacle, tracking of liners, documentation and key accountability; and**

1293

1294 **(c) Personnel training and accountability.**

1295



1296 **(3) A Remote Dispensing Site Pharmacy must inform consumers to directly deposit drugs into the**  
1297 **collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs**  
1298 **collected.**

1299  
1300 **(4) A Remote Dispensing Site Pharmacy must not dispose of drugs from pharmacy stock in a collection**  
1301 **receptacle.**

1302  
1303 **(5) The liner must be inserted and removed from a locked collection receptacle only by or under the**  
1304 **supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed,**  
1305 **and the pharmacy employees must document their participation in the insertion and removal of each**  
1306 **liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed or penetrated**  
1307 **at any time by the pharmacy or pharmacy personnel.**

1308  
1309 **(6) Liners that have been removed from a collection receptacle and immediately sealed must be**  
1310 **directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer**  
1311 **than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution**  
1312 **agent (such as registered UPS, FedEx or USPS) or a reverse wholesaler registered with the DEA and the**  
1313 **board.**

1314  
1315 **(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to**  
1316 **the board in writing within one day of discovery.**

1317  
1318 **(8) A Remote Dispensing Site Pharmacy must maintain all drug disposal records for a minimum of 3**  
1319 **years.**

1320  
1321 **(9) Authorized collectors are required to comply with the following federal and state laws:**

1322  
1323 **(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS**  
1324 **459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236,**  
1325 **ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS**  
1326 **459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;**

1327  
1328 **(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370,**  
1329 **and OAR 340-098-0390;**

1330  
1331 **(c) 21 CFR 1317.30 (04/01/2020), 21 CFR 1317.35 (04/01/2020), 21 CFR 1317.40 (04/01/2020), 21 CFR**  
1332 **1317.55 (04/01/2020), 21 CFR 1317.60 (04/01/2020), 21 CFR 1317.65 (04/01/2020), 21 CFR 1317.70**  
1333 **(04/01/2020), 21 CFR 1317.75 (04/01/2020), 21 CFR 1317.80 (04/01/2020), and 21 CFR 1317.85**  
1334 **(04/01/2020); and**

1335  
1336 **(d) 21 USC 822 (04/01/2021), 21 USC 822a (04/01/2021).**

1337  
1338 **Statutory/Other Authority: ORS 689.205 & ORS 459A.266**

1339 **Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215 & ORS 495A.218**

1340

1341

1342

1343 **855-139-0500**

1344 **Policies and Procedures**

1345

1346 **(1) The Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy and the Affiliated Pharmacy**  
1347 **drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures**  
1348 **for the Remote Dispensing Site Pharmacy. The written policies and procedures must be maintained at**  
1349 **the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy and must be available to the board**  
1350 **upon request.**

1351

1352 **(2) The written policies and procedures must include at a minimum the responsibilities of the**  
1353 **Affiliated Pharmacy and each Remote Dispensing Site Pharmacy including;**

1354

1355 **(a) Security;**

1356

1357 **(b) Operation, testing and maintenance of the telepharmacy system;**

1358

1359 **(c) Sanitation;**

1360

1361 **(d) Storage of drugs;**

1362

1363 **(e) Dispensing;**

1364

1365 **(f) Oregon licensed Pharmacist supervision, direction and control of pharmacy technicians;**

1366

1367 **(g) Documenting the identity, function, location, date and time of the licensees engaging in**  
1368 **telepharmacy;**

1369

1370 **(h) Drug and/or device procurement;**

1371

1372 **(i) Receiving of drugs and/or devices;**

1373

1374 **(j) Delivery of drugs and/or devices;**

1375

1376 **(k) Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling);**

1377

1378 **(l) Recordkeeping;**

1379

1380 **(m) Patient confidentiality;**

1381

1382 **(n) On-site inspection by an Oregon licensed Pharmacist;**

1383

1384 **(o) Continuous quality improvement;**

1385

1386 **(p) Plan for discontinuing and recovering services if telepharmacy system disruption occurs;**

1387

1388 **(q) Training: initial and ongoing; and**

1389

1390 **(r) Interpretation, translation and prescription reader services.**

1391  
1392 **(3) If non-prescription drugs are offered for sale at the Remote Dispensing Site Pharmacy, the policies**  
1393 **and procedures must outline the process for the Oregon licensed Pharmacist counseling and advice.**  
1394

1395 **(4) If non-sterile preparations are compounded at the Remote Dispensing Site Pharmacy, the policies**  
1396 **and procedures must meet the requirements of OAR 855-045.**  
1397

1398 **(5) If controlled substances are stored at the Remote Dispensing Site Pharmacy, the policies and**  
1399 **procedures must include the following processes:**  
1400

1401 **(a) Reviewing of controlled substance prescriptions for unauthorized alterations and inspected for**  
1402 **legitimacy by the Oregon licensed Pharmacist during inspection visits;**  
1403

1404 **(b) Maintaining an accurate controlled substance perpetual inventory for all controlled substances**  
1405 **that are stocked at the Remote Dispensing Site Pharmacy; and**  
1406

1407 **(c) Conducting and reconciling the controlled substance inventory.**  
1408

1409 **(6) An Affiliated Pharmacy that provides remote pharmacy services through a telepharmacy system at**  
1410 **a Remote Dispensing Site Pharmacy must review its written policies and procedures every 12 months,**  
1411 **revise them if necessary, and document the review.**  
1412

1413 **Statutory/Other Authority: ORS 689.205**

1414 **Statutes/Other Implemented: ORS 689.155**  
1415  
1416  
1417

1418 **855-139-0550**

1419 **Records: General Requirements**  
1420

1421 **(1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other**  
1422 **recordkeeping rules of the board. Unless otherwise specified, all records and documentation required**  
1423 **by these rules, must be retained for three years and made available to the board for inspection upon**  
1424 **request. Records must be stored onsite for at least one year and may be stored, after one year, in a**  
1425 **secured off-site location if retrievable within three business days. Records and documentation may be**  
1426 **written, electronic or a combination of the two.**  
1427

1428 **(2) The Remote Dispensing Site Pharmacy must maintain all required records unless these records are**  
1429 **maintained in the Affiliated Pharmacy.**  
1430

1431 **(3) Records retained by the Drug Outlet must include, but are not limited to:**  
1432

1433 **(a) Patient profiles and records;**  
1434

1435 **(b) Date, time and identification of each individual and activity or function performed;**  
1436

1437 **(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or**  
1438 **function of the person performing each step in the dispensing process;**

1439  
1440 **(d) Controlled substance inventory and reconciliation;**  
1441  
1442 **(e) Oregon licensed Pharmacist physical inspection of Remote Dispensing Site Pharmacy;**  
1443  
1444 **(f) Audio and visual connection testing and individual training on use of the audio and visual**  
1445 **connection;**  
1446  
1447 **(g) Data, telephone audio, audio and video, still image capture, store and forward images, security**  
1448 **and surveillance data. This must be retained according to (1); and**  
1449  
1450 **(h) Any errors or irregularities identified by the quality improvement program.**  
1451  
1452 **(4) All data, telephone audio, audio and video, still image capture and store and forward images**  
1453 **collected by the telepharmacy, security and surveillance systems must be retained according to (1).**  
1454  
1455 **Statutory/Other Authority: ORS 689.205**  
1456 **Statutes/Other Implemented: ORS 689.155, ORS 689.508**  
1457  
1458  
1459 **855-139-0555**  
1460 **Records: Patient**  
1461  
1462 **A patient record system must be maintained by pharmacies for all patients for whom a prescription**  
1463 **drug is dispensed. The patient record system must provide information necessary for the dispensing**  
1464 **Oregon licensed Pharmacist to identify previously dispensed drugs at the time a prescription is**  
1465 **presented for dispensing. The pharmacist must make a reasonable effort to obtain, record, and**  
1466 **maintain the following information:**  
1467  
1468 **(1) Full name of the patient for whom the drug is intended;**  
1469  
1470 **(2) Address and telephone number of the patient;**  
1471  
1472 **(3) Patient's age or date of birth;**  
1473  
1474 **(4) Patient's gender;**  
1475  
1476 **(5) Chronic medical conditions;**  
1477  
1478 **(6) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the**  
1479 **patient record showing the name of the drug or device, prescription number, name and strength of**  
1480 **the drug, the quantity and date received, and the name of the prescriber;**  
1481  
1482 **(7) Known allergies, drug reactions, and drug idiosyncrasies; and**  
1483  
1484 **(8) If deemed relevant in the Oregon licensed Pharmacist's professional judgment;**  
1485

1486 **(a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any**  
1487 **other information peculiar to the specific patient or drug; and**

1488  
1489 **(b) Additional information such as chronic conditions or disease states of the patient, the patient's**  
1490 **current weight, and the identity of any other drugs, including over-the-counter drugs, or devices**  
1491 **currently being used by the patient which may relate to prospective drug review.**

1492  
1493 **Statutory/Other Authority: ORS 689.205**  
1494 **Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508**

1495  
1496  
1497  
1498 **855-139-0600**  
1499 **Prohibited Practices: General**

1500  
1501 **A Retail Drug Outlet Remote Dispensing Site Pharmacy may not:**

1502  
1503 **(1) Allow a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent**  
1504 **which screen and/or limit interaction with the Oregon licensed Pharmacist;**

1505  
1506 **(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide**  
1507 **pharmacy services unless the person is registered with the board pursuant to ORS 689.305.**

1508  
1509 **(3) Deliver a prescription;**

1510  
1511 **(4) Provide non-prescription or prescription drugs when the Remote Dispensing Site Pharmacy is**  
1512 **closed;**

1513  
1514 **(5) Compound sterile preparations; or**

1515  
1516 **(6) Repackage drugs.**

1517  
1518 **Statutory/Other Authority: ORS 475.035, , ORS 689.205, ORS 689.305, ORS 689.315**  
1519 **Statutes/Other Implemented: ORS 689.155**

1520  
1521  
1522  
1523 **855-139-0602**  
1524 **Prohibited Practices: Disclosure of Patient Information**

1525  
1526 **(1) Allow a licensee or registrant of the board who obtains any patient information to disclose that**  
1527 **information to a third party without the consent of the patient except as provided in (2) of this rule**

1528  
1529 **(2) A licensee may disclose patient information:**

1530  
1531 **(a) To the board;**

1532

1533 **(b) To a practitioner, Oregon licensed Pharmacist, Intern, Pharmacy Technician, or Certified Oregon**  
1534 **Pharmacy Technician, if disclosure is authorized by an Oregon-licensed Pharmacist who reasonably**  
1535 **believes that disclosure is necessary to protect the patient’s health or well-being; or**  
1536

1537 **(c) To a third-party when disclosure is authorized or required by law; or**  
1538

1539 **(d) As permitted pursuant to federal and state patient confidentiality laws; or**  
1540

1541 **(e) To the patient or to persons as authorized by the patient.**  
1542

1543 **(3) Allow a licensee or registrant of the board to access or obtain any patient information unless it is**  
1544 **accessed or obtained for the purpose of patient care.**  
1545

1546 **Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315**

1547 **Statutes/Other Implemented: ORS 689.155**  
1548

1551 **855-139-0650**

1552 **Grounds for Discipline**  
1553

1554 **The State Board of Pharmacy may impose one or more of the following penalties which includes:**  
1555 **suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet**  
1556 **upon the following grounds:**  
1557

1558 **(1) Unprofessional conduct as defined in OAR 855-006-0020;**  
1559

1560 **(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including,**  
1561 **but not be limited to, advertising or soliciting that:**  
1562

1563 **(a) Is false, fraudulent, deceptive, or misleading; or**  
1564

1565 **(b) Makes any claim regarding a professional service or product or the cost or price thereof which**  
1566 **cannot be substantiated by the licensee.**  
1567

1568 **(3) Failure to provide a working environment that protects the health, safety and welfare of a patient**  
1569 **which includes but is not limited to:**  
1570

1571 **(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with an**  
1572 **Oregon licensed Pharmacist’s ability to practice with reasonable competency and safety.**  
1573

1574 **(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.**  
1575

1576 **(c) Adequate time for an Oregon licensed Pharmacist to complete professional duties and**  
1577 **responsibilities including, but not limited to:**  
1578

1579 **(A) Drug Utilization Review;**  
1580

- 1581 **(B) Verification of the accuracy of a prescription;**  
1582  
1583 **(C) Counseling; and**  
1584  
1585 **(D) All other duties and responsibilities of an Oregon licensed Pharmacist as specified in OAR 855-019.**  
1586

1587 **(4) Introducing external factors such as productivity or production quotas or other programs to the**  
1588 **extent that they interfere with the ability to provide appropriate professional services to the public.**  
1589

1590 **(5) Incenting or inducing the transfer of a prescription absent professional rationale.**  
1591

1592 **Statutory/Other Authority: ORS 689.151, ORS 689.155, ORS 689.205, ORS 689.225**

1593 **Statutes/Other Implemented: ORS 689.155**  
1594  
1595  
1596

1597 **855-139-0710**

1598 **Service: Epinephrine- Definitions**  
1599

1600 **The following words and terms, when used in OAR 855-139-0210 through OAR 855-139-0211 have the**  
1601 **following meanings, unless the context clearly indicates otherwise.**  
1602

1603 **(1) "Allergic reaction" means a medical condition caused by exposure to an allergen, with physical**  
1604 **symptoms that may be life threatening, ranging from localized itching to severe anaphylactic shock**  
1605 **and death.**  
1606

1607 **(2) "Authorization to Obtain Epinephrine" means a certificate that contains the name, signature, and**  
1608 **license number of the supervising professional authorizing the dispensing of epinephrine to the**  
1609 **individual whose name appears on the certificate. Additionally, the certificate contains a record of the**  
1610 **number of epinephrine orders filled to date.**  
1611

1612 **(3) "Statement of Completion" means a certificate that states the specific type of emergency the**  
1613 **trainee was trained to respond to, the trainee's name and address, the name of the authorized trainer**  
1614 **and the date that the training was completed.**  
1615

1616 **(4) "Trainee" means an individual who has attended and successfully completed the formal training**  
1617 **pursuant to the protocols and criteria established by the Oregon Health Authority, Public Health**  
1618 **Division.**  
1619

1620 **Statutory/Other Authority: ORS 689.205 & ORS 689.681**

1621 **Statutes/Other Implemented: ORS 689.155 & ORS 689.681**  
1622  
1623  
1624

1625 **855-139-0715**

1626 **Service: Epinephrine- General Requirements**  
1627

1628 **(1) A Certified Oregon Pharmacy Technician may prepare for Oregon licensed Pharmacist verification**  
1629 **an order for epinephrine to be used by trainees to treat an anaphylactic reaction. Trainees must be 18**  
1630 **years of age or older and must have responsibility for or contact with at least one (1) other person as**  
1631 **a result of the trainee’s occupation or volunteer status, such as, but not limited to, a camp counselor,**  
1632 **scout leader, forest ranger, school employee, tour guide or chaperone.**  
1633

1634 **(2) Individuals must successfully complete a training program approved by the Oregon Health**  
1635 **Authority, Public Health Division. Upon successful completion, the trainee will receive the following**  
1636 **certificates:**  
1637

1638 **(a) Statement of Completion; and**  
1639

1640 **(b) Authorization to Obtain Epinephrine.**  
1641

1642 **(3) Acquisition of epinephrine from a pharmacy to be used for the treatment of allergic emergencies**  
1643 **may occur in the following manners:**  
1644

1645 **(a) An Oregon licensed Pharmacist may dispense epinephrine to a trainee upon presentation of the**  
1646 **Statement of Completion and Authorization to Obtain Epinephrine certificate to a pharmacy when:**  
1647

1648 **(A) An Oregon licensed Pharmacist may generate a prescription for and dispense an emergency supply**  
1649 **of epinephrine for not more than one adult and one child dose package, as specified by the**  
1650 **supervising professional whose name, signature, and license number appear on the Authorization to**  
1651 **Obtain Epinephrine certificate.**  
1652

1653 **(B) The Oregon licensed Pharmacist who generates the hardcopy prescription for epinephrine in this**  
1654 **manner must reduce the prescription to writing and file the prescription in a manner appropriate for a**  
1655 **non-controlled substance.**  
1656

1657 **(C) Once the Oregon licensed Pharmacist generates the epinephrine prescription, the Certified Oregon**  
1658 **Pharmacy Technician must write in the appropriate space provided on the Authorization to Obtain**  
1659 **Epinephrine certificate the date and the number of doses dispensed, the Oregon licensed Pharmacist**  
1660 **must verify the accuracy of data written on the certificate and the Certified Oregon Pharmacy**  
1661 **Technician must return the completed certificate to the trainee.**  
1662

1663 **(D) The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used**  
1664 **to obtain epinephrine up to four (4) times within three (3) years from the date of the initial training.**  
1665

1666 **(E) Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire**  
1667 **three (3) years from the date of the trainee’s last Oregon Health Authority approved allergy response**  
1668 **training.**  
1669

1670 **(F) Upon completion of the training, the trainee will receive a new Statement of Completion and**  
1671 **Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.**  
1672

1673 **(b) A Certified Oregon Pharmacy Technician may prepare for Oregon licensed Pharmacist verification**  
1674 **epinephrine to be dispensed to an entity when:**



- 1675  
1676 **(A) The epinephrine is acquired by a valid prescription presented to the pharmacy;**  
1677  
1678 **(B) The prescription identifies the entity as the patient for the purpose of prescribing and labeling the**  
1679 **prescription.**

1680  
1681 **Statutory/Other Authority: ORS 689.205**  
1682 **Statutes/Other Implemented: ORS 689.155 & ORS 433.825**

1683  
1684  
1685 **855-139-0720**  
1686 **Service: Naloxone- General Requirements**

1687  
1688 **Pharmacies providing naloxone services must establish, maintain and enforce written procedures**  
1689 **including, but not limited to:**

1690  
1691 **(1) Providing a workflow process and physical location that maintains confidentiality and is not**  
1692 **susceptible to distraction;**

1693  
1694 **(2) Documentation and recordkeeping: and**

1695  
1696 **(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies**  
1697 **to administer naloxone are available at the pharmacy.**

1698  
1699 **Statutory/Other Authority: ORS 689.205**  
1700 **Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682**

1701  
1702  
1703  
1704 **855-139-0725**  
1705 **Service: Expedited Partner Therapy (EPT)- Purpose**

1706  
1707 **(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases**  
1708 **can be reduced by treating all sexual partners for the disease, even when the treating clinician has not**  
1709 **examined those partners. This practice is known as Expedited Partner Therapy.**

1710  
1711 **(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022**  
1712 **authorizing this practice. This law permits health professional regulatory boards to adopt rules**  
1713 **permitting practitioners to practice Expedited Partner Therapy.**

1714  
1715 **(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid,**  
1716 **even if the name of the patient the prescription is intended for is not on the prescription.**

1717  
1718 **Statutory/Other Authority: ORS 689.205**  
1719 **Statutes/Other Implemented: ORS 689.505**

1720  
1721  
1722

1723 **855-139-0730**

1724 **Service: Expedited Partner Therapy (EPT) - Procedures**

1725

1726 **(1) “Expedited Partner Therapy (EPT)” means the practice of prescribing or dispensing an antibiotic**  
1727 **drug for the treatment of a sexually transmitted disease to the partner of a patient without first**  
1728 **examining that partner.**

1729

1730 **(2) Notwithstanding any other rules in this division that mandate requirements for a valid prescription**  
1731 **and for labeling, when a prescription is marked EPT or a similar notation by the prescribing**  
1732 **practitioner, this rule govern.**

1733

1734 **(3) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon**  
1735 **Health Authority (OHA) to be appropriately used for EPT.**

1736

1737 **Prescription**

1738

1739 **(4) An EPT treatment protocol must conform to the following:**

1740

1741 **(a) It must include a prescription for each named or unnamed partner of the patient;**

1742

1743 **(b) It must contain a handwritten or electronic signature of the prescribing practitioner;**

1744

1745 **(c) The practitioner must identify the prescription in the following manner:**

1746

1747 **(A) Write “for EPT,” or a similar notation, on the face of the prescription;**

1748

1749 **(B) For a verbal order, the practitioner must identify the prescription as an “EPT Prescription,” or**  
1750 **similar identification;**

1751

1752 **(C) The practitioner must identify the prescription for each partner either by including the name of the**  
1753 **patient, such as “John Doe – Partner 1” or by labeling the prescription as “EPT Partner”**

1754

1755 **(d) An EPT Prescription expires 30 days after the date written;**

1756

1757 **(e) An EPT Prescription may not be refilled;**

1758

1759 **(f) If any component of the prescription is missing, the Oregon licensed Pharmacist must contact the**  
1760 **prescriber or the prescriber’s agent and must record the additional information on the prescription.**

1761

1762 **(5) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy**  
1763 **of their choice; or the patient may give all prescriptions to one pharmacy and then give the dispensed**  
1764 **drugs to each unnamed partner.**

1765

1766 **Labeling**

1767

1768 **(6) The Certified Oregon Pharmacy Technician must label the drug for the named patient in**  
1769 **accordance with normal procedures as specified in the other rules of this division, however when**

1770 either the patient or partner is unnamed, the pharmacy may create a unique identifier and use that  
1771 instead of a name for both labeling and record keeping purposes.

1772  
1773 **(7)** The Oregon licensed Pharmacist must assign a separate and unique identifier to each prescription  
1774 and clearly identify this number on each corresponding prescription label.

1775  
1776 **Counseling**

1777  
1778 **(8)** The Oregon licensed Pharmacist is not required to obtain an EPT patient's or partner's name,  
1779 address, or demographics; however, the Oregon licensed Pharmacist must:

1780  
1781 **(a)** Provide counseling in the form of written patient information to accompany each prescription for  
1782 each partner and ask the patient about any known allergies or other drugs being taken by each  
1783 partner. The Oregon licensed Pharmacist should advise the patient to encourage each partner to call  
1784 the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the  
1785 past or if they are taking other drugs;

1786  
1787 **(b)** Document counseling.

1788  
1789 **Records**

1790  
1791 **(9)** All documentation required by this rule must be attached to the prescription and must be  
1792 referenced to each partner's prescription. Such documentation must be retained in accordance with  
1793 the other rules in this division and must be made available to the board upon request.

1794  
1795 **Statutory/Other Authority: ORS 689.205**  
1796 **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.

1 Division 41  
2 OPERATION OF PHARMACIES (AMBULATORY AND RESIDENTIAL DRUG OUTLETS)

3  
4 **855-041-1030**  
5 **Reporting Drug Loss**

6  
7 (1) Disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or  
8 devices shall immediately be reported to the ~~B~~board.

9  
10 (2) The outlet ~~shall~~must notify the ~~B~~board in the event of a significant drug loss or violation related to  
11 drug theft within one (1) business day. **A pharmacy must consider a controlled drug loss to be**  
12 **significant when:**

13  
14 **(a) The percentage of dosage units of a specific drug exceeds 2% of monthly dispensing volume; or**

15  
16 **(b) Fifteen or more dosage units are not accounted for.**

17  
18 **(3) At the time a Report of Theft or Loss of Controlled Substances (D-E-A- Form 106) or Report of Theft**  
19 **or Loss of Listed Chemicals (DEA Form 107)** is sent to the Drug Enforcement Administration, a copy ~~shall~~  
20 ~~be~~ is sent to the ~~B~~board.

21  
22  
23 Statutory/Other Authority: ORS 475.035, **ORS 689.155**, **ORS 689.205**, **ORS 689.305**, **ORS 689.315**  
24 Statutes/Other Implemented: ORS 689.155

25 Division 80  
26 SCHEDULE OF CONTROLLED SUBSTANCES

27  
28 **855-080-0023**  
29 **Schedule III**

30  
31 Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or  
32 brand name designated, listed in 21 CFR 1308.13 (04/01/2020); ~~and~~

33  
34 ~~(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.~~

35  
36 ~~(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.~~

37  
38 ~~(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active~~  
39 ~~ingredient.~~

40  
41 Statutory/Other Authority: ORS 689.205, ORS 475.973  
42 Statutes/Other Implemented: ORS 475.035

43  
44  
45 **855-080-0026**  
46 **Schedule V**

47  
48 Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical,  
49 or brand name designated, listed in 21 CFR 1308.15 (04/01/2020); and

50  
51 **(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.**

52  
53 **(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.**

54  
55 **(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active**  
56 **ingredient.**

57  
58 **(4) In order to provide non-prescription pseudoephedrine or ephedrine to a purchaser, a pharmacy**  
59 **must:**

60  
61 **(a) Store all pseudoephedrine and ephedrine behind the pharmacy counter in an area that is**  
62 **inaccessible to the public;**

63  
64 **(b) Utilize an electronic system meeting the requirements under ORS XXX.XXX [section 2 of HB 2648**  
65 **(2021)]; and**

66  
67 **(c) Train individuals who are responsible for providing pseudoephedrine or ephedrine to purchasers**  
68 **on the requirements of the Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA**  
69 **PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177), the Combat**  
70 **Methamphetamine Enhancement Act of 2010, P.L. 111-268, and use of the electronic system as**  
71 **described in 2021 HB 2648;**

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

74  
75 **(A) Verifying that the purchaser is 18 years of age or older;**

76  
77 **(B) Verifying the identity of the purchaser with valid government-issued photo identification; and**

78  
79 **(C) Confirming the purchase is allowed via the electronic system**

80  
81 **(e) Maintain an electronic log for at least three years from the date of the transaction that documents**  
82 **the following elements:**

83  
84 **(A) Date and time of the purchase;**

85  
86 **(B) Name, address and date of birth of the purchaser;**

87  
88 **(C) Form of government-issued photo identification and the identification number used to verify the**  
89 **identity of the purchaser;**

90  
91 **(D) Name of the government agency that issued the photo identification in (C);**

92  
93 **(E) Name of product purchased;**

94  
95 **(F) Quantity in grams of product purchased;**

96  
97 **(G) Name or initials of Pharmacist, Certified Oregon Pharmacy Technician or Pharmacy Technician who**  
98 **provides the drug; and**

99  
100 **(H) Signature of the purchaser. The signature of the purchaser may be recorded on a written log that**  
101 **also contains the transaction ID generated by the electronic system.**

102  
103 **(5) All sales of pseudoephedrine or ephedrine are subject to the following quantity limits and**  
104 **restrictions:**

105  
106 **(a) No more than 3.6 grams in a 24-hour period, no more than 9 grams in a 30-day period without**  
107 **regard to the number of transactions; and**

108  
109 **(b) For non-liquids, product packaging is limited to blister packs containing no more than 2 dosage**  
110 **units per blister. Where blister packs are not technically feasible, the product must be packaged in**  
111 **unit dose packets or pouches.**

112  
113 **(6) Sections (4) and (5) do not apply to a pseudoephedrine or ephedrine when the drug is dispensed**  
114 **pursuant to a prescription.**

115  
116 **(7) Pharmacies, Pharmacists, Certified Oregon Pharmacy Technicians and Pharmacy Technicians**  
117 **involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the**  
118 **provisions of 21 CFR 1314.01 (04/01/2020), 21 CFR 1314.02 (04/01/2020), 21 CFR 1314.03**

119 (04/01/2020), 21 CFR 1314.05 (04/01/2020), 21 CFR 1314.10 (04/01/2020), 21 CFR 1314.15  
120 (04/01/2020), 21 CFR 1314.20 (04/01/2020), 21 CFR 1314.25, (04/01/2020); 21 CFR 1314.30  
121 (04/01/2020), 21 CFR 1314.35 (04/01/2020), 21 CFR 1314.40 (04/01/2020), 21 CFR 1314.42  
122 (04/01/2020), 21 CFR 1314.45 (04/01/2020); and 21 CFR 1314.50 (04/01/2020).

123  
124 Statutory/Other Authority: ORS 689.205, 2021 HB 2648  
125 Statutes/Other Implemented: ORS 475.035, 2021 HB 2648

126  
127  
128 **855-080-0028**  
129 **Excluded or Exempted Substances**

130  
131 **(1) Drugs and their generic equivalents listed The board adopts the excluded substances list found** in 21  
132 **CFR 1308.22 (04/01/2020) are excluded from the schedules in OAR 855-080-0021 through 855-080-**  
133 **0026.**

134  
135 **(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/2020).**

136  
137 **(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription**  
138 **Products (06/26/2021) pursuant to 21 CFR 1308.32 (04/01/2020).**

139  
140 Statutory/Other Authority: ORS 689.205  
141 Statutes/Other Implemented: ORS 689.155

142  
143 **OAR 855-080-0029**  
144 **Acceptable Subpoenas for Law Enforcement Agencies to Obtain Pseudoephedrine or Ephedrine Log**  
145 **Information**

146  
147 **(1) "Law Enforcement Agency" includes the following:**

148  
149 **(a) County sheriffs, municipal police departments, police departments established by a university**  
150 **under ORS 352.121 or 353.125 and state police;**

151  
152 **(b) Other police officers of this state or another state, including humane special agents as defined in**  
153 **ORS 181A.345;**

154  
155 **(c) The Oregon Department of Justice when conducting a criminal investigation;**

156  
157 **(d) A tribal government as defined in ORS 181A.680 that employs authorized tribal police officers as**  
158 **defined in ORS 181A.680; and**

159  
160 **(e) Law enforcement agencies of the federal government.**

161  
162 **(2) Acceptable subpoenas for a law enforcement agency to obtain information in a pseudoephedrine**  
163 **or ephedrine log are subpoenas lawfully issued by:**

164  
165 **(a) A grand jury under ORS 136.563;**



- 166  
167 **(b) A district attorney under ORS 136.565;**  
168  
169 **(c) The Oregon Attorney General under ORS 183.073;**  
170  
171 **(d) A law enforcement agency of a tribal government under tribal subpoena authority; and**  
172  
173 **(e) A federal law enforcement agency under federal subpoena power.**  
174  
175 **(3) Subpoenas that meet the criteria in (2) are accepted by the Board under ORS XXX.XXX [section 2,**  
176 **subsection 5 of HB 2648 (2021)]. The Board does not act as a decisionmaker as to a subpoena issued**  
177 **for pseudoephedrine or ephedrine logs under this rule. The Board is not a party to a subpoena for**  
178 **information contained in a pseudoephedrine or ephedrine log under this rule.**  
179

180 Statutory/Other Authority: ORS 689.205, **2021 HB 2648**  
181 Statutes/Other Implemented: ORS 475.035, **2021 HB 2648**  
182

#### 183 **855-080-0031**

#### 184 **Registration Requirements**

185  
186  
187 **(1) Every person who manufactures, delivers or dispenses any controlled substance within this state or**  
188 **who proposes to engage in the manufacture, delivery or dispensing of any controlled substance within**  
189 **this state must obtain a controlled substance registration annually issued by the State Board of**  
190 **Pharmacy.**  
191

192 **(2) The board adopts the exceptions to registration for distribution by dispenser to another**  
193 **practitioner pursuant to 21 CFR 1307.11 (04/01/2020).**  
194

195 **(3) The board adopts the exceptions to registration for the incidental manufacture of controlled**  
196 **substances pursuant to 21 CFR 1307.13 (04/01/2020).**  
197

198 Statutory/Other Authority: ORS 689.155 & ORS 689.205  
199 Statutes/Other Implemented: ORS 475.125  
200

#### 201 **855-080-0080**

#### 202 **Special-Exceptions**

203  
204 ~~The board adopts the exceptions to registration found in 21 CFR 1307.11 (04/01/2020) and 21 CFR~~  
205 ~~1307.13 (04/01/2020).~~  
206

207 ~~Statutory/Other Authority: ORS 689.205~~  
208 ~~Statutes/Other Implemented: ORS 475.035~~  
209  
210  
211  
212

213 **855-080-0085**  
214 **Prescription Requirements**  
215

216 **(1)** Registrants, practitioners and pharmacists as specified therein in the issuance, preparation, labeling  
217 dispensing, recordkeeping and filing of prescriptions for controlled substances must comply with the  
218 provisions of 21 CFR 1306.01 (04/01/2020), 21 CFR 1306.02 (04/01/2020), 21 CFR 1306.03 (04/01/2020),  
219 21 CFR 1306.04 (04/01/2020), 21 CFR 1306.05 (04/01/2020), 21 CFR 1306.06 (04/01/2020), 21 CFR  
220 1306.07 (04/01/2020), 21 CFR 1306.08 (04/01/2020), 21 CFR 1306.09 (04/01/2020); 21 CFR 1306.11  
221 (04/01/2020), 21 CFR 1306.12 (04/01/2020), 21 CFR 1306.13 (04/01/2020), 21 CFR 1306.14  
222 (04/01/2020), 21 CFR 1306.15 (04/01/2020); 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.22  
223 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25  
224 (04/01/2020), ~~21 CFR 1306.26 (04/01/2020)~~, 21 CFR 1306.27 (04/01/2020); and 21 CFR 1304.03(d)  
225 (04/01/2020).

226  
227 **(2)** Controlled substances listed in 21 CFR 1308.15 (XX/XX/XXXX) as schedule V are prescription drugs.  
228

229 **(3)** Pseudoephedrine, ephedrine and phenylpropanolamine may be:  
230

231 **(a)** Provided to a patient without a prescription under ORS XXX.XXX [section 2 of HB 2648 (2021)].  
232

233 **(b)** Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR  
234 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24  
235 (04/01/2020), 21 CFR 1306.25 (04/01/2020), and 21 CFR 1306.27 (04/01/2020).  
236

237 Statutory/Other Authority: ORS 689.205

238 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.

1 Division 41  
2 OPERATION OF PHARMACIES (AMBULATORY AND RESIDENTIAL DRUG OUTLETS)

3  
4 **855-041-1030**  
5 **Reporting Drug Loss**

6  
7 (1) Disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or  
8 devices shall immediately be reported to the ~~B~~board.

9  
10 **(2)** The outlet shall **must ensure that confirmed** notify the Board in the event of a significant drug loss or  
11 violation ~~any loss~~ related to **suspected** drug theft **of a controlled substance is reported to the board**  
12 within one (~~1~~) business day.

13  
14 **(3)** At the time a Report of Theft or Loss of Controlled Substances (D-E-A- Form 106) **or Report of Theft**  
15 **or Loss of Listed Chemicals (DEA Form 107)** is sent to the Drug Enforcement Administration, a copy shall  
16 ~~be is~~ sent to the ~~B~~board.

17  
18  
19 Statutory/Other Authority: ORS 475.035, **ORS** 689.155, **ORS** 689.205, **ORS** 689.305, **ORS** 689.315  
20 Statutes/Other Implemented: ORS 689.155

21 Division 80  
22 SCHEDULE OF CONTROLLED SUBSTANCES

23  
24 **855-080-0023**  
25 **Schedule III**

26  
27 Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or  
28 brand name designated, listed in 21 CFR 1308.13 (04/01/2020); ~~and~~

29  
30 ~~(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.~~

31  
32 ~~(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.~~

33  
34 ~~(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active~~  
35 ~~ingredient.~~

36  
37 Statutory/Other Authority: ORS 689.205, ORS 475.973  
38 Statutes/Other Implemented: ORS 475.035

39  
40  
41 **855-080-0026**  
42 **Schedule V**

43  
44 Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical,  
45 or brand name designated, listed in 21 CFR 1308.15 (04/01/2020); and

46  
47 **(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.**

48  
49 **(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.**

50  
51 **(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active**  
52 **ingredient.**

53  
54 **(4) In order to provide non-prescription pseudoephedrine or ephedrine to a purchaser, a pharmacy**  
55 **must:**

56  
57 **(a) Store all pseudoephedrine and ephedrine behind the pharmacy counter in an area that is**  
58 **inaccessible to the public;**

59  
60 **(b) Utilize an electronic system meeting the requirements under ORS XXX.XXX [section 2 of HB 2648**  
61 **(2021)]; and**

62  
63 **(c) Train individuals who are responsible for providing pseudoephedrine or ephedrine to purchasers**  
64 **on the requirements of the Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA**  
65 **PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177), the Combat**  
66 **Methamphetamine Enhancement Act of 2010, P.L. 111-268, and use of the electronic system as**  
67 **described in 2021 HB 2648;**

- 68 **(d) Ensure that only a Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician**  
69 **provides pseudoephedrine or ephedrine to the purchaser after:**  
70  
71 **(A) Verifying that the purchaser is 18 years of age or older;**  
72  
73 **(B) Verifying the identity of the purchaser with valid government-issued photo identification; and**  
74  
75 **(C) Confirming the purchase is allowed via the electronic system**  
76  
77 **(e) Maintain an electronic log for at least three years from the date of the transaction that documents**  
78 **the following elements:**  
79  
80 **(A) Date and time of the purchase;**  
81  
82 **(B) Name, address and date of birth of the purchaser;**  
83  
84 **(C) Form of government-issued photo identification and the identification number used to verify the**  
85 **identity of the purchaser;**  
86  
87 **(D) Name of the government agency that issued the photo identification in (C);**  
88  
89 **(E) Name of product purchased;**  
90  
91 **(F) Quantity in grams of product purchased;**  
92  
93 **(G) Name or initials of Pharmacist, Certified Oregon Pharmacy Technician or Pharmacy Technician who**  
94 **provides the drug; and**  
95  
96 **(H) Signature of the purchaser. The signature of the purchaser may be recorded on a written log that**  
97 **also contains the transaction ID generated by the electronic system.**  
98  
99 **(5) All sales of pseudoephedrine or ephedrine are subject to the following quantity limits and**  
100 **restrictions:**  
101  
102 **(a) No more than 3.6 grams in a 24-hour period, no more than 9 grams in a 30-day period without**  
103 **regard to the number of transactions; and**  
104  
105 **(b) For non-liquids, product packaging is limited to blister packs containing no more than 2 dosage**  
106 **units per blister. Where blister packs are not technically feasible, the product must be packaged in**  
107 **unit dose packets or pouches.**  
108  
109 **(6) Sections (4) and (5) do not apply to a pseudoephedrine or ephedrine when the drug is dispensed**  
110 **pursuant to a prescription.**  
111  
112 **(7) Pharmacies, Pharmacists, Certified Oregon Pharmacy Technicians and Pharmacy Technicians**  
113 **involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the**  
114 **provisions of 21 CFR 1314.01 (04/01/2020), 21 CFR 1314.02 (04/01/2020), 21 CFR 1314.03**

115 (04/01/2020), 21 CFR 1314.05 (04/01/2020), 21 CFR 1314.10 (04/01/2020), 21 CFR 1314.15  
116 (04/01/2020), 21 CFR 1314.20 (04/01/2020), 21 CFR 1314.25, (04/01/2020); 21 CFR 1314.30  
117 (04/01/2020), 21 CFR 1314.35 (04/01/2020), 21 CFR 1314.40 (04/01/2020), 21 CFR 1314.42  
118 (04/01/2020), 21 CFR 1314.45 (04/01/2020); and 21 CFR 1314.50 (04/01/2020).

119  
120 Statutory/Other Authority: ORS 689.205, 2021 HB 2648  
121 Statutes/Other Implemented: ORS 475.035, 2021 HB 2648

122  
123  
124 **855-080-0028**  
125 **Excluded or Exempted Substances**

126  
127 **(1) Drugs and their generic equivalents listed The board adopts the excluded substances list found** in 21  
128 **CFR 1308.22 (04/01/2020) are excluded from the schedules in OAR 855-080-0021 through 855-080-**  
129 **0026.**

130  
131 **(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/2020).**

132  
133 **(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription**  
134 **Products (06/26/2021) pursuant to 21 CFR 1308.32 (04/01/2020).**

135  
136 Statutory/Other Authority: ORS 689.205  
137 Statutes/Other Implemented: ORS 689.155

138  
139 **OAR 855-080-0029**  
140 **Acceptable Subpoenas for Law Enforcement Agencies to Obtain Pseudoephedrine or Ephedrine Log**  
141 **Information**

142  
143 **(1) “Law Enforcement Agency” includes the following:**

144  
145 **(a) County sheriffs, municipal police departments, police departments established by a university**  
146 **under ORS 352.121 or 353.125 and state police;**

147  
148 **(b) Other police officers of this state or another state, including humane special agents as defined in**  
149 **ORS 181A.345;**

150  
151 **(c) The Oregon Department of Justice when conducting a criminal investigation;**

152  
153 **(d) A tribal government as defined in ORS 181A.680 that employs authorized tribal police officers as**  
154 **defined in ORS 181A.680; and**

155  
156 **(e) Law enforcement agencies of the federal government.**

157  
158 **(2) Acceptable subpoenas for a law enforcement agency to obtain information in a pseudoephedrine**  
159 **or ephedrine log are subpoenas lawfully issued by:**

160  
161 **(a) A grand jury under ORS 136.563;**

- 162  
163 **(b) A district attorney under ORS 136.565;**  
164  
165 **(c) The Oregon Attorney General under ORS 183.073;**  
166  
167 **(d) A law enforcement agency of a tribal government under tribal subpoena authority; and**  
168  
169 **(e) A federal law enforcement agency under federal subpoena power.**  
170  
171 **(3) Subpoenas that meet the criteria in (2) are accepted by the Board under ORS XXX.XXX [section 2,**  
172 **subsection 5 of HB 2648 (2021)]. The Board does not act as a decisionmaker as to a subpoena issued**  
173 **for pseudoephedrine or ephedrine logs under this rule. The Board is not a party to a subpoena for**  
174 **information contained in a pseudoephedrine or ephedrine log under this rule.**  
175

176 Statutory/Other Authority: ORS 689.205, **2021 HB 2648**  
177 Statutes/Other Implemented: ORS 475.035, **2021 HB 2648**

178  
179  
180 **855-080-0031**

181 **Registration Requirements**

182  
183 **(1) Every person who manufactures, delivers or dispenses any controlled substance within this state or**  
184 **who proposes to engage in the manufacture, delivery or dispensing of any controlled substance within**  
185 **this state must obtain a controlled substance registration annually issued by the State Board of**  
186 **Pharmacy.**  
187

188 **(2) The board adopts the exceptions to registration for distribution by dispenser to another**  
189 **practitioner pursuant to 21 CFR 1307.11 (04/01/2020).**  
190

191 **(3) The board adopts the exceptions to registration for the incidental manufacture of controlled**  
192 **substances pursuant to 21 CFR 1307.13 (04/01/2020).**  
193

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

196  
197 **855-080-0080**  
198 **Special-Exceptions**

199  
200 ~~The board adopts the exceptions to registration found in 21 CFR 1307.11 (04/01/2020) and 21 CFR~~  
201 ~~1307.13 (04/01/2020).~~  
202

203 ~~Statutory/Other Authority: ORS 689.205~~  
204 ~~Statutes/Other Implemented: ORS 475.035~~  
205  
206  
207  
208



209 **855-080-0085**  
210 **Prescription Requirements**

211  
212 **(1)** Registrants, practitioners and pharmacists as specified therein in the issuance, preparation, labeling  
213 dispensing, recordkeeping and filing of prescriptions for controlled substances must comply with the  
214 provisions of 21 CFR 1306.01 (04/01/2020), 21 CFR 1306.02 (04/01/2020), 21 CFR 1306.03 (04/01/2020),  
215 21 CFR 1306.04 (04/01/2020), 21 CFR 1306.05 (04/01/2020), 21 CFR 1306.06 (04/01/2020), 21 CFR  
216 1306.07 (04/01/2020), 21 CFR 1306.08 (04/01/2020), 21 CFR 1306.09 (04/01/2020); 21 CFR 1306.11  
217 (04/01/2020), 21 CFR 1306.12 (04/01/2020), 21 CFR 1306.13 (04/01/2020), 21 CFR 1306.14  
218 (04/01/2020), 21 CFR 1306.15 (04/01/2020); 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.22  
219 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25  
220 (04/01/2020), ~~21 CFR 1306.26 (04/01/2020)~~, 21 CFR 1306.27 (04/01/2020); and 21 CFR 1304.03(d)  
221 (04/01/2020).

222  
223 **(2)** Controlled substances listed in 21 CFR 1308.15 (XX/XX/XXXX) as schedule V are prescription drugs.

224  
225 **(3)** Pseudoephedrine, ephedrine and phenylpropanolamine may be:

226  
227 **(a)** Provided to a patient without a prescription under ORS XXX.XXX [section 2 of HB 2648 (2021)].

228  
229 **(b)** Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR  
230 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24  
231 (04/01/2020), 21 CFR 1306.25 (04/01/2020), and 21 CFR 1306.27 (04/01/2020).

232  
233 Statutory/Other Authority: ORS 689.205

234 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.

1 Division 19  
2 PHARMACISTS

3  
4 **855-019-0120**  
5 **Licensure**

6  
7 (1) Before licensure as a pharmacist, an applicant must meet the following requirements:

8  
9 (a) Provide evidence from a school or college of pharmacy approved by the **B**board that they have  
10 successfully completed all the requirements for graduation and, starting with the graduating class of  
11 2011, including not less than 1440 hours of School-based Rotational Internships as that term is defined  
12 in OAR 855-031-0005, and that a degree will be conferred;

13  
14 (b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less  
15 than 75. This score ~~shall remain is~~ valid for only one year unless the **B**board grants an extension. A  
16 candidate who does not attain this score may retake the exam after a minimum of 45 days with a limit  
17 of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times-;

18  
19 (c) Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) exam with a score of not less than  
20 75. The applicant may not take the MPJE until they have graduated from a school or college of pharmacy  
21 approved by the **B**board. A candidate who does not attain this score may retake the exam after a  
22 minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime  
23 maximum of 5 times. The MPJE score ~~shall be is~~ valid for 6 months unless extended by the **B**board;

24  
25 (d) Complete an application for licensure, provide the **B**board with a valid e-mail address, and a  
26 fingerprint card or other documentation required to conduct a criminal background check-; and

27  
28 (e) Complete one hour of continuing pharmacy education in pain management, provided by the Pain  
29 Management Commission of the Oregon Health Authority.  
30

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

33  
34 Statutory/Other Authority: ORS 689.205  
35 Statutes/Other Implemented: ORS 689.151 & 2021 HB 2078

36  
37 Division 21  
38 CONTINUING PHARMACY EDUCATION

39  
40 **855-021-0001**  
41 **Definitions**

42  
43 (1) "Continuing Pharmacy Education" or "CPE" means classes of post graduate studies, informal study  
44 group participation, institutes, seminars, lectures, conferences, workshops, extension study,  
45 correspondence courses, teaching, planned and professional meetings, self-study courses, cassette or  
46 audio visual tape/slides or materials, and other self-instruction units applicable to the practice of  
47 pharmacy.

48  
49 (2) "Contact hour" means fifty minutes of continuing pharmacy education.

50  
51 (3) "Patient safety" means systems, procedures and processes that ensure that the correct patient  
52 receives the correct drug in the correct dose and is counseled appropriately.

53  
54 (4) "Medication error prevention" means systems, procedures and processes to prevent and avoid  
55 adverse events and to ensure that the correct patient receives the correct drug in the correct dose.

56  
57 (5) "Pain management education program" means a specific one hour web-based program developed by  
58 the Oregon Pain Commission, ~~in addition to six accredited hours of continuing education in pain~~  
59 ~~management, end of life care or a combination of both.~~

60  
61 (6) "Cultural competence" means the lifelong process of examining the values and beliefs and  
62 developing and applying an inclusive approach to health care practice in a manner that recognizes the  
63 content and complexities of provider-patient communication and interaction and preserves the dignity  
64 of individuals, families, and communities.

65  
66 (a) Cultural competence applies to all patients.

67  
68 (b) Culturally competent providers do not make assumptions on the basis of an individual's actual or  
69 perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race,  
70 color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital  
71 status, socio-economic status, veteran's status, sexual orientation, gender identity, gender expression,  
72 gender transition status, level of formal education, physical or mental disability, medical condition or  
73 any consideration recognized under federal, state and local law.

74  
75 Statutory/Other Authority: ORS 689.205 & ORS 676.850  
76 Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 413.590

77  
78

79 **855-021-0005**

80 **Continuing Pharmacy Education Required for Pharmacist License Renewal**

81

82 (1) During the period from July 1 through June 30 of each biennial license renewal cycle, a pharmacist  
83 must have satisfactorily completed at least 30 hours of continuing pharmacy education. These hours  
84 must include at least:

85

86 (a) Two hours of continuing pharmacy education in pharmacy law;

87

88 (b) Two hours of continuing pharmacy education in patient safety or medication error prevention;

89

90 (c) Two hours of continuing pharmacy education in cultural competency either approved by the Oregon  
91 Health Authority under ORS 413.450 or any cultural competency CPE; and

92

93 **(d) One hour of continuing pharmacy education in pain management, provided by the Pain**  
94 **Management Commission of the Oregon Health Authority; and**

95

96 ~~(de)~~ Twenty three ~~four~~ additional hours of continuing pharmacy education.

97

98 ~~(2) Prior to the second license renewal, a pharmacist licensed under these rules must complete seven~~  
99 ~~hours of continuing education in pain management as detailed in the following sub-sections.~~

100

101 ~~(a) A one-hour pain management course, specific to Oregon, provided by the Pain Management~~  
102 ~~Commission of the Oregon Health Authority; and~~

103

104 ~~(b) A minimum of six hours of continuing education in pain management. This requirement may be~~  
105 ~~fulfilled by any combination of continuing education coursework focusing on pain management~~  
106 ~~including but not limited to the treatment of terminally ill and dying patients, and those with chronic,~~  
107 ~~non-malignant pain.~~

108

109 ~~(c) The pain management continuing education required under this rule may count towards the required~~  
110 ~~30 continuing pharmacy education contact hours.~~

111

112 ~~(32)~~ Section (1) does not apply to pharmacists applying for the first renewal of their license if they have  
113 not been licensed by the board for at least one year prior to July 1 of the renewal period.

114

115 ~~(43)~~ A pharmacist must retain documentation of completed continuing pharmacy education for six years  
116 and must provide this documentation if requested by the board.

117

118 ~~(54)~~ Continuing pharmacy education credit accumulated in excess of the required 30 contact hours for  
119 biennial license renewal cannot be carried forward.

120

121 Statutory/Other Authority: ORS 689.205 & ORS 676.850

122 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

4 **855-020-0110**

5 **Prescribing Practices**

6

7 (1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and  
8 devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist  
9 ~~shall~~may only prescribe a drug or device consistent with the parameters of the Formulary and Protocol  
10 Compendia, and in accordance with federal and state regulations.

11

12 (2) A pharmacist must create, approve, and maintain policies and procedures for prescribing post-  
13 diagnostic drugs and devices or providing patient care services pursuant to statewide drug therapy  
14 management protocols. The policies and procedures ~~shall~~must describe current and referenced clinical  
15 guidelines, and include but not be limited to:

16

17 (a) Patient inclusion and exclusion criteria;

18

19 (b) Explicit medical referral criteria;

20

21 (c) Care plan preparation, implementation, and follow-up;

22

23 (d) Patient education; and

24

25 (e) Provider notification; and

26

27 (f) Maintaining confidentiality.

28

29 (3) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving  
30 situations beyond their expertise by consulting with or referring patients to another health care  
31 provider.

32

33 (4) For each drug or device the pharmacist prescribes, the pharmacist must:

34

35 (a) Assess patient and collect subjective and objective information, including the diagnosis for Formulary  
36 Compendia items, about the patient's health history and clinical status. The pharmacist's ~~patient~~physical  
37 assessment ~~shall~~must be performed in a face-to-face, in-person interaction and not through electronic  
38 means; and

39

40 (b) Utilize information obtained in the assessment to evaluate and develop an individualized patient-  
41 centered care plan, pursuant to the statewide drug therapy management protocol and policies and  
42 procedures; and

43

44 (c) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-  
45 up; and

46

47 (d) Provide notification to the patient's identified primary care provider or other care providers when  
48 applicable within five business days following the prescribing of a Compendia drug or device.

49

50 (5) The pharmacist ~~shall~~must maintain all records associated with prescribing and other related activities  
51 performed for a minimum of 10 years, and a copy must be made available to the patient and provider

52 upon request. Pharmacy records must be retained and made available to the Board for inspection upon  
53 request. Records must be stored onsite for at least one year and then may be stored in a secure off-site  
54 location if retrievable within three business days. Records and documentation may be written,  
55 electronic or a combination of the two.

56  
57 **(6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use**  
58 **real-time audio-visual communication to conduct the consultation.**

59  
60 Statutory/Other Authority: ORS 689.205

61 Statutes/Other Implemented: ORS 689.645 & ORS 689.649

62

63

64

65 **855-020-0300**

66 **Protocol Compendium**

67

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

70

71 (1) Continuation of therapy (v. 06/2021)

72

73 (2) Conditions

74

75 (a) Cough and cold symptom management

76

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

78

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

80

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

82

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

84

85 (b) Vulvovaginal candidiasis (VVC) Protocol (v. 06/2021)

86

87 (c) COVID-19 Monoclonal Antibody (**mAb**) Protocol (v. 08~~9~~9/2021)

88

89 (3) Preventative care

90

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

92

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

94

95 (c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT Protocol (v. 06/2021);

96

97 (d) Travel Medications Protocol (v. 06/2021)

98

99 (e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 06~~9~~/2021); and

100

101 (f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. 06~~9~~/2021)

102

103 [Publications referenced are available for inspection in the office of the Board of Pharmacy per OAR 855-  
104 010-0021.]

105

106 Statutory/Other Authority: ORS 689.205

107 Statutes/Other Implemented: ORS 689.645 & ORS 689.649

PROPOSED



**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 Micronesia 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 **one** 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

**STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST**

REALD Data Collection Form

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: <input type="checkbox"/> Fever <input type="checkbox"/> Chills <input type="checkbox"/> Cough <input type="checkbox"/> Shortness of breath <input type="checkbox"/> Difficulty breathing <input type="checkbox"/> Fatigue <input type="checkbox"/> Headache <input type="checkbox"/> Muscle or body aches <input type="checkbox"/> New loss of taste or smell <input type="checkbox"/> Sore throat <input type="checkbox"/> Congestion <input type="checkbox"/> Runny nose <input type="checkbox"/> Nausea <input type="checkbox"/> Vomiting <input type="checkbox"/> 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..... B. Cancer..... C. Chronic kidney disease..... D. Chronic lung diseases (e.g., chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)..... E. Dementia or other neurological conditions..... F. Diabetes (Type 1 or Type 2) ..... G. Heart conditions (such as heart failure, coronary artery disease, cardiomyopathies or hypertension) ..... H. HIV Infection..... I. Immunocompromised state (weakened immune system) ..... J. Liver Disease..... K. Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or oxygen supplementation (not related to COVID 19))..... 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 ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ 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. SpO<sub>2</sub> < 94% or if patient self-reports SpO<sub>2</sub> is regularly 91-93% and SpO<sub>2</sub> 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.

# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

### 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.

# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

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](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.



# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

### 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](http://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 adverse events 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>

# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

### 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<sup>2</sup>, or if age 12-17 years, have BMI ≥85<sup>th</sup> percentile for their age and gender based on CDC growth charts, [https://www.cdc.gov/growthcharts/clinical\\_charts.htm](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>.

# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

### 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)

# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

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.

# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

### 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 <b>4 Syringes</b>
Using Casirivimab and Imdevimab <i>Co-formulated Vial</i>	Withdraw 2.5 mL solution per syringe into FOUR separate syringes.
Using Casirivimab <i>individual vial</i> and Imdevimab <i>individual vial</i>	<ul style="list-style-type: none"> <li>• Casirivimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes.</li> <li>• Imdevimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes.</li> </ul> <p>For total of 4 syringes.</p>

# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

**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 <b>2 Syringes</b>
Using Casirivimab and Imdevimab <i>Co-formulated Vial</i>	Withdraw 2.5 mL solution per syringe into TWO separate syringes.
Using Casirivimab <i>individual vial</i> and Imdevimab <i>individual vial</i>	<ul style="list-style-type: none"> <li>• Casirivimab: Withdraw 2.5 mL solution per syringe into ONE syringe.</li> <li>• Imdevimab: Withdraw 2.5 mL solution per syringe into ONE syringe.</li> </ul> <p>For total of 2 syringes.</p>

\* 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.](#)

# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

### 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](http://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.



# Standardized Assessment and Treatment Care Pathway

## COVID Monoclonal Antibodies (REGEN-COV™)

### XII. **ADVERSE REACTIONS AND MEDICATION ERRORS REPORTING REQUIREMENTS:**

The prescribing pharmacist 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](http://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

## Standardized Assessment and Treatment Care Pathway COVID Monoclonal Antibodies (REGEN-COV™)

- 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](mailto: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  $\geq 1$  COVID-19-related hospitalization or all-cause death through Day 29. The results for subjects treated with 600 mg of casirivimab 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.**

	Casirivimab 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,

## Standardized Assessment and Treatment Care Pathway COVID Monoclonal Antibodies (REGEN-COV™)

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 casirivimab 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.**

	Casirivimab 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:

## Standardized Assessment and Treatment Care Pathway COVID Monoclonal Antibodies (REGEN-COV™)

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](http://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](http://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

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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:

<u>Test Name</u>	<u>Date of Test</u>	<u>Result</u>
SARS-CoV-2 (molecular or antigen)	1) ____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> <i>indeterminate/inconclusive</i> <input type="checkbox"/> negative
	2*) ____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> <i>indeterminate/inconclusive</i> <input type="checkbox"/> negative

\*2<sup>nd</sup> test only required if 1<sup>st</sup> 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)**

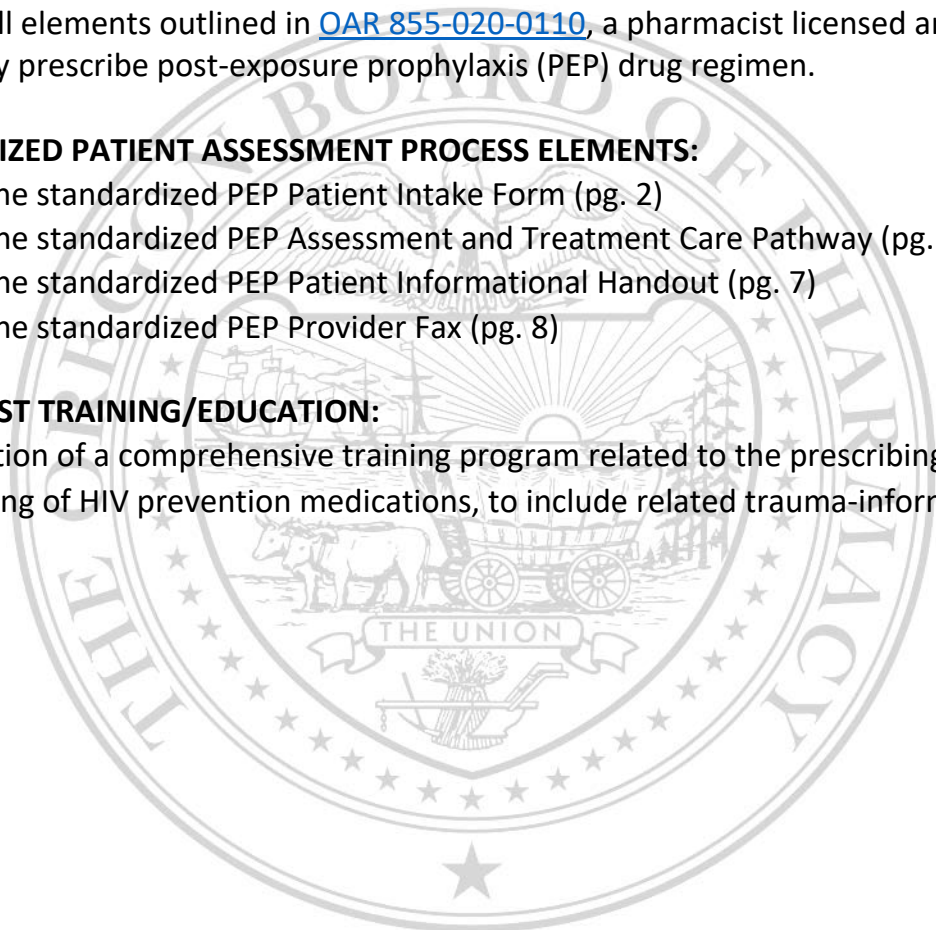
**STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST**

**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)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: <input type="checkbox"/> Blood <input type="checkbox"/> Tissue fluids <input type="checkbox"/> Semen <input type="checkbox"/> Vaginal secretions <input type="checkbox"/> Saliva <input type="checkbox"/> Tears <input type="checkbox"/> Sweat <input type="checkbox"/> Other (please specify): _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
7.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? <input type="checkbox"/> persons with known HIV infection <input type="checkbox"/> men who have sex with men with unknown HIV status <input type="checkbox"/> persons who inject drugs <input type="checkbox"/> sex workers	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 <input type="checkbox"/> No <input type="checkbox"/> Not sure

### Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
13.	Are you seeing a provider for management of Hepatitis B?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
15.	Are you seeing a kidney specialist?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
16.	Are you currently pregnant?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
17.	Are you currently breast-feeding?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? <input type="checkbox"/> Orlistat (Alli®) <input type="checkbox"/> aspirin ≥ 325 mg <input type="checkbox"/> naproxen (Aleve®) <input type="checkbox"/> ibuprofen (Advil®) <input type="checkbox"/> antacids (Tums® or Rolaids®), <input type="checkbox"/> vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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: \_\_\_/\_\_\_/\_\_\_\_\_

1. Is the patient less than 13 years old?		Notes:
<input type="checkbox"/> 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	<input type="checkbox"/> No: Go to #2	
2. Was the patient a survivor of sexual assault?		Notes:
<input type="checkbox"/> 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.**	<input type="checkbox"/> No: Go to #3	
3. Is the patient known to be HIV-positive?		Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.
<input type="checkbox"/> Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.	<input type="checkbox"/> No: Go to #4. Conduct 4 <sup>th</sup> generation HIV fingerstick test if available (optional).	
4. What time did the exposure occur?		Notes:
<input type="checkbox"/> >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.	<input type="checkbox"/> ≤72 hours ago: go to #5	
5. Was the exposure from a source person known to be HIV-positive?		
<input type="checkbox"/> Yes: Go to #6	<input type="checkbox"/> No: Go to #7	
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:		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.
Please check any/all that apply: <input type="checkbox"/> Blood <input type="checkbox"/> Semen <input type="checkbox"/> Vaginal secretions <input type="checkbox"/> Rectal secretions <input type="checkbox"/> Breast milk <input type="checkbox"/> Any body fluid that is visibly contaminated with blood  If any boxes are checked, go to #9.	Please check any/all that apply ( <i>Note: only applicable if not visibly contaminated with blood</i> ): <input type="checkbox"/> Urine <input type="checkbox"/> Nasal Secretions <input type="checkbox"/> Saliva <input type="checkbox"/> Sweat <input type="checkbox"/> Tears <input type="checkbox"/> None of the above  Go to #7	
7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?		Notes: This type of exposure puts the patient at a high risk for HIV acquisition
<input type="checkbox"/> Yes: Go to #9	<input type="checkbox"/> No: Go to #8	

# Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

## Assessment and Treatment Care Pathway (CONFIDENTIAL-Protected Health Information)

<p>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?</p>		<p>Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.</p>
<p><input type="checkbox"/> Yes: Please check all that apply and go to #9:</p> <p><input type="checkbox"/> Was the source person known to be HIV-positive?</p> <p><input type="checkbox"/> Were there cuts/openings/sores/ulcers on the oral mucosa?</p> <p><input type="checkbox"/> Was blood present?</p> <p><input type="checkbox"/> Has this happened more than once without PEP treatment?</p> <p><input type="checkbox"/> None of the above</p>	<p><input type="checkbox"/> No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.</p>	
<p>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?</p>		<p>Notes: Connection to care is critical for future recommended follow-up.</p>
<p><input type="checkbox"/> Yes: Go to #10</p>	<p><input type="checkbox"/> 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.</p>	
<p>10. Does the patient have history of known Hepatitis B infection (latent or active)?</p>		<p>Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</p>
<p><input type="checkbox"/> 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.</p>	<p><input type="checkbox"/> No. Go to #11</p>	
<p>11. Has the patient received the full Hepatitis B vaccination series? <input type="checkbox"/> Yes <input type="checkbox"/> No Verify vaccine records or Alert-IIS. Dates: _____</p>		
<p><input type="checkbox"/> Yes: Go to #13</p>	<p><input type="checkbox"/> No: Go to #12</p>	
<p>12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.</p> <p><input type="checkbox"/> Vaccine administered</p> <p>Lot: _____ Exp: _____ Signature: _____</p>		
<p>13. Does the patient have known chronic kidney disease or reduced renal function?</p>		<p>Notes: Truvada® requires renal dose adjustment when the CrCl &lt;50 mL/min</p>
<p><input type="checkbox"/> 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.</p>	<p><input type="checkbox"/> 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.</p>	



# 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 fumarate 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, 4<sup>th</sup> 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: \_\_\_\_\_

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Patient Information  
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

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 4<sup>th</sup> 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](https://www.cdc.gov/hiv/basics/pep.html).

**PREVENTIVE CARE**

**HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)**

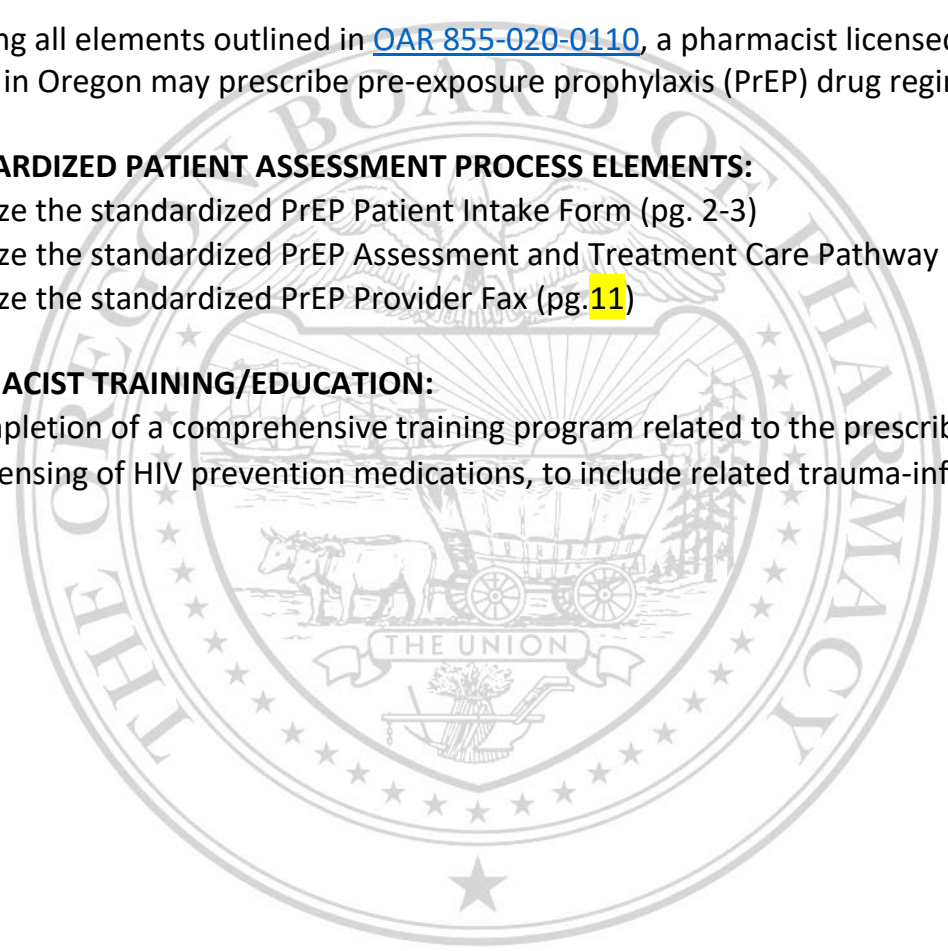
**STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST**

**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? <ul style="list-style-type: none"> <li>• Giving- you perform oral sex on someone else</li> <li>• Receiving- someone performs oral sex on you</li> </ul>
4. Do you have vaginal sex? <ul style="list-style-type: none"> <li>• Receptive- you have a vagina and you use it for vaginal sex</li> <li>• Insertive- you have a penis and you use it for vaginal sex</li> </ul>
5. Do you have anal sex? <ul style="list-style-type: none"> <li>• Receptive- someone uses their penis to perform anal sex on you</li> <li>• Insertive- you use your penis to perform anal sex on someone else</li> </ul>
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)?	<input type="checkbox"/> yes <input type="checkbox"/> no
2. Do you see a (healthcare provider) for management of Hepatitis B?	<input type="checkbox"/> yes <input type="checkbox"/> no
3. Have you ever received an immunization for Hepatitis B? If yes, when: <ul style="list-style-type: none"> <li>• If no, would you like a Hepatitis B immunization today? <input type="checkbox"/> yes <input type="checkbox"/> no</li> </ul>	<input type="checkbox"/> yes <input type="checkbox"/> no Date of vaccine __/__/__
4. Do you see a healthcare provider for problems with your kidneys?	<input type="checkbox"/> yes <input type="checkbox"/> no
5. Do you take non-steroid anti-inflammatory drugs (NSAIDs)? <ul style="list-style-type: none"> <li>• Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)</li> </ul>	<input type="checkbox"/> yes <input type="checkbox"/> no
6. Are you currently or planning to become pregnant or breastfeeding?	<input type="checkbox"/> yes <input type="checkbox"/> no
7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	<input type="checkbox"/> yes <input type="checkbox"/> 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. <ul style="list-style-type: none"><li>• I may be able to have tests performed at the pharmacy.</li><li>• I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks.<ul style="list-style-type: none"><li>○ I brought my labs in today <input type="checkbox"/> Yes <input type="checkbox"/> No</li></ul></li><li>• 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.</li></ul>	<input type="checkbox"/> Yes <input type="checkbox"/> 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. <ul style="list-style-type: none"><li>• 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.</li></ul>	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> 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](https://www.cdc.gov/hiv).

Risk Factor:	Notes and considerations
1. Sexual partners	<ul style="list-style-type: none"> <li>MSM activity is highest risk for HIV.</li> <li>Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present.</li> </ul>
2. Estimated condom use _____% of the time ___/___/___ last sex without a condom	<ul style="list-style-type: none"> <li>Condomless sex greatly increases risk of HIV and STIs.</li> <li>For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP).</li> <li>Condomless sex within last 14 days, repeat HIV test in one month.</li> </ul>
3. Oral sex	<ul style="list-style-type: none"> <li>Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals.</li> <li>STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex.</li> </ul>
4. Vaginal sex	<ul style="list-style-type: none"> <li>Receptive vaginal sex can be high risk for HIV.</li> <li>Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present.</li> </ul>
5. Anal sex	<ul style="list-style-type: none"> <li>Receptive anal sex has the most risk of HIV of any sex act.</li> <li>Insertive anal sex has high risk for HIV.</li> <li>STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex.</li> </ul>
6. Injection drug use	<ul style="list-style-type: none"> <li>Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.</li> </ul>
7. HIV-positive partner	<ul style="list-style-type: none"> <li>People living with HIV who have undetectable viral loads will not transmit HIV.</li> <li>For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP.</li> </ul>
8. Exchanging sex for money or goods	<ul style="list-style-type: none"> <li>People who buy or sell sex are at high risk for HIV.</li> </ul>
9. Popper and/or methamphetamine use	<ul style="list-style-type: none"> <li>Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV.</li> <li>Recommend adequate lubrication in persons who use poppers for sex.</li> </ul>

**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
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• HIV ag/ab (4th gen) test:	___/___/___	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive	<input type="checkbox"/> 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:	___/___/___	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive	<input type="checkbox"/> 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:	___/___/___	<input type="checkbox"/> reactive <input type="checkbox"/> non-reactive	<input type="checkbox"/> 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:	___/___/___	<input type="checkbox"/> reactive <input type="checkbox"/> non-reactive	<input type="checkbox"/> 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:	___/___/___		<input type="checkbox"/> Yes
------------------------	-------------	--	------------------------------

Urinalysis result:	Pharyngeal test result:	Rectal test result:
<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate
<input type="checkbox"/> non-reactive	<input type="checkbox"/> non-reactive	<input type="checkbox"/> 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):	___/___/___	_____ mL/min	<input type="checkbox"/> CrCl > 60 mL/min <input type="checkbox"/> Yes
SCr _____mg/dL			<input type="checkbox"/> CrCl 30-60 mL/min <input type="checkbox"/> CrCl < 30 mL/min

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:	___/___/___	<input type="checkbox"/> Present	<input type="checkbox"/> Yes
--------------------------------------------------	-------------	----------------------------------	------------------------------

• Condomless sex in past two weeks	___/___/___	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
------------------------------------	-------------	------------------------------	------------------------------

## 2. Is HIV ab/ag 4<sup>th</sup> 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 may NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.
- If no, obtain HIV ab/ag 4<sup>th</sup> 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.

# Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

**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<br><i>Needs Referral:</i><br><input type="checkbox"/> yes <input type="checkbox"/> no                    | <ul style="list-style-type: none"><li>• A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation.</li><li>• Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management.</li></ul>                                                                                           |
| 2. Presence of Hepatitis B infection<br><i>Needs Referral:</i><br><input type="checkbox"/> yes <input type="checkbox"/> no    | <ul style="list-style-type: none"><li>• Truvada and Descovy are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare.</li><li>• People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.</li></ul>                                                                                                                    |
| 3. Presence of Hepatitis C exposure<br><i>Needs Referral:</i><br><input type="checkbox"/> yes <input type="checkbox"/> no     | <ul style="list-style-type: none"><li>• <b>People</b> 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.</li></ul>                                                                                                                |
| 4. Impaired kidney function (<30mL/min)<br><i>Needs Referral:</i><br><input type="checkbox"/> yes <input type="checkbox"/> no | <ul style="list-style-type: none"><li>• Truvada is approved for patients with a CrCl &gt;60mL/min.</li><li>• Consider Descovy in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl &gt;30mL/min, but less than 60mL/min.</li><li>• Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease.</li></ul> |
| 5. Other medications<br><i>Needs Referral:</i><br><input type="checkbox"/> yes <input type="checkbox"/> no                    | <ul style="list-style-type: none"><li>• Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density.</li><li>• 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.</li></ul>                                                                                                  |

### CONSIDERATIONS

- |                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6. NSAID use<br>Precaution- Counselled on limiting use:<br><input type="checkbox"/> yes <input type="checkbox"/> no                       | <ul style="list-style-type: none"><li>• Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage.</li><li>• Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.</li></ul>                                                                                                    |
| 7. Hepatitis B vaccinated<br>If not, would the patient like to be vaccinated?<br><input type="checkbox"/> yes <input type="checkbox"/> no | <ul style="list-style-type: none"><li>• Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP.</li><li>• Counsel on risk factors for Hepatitis B and recommend vaccination.</li><li>• If patient would like to be vaccinated, proceed according to <a href="#">OAR 855-019-0280</a>.</li></ul> |
| 8. Pregnant or breastfeeding                                                                                                              | <ul style="list-style-type: none"><li>• Pregnancy and breastfeeding are not contraindications for PrEP.</li><li>• Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence.</li><li>• Truvada is preferred due to better data in these populations.</li></ul>                                               |

## 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. <ul style="list-style-type: none"> <li>• Both Truvada and Descovy are FDA approved in these populations. May prescribe based on patient preference.</li> </ul>	May choose Truvada or Descovy
Cis-gender female or female to male transgender man. <ul style="list-style-type: none"> <li>• Only Truvada is FDA approved in these populations.</li> <li>• 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.</li> </ul>	Truvada
NSAID use <ul style="list-style-type: none"> <li>• If patient is male or a male to female transgender woman, consider Descovy</li> </ul>	Descovy
Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist. <ul style="list-style-type: none"> <li>• If patient is male or male to female transgender woman, consider Descovy</li> </ul>	Descovy
Patient has decreased bone mineral density or on medications that affect bone mineral density. <ul style="list-style-type: none"> <li>• If patient is male or male to female transgender woman, consider Descovy.</li> </ul>	Descovy
Patient is pregnant or breastfeeding <ul style="list-style-type: none"> <li>• Descovy has not been studied in these populations. Truvada is approved in these populations.</li> </ul>	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):**

- |                                                                                                                                                  |                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets<br>• Take one tablet by mouth daily for 90 days | <input type="checkbox"/> Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets<br>• 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):	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive	<input type="checkbox"/> Yes
• Syphilis/Treponemal antibody:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive	<input type="checkbox"/> Yes
• Hepatitis B surface antigen:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> non-reactive	<input type="checkbox"/> Yes
• Hepatitis C antibody:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> non-reactive	<input type="checkbox"/> Yes
• Gonorrhea/Chlamydia:	____/____/____		<input type="checkbox"/> Yes
Urinalysis result:	Pharyngeal test result:	Rectal test result:	
<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate	
<input type="checkbox"/> non-reactive	<input type="checkbox"/> non-reactive	<input type="checkbox"/> non-reactive	
• Renal function (CrCl):	____/____/____ mL/min		<input type="checkbox"/> Yes
<input type="checkbox"/> CrCl >60mL/min	<input type="checkbox"/> CrCl 30mL/min - 60mL/min	<input type="checkbox"/> CrCl <30mL/min	
• Signs/symptoms of STI not otherwise specified:	____/____/____	<input type="checkbox"/> present	<input type="checkbox"/> Yes
• Condomless sex in past two weeks	____/____/____	<input type="checkbox"/> yes	<input type="checkbox"/> 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](https://www.cdc.gov/hiv).

**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 meet 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.

1 Division 43  
2 PRACTITIONER DISPENSING

3  
4 **855-043-0002**

5 **Definitions**

6  
7 In this division of rules:

8  
9 (1) "Administer" means the direct application of a drug or device whether by injection, inhalation,  
10 ingestion, or any other means, to the body of a patient by:

11  
12 (a) A practitioner or the practitioner's authorized agent; or

13  
14 (b) The patient at the direction of the practitioner.

15  
16 **(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.**

17  
18  
19  
20  
21  
22 ~~(23)~~ "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a  
23 lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration  
24 to or use by a patient or other individual entitled to receive the prescription drug.

25  
26 **(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.**

27  
28  
29  
30 ~~(35)~~ "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or  
31 preventative measures such as immunization or birth control approved by the Board or by the  
32 Department of Human Services (~~DHS~~) **Oregon Health Authority (OHA)**.

33  
34 ~~(46)~~ "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of  
35 Naturopathic Medicine and employed by or under contract with a county or district health department  
36 or ~~DHS~~ **OHA**.

37  
38 **(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.**

39  
40  
41 **(8) "Limited English proficiency" means not fluent in the English language.**

42  
43 ~~(59)~~ "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center,  
44 treatment center, or other establishment from which a physician assistant dispenses drugs, but that is  
45 not otherwise registered with the Board in the category of Retail Drug Outlet.

46  
47 Statutory/Other Authority: ORS 689.205

48 Statutes/Other Implemented: ORS 689.155



49 **855-043-0003**

50 **Expedited Partner Therapy**

51

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

55

56 ~~(2) An EPT prescription may only be dispensed for a drug and a disease that has been determined by~~  
57 ~~DHS to be appropriately addressed by EPT.~~

58

59 **(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases**  
60 **can be reduced by treating all sexual partners for the disease, even when the treating clinician has not**  
61 **examined those partners. This practice is known as Expedited Partner Therapy.**

62

63 **(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022**  
64 **authorizing this practice. This law permits health professional regulatory boards to adopt rules**  
65 **permitting practitioners to practice Expedited Partner Therapy.**

66

67 **(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid,**  
68 **even if the name of the patient the prescription is intended for is not on the prescription.**

69

70 **Statutory/Other Authority: ORS 689.205**

71 **Statutes/Other Implemented: ORS 689.505**

72

73

74 **855-043-0004**

75 **Expedited Partner Therapy (EPT) - Procedures**

76

77 **(1) Notwithstanding any other rules in this division that mandate requirements for a valid prescription**  
78 **and for labeling, when a prescription is marked EPT or a similar notation by the prescribing**  
79 **practitioner, this rule governs.**

80

81 **(2) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon**  
82 **Health Authority to be appropriately used for EPT.**

83

84 **Prescription**

85 **(3) An EPT treatment protocol must conform to the following:**

86

87 **(a) It must include a prescription for each named or unnamed partner of the patient;**

88

89 **(b) It must contain a hand written or electronic signature of the prescribing practitioner;**

90

91 **(c) The practitioner must identify the prescription in the following manner:**

92

93 **(A) Write “for EPT,” or a similar notation, on the face of the prescription;**

94

95 **(B) For a verbal order, the practitioner must identify the prescription as an “EPT Prescription,” or**  
96 **similar identification;**

97  
98 **(C) The practitioner must identify the prescription for each partner either by including the name of the**  
99 **patient, such as “John Doe – Partner 1” or by labeling the prescription as “EPT Partner”**

100  
101 **(d) An EPT Prescription expires 30 days after the date written;**

102  
103 **(e) An EPT Prescription may not be refilled;**

104  
105 **(f) If any component of the prescription is missing, the DPDO must contact the prescriber or the**  
106 **prescriber’s agent and must record the additional information on the prescription.**

107  
108 **(4) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy**  
109 **of their choice; or the patient may elect for a DPDO to dispense all prescriptions and then give the**  
110 **dispensed drugs to each unnamed partner.**

111  
112 **Labeling**

113 **(5) The DPDO must label the drug for the named patient in accordance with normal procedures as**  
114 **specified in the other rules of this division, however when either the patient or partner is unnamed,**  
115 **the DPDO may create a unique identifier and use that instead of a name for both labeling and record**  
116 **keeping purposes.**

117  
118 **(6) The DPDO must assign a separate and unique identifier to each prescription and clearly identify**  
119 **this number on each corresponding prescription label.**

120  
121 **Counseling**

122 **(7) The DPDO is not required to obtain an EPT patient’s or partner’s name, address, or demographics;**  
123 **however, the DPDO must:**

124  
125 **(a) Provide counseling in the form of written patient information to accompany each prescription for**  
126 **each partner and ask the patient about any known allergies or other drugs being taken by each**  
127 **partner. The DPDO should advise the patient to encourage each partner to call the DPDO before**  
128 **taking the drug if they have experienced any adverse effect from a drug in the past or if they are**  
129 **taking other drugs;**

130  
131 **(b) Document counseling.**

132  
133 **Records**

134 **(8) All documentation required by this rule must be attached to the prescription and must be**  
135 **referenced to each partner’s prescription. Such documentation must be retained in accordance with**  
136 **the other rules in this division and must be made available to the board upon request.**

137  
138 **Statutory/Other Authority: ORS 689.205**

139 **Statutes/Other Implemented: ORS 689.505**

140  
141  
142 **855-043-0005**

143 **Practitioner Labeling**

144

145 All drugs dispensed by a practitioner must be labeled with the following information:  
146

147 (1) Name, address and telephone number of the practitioner;  
148

149 (2) Date;  
150

151 (3) Name of the patient or the owner of the animal for which the drug is dispensed. If the prescription is  
152 for an animal, the species of the animal for which the drug is dispensed;  
153

154 (4) Name of drug, strength, the quantity dispensed. When a generic name is used, the label must also  
155 contain the name of the manufacturer or distributor;  
156

157 (5) Directions for use;  
158

159 (6) Required precautionary information regarding controlled substances;  
160

161 (7) Such other cautionary information as required for patient safety; and  
162

163 (8) An expiration date after which the patient should not use the drug or medicine. The expiration date  
164 on a drug dispensed must be the same as that on the original container unless, in the practitioner's  
165 professional judgment, a shorter expiration date is warranted. A drug must not be dispensed after the  
166 expiration date of the drug.  
167

168 (9) Notwithstanding the labeling requirements in this rule, when a drug is dispensed in the practice of  
169 an Expedited Partner Therapy treatment protocol, the name of the patient or the patient's partner may  
170 be omitted from the label.  
171

172 Statutory/Other Authority: ORS 689.205

173 Statutes/Other Implemented: ORS 689.155 & ORS 689.505  
174

175

176 **855-043-0210**

177 **Oregon Nurse Practitioner Dispensing**  
178

179 The Oregon State Board of Nursing may grant to a certified nurse practitioner or Clinical Nurse Specialist  
180 the privilege of writing prescriptions described in the formulary under ORS 678.385. A certified nurse  
181 practitioner or Clinical Nurse Specialist may submit an application to the Oregon State Board of Nursing  
182 to dispense prescription drugs. An application for the authority to dispense prescription drugs as  
183 authorized by ORS 678.385 shall include evidence of completion of a prescription drug dispensing  
184 training program jointly developed and adopted by rule by the Oregon State Board of Nursing (851-050-  
185 0162) and the State Board of Pharmacy. The training program shall be as follows:  
186

187 (1) Documented review of content regarding safe dispensing listed below:  
188

189 (a) Board of Nursing handbook "Prescriptive Authority in Oregon for Nurse Practitioners and Clinical  
190 Nurse Specialists";  
191

192 (b) The Drug Enforcement Administration Pharmacist's Manual (2004);  
193

*Oregon Board of Pharmacy*

*Div 043– Practitioner Dispensing  
(SPDO/DPDO, OSBN, Procedural Rule Review)  
v. 10/2021*

- 193  
194 (c) OAR 851, division 56;  
195  
196 (d) ORS Chapter 689 and OAR chapter 855;  
197  
198 (e) US Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for  
199 Pharmacist's and Physicians;"  
200  
201 (f) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and  
202 Dose Designations" (Nov. 2006); and  
203  
204 (g) Information on available electronic or hard copy prescription drug references which provide  
205 information to professionals authorized to dispense prescription medications  
206  
207 (2) Successful self examination as provided by the Board of Nursing on these materials.  
208  
209 [Publications: Publications referenced are available from the agency.]

210  
211 Statutory/Other Authority: ORS 678.390 & ORS 689.205  
212 Statutes/Other Implemented: ORS 689.205

213  
214  
215 **855-043-0405**

216 **Supervising Physician Dispensing Outlet – Purpose and Scope**

217  
218 A supervising physician or supervising physician organization that supervises a physician assistant with  
219 dispensing authority must register the dispensing site with the Board as a Supervising Physician  
220 Dispensing Outlet (SPDO) and must comply with the rules in OAR chapter 855, division 43.

221  
222 Statutory/Other Authority: ORS 689.205  
223 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

224  
225  
226  
227 **855-043-0410**

228 **Supervising Physician Dispensing Outlet – Registration**

229  
230 (1) A Supervising Physician Dispensing Outlet must register with the Board as a SPDO in the category of  
231 Retail Drug Outlet on a form provided by the Board, and must renew its registration annually on a  
232 renewal form provided by the Board.

233  
234 (2) The initial application must state the location of the SPDO and the name of the person applying for  
235 registration. When the person applying for registration is not the owner of the dispensing site, the  
236 application must disclose the name and address of the owner and the applicant's affiliation with the  
237 owner.  
238

- 239 (a) If more than one individual owns the dispensing site, the names and addresses of the partners or  
240 persons holding the three largest ownership interests in the dispensing site must be disclosed on the  
241 application.  
242
- 243 (b) If the owner is a corporation, the application must state the name of the corporation as filed with the  
244 Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.  
245
- 246 (3) Upon request by the Board, the applicant must furnish such information as required by the Board  
247 regarding the partners, stockholders, or other persons not named in the application.  
248
- 249 (4) An initial application must be accompanied by the fee established in division 110 of this chapter.  
250
- 251 (5) A certificate of registration will be issued upon Board approval of the application.  
252
- 253 (6) All registration renewal applications must be accompanied by the annual renewal fee established in  
254 Division 110 of this chapter and must contain the information required in sections (2) and (3) of this  
255 rule.  
256
- 257 (7) The SPDO registration expires March 31, annually. If the annual renewal fee referred to in section (5)  
258 of this rule is not paid by February 28 of the current year, the applicant for renewal must submit the  
259 delinquent fee established in division 110 of this chapter with the renewal application.  
260
- 261 (8) The registration is not transferable and the registration fee cannot be prorated.  
262
- 263 (9) The registrant must notify the Board, within 15 days, of any substantial change to the information  
264 provided on the registration application. Substantial change shall include but not be limited to: change  
265 of ownership; change of business address; change of normal business hours; any disciplinary action  
266 taken or pending by any state or federal authority against the registrant, or any of its principals, owners,  
267 directors, officers, consultant pharmacist or supervising physician.  
268
- 269 (10) A new registration form is required for a change of ownership or location and must be submitted to  
270 the Board with the fees as specified in division 110 of this chapter within 15 days of the change.  
271

272 Statutory/Other Authority: ORS 689.205

273 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

274  
275  
276 **~~855-043-0415~~**

277 **~~Supervising Physician Dispensing Outlet—Consulting Pharmacist~~**

278  
279 (1) A SPDO must retain a pharmacist licensed in Oregon for consultation purposes.  
280

281 (2) The consulting pharmacist must conduct and document an annual inspection of the outlet on a form  
282 provided by the Board. The completed inspection report form must be filed in the outlet, retained on  
283 file for three years and be available to the Board for inspection.

284 (3) The duties of the consulting pharmacist shall be clearly defined in writing within the organization.  
285 The consulting pharmacist must:  
286

- 287 (a) Develop policies and procedures for the outlet in collaboration with the supervising physician; and  
288  
289 (b) Work in consultation with the supervising physician in the development of the formulary of drugs  
290 and classes of drugs for the outlet.

291  
292 Statutory/Other Authority: ORS 689.205  
293 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

294  
295  
296

297 **855-043-0420**

298 **Supervising Physician Dispensing Outlet – Policies and Procedures**

299  
300 The registered SPDO must:

- 301  
302 (1) Maintain written policies and procedures for drug management, including storage, security, integrity,  
303 access, dispensing, disposal, record keeping and accountability;  
304  
305 (2) Maintain all drug records required by federal and state law;  
306  
307 (3) Establish procedures for procurement of drugs; and  
308  
309 (4) Establish procedures to train physician assistants who dispense drugs and to ensure the continued  
310 competence of physician assistants who dispense drugs.

311  
312 Statutory/Other Authority: ORS 689.205  
313 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

314  
315  
316

317 **855-043-0425**

318 **Supervising Physician Dispensing Outlet – Security**

- 319  
320 (1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently  
321 secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must  
322 remain locked and secured when not in use.  
323  
324 (2) No drug dispensing machine may be placed in a waiting room or an area that is accessible by the  
325 public.

326  
327 Statutory/Other Authority: ORS 689.205  
328 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

329  
330  
331

332 **855-043-0430**

333 **Supervising Physician Dispensing Outlet – Storage of Drugs**

334

335 All drugs, including drug samples, must be stored under conditions that ensure proper sanitation,  
336 temperature, light, ventilation, moisture control, and any other condition recommended by the  
337 manufacturer.

338

339 ~~Statutory/Other Authority: ORS 689.205~~

340 ~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

341

342

343

344 **855-043-0435**

345 **Supervising Physician Dispensing Outlet – Labeling**

346

347 (1) A prescription must be labeled with the following information:

348

349 (a) Unique identifier;

350

351 (b) Name of patient;

352

353 (c) Name of prescriber;

354

355 (d) Name, address, and phone number of the clinic;

356

357 (e) Date of dispensing;

358

359 (f) Name and strength of the drug. If the drug does not have a brand name, then the generic name of  
360 the drug and the drug manufacturer must be stated;

361

362 (g) Quantity dispensed;

363

364 (h) Directions for use;

365

366 (i) Initials of the physician assistant or practitioner dispensing;

367

368 (j) Cautionary statements, if any, as required by law; and

369

370 (k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not  
371 use the drug; and

372

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

376

377 (2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an  
378 Expedited Partner Therapy treatment protocol, as described in OAR 855-041-4000 through 4005, the  
379 name of the patient may be omitted.

380 ~~Statutory/Other Authority: ORS 689.205~~

381 ~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

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**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**



431 (1) Drugs dispensed from a SPO by a physician assistant with dispensing authority or a practitioner must  
432 be personally dispensed by the practitioner or physician assistant.

433  
434 (2) Prior to dispensing a medication a drug utilization review must be performed by the physician  
435 assistant or practitioner which includes but is not limited to drug interactions, drug allergies and  
436 duplicate drug therapy.

437  
438 (3) The physician assistant or practitioner must orally counsel the patient concerning all new drugs,  
439 unless circumstances would render oral counseling ineffective.

440  
441 (4) When dispensed, a drug must be accompanied by written information that contains at least the  
442 following information:

443  
444 (a) Drug name, class and indications;

445  
446 (b) Proper use and storage;

447  
448 (c) Common side effects;

449  
450 (d) Precautions and contraindications; and

451  
452 (e) Significant drug interactions.

453  
454 (5) Each authorized dispenser of a prescription drug product for which a Medication Guide is required  
455 must provide the Medication Guide directly to each patient or patient's agent when the product is  
456 dispensed, unless an exemption applies.

457  
458 (6) Any other requirement of State or federal law.

459  
460 (7) A SPDO must dispense a drug in a new container that complies with the current provisions of the  
461 Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations  
462 and with the current United States Pharmacopoeia/National Formulary monographs for preservation,  
463 packaging, storage and labeling.

464  
465 (8) Drugs must be prepackaged by a pharmacy or manufacturer registered with the Board.

466  
467 (9) A SPDO may not accept the return of drugs from a previously dispensed prescription and must  
468 maintain a list of sites in Oregon where drugs may be disposed.

469  
470 (10) The most current issue of at least one pharmaceutical reference with current, properly filed  
471 supplements and updates appropriate to and based on the standards of practice for the setting.

472  
473 Statutory/Other Authority: ORS 689.205

474 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

475  
476 **~~855-043-0445~~**

477 **~~Supervising Physician Dispensing Outlet – Drug Dispensing Training Program~~**

478

479 A physician assistant must complete a drug dispensing training program jointly developed by the Oregon  
480 Medical Board and the Board of Pharmacy before dispensing drugs to patients.

481

482 Statutory/Other Authority: ORS 689.205

483 Statutes/Other Implemented: ~~ORS 689.155, ORS 689.305 & ORS 677.511~~

484 History:

485 ~~BP 62-2020, minor correction filed 08/06/2020, effective 08/06/2020~~

486 ~~BP 3-2012, f. & cert. ef. 6-19-12~~

487

488

489 **~~855-043-0450~~**

490 **~~Supervising Physician Dispensing Outlet—Disposal of Drugs~~**

491

492 ~~Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be documented,~~  
493 ~~quarantined and physically separated from other drugs until they are destroyed or returned to their~~  
494 ~~supplier.~~

495

496 Statutory/Other Authority: ORS 689.205

497 Statutes/Other Implemented: ~~ORS 689.155, ORS 689.305 & ORS 677.511~~

498

499

500

501 **~~855-043-0455~~**

502 **~~Supervising Physician Dispensing Outlet—Record Keeping~~**

503

504 ~~(1) A dispensing record must be maintained separately from the patient chart and kept for a minimum~~  
505 ~~of three years. The record must show, at a minimum, the following:~~

506

507 ~~(a) Name of patient;~~

508

509 ~~(b) Unique identifier;~~

510

511 ~~(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and~~  
512 ~~name of manufacturer or distributor;~~

513

514 ~~(d) Directions for use;~~

515

516 ~~(e) Date of dispensing; and~~

517

518 ~~(f) Initials of person dispensing the prescription.~~

519

520 ~~(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.~~

521

522 ~~(3) Records documenting training required by OAR 855-043-0445 must be kept for three years.~~

523

524 ~~(4) All records required by these rules or by other State and federal law must be readily retrievable and~~  
525 ~~available for inspection by the Board.~~

526 Statutory/Other Authority: ORS 689.205

527 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

528

529

530 **855-043-0505**

531 **Dispensing Practitioner Drug Outlets - Purpose**

532 A practitioner's facility that engages in dispensing certain FDA-approved human prescription drug  
533 therapies greater than a 72 hours supply or any medication refill. **Unless subject to an exemption in OAR**  
534 **855-043-0510(2), a practitioner that engages in dispensing human prescription drug therapies** must  
535 register their dispensing site as a drug outlet with the Board as a Dispensing Practitioner Drug Outlet  
536 (DPDO).

537

538 Statutory/Other Authority: ORS 689.205

539 Statutes/Other Implemented: ORS 689.155 & ORS 689.305

540

541

542 **855-043-0510**

543 **Dispensing Practitioner Drug Outlets - Registration**

544

545 (1) **Unless subject to an exemption in OAR 855-043-0510(2), a practitioner that engages in dispensing**  
546 **human prescription drug therapies** A practitioner's facility that engages in dispensing FDA-approved  
547 human prescription drug therapies greater than 72 hours supply or any medication refill must register  
548 their dispensing site as a drug outlet with the Board as a DPDO on a form provided **prescribed** by the  
549 Board, and must renew its registration annually on a renewal form provided **prescribed** by the Board.

550

551 (2) A practitioner's facility is exempt from this registration requirement if the practitioner and facility  
552 only engages in:

553

554 (A) Dispensing FDA approved drug samples; or

555

556 (B) Dispensing Medication Assistance Program (MAP) drugs; or

557

558 (C) Dispensing homeopathic products; or

559

560 (D) Dispensing natural thyroid supplemental products; or

561

562 (E) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to  
563 a 72 hour supply; or

564

565 (F) An amount greater than a 72 hour supply if the drug is:

566

567 (i) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-inhaler or bottle  
568 of fluoride rinse; or

569

570 (ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient's  
571 best interest, such as a course of antibiotic therapy.

572

573 (3) The initial **and renewal** applications must state the location of the DPDO and the name of the person  
574 applying for registration. When the person applying for registration is not the owner of the dispensing

575 site, the application must disclose the name and address of the owner and the applicant's affiliation  
576 with the owner.

577  
578 (a) If more than one individual owns the dispensing site, the names and addresses of the partners or  
579 persons holding the three largest ownership interests in the dispensing site must be disclosed on the  
580 application.

581  
582 (b) If the owner is a corporation, the application must state the name of the corporation as filed with the  
583 Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.

584  
585 (4) Upon request by the ~~B~~board, the applicant must furnish such information as required by the ~~B~~board  
586 regarding the partners, stockholders, or other persons not named in the application.

587  
588 (5) An initial and renewal applications must be accompanied by the fee established OAR 855-110~~in~~  
589 ~~division 110 of this chapter.~~

590  
591 (6) A certificate of registration will be issued upon ~~B~~board approval of the application.

592  
593 ~~(7) All registration renewal applications must be accompanied by the annual renewal fee established in~~  
594 ~~division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.~~

595  
596 ~~(87)~~ The DPDO registration expires March 31, annually. If the annual renewal fee is not paid by February  
597 ~~28~~ **March 31** of the current year, the applicant for renewal must submit the ~~delinquent~~ **late renewal** fee  
598 established in OAR 855-110~~in division 110 of this chapter~~ with the renewal application.

599  
600 ~~(98)~~ The registration is not transferable and the registration fee cannot be prorated.

601  
602 ~~(109)~~ The registrant must notify the ~~B~~board, within 15 days **prior to**, of any substantial change to the  
603 information provided on the registration application. Substantial change ~~shall~~ includes but **is** not be  
604 limited to: change of ownership; change of business name; change of business address; change of  
605 normal business hours; any disciplinary action taken or pending by any state or federal authority against  
606 the registrant, or any of its principals, owners, directors, **or** officers, ~~or supervising practitioner.~~

607  
608 ~~(1110)~~ A new registration form is required for a change of ownership or location and must be submitted  
609 to the ~~B~~board with the fees as specified in OAR 855-110~~in division 110 of this chapter~~ within 15 days  
610 **prior to** of the change.

611  
612 ~~(1211)~~ The ~~B~~board may grant a time-limited waiver exempting DPDO registration when a practitioner  
613 licensing board submits a request to the ~~B~~board with a plan to annually inspect the dispensing facility to  
614 the standards of the ~~B~~board.

615  
616 **(12) All Supervising Physician Dispensing Outlet registrations expire on March 31, 2022. Outlets that**  
617 **utilize dispensing Physician Assistants must apply for and be granted registration as a Dispensing**  
618 **Practitioner Dispensing Outlet upon the expiration of the Supervising Physician Dispensing Outlet**  
619 **Registration unless subject to an exemption in OAR 855-043-0510(2).**

620  
621 Statutory/Other Authority: ORS 689.205

622 Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 475.125

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**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 an **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**

- 671  
672 (1) A prescription must be labeled with the following information:  
673  
674 (a) Name of patient;  
675  
676 (b) Name of prescriber;  
677  
678 (c) Name, address, and phone number of the clinic;  
679  
680 (d) Date of dispensing;  
681  
682 (e) Name and strength of the drug. If the drug does not have a brand name, then the generic name of  
683 the drug and the drug manufacturer must be stated;  
684  
685 (f) Quantity dispensed;  
686  
687 (g) Directions for use;  
688  
689 (h) Cautionary statements, if any, as required by law; and  
690  
691 (i) ~~Manufacturer's~~ **An** expiration date, ~~or an earlier date if preferable,~~ after which the patient should not  
692 use the drug ~~or medicine;~~ **and, Expiration dates on prescriptions must be the same as that on the**  
693 **original container or one year from the date the drug was originally dispensed and placed in the new**  
694 **container, whichever date is earlier. Any drug expiring before the expected length of time for course**  
695 **of therapy must not be dispensed.**  
696  
697 (j) Any dispensed prescription medication, other than those in unit dose or unit of use packaging,  
698 ~~shall~~**must** be labeled with its physical description, including any identification code that may appear on  
699 tablets and capsules.  
700  
701 (2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an  
702 Expedited Partner Therapy treatment protocol, as described in OAR 855-~~043-0004~~**041-4000** through  
703 ~~4005~~, the name of the patient may be omitted.  
704

705 Statutory/Other Authority: ORS 689.205

706 Statutes/Other Implemented: ORS 689.155, **ORS 689.305**

707

708

709 **855-043-0541**

710 **Dispensing Practitioner Drug Outlet - **Limited English Proficiency and Accessibility****

711

712 (1) Upon request of a patient or a patient's agent, each drug dispensed by a drug outlet for a patient's  
713 self-administration must bear a label in both English and the language requested for an individual with  
714 limited English proficiency, defined as a person who is not fluent in the English language. This does not  
715 apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.  
716

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

- 719  
720 (a) Spanish;  
721  
722 (b) Russian;  
723  
724 (c) Somali;  
725  
726 (d) Arabic;  
727  
728 (e) Chinese (simplified);  
729  
730 (f) Vietnamese;  
731  
732 (g) Farsi;  
733  
734 (h) Korean;  
735  
736 (i) Romanian;  
737  
738 (j) Swahili;  
739  
740 (k) Burmese;  
741  
742 (l) Nepali;  
743  
744 (m) Amharic; and  
745  
746 (n) Pashtu.

747  
748 (3) The board must reassess and update (2) as necessary and at least every ten years.  
749

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

752  
753 **(5) When an informational insert is used, the prescription label affixed to the prescription container**  
754 **must state in the language requested by the patient that an informational insert is being used.**

755  
756 **(6) At a minimum, the informational insert must include the:**

757  
758 **(a) Directions for use by the patient in both English and the language requested;**

759  
760 **(b) Identifying number;**

761  
762 **(c) Name of patient;**

763  
764 **(d) Name of drug and strength; and**

765  
766 **(e) Date of fill.**

767  
768 Statutory/Other Authority: ORS 689.564  
769 Statutes/Other Implemented: ORS 689.205

770  
771  
772 **855-043-0545**

773 **Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery**

774  
775 **(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized**  
776 **by the practitioner's licensing board.**

777  
778 ~~(12)~~ Drugs dispensed from the DPDO by a practitioner shall **must** be dispensed in compliance with the  
779 requirements of the practitioner's licensing ~~B~~board.

780  
781 ~~(23)~~ A DPDO must comply with all requirements of State or federal law.

782  
783 ~~(34)~~ A DPDO must dispense a drug in a new container that complies with the current provisions of the  
784 Federal Consumer **Poison Prevention** Packaging Act in **16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701**  
785 **(XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX)** (Public Law 91-601, 91st Congress, S. 2162) and rules or  
786 regulations and with the current United States Pharmacopoeia/National Formulary monographs for  
787 preservation, packaging, storage and labeling.

788  
789 ~~(45)~~ **Dispensed** drugs must be packaged by the practitioner **DPDO**, a pharmacy, or a manufacturer  
790 registered with the ~~B~~board.

791  
792 ~~(56)~~ A DPDO may not accept the return of drugs from a previously dispensed prescription and shall **must**  
793 maintain a list of sites in Oregon where drugs may be disposed.

794  
795 **(7) A DPDO may deliver or mail prescription to the patient if:**

796  
797 **(a) Proper drug storage conditions are maintained; and**

798  
799 **(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the**  
800 **practitioner, and information about the drug, including, but not limited to:**

801  
802 **(A) Drug name, class and indications;**

803  
804 **(B) Proper use and storage;**

805  
806 **(C) Common side effects;**

807  
808 **(D) Precautions and contraindications; and**

809  
810 **(E) Significant drug interactions.**

811  
812 **(8) The DPDO must ensure that all prescriptions, prescription refills, and drug orders are correctly**  
813 **dispensed in accordance with the prescribing practitioner's authorization and any other requirement**  
814 **of State or federal law.**



815  
816 **(9) Each authorized dispenser of a prescription drug product for which a Medication Guide is required**  
817 **must provide the Medication Guide directly to each patient or patient’s agent when the product is**  
818 **dispensed, unless an exemption applies.**

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

821  
822  
823  
824 **855-043-0550**  
825 **Dispensing Practitioner Drug Outlets - Disposal of Drugs**

826  
827 Drugs that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, or identified as  
828 suspect or illegitimate must be documented, quarantined and physically separated from other drugs  
829 until they are destroyed or returned to the supplier.

830  
831 Statutory/Other Authority: ORS 689.205  
832 Statutes/Other Implemented: ORS 689.155, ORS 689.305

833  
834  
835 **855-043-0555**  
836 **Dispensing Practitioner Drug Outlets - Records Keeping**

837  
838 (1) A unique dispensing record ~~shall~~**must** be maintained, be readily retrievable, and kept for a minimum  
839 of three years. The record must show, at a minimum, the following:

- 840  
841 (a) Name of patient;  
842  
843 (b) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and  
844 name of manufacturer or distributor;  
845  
846 (c) Directions for use;  
847  
848 (d) Date of dispensing; and  
849  
850 (e) Initials of person dispensing the prescription.

851  
852 (2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

853  
854 ~~(3) All records required by these rules or by other State and federal law must be readily retrievable and~~  
855 ~~available for inspection by the Board.~~

856  
857 **(3) All records and documents required by ORS 475, ORS 689, and OAR 855:**

858  
859 **(a) Must be stored on-site for 12 months and must be provided to the board immediately upon**  
860 **request at the time of inspection;**

861

862 **(b) May be stored in a secured off-site location after 12 months of on-site storage and must be**  
863 **provided to the board upon request within three business days; and**

864  
865 **(c) May be in written or electronic format.**  
866

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

869  
870  
871 **855-043-0560**  
872 **Dispensing Practitioner Drug Outlets - Inspections**

- 873  
874 (1) The DPDO must complete the **B**board Self Inspection Form by February 1, annually.  
875  
876 (2) Each DPDO will be inspected **per OAR 855-001-0040** on a routine basis and ~~shall~~**must** be scheduled in  
877 advance with the ~~practitioner~~**DPDO**, to occur during normal business hours.  
878  
879 (3) The inspection ~~shall~~**must** focus on the acquisition, storage, labeling and recordkeeping of drugs  
880 intended for dispensing and any violation will apply to the DPDO registration and not to the practitioner.  
881  
882 (4) The Board of Pharmacy ~~shall~~**must** notify the practitioner's licensing **B**board of any disciplinary action  
883 taken against a DPDO.

884  
885 Statutory/Other Authority: ORS 689.205  
886 Statutes/Other Implemented: ORS 689.155, **ORS** 689.305

887  
888  
889 **855-043-0705**  
890 **Community Health Clinic (CHC) - Registration**

- 891  
892 (1) A Community Health Clinic Drug Outlet must register with the **B**board on a form prescribed by the  
893 **B**board, and must renew its registration annually on a renewal form prescribed by the **B**board.  
894  
895 (2) An initial application and renewal application must be accompanied by the fee established in **OAR**  
896 **855-110** ~~in division 110 of this Chapter.~~  
897  
898 (3) A certificate of registration will be issued upon **B**board approval of the application.  
899  
900 (4) The CHC Drug Outlet registration expires March 31, annually. If the annual renewal fee is not paid by  
901 ~~February 28~~**March 31** of the current year, the applicant for renewal must submit the ~~delinquent~~ **late**  
902 **renewal** fee established in **OAR 855-110** ~~division 110 of this Chapter~~ with the renewal application.  
903  
904 (5) The registration is not transferable and the registration fee cannot be prorated.  
905  
906 (6) The registrant must notify the **B**board, within 15 days, of any substantial change to the information  
907 provided on the registration application. A substantial change shall include but not be limited to: a  
908 change of ownership; change of business address; change of normal business hours; any disciplinary

909 action taken or pending by any state or federal authority against the registrant, or any of its principals,  
910 owners, directors, officers, or Medical Director.

911  
912 (7) A new registration form is required for a change of ownership or location and must be submitted to  
913 the ~~B~~board with the fees as specified in OAR 855-110 ~~division 110 of this Chapter~~ within 15 days of the  
914 change.

915  
916 (8) A CHC Drug Outlet may be inspected by the ~~B~~board.

917  
918 Statutory/Other Authority: ORS 689.205  
919 Statutes/Other Implemented: ORS 689.305

920  
921  
922 **855-043-0740**

923 **Community Health Clinic (CHC) - Dispensing and Drug Delivery**

924  
925 (1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their  
926 licensing Board or by a Registered Nurse.

927  
928 (2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.

929  
930 (3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.

931  
932 (4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and  
933 completeness of the prescription is verified by a practitioner who has been given dispensing privileges  
934 by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

935  
936 (5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can  
937 be provided by the Registered Nurse or practitioner at the time of dispensing.

938  
939 (6) ~~All drugs~~ **CHC must be dispensed a drug** in a new container that complies with the current provisions  
940 of the Federal Consumer **Poison Prevention** Packaging Act in **16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701**  
941 **(XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX)** and rules or regulations and with the current United  
942 States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and  
943 labeling.

944  
945 (7) **Dispensed** drugs must be repackaged by the practitioner, Registered Nurse, a pharmacy; or a  
946 manufacturer registered with the ~~B~~board.

947  
948 (8) A CHC may not accept the return of drugs from a previously dispensed prescription and must  
949 maintain a list of sites in Oregon where drugs may be disposed.

950  
951 (9) A CHC must have access to the most current issue of at least one pharmaceutical reference with  
952 current, properly filed supplements and updates appropriate to and based on the standards of practice  
953 for the setting.

954  
955 **(10) A CHC may deliver or mail prescription to the patient if:**

956

957 **(a) Proper drug storage conditions are maintained; and**

958

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

961

962 **(A) Drug name, class and indications;**

963

964 **(B) Proper use and storage;**

965

966 **(C) Common side effects;**

967

968 **(D) Precautions and contraindications; and**

969

970 **(E) Significant drug interactions.**

971

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

975

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

979

980 Statutory/Other Authority: ORS 689.205

981 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 meet 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.

1 Division 43  
2 PRACTITIONER DISPENSING

3  
4 **855-043-0002**

5 **Definitions**

6  
7 In this division of rules:

8  
9 (1) "Administer" means the direct application of a drug or device whether by injection, inhalation,  
10 ingestion, or any other means, to the body of a patient by:

11  
12 (a) A practitioner or the practitioner's authorized agent; or

13  
14 (b) The patient at the direction of the practitioner.

15  
16 **(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.**

17  
18  
19  
20  
21  
22 ~~(3)~~ "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a  
23 lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration  
24 to or use by a patient or other individual entitled to receive the prescription drug.

25  
26 **(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.**

27  
28  
29  
30 ~~(5)~~ "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or  
31 preventative measures such as immunization or birth control approved by the Board or by the  
32 Department of Human Services (DHS) **Oregon Health Authority (OHA)**.

33  
34 **(46) "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.**

35  
36  
37  
38 ~~(57) "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.~~

39  
40  
41  
42 **NOTE:** (7) will be repealed on 3/31/2022.

43  
44 Statutory/Other Authority: ORS 689.205

45 Statutes/Other Implemented: ORS 689.155

48 **855-043-0003**

49 **Expedited Partner Therapy**

50

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

54

55 ~~(2) An EPT prescription may only be dispensed for a drug and a disease that has been determined by~~  
56 ~~DHS to be appropriately addressed by EPT.~~

57

58 **(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases**  
59 **can be reduced by treating all sexual partners for the disease, even when the treating clinician has not**  
60 **examined those partners. This practice is known as Expedited Partner Therapy.**

61

62 **(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022**  
63 **authorizing this practice. This law permits health professional regulatory boards to adopt rules**  
64 **permitting practitioners to practice Expedited Partner Therapy.**

65

66 **(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid,**  
67 **even if the name of the patient the prescription is intended for is not on the prescription.**

68

69 **Statutory/Other Authority: ORS 689.205**

70 **Statutes/Other Implemented: ORS 689.505**

71

72

73 **855-043-0004**

74 **Expedited Partner Therapy (EPT) - Procedures**

75

76 **(1) Notwithstanding any other rules in this division that mandate requirements for a valid prescription**  
77 **and for labeling, when a prescription is marked EPT or a similar notation by the prescribing**  
78 **practitioner, this rule governs.**

79

80 **(2) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon**  
81 **Health Authority to be appropriately used for EPT.**

82

83 **Prescription**

84 **(3) An EPT treatment protocol must conform to the following:**

85

86 **(a) It must include a prescription for each named or unnamed partner of the patient;**

87

88 **(b) It must contain a hand written or electronic signature of the prescribing practitioner;**

89

90 **(c) The practitioner must identify the prescription in the following manner:**

91

92 **(A) Write “for EPT,” or a similar notation, on the face of the prescription;**

93

94 **(B) For a verbal order, the practitioner must identify the prescription as an “EPT Prescription,” or**  
95 **similar identification;**

96  
97 **(C) The practitioner must identify the prescription for each partner either by including the name of the**  
98 **patient, such as “John Doe – Partner 1” or by labeling the prescription as “EPT Partner”**  
99

100 **(d) An EPT Prescription expires 30 days after the date written;**

101  
102 **(e) An EPT Prescription may not be refilled;**

103  
104 **(f) If any component of the prescription is missing, the DPDO must contact the prescriber or the**  
105 **prescriber’s agent and must record the additional information on the prescription.**

106  
107 **(4) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy**  
108 **of their choice; or the patient may elect for a DPDO to dispense all prescriptions and then give the**  
109 **dispensed drugs to each unnamed partner.**

110  
111 **Labeling**

112 **(5) The DPDO must label the drug for the named patient in accordance with normal procedures as**  
113 **specified in the other rules of this division, however when either the patient or partner is unnamed,**  
114 **the DPDO may create a unique identifier and use that instead of a name for both labeling and record**  
115 **keeping purposes.**

116  
117 **(6) The DPDO must assign a separate and unique identifier to each prescription and clearly identify**  
118 **this number on each corresponding prescription label.**

119  
120 **Counseling**

121 **(7) The DPDO is not required to obtain an EPT patient’s or partner’s name, address, or demographics;**  
122 **however, the DPDO must:**

123  
124 **(a) Provide counseling in the form of written patient information to accompany each prescription for**  
125 **each partner and ask the patient about any known allergies or other drugs being taken by each**  
126 **partner. The DPDO should advise the patient to encourage each partner to call the DPDO before**  
127 **taking the drug if they have experienced any adverse effect from a drug in the past or if they are**  
128 **taking other drugs;**

129  
130 **(b) Document counseling.**

131  
132 **Records**

133 **(8) All documentation required by this rule must be attached to the prescription and must be**  
134 **referenced to each partner’s prescription. Such documentation must be retained in accordance with**  
135 **the other rules in this division and must be made available to the board upon request.**

136  
137 **Statutory/Other Authority: ORS 689.205**

138 **Statutes/Other Implemented: ORS 689.505**

139  
140  
141  
142



143 ~~855-043-0005~~

144 ~~Practitioner Labeling~~

145

146 All drugs dispensed by a practitioner must be labeled with the following information:

147

148 (1) Name, address and telephone number of the practitioner;

149

150 (2) Date;

151

152 (3) Name of the patient or the owner of the animal for which the drug is dispensed. If the prescription is  
153 for an animal, the species of the animal for which the drug is dispensed;

154

155 (4) Name of drug, strength, the quantity dispensed. When a generic name is used, the label must also  
156 contain the name of the manufacturer or distributor;

157

158 (5) Directions for use;

159

160 (6) Required precautionary information regarding controlled substances;

161

162 (7) Such other cautionary information as required for patient safety; and

163

164 (8) An expiration date after which the patient should not use the drug or medicine. The expiration date  
165 on a drug dispensed must be the same as that on the original container unless, in the practitioner's  
166 professional judgment, a shorter expiration date is warranted. A drug must not be dispensed after the  
167 expiration date of the drug.

168

169 (9) Notwithstanding the labeling requirements in this rule, when a drug is dispensed in the practice of  
170 an Expedited Partner Therapy treatment protocol, the name of the patient or the patient's partner may  
171 be omitted from the label.

172

173 Statutory/Other Authority: ORS 689.205

174 Statutes/Other Implemented: ORS 689.155 & ORS 689.505

175

176

177 ~~855-043-0210~~

178 ~~Oregon Nurse Practitioner Dispensing~~

179

180 The Oregon State Board of Nursing may grant to a certified nurse practitioner or Clinical Nurse Specialist  
181 the privilege of writing prescriptions described in the formulary under ORS 678.385. A certified nurse  
182 practitioner or Clinical Nurse Specialist may submit an application to the Oregon State Board of Nursing  
183 to dispense prescription drugs. An application for the authority to dispense prescription drugs as  
184 authorized by ORS 678.385 shall include evidence of completion of a prescription drug dispensing  
185 training program jointly developed and adopted by rule by the Oregon State Board of Nursing (851-050-  
186 0162) and the State Board of Pharmacy. The training program shall be as follows:

187

188 (1) Documented review of content regarding safe dispensing listed below:

189

190 (a) Board of Nursing handbook "Prescriptive Authority in Oregon for Nurse Practitioners and Clinical  
191 Nurse Specialists";

192

193 (b) The Drug Enforcement Administration Pharmacist's Manual (2004);

194

195 (c) OAR 851, division 56;

196

197 (d) ORS Chapter 689 and OAR chapter 855;

198

199 (e) US Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for  
200 Pharmacist's and Physicians;"

201

202 (f) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and  
203 Dose Designations" (Nov. 2006); and

204

205 (g) Information on available electronic or hard-copy prescription drug references which provide  
206 information to professionals authorized to dispense prescription medications

207

208 (2) Successful self-examination as provided by the Board of Nursing on these materials.

209

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

211

212 Statutory/Other Authority: ORS 678.390 & ORS 689.205

213 Statutes/Other Implemented: ORS 689.205

214

215

216 **NOTE:** 855-043-0405 through 855-043-0455 will be repealed on 3/31/2022.

217 **855-043-0405**

218 **Supervising Physician Dispensing Outlet—Purpose and Scope**

219

220 A supervising physician or supervising physician organization that supervises a physician assistant with  
221 dispensing authority must register the dispensing site with the Board as a Supervising Physician  
222 Dispensing Outlet (SPDO) and must comply with the rules in OAR chapter 855, division 43.

223

224 Statutory/Other Authority: ORS 689.205

225 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

226

227

228

229 **855-043-0410**

230 **Supervising Physician Dispensing Outlet—Registration**

231

232 (1) A Supervising Physician Dispensing Outlet must register with the Board as a SPDO in the category of  
233 Retail Drug Outlet on a form provided by the Board, and must renew its registration annually on a  
234 renewal form provided by the Board.

235

236 (2) The initial application must state the location of the SPDO and the name of the person applying for  
237 registration. When the person applying for registration is not the owner of the dispensing site, the

238 application must disclose the name and address of the owner and the applicant's affiliation with the  
239 owner.  
240  
241 (a) If more than one individual owns the dispensing site, the names and addresses of the partners or  
242 persons holding the three largest ownership interests in the dispensing site must be disclosed on the  
243 application.  
244  
245 (b) If the owner is a corporation, the application must state the name of the corporation as filed with the  
246 Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.  
247  
248 (3) Upon request by the Board, the applicant must furnish such information as required by the Board  
249 regarding the partners, stockholders, or other persons not named in the application.  
250  
251 (4) An initial application must be accompanied by the fee established in division 110 of this chapter.  
252  
253 (5) A certificate of registration will be issued upon Board approval of the application.  
254  
255 (6) All registration renewal applications must be accompanied by the annual renewal fee established in  
256 Division 110 of this chapter and must contain the information required in sections (2) and (3) of this  
257 rule.  
258  
259 (7) The SPDO registration expires March 31, annually. If the annual renewal fee referred to in section (5)  
260 of this rule is not paid by February 28 of the current year, the applicant for renewal must submit the  
261 delinquent fee established in division 110 of this chapter with the renewal application.  
262  
263 (8) The registration is not transferable and the registration fee cannot be prorated.  
264  
265 (9) The registrant must notify the Board, within 15 days, of any substantial change to the information  
266 provided on the registration application. Substantial change shall include but not be limited to: change  
267 of ownership; change of business address; change of normal business hours; any disciplinary action  
268 taken or pending by any state or federal authority against the registrant, or any of its principals, owners,  
269 directors, officers, consultant pharmacist or supervising physician.  
270  
271 (10) A new registration form is required for a change of ownership or location and must be submitted to  
272 the Board with the fees as specified in division 110 of this chapter within 15 days of the change.

273  
274 Statutory/Other Authority: ORS 689.205  
275 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511  
276

277  
278 **855-043-0415**

279 **Supervising Physician Dispensing Outlet—Consulting Pharmacist**

280  
281 (1) A SPDO must retain a pharmacist licensed in Oregon for consultation purposes.  
282  
283 (2) The consulting pharmacist must conduct and document an annual inspection of the outlet on a form  
284 provided by the Board. The completed inspection report form must be filed in the outlet, retained on  
285 file for three years and be available to the Board for inspection.

286 ~~(3) The duties of the consulting pharmacist shall be clearly defined in writing within the organization.~~  
287 ~~The consulting pharmacist must:~~

288  
289 ~~(a) Develop policies and procedures for the outlet in collaboration with the supervising physician; and~~  
290

291 ~~(b) Work in consultation with the supervising physician in the development of the formulary of drugs~~  
292 ~~and classes of drugs for the outlet.~~

293  
294 ~~Statutory/Other Authority: ORS 689.205~~

295 ~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

296  
297

298  
299 ~~**855-043-0420**~~

300 ~~**Supervising Physician Dispensing Outlet – Policies and Procedures**~~

301  
302 ~~The registered SPDO must:~~

303  
304 ~~(1) Maintain written policies and procedures for drug management, including storage, security, integrity,~~  
305 ~~access, dispensing, disposal, record keeping and accountability;~~

306  
307 ~~(2) Maintain all drug records required by federal and state law;~~

308  
309 ~~(3) Establish procedures for procurement of drugs; and~~

310  
311 ~~(4) Establish procedures to train physician assistants who dispense drugs and to ensure the continued~~  
312 ~~competence of physician assistants who dispense drugs.~~

313  
314 ~~Statutory/Other Authority: ORS 689.205~~

315 ~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

316  
317

318  
319 ~~**855-043-0425**~~

320 ~~**Supervising Physician Dispensing Outlet – Security**~~

321  
322 ~~(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently~~  
323 ~~secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must~~  
324 ~~remain locked and secured when not in use.~~

325  
326 ~~(2) No drug dispensing machine may be placed in a waiting room or an area that is accessible by the~~  
327 ~~public.~~

328  
329 ~~Statutory/Other Authority: ORS 689.205~~

330 ~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

331  
332

333

334 ~~855-043-0430~~

335 ~~Supervising Physician Dispensing Outlet – Storage of Drugs~~

336

337 All drugs, including drug samples, must be stored under conditions that ensure proper sanitation,  
338 temperature, light, ventilation, moisture control, and any other condition recommended by the  
339 manufacturer.

340

341 Statutory/Other Authority: ORS 689.205

342 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

343

344

345

346 ~~855-043-0435~~

347 ~~Supervising Physician Dispensing Outlet – Labeling~~

348

349 (1) A prescription must be labeled with the following information:

350

351 (a) Unique identifier;

352

353 (b) Name of patient;

354

355 (c) Name of prescriber;

356

357 (d) Name, address, and phone number of the clinic;

358

359 (e) Date of dispensing;

360

361 (f) Name and strength of the drug. If the drug does not have a brand name, then the generic name of  
362 the drug and the drug manufacturer must be stated;

363

364 (g) Quantity dispensed;

365

366 (h) Directions for use;

367

368 (i) Initials of the physician assistant or practitioner dispensing;

369

370 (j) Cautionary statements, if any, as required by law; and

371

372 (k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not  
373 use the drug; and

374

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

378

379 (2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an  
380 Expedited Partner Therapy treatment protocol, as described in OAR 855-041-4000 through 4005, the  
381 name of the patient may be omitted.

382 Statutory/Other Authority: ORS 689.205  
383 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

384  
385

386 ~~855-043-0436~~

387 ~~Supervising Physician Dispensing Outlet – Limited English Proficiency and Accessibility~~

388

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

393

394 (2) When dispensing a drug under (1), a drug outlet must provide labels and informational inserts in  
395 both English and one of the following languages:

396

397 (a) Spanish;

398

399 (b) Russian;

400

401 (c) Somali;

402

403 (d) Arabic;

404

405 (e) Chinese (simplified);

406

407 (f) Vietnamese;

408

409 (g) Farsi;

410

411 (h) Korean;

412

413 (i) Romanian;

414

415 (j) Swahili;

416

417 (k) Burmese;

418

419 (l) Nepali;

420

421 (m) Amharic; and

422

423 (n) Pashtu.

424

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

426

427 Statutory/Other Authority: ORS 689.564

428 Statutes/Other Implemented: ORS 689.205

429

430 ~~855-043-0440~~

431 ~~Supervising Physician Dispensing Outlet—Dispensing and Drug Delivery~~

432

433 (1) ~~Drugs dispensed from a SPO by a physician assistant with dispensing authority or a practitioner must~~  
434 ~~be personally dispensed by the practitioner or physician assistant.~~

435

436 (2) ~~Prior to dispensing a medication a drug utilization review must be performed by the physician~~  
437 ~~assistant or practitioner which includes but is not limited to drug interactions, drug allergies and~~  
438 ~~duplicate drug therapy.~~

439

440 (3) ~~The physician assistant or practitioner must orally counsel the patient concerning all new drugs,~~  
441 ~~unless circumstances would render oral counseling ineffective.~~

442

443 (4) ~~When dispensed, a drug must be accompanied by written information that contains at least the~~  
444 ~~following information:~~

445

446 (a) ~~Drug name, class and indications;~~

447

448 (b) ~~Proper use and storage;~~

449

450 (c) ~~Common side effects;~~

451

452 (d) ~~Precautions and contraindications; and~~

453

454 (e) ~~Significant drug interactions.~~

455

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

459

460 (6) ~~Any other requirement of State or federal law.~~

461

462 (7) ~~A SPDO must dispense a drug in a new container that complies with the current provisions of the~~  
463 ~~Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations~~  
464 ~~and with the current United States Pharmacopoeia/National Formulary monographs for preservation,~~  
465 ~~packaging, storage and labeling.~~

466

467 (8) ~~Drugs must be prepackaged by a pharmacy or manufacturer registered with the Board.~~

468

469 (9) ~~A SPDO may not accept the return of drugs from a previously dispensed prescription and must~~  
470 ~~maintain a list of sites in Oregon where drugs may be disposed.~~

471

472 (10) ~~The most current issue of at least one pharmaceutical reference with current, properly filed~~  
473 ~~supplements and updates appropriate to and based on the standards of practice for the setting.~~

474

475 ~~Statutory/Other Authority: ORS 689.205~~

476 ~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

477

478 ~~855-043-0445~~

479 ~~Supervising Physician Dispensing Outlet – Drug Dispensing Training Program~~

480

481 A physician assistant must complete a drug dispensing training program jointly developed by the Oregon  
482 Medical Board and the Board of Pharmacy before dispensing drugs to patients.

483

484 Statutory/Other Authority: ORS 689.205

485 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

486 History:

487 BP 62-2020, minor correction filed 08/06/2020, effective 08/06/2020

488 BP 3-2012, f. & cert. ef. 6-19-12

489

490

491 ~~855-043-0450~~

492 ~~Supervising Physician Dispensing Outlet – Disposal of Drugs~~

493

494 Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be documented,  
495 quarantined and physically separated from other drugs until they are destroyed or returned to their  
496 supplier.

497

498 Statutory/Other Authority: ORS 689.205

499 Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511

500

501

502

503 ~~855-043-0455~~

504 ~~Supervising Physician Dispensing Outlet – Record Keeping~~

505

506 (1) A dispensing record must be maintained separately from the patient chart and kept for a minimum  
507 of three years. The record must show, at a minimum, the following:

508

509 (a) Name of patient;

510

511 (b) Unique identifier;

512

513 (c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and  
514 name of manufacturer or distributor;

515

516 (d) Directions for use;

517

518 (e) Date of dispensing; and

519

520 (f) Initials of person dispensing the prescription.

521

522 (2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

523

524 (3) Records documenting training required by OAR 855-043-0445 must be kept for three years.

525



526 (4) All records required by these rules or by other State and federal law must be readily retrievable and  
527 available for inspection by the Board.

528

529 Statutory/Other Authority: ORS 689.205

530 Statutes/Other Implemented: ~~ORS 689.155, ORS 689.305 & ORS 677.511~~

531

532

533 **855-043-0505**

534 **Dispensing Practitioner Drug Outlets - Purpose**

535 A practitioner's facility that engages in dispensing certain FDA-approved human prescription drug  
536 therapies greater than a 72 hours supply or any medication refill. Unless subject to an exemption in OAR  
537 855-043-0510(2), a practitioner that engages in dispensing human prescription drug therapies must  
538 register their dispensing site as a drug outlet with the Board as a Dispensing Practitioner Drug Outlet  
539 (DPDO).

540

541 Statutory/Other Authority: ORS 689.205

542 Statutes/Other Implemented: ORS 689.155 & ORS 689.305

543

544

545 **855-043-0510**

546 **Dispensing Practitioner Drug Outlets - Registration**

547

548 (1) Unless subject to an exemption in OAR 855-043-0510(2), a practitioner that engages in dispensing  
549 human prescription drug therapies A practitioner's facility that engages in dispensing FDA-approved  
550 human prescription drug therapies greater than 72 hours supply or any medication refill must register  
551 their dispensing site as a drug outlet with the Board as a DPDO on a form ~~provided~~ prescribed by the  
552 Board, and must renew its registration annually on a renewal form ~~provided~~ prescribed by the Board.

553

554 (2) A practitioner's facility is exempt from this registration requirement if the practitioner and facility  
555 only engages in:

556

557 (A) Dispensing FDA approved drug samples; or

558

559 (B) Dispensing Medication Assistance Program (MAP) drugs; or

560

561 (C) Dispensing homeopathic products; or

562

563 (D) Dispensing natural thyroid supplemental products; or

564

565 (E) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to  
566 a 72 hour supply; or

567

568 (F) An amount greater than a 72 hour supply if the drug is:

569

570 (i) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-inhaler or bottle  
571 of fluoride rinse; or

572

573 (ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient's  
574 best interest, such as a course of antibiotic therapy.

575  
576 (3) The initial **and renewal** applications must state the location of the DPDO and the name of the person  
577 applying for registration. When the person applying for registration is not the owner of the dispensing  
578 site, the application must disclose the name and address of the owner and the applicant's affiliation  
579 with the owner.

580  
581 (a) If more than one individual owns the dispensing site, the names and addresses of the partners or  
582 persons holding the three largest ownership interests in the dispensing site must be disclosed on the  
583 application.

584  
585 (b) If the owner is a corporation, the application must state the name of the corporation as filed with the  
586 Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.

587  
588 (4) Upon request by the **B**board, the applicant must furnish such information as required by the **B**board  
589 regarding the partners, stockholders, or other persons not named in the application.

590  
591 (5) An initial **and renewal** applications must be accompanied by the fee established **OAR 855-110**  
592 ~~in division 110 of this chapter.~~

593  
594 (6) A certificate of registration will be issued upon **B**board approval of the application.

595  
596 ~~(7) All registration renewal applications must be accompanied by the annual renewal fee established in~~  
597 ~~division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.~~

598  
599 ~~(87)~~ The DPDO registration expires March 31, annually. If the annual renewal fee is not paid by ~~February~~  
600 **28 March 31** of the current year, the applicant for renewal must submit the ~~delinquent~~ **late renewal** fee  
601 established in **OAR 855-110** ~~in division 110 of this chapter~~ with the renewal application.

602  
603 ~~(98)~~ The registration is not transferable and the registration fee cannot be prorated.

604  
605 ~~(109)~~ The registrant must notify the **B**board, ~~within 15 days prior to,~~ of any substantial change to the  
606 information provided on the registration application. Substantial change ~~shall~~ includes but ~~is~~ not ~~be~~  
607 limited to: change of ownership; change of business name; change of business address; change of  
608 normal business hours; any disciplinary action taken or pending by any state or federal authority against  
609 the registrant, or any of its principals, owners, directors, or officers, ~~or supervising practitioner.~~

610  
611 ~~(110)~~ A new registration form is required for a change of ownership or location and must be submitted  
612 to the **B**board with the fees as specified in **OAR 855-110** ~~in division 110 of this chapter~~ **within 15 days**  
613 **prior to** of the change.

614  
615 ~~(1211)~~ The **B**board may grant a time-limited waiver exempting DPDO registration when a practitioner  
616 licensing board submits a request to the **B**board with a plan to annually inspect the dispensing facility to  
617 the standards of the **B**board.

618  
619 **(12) All Supervising Physician Dispensing Outlet registrations expire on March 31, 2022. Outlets that**  
620 **utilize dispensing Physician Assistants must apply for and be granted registration as a Dispensing**

621 **Practitioner Dispensing Outlet upon the expiration of the Supervising Physician Dispensing Outlet**  
622 **Registration unless subject to an exemption in OAR 855-043-0510(2).**

623

624 Statutory/Other Authority: ORS 689.205

625 Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 475.125

626

627 **855-043-0520**

628 **Dispensing Practitioner Drug Outlets - Policies and Procedures**

629

630 The registered DPDO must maintain written policies and procedures for the management of drugs  
631 intended for dispensing, to include security, acquisition, storage, dispensing and drug delivery, disposal  
632 and record keeping.

633

634 Statutory/Other Authority: ORS 689.205

635 Statutes/Other Implemented: ORS 689.155, ORS 689.305

636

637

638 **855-043-0525**

639 **Dispensing Practitioner Drug Outlets - Security**

640

641 (1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently  
642 secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must  
643 remain locked and secured when not in use.

644

645 (2) A drug dispensing machine cannot be placed in a waiting room or an area that is accessible by the  
646 public.

647

648 Statutory/Other Authority: ORS 689.205

649 Statutes/Other Implemented: ORS 689.155, ORS 689.305

650

651

652 **855-043-0530**

653 **Dispensing Practitioner Drug Outlets - Drug Acquisition-Receipt**

654

655 The registered DPDO ~~must verify that all~~ **may only receive** drugs are acquired from an **Oregon**  
656 **Registered Drug Outlet (e.g. Wholesaler, Manufacturer or Pharmacy)** registrant of the Board.

657

658 Statutory/Other Authority: ORS 689.205

659 Statutes/Other Implemented: ORS 689.155, ORS 689.305

660

661

662 **855-043-0535**

663 **Dispensing Practitioner Drug Outlets - Drug Storage**

664

665 All drugs must be stored according to manufacturer's published guidelines and be stored in appropriate  
666 conditions of temperature, light, humidity, sanitation, ventilation, and space.

667

668 Statutory/Other Authority: ORS 689.205

669 Statutes/Other Implemented: ORS 689.155, ORS 689.305

670

671

672 **855-043-0540**

673 **Dispensing Practitioner Drug Outlet - Labeling**

674

675 (1) A prescription must be labeled with the following information:

676

677 (a) Name of patient;

678

679 (b) Name of prescriber;

680

681 (c) Name, address, and phone number of the clinic;

682

683 (d) Date of dispensing;

684

685 (e) Name and strength of the drug. If the drug does not have a brand name, then the generic name of  
686 the drug and the drug manufacturer must be stated;

687

688 (f) Quantity dispensed;

689

690 (g) Directions for use;

691

692 (h) Cautionary statements, if any, as required by law; and

693

694 (i) ~~Manufacturer's~~ **An** expiration date, ~~or an earlier date if preferable,~~ after which the patient should not  
695 use the drug ~~or medicine;~~ **and. Expiration dates on prescriptions must be the same as that on the**  
696 **original container or one year from the date the drug was originally dispensed and placed in the new**  
697 **container, whichever date is earlier. Any drug expiring before the expected length of time for course**  
698 **of therapy must not be dispensed.**

699

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

703

704 (2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an  
705 Expedited Partner Therapy treatment protocol, as described in OAR 855-~~043-0004~~041-4000 through  
706 ~~4005~~, the name of the patient may be omitted.

707

708 Statutory/Other Authority: ORS 689.205

709 Statutes/Other Implemented: ORS 689.155, ORS 689.305

710

711

712

713

714

715

716

717 **855-043-0545**

718 **Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery**

719

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

722

723 (~~12~~) Drugs dispensed from the DPDO by a practitioner shall must be dispensed in compliance with the  
724 requirements of the practitioner's licensing Bboard.

725

726 (~~23~~) A DPDO must comply with all requirements of State or federal law.

727

728 (~~34~~) A DPDO must dispense a drug in a new container that complies with the current provisions of the  
729 Federal Consumer **Poison Prevention** Packaging Act in **16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701**  
730 **(XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX)** (Public Law 91-601, 91st Congress, S. 2162) and rules or  
731 regulations and with the current United States Pharmacopoeia/National Formulary monographs for  
732 preservation, packaging, storage and labeling.

733

734 (~~45~~) **Dispensed** drugs must be packaged by the practitioner DPDO, a pharmacy, or a manufacturer  
735 registered with the Bboard.

736

737 (~~56~~) A DPDO may not accept the return of drugs from a previously dispensed prescription and shall must  
738 maintain a list of sites in Oregon where drugs may be disposed.

739

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

741

742 **(a) Proper drug storage conditions are maintained; and**

743

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

746

747 **(A) Drug name, class and indications;**

748

749 **(B) Proper use and storage;**

750

751 **(C) Common side effects;**

752

753 **(D) Precautions and contraindications; and**

754

755 **(E) Significant drug interactions.**

756

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

760

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

764

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

767  
768

769 **855-043-0550**

770 **Dispensing Practitioner Drug Outlets - Disposal of Drugs**

771

772 Drugs that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, or identified as  
773 suspect or illegitimate must be documented, quarantined and physically separated from other drugs  
774 until they are destroyed or returned to the supplier.

775

776 Statutory/Other Authority: ORS 689.205

777 Statutes/Other Implemented: ORS 689.155, ORS 689.305

778

779

780 **855-043-0555**

781 **Dispensing Practitioner Drug Outlets - Records Keeping**

782

783 (1) A unique dispensing record ~~shall~~must be maintained, be readily retrievable, and kept for a minimum  
784 of three years. The record must show, at a minimum, the following:

785

786 (a) Name of patient;

787

788 (b) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and  
789 name of manufacturer or distributor;

790

791 (c) Directions for use;

792

793 (d) Date of dispensing; and

794

795 (e) Initials of person dispensing the prescription.

796

797 (2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

798

799 ~~(3) All records required by these rules or by other State and federal law must be readily retrievable and~~  
800 ~~available for inspection by the Board.~~

801

802 **(3) All records and documents required by ORS 475, ORS 689, and OAR 855:**

803

804 **(a) Must be stored on-site for 12 months and must be provided to the board immediately upon**  
805 **request at the time of inspection;**

806

807 **(b) May be stored in a secured off-site location after 12 months of on-site storage and must be**  
808 **provided to the board upon request within three business days; and**

809

810 **(c) May be in written or electronic format.**

811

812 Statutory/Other Authority: ORS 689.205

813 Statutes/Other Implemented: ORS 689.155, ORS 689.305

814

815

816 **855-043-0560**

817 **Dispensing Practitioner Drug Outlets - Inspections**

818

819 (1) The DPDO must complete the ~~B~~board Self Inspection Form by February 1, annually.

820

821 (2) Each DPDO will be inspected per OAR 855-001-0040 on a routine basis and ~~shall~~must be scheduled in  
822 advance with the ~~practitioner~~DPDO, to occur during normal business hours.

823

824 (3) The inspection ~~shall~~must focus on the acquisition, storage, labeling and recordkeeping of drugs  
825 intended for dispensing and any violation will apply to the DPDO registration and not to the practitioner.

826

827 (4) The Board of Pharmacy ~~shall~~must notify the practitioner's licensing ~~B~~board of any disciplinary action  
828 taken against a DPDO.

829

830 Statutory/Other Authority: ORS 689.205

831 Statutes/Other Implemented: ORS 689.155, ORS 689.305

832

833

834 **855-043-0705**

835 **Community Health Clinic (CHC) - Registration**

836

837 (1) A Community Health Clinic Drug Outlet must register with the ~~B~~board on a form prescribed by the  
838 ~~B~~board, and must renew its registration annually on a renewal form prescribed by the ~~B~~board.

839

840 (2) An initial application and renewal application must be accompanied by the fee established in OAR  
841 855-110 in ~~division 110 of this Chapter~~.

842

843 (3) A certificate of registration will be issued upon ~~B~~board approval of the application.

844

845 (4) The CHC Drug Outlet registration expires March 31, annually. If the annual renewal fee is not paid by  
846 ~~February 28~~March 31 of the current year, the applicant for renewal must submit the ~~delinquent~~ late  
847 renewal fee established in OAR 855-110 ~~division 110 of this Chapter~~ with the renewal application.

848

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

850

851 (6) The registrant must notify the ~~B~~board, within 15 days, of any substantial change to the information  
852 provided on the registration application. A substantial change shall include but not be limited to: a  
853 change of ownership; change of business address; change of normal business hours; any disciplinary  
854 action taken or pending by any state or federal authority against the registrant, or any of its principals,  
855 owners, directors, officers, or Medical Director.

856

857 (7) A new registration form is required for a change of ownership or location and must be submitted to  
858 the ~~B~~board with the fees as specified in OAR 855-110 ~~division 110 of this Chapter~~ within 15 days of the  
859 change.

860

861 (8) A CHC Drug Outlet may be inspected by the ~~B~~board.  
862

863 Statutory/Other Authority: ORS 689.205

864 Statutes/Other Implemented: ORS 689.305  
865

866  
867 **855-043-0740**

868 **Community Health Clinic (CHC) - Dispensing and Drug Delivery**  
869

870 (1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their  
871 licensing Board or by a Registered Nurse.  
872

873 (2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.  
874

875 (3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.  
876

877 (4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and  
878 completeness of the prescription is verified by a practitioner who has been given dispensing privileges  
879 by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.  
880

881 (5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can  
882 be provided by the Registered Nurse or practitioner at the time of dispensing.  
883

884 (6) ~~All drugs~~ **CHC must be dispensed a drug** in a new container that complies with the current provisions  
885 of the ~~Federal Consumer~~ **Poison Prevention** Packaging Act in **16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701**  
886 **(XX/XX/XXXX) and 16 CFR 1702 (XX/XX/XXXX)** and rules or regulations and with the current United  
887 States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and  
888 labeling.  
889

890 (7) **Dispensed** drugs must be repackaged by the practitioner, Registered Nurse, a pharmacy; or a  
891 manufacturer registered with the ~~B~~board.  
892

893 (8) A CHC may not accept the return of drugs from a previously dispensed prescription and must  
894 maintain a list of sites in Oregon where drugs may be disposed.  
895

896 (9) A CHC must have access to the most current issue of at least one pharmaceutical reference with  
897 current, properly filed supplements and updates appropriate to and based on the standards of practice  
898 for the setting.  
899

900 **(10) A CHC may deliver or mail prescription to the patient if:**  
901

902 **(a) Proper drug storage conditions are maintained; and**  
903

904 **(b) The CHC offers in writing, to provide direct counseling, information on how to contact the**  
905 **practitioner, and information about the drug, including, but not limited to:**  
906

907 **(A) Drug name, class and indications;**  
908



909 **(B) Proper use and storage;**

910

911 **(C) Common side effects;**

912

913 **(D) Precautions and contraindications; and**

914

915 **(E) Significant drug interactions.**

916

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

920

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

924

925 Statutory/Other Authority: ORS 689.205

926 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.

1 Division 60  
2 PHARMACEUTICAL MANUFACTURERS

3  
4 **855-060-0001**  
5 **Application**

6  
7 No place of manufacturing, wholesaling or repackaging of drugs or medicines, as defined in ORS  
8 689.005(20), (35), and (36) ~~shall may~~ be conducted or operated until it has been registered by the State  
9 Board of Pharmacy, ~~except that compounding or repackaging, as a part of a Shared Pharmacy Services~~  
10 ~~agreement as defined in OAR 855-006-0005(20), does not constitute manufacturing. Manufacturing~~  
11 ~~registration expires September 30th annually.~~

12  
13 (1) All applications for registration of a new or relocated manufacturer shall be accompanied by the  
14 required fees as set forth in OAR 855-110-0007(3).

15  
16 (2) Application ~~shall must~~ specify the location of the manufacturer premises. When the applicant is not  
17 the owner of the business, the application shall indicate the owner and the applicant's affiliation with  
18 the owner;

19  
20 (a) If the owner is a partnership or other multiple owner, the names of the partners or person holding  
21 the five largest interests shall be indicated on the application.

22  
23 (b) If the owner is a corporation, the name filed ~~shall must~~ be the same as filed with the Corporation  
24 Commissioner. The name of the corporation, the names of the corporation officers and the names of  
25 the stockholders who own the five largest interests shall be indicated on the application.

26  
27 (c) Upon request by the ~~B~~board, the applicant ~~shall must~~ furnish such information as required by the  
28 ~~B~~board regarding the partners, stockholders, or other persons not named in the application.

29

30 (3) All registration renewal applications ~~shall~~**must** be accompanied by the annual fee and contain the  
31 same information required in subsection (2)(a), (b), and (c) of this rule.

32

33 (4) A change of ownership or location requires a new application, fee, and registration within 15 days.

34

35 (5) The registration certificate is issued to a person or firm and is non-transferable. Additions or  
36 deletions of a partner/partners ~~shall~~**must** be considered as a change of ownership.

37

38 (6) **Manufacturing registration expires September 30th annually.** The registration cannot be prorated.

39

40 Statutory/Other Authority: ORS 689.205

41 Statutes/Other Implemented: ORS 689.155, **ORS** 689.305, **ORS** 689.315 & **ORS** 689.325

42

PROPOSED

43 Division 110

44 FEES

45

46 **855-110-0003**

47 **General**

48

49 (1) All fees paid under these rules are non-refundable.

50

51 (2) Fees cannot be prorated.

52

53 (3) Fees for initial licensure as a Pharmacist or Certified Oregon Pharmacy Technician may be reduced to  
54 one-half of a biennial rate, if the application is received ~~or the mailing date of the application is~~  
55 ~~postmarked~~ within 180 days of expiration.

56

57 (4) A delinquent late fee must be paid: when a renewal application is received after the date specified  
58 in these rules.

59

60 (a) ~~When an application is postmarked after the date specified in these rules; or~~

61

62 (b) ~~When the Board requests additional information from an applicant and this information is not~~  
63 ~~provided within 30 days.~~

64

65 (5) ~~A delinquent fee may be assessed when an application is submitted incomplete and the Board~~  
66 ~~requests the missing information.~~

67

68 Statutory/Other Authority: ORS 689.205

69 Statutes/Other Implemented: ORS 689.135

70

71

72

73 **855-110-0005**

74 **Licensing Fees**

75

76 (1) Pharmacist license examination (NAPLEX) ~~and re-examination~~ fee - \$50.

77

78 (2) Pharmacist jurisprudence (MPJE) re-examination fee - \$25.

79

80 (3) Pharmacist licensing by reciprocity fee - ~~\$250~~100.

81

82 (4) Pharmacist licensing by score transfer fee - \$250.

83

84 (5) Intern license fee. Expires November 30 every two years - \$100.

85

86 (6) Pharmacist:

87  
88 (a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is - \$250. Late  
89 renewal fee (received after June 30) - \$50.

90  
91 (b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially - ~~\$570~~. (This is a mandatory  
92 fee, required by ORS ~~431.972~~ **431A.880** that must be paid with the pharmacist license renewal fee).

93  
94 (c) Workforce Data Collection fee. Due by June 30 biennially - \$4. (This is a mandatory fee as required by  
95 OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.)

96  
97 (7) Certification of approved provider of continuing education course fee, none at this time.

98  
99 (8) Pharmacy Technician license fee - \$100.

100  
101 (9) Certified Oregon Pharmacy Technician:

102  
103 (a) Biennial license fee. Expires June 30 each even numbered year - \$100. Late renewal fee (received  
104 after June 30) - \$20.

105  
106 (b) Workforce Data Collection fee. Due by June 30 biennially - \$4. (This is a mandatory fee as required by  
107 OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy Technician license renewal  
108 fee.)

109  
110 Statutory/Other Authority: ORS 689.205, ORS 291.055 & ORS 183.705  
111 Statutes/Other Implemented: ORS 689.135, ORS 676.410 & ORS 431A.880

112  
113  
114 **855-110-0007**

115 **Fees for Registration, Renewal, and Reinspection of Drug Outlets**

116  
117 (1) Community Health Clinic. Expires March 31 annually - \$100. Late renewal fee (received after March  
118 31) - \$25.

119  
120 (2) Drug Distribution Agent. Expires September 30 annually - \$400. Late renewal fee (received after  
121 September 30) - \$100.

122  
123 (3) Drug Room (including ~~e~~Correctional ~~f~~Facility). Expires March 31 annually - \$100. Late renewal fee  
124 (received after March 31) - \$75.

125  
126 (4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III).  
127 Expires September 30 annually - \$525. Late renewal fee (received after September 30) - \$100.

128  
129 (5) Medical Device, Equipment & Gas Class C. Expires January 31 annually - \$75. Late renewal fee  
130 (received after January 31) - \$25.

- 131  
132 (6) Nonprescription Class A. Expires January 31 annually - \$75. Late renewal fee (received after January  
133 31) - \$25.  
134  
135 (7) Nonprescription Class B. Expires January 31 annually - \$75. Late renewal fee (received after January  
136 31) - \$25.  
137  
138 (8) Nonprescription Class D. Expires January 31 annually - \$100. Late renewal fee (received after January  
139 31) - \$25.  
140  
141 (9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - \$50. Expires December 31  
142 annually.  
143  
144 (10) Re-inspection fee - \$100. Applies to any re-inspection of a drug outlet occasioned to verify  
145 corrections of violations found in an initial inspection.  
146  
147 (11) Retail, Institutional, or Consulting/"Drugless". Expires March 31 annually - \$225. Late renewal fee  
148 (received after March 31) - \$75.  
149  
150 (12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires  
151 September 30 annually - \$525. Late renewal fee (received after September 30) - \$100.  
152  
153 (13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually - \$120. Due  
154 by March 31 annually.  
155  
156 (14) Charitable Pharmacy. Expires March 31 annually - \$75. Late renewal fee (received after March 31) -  
157 \$25.  
158  
159 (15) Home Dialysis. Expires March 31 annually - \$225. Late renewal fee (received after March 31) - \$75.  
160  
161 ~~(16) Supervising Physician Dispensing Outlet. Expires March 31 annually - \$175. Late renewal fee~~  
162 ~~(received after March 31) - \$75.~~  
163  
164 ~~(17)~~**16** Dispensing Practitioner Drug Outlet. Expires March 31 annually - \$100. Late renewal fee (received  
165 after March 31) — \$25.  
166

167 Statutory/Other Authority: ORS 689.205 & ORS 291.055

168 Statutes/Other Implemented: ORS 689.135, ORS 689.774 & ORS 689.305

169  
170  
171  
172  
173  
174

**855-110-0010**

**Fees for Registration for Controlled Substances under ORS 475.095**

- 175 (1) Animal Euthanasia controlled substance registration fee — \$75 annually.  
176  
177 (2) Drug Distribution Agent controlled substance registration fee — \$100 annually.  
178  
179 (3) Drug Room (including ~~e~~Correctional ~~f~~Facility) controlled substance registration fee — \$100 annually.  
180  
181 (4) Manufacturer controlled substance registration fee — \$100 annually.  
182  
183 (5) Retail or Institutional Drug Outlet controlled substance registration fee — \$100 annually.  
184  
185 (6) Schedule II Precursor registration fee — \$75 annually.  
186  
187 (7) Wholesaler controlled substance registration fee — \$100 annually.  
188  
189 (8) Remote Distribution Facility controlled substance registration fee — \$100 annually.  
190  
191 Statutory/Other Authority: ORS 689.205, & ORS 291.055, **ORS 475.095**  
192 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 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.

2 Division 6  
3 DEFINITIONS

4  
5 **855-006-0005**  
6 **Definitions**

7  
8 As used in OAR chapter 855:

9  
10 **(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).**

11  
12 ~~(12)~~ "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the  
13 context.

14  
15 ~~(23)~~ "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy  
16 who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board and has  
17 completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for  
18 clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by  
19 the pharmacist are not considered pharmacy technicians.

20  
21 ~~(34)~~ "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a  
22 health care organization or a physician that permits the pharmacist to engage in the practice of clinical  
23 pharmacy for the benefit of the patients of the health care organization or physician.

24  
25 ~~(45)~~ "Collaborative Drug Therapy Management" means the participation by a pharmacist in the  
26 management of drug therapy pursuant to a written protocol that includes information specific to the  
27 dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and  
28 initiated upon a prescription order for an individual patient and:

29  
30 (a) Is agreed to by one pharmacist and one practitioner; or

31  
32 (b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or  
33 more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group  
34 practice, including but not limited to organized medical groups using a pharmacy and therapeutics  
35 committee.

36  
37 ~~(56)~~ "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or  
38 device:

39  
40 (a) As the result of a practitioner's prescription drug order, or initiative based on the relationship  
41 between the practitioner, the pharmacist and the patient, in the course of professional practice; or

42  
43 (b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or  
44 dispensing; or

45  
46 (c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine,  
47 regularly observed prescribing patterns.

48  
49 ~~(67)~~ "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

50  
51 ~~(78)~~ "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient  
52 medication, therapy management, drug storage and management, security, education, or any other  
53 pharmaceutical service.

54  
55 ~~(89)~~ The "Container" is the device that holds the drug and that is or may be in direct contact with the  
56 drug.

57  
58 ~~(910)~~ "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a  
59 lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration  
60 to or use by a patient or other individual entitled to receive the prescription drug.

61  
62 ~~(1011)~~ "Interpretation and evaluation of prescription orders" means the review of the order for  
63 therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug  
64 ordered, its applicability and its relationship to the other known medications used by the patient and  
65 determination of whether or not the dose and time interval of administration are within accepted limits  
66 of safety. The legal review for correctness of the prescription order includes a determination that the  
67 order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose,  
68 contains all information required by federal and state law, and is within the practitioner's scope of  
69 practice.

70  
71 ~~(1112)~~ "Labeling" means the process of preparing and affixing of a label to any drug container exclusive,  
72 however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or  
73 commercially packaged legend drug or device.

74  
75 **(13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).**

76  
77 ~~(1214)~~ "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of  
78 the therapeutic or adverse effect of medication upon a patient, including direct consultation with the  
79 patient or his agent and review of patient records, as to result and side effect, and the analysis of  
80 possible interactions with other medications that may be in the medication regimen of the patient. This  
81 section shall not be construed to prohibit monitoring by practitioners or their agents.

82  
83 ~~(1315)~~ "Medication Therapy Management (MTM)" means a distinct service or group of services that is  
84 intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management  
85 services are independent of, but can occur in conjunction with, the provision of a medication product.

86  
87 ~~(1416)~~ "Nationally Certified Exam" means an exam that is approved by the Board which demonstrates  
88 successful completion of a Specialized Education Program. The exam must be reliable, psychometrically  
89 sound, legally defensible and valid.

90  
91 ~~(1517)~~ "Non-legend drug" means a drug which does not require dispensing by prescription and which is  
92 not restricted to use by practitioners only.

93  
94 ~~(1618)~~ "Offering or performing of those acts, services, operations or transactions necessary in the  
95 conduct, operation, management and control of pharmacy" means, among other things:

96  
97 (a) The creation and retention of accurate and complete patient records;

- 98  
99 (b) Assuming authority and responsibility for product selection of drugs and devices;  
100  
101 (c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the  
102 general public;  
103  
104 (d) Maintaining confidentiality of patient information.  
105

106 **(19) "Official compendium" means the official United States Pharmacopeia <USP>, official National**  
107 **Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States**  
108 **<HPUS> (v.2021), or any supplement to any of these.**  
109

110 (~~1720~~) "Oral Counseling" means an oral communication process between a pharmacist and a patient or  
111 a patient's agent in which the pharmacist obtains information from the patient (or agent) and the  
112 patient's pharmacy records, assesses that information and provides the patient (or agent) with  
113 professional advice regarding the safe and effective use of the prescription drug for the purpose of  
114 assuring therapeutic appropriateness.  
115

116 (~~1821~~) Participation in Drug Selection and Drug Utilization Review:  
117

118 (a) "Participation in drug selection" means the consultation with the practitioner in the selection of the  
119 best possible drug for a particular patient.  
120

121 (b) "Drug utilization review" means evaluating prescription drug order in light of the information  
122 currently provided to the pharmacist by the patient or the patient's agent and in light of the information  
123 contained in the patient's record for the purpose of promoting therapeutic appropriateness by  
124 identifying potential problems and consulting with the prescriber, when appropriate. Problems subject  
125 to identification during drug utilization review include, but are not limited to:  
126

127 (A) Over-utilization or under-utilization;  
128

129 (B) Therapeutic duplication;  
130

131 (C) Drug-disease contraindications;  
132

133 (D) Drug-drug interactions;  
134

135 (E) Incorrect drug dosage;  
136

137 (F) Incorrect duration of treatment;  
138

139 (G) Drug-allergy interactions; and  
140

141 (H) Clinical drug abuse or misuse.  
142

143 (~~1922~~) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of  
144 achieving definite outcomes that improve a patient's quality of life. These outcomes include:  
145

- 146 (a) Cure of a disease;  
147  
148 (b) Elimination or reduction of a patient's symptomatology;  
149  
150 (c) Arrest or slowing of a disease process; or  
151  
152 (d) Prevention of a disease or symptomatology.  
153  
154 ~~(2023)~~ "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the  
155 pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the  
156 specialized education program pursuant to OAR 855-025-0012.  
157  
158 ~~(2124)~~ "Practice of clinical pharmacy" means:  
159  
160 (a) The health science discipline in which, in conjunction with the patient's other practitioners, a  
161 pharmacist provides patient care to optimize medication therapy and to promote disease prevention  
162 and the patient's health and wellness;  
163  
164 (b) The provision of patient care services, including but not limited to post-diagnostic disease state  
165 management services; and  
166  
167 (c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.  
168  
169 ~~(2225)~~ "Practice of pharmacy" is as defined in ORS 689.005.  
170  
171 ~~(2326)~~ "Prescription released by the pharmacist" means, a prescription which has been reviewed by the  
172 pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.  
173  
174 ~~(2427)~~ "Prohibited conduct" means conduct by a licensee that:  
175  
176 (a) Constitutes a criminal act against a patient or client; or  
177  
178 (b) Constitutes a criminal act that creates a risk of harm to a patient or client.  
179  
180 ~~(2528)~~ "Proper and safe storage of drugs and devices and maintenance of proper records therefore"  
181 means housing drugs and devices under conditions and circumstances that:  
182  
183 (a) Assure retention of their purity and potency;  
184  
185 (b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;  
186  
187 (c) Assure security and minimize the risk of their loss through accident or theft;  
188  
189 (d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;  
190  
191 (e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from  
192 harmful exposure to hazardous substances.  
193

194 ~~(2629)~~ "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned  
195 and systematic process for the monitoring and evaluation of the quality and appropriateness of  
196 pharmacy services and for identifying and resolving problems.

197  
198 ~~(2730)~~ "Responsibility for advising, when necessary or when regulated, of therapeutic values, content,  
199 hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing  
200 as required by these rules or federal regulation, of the possible therapeutic response to the medication,  
201 the names of the chemicals in the medication, the possible side effects of major importance, and the  
202 methods of use or administration of a medication.

203  
204 ~~(2831)~~ "Specialized Education Program" means;

205  
206 (a) A program providing education for persons desiring licensure as pharmacy technicians that is  
207 approved by the board and offered by an accredited college or university that grants a two-year degree  
208 upon successful completion of the program; or

209  
210 (b) A structured program approved by the board and designed to educate pharmacy technicians in one  
211 or more specific issues of patient health and safety that is offered by:

212  
213 (A) An organization recognized by the board as representing pharmacists or pharmacy technicians;

214  
215 (B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

216  
217 (C) A trade association recognized by the board as representing pharmacies.

218  
219 ~~(29) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy~~  
220 ~~technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control~~  
221 ~~and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action.~~  
222 ~~During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic,~~  
223 ~~"supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being~~  
224 ~~supervised, coupled with the ability to control and be responsible for the technician or interns actions~~  
225 ~~and for the following remote processing functions only: prescription or order entry, other data entry,~~  
226 ~~and insurance processing of prescriptions and medication orders.~~

227  
228 ~~(3032)~~ "Therapeutic substitution" means the act of dispensing a drug product with a different chemical  
229 structure for the drug product prescribed under circumstances where the prescriber has not given clear  
230 and conscious direction for substitution of the particular drug for the one which may later be ordered.

231  
232 ~~(3133)~~ "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy  
233 and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a  
234 certified Oregon pharmacy technician.

235  
236 Statutory/Other Authority: ORS 689.205

237 Statutes/Other Implemented: ORS 689.151 & ORS 689.155

238  
239  
240  
241

242 **855-041-1060**

243 **Non-Resident Pharmacies**

244

245 (1) For the purpose of these rules, a non-resident pharmacy **is any establishment located out of Oregon**  
246 **that engages in the dispensing, delivery or distribution of drugs to Oregon. A non-resident pharmacy**  
247 **also includes entities that provide pharmacy services to Oregon, such as drugless/consulting outlets,**  
248 **even if the entity is not dispensing, delivering or distributing drugs into Oregon.** ~~includes, but is not~~  
249 ~~limited to: Retail, Institutional, Remote Processing, Central Fill, and Drugless/Consulting Drug Outlets.~~

250

251 (2) Every non-resident pharmacy that provides drugs, devices or services to a resident in this state  
252 ~~shall~~**must** be registered with the Oregon Board of Pharmacy.

253

254 (3) To qualify for registration under these rules, every non-resident pharmacy ~~shall~~**must** be registered  
255 and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

256

257 (4) Every out-of-state non-resident pharmacy ~~shall~~**must** designate an Oregon licensed Pharmacist-in-  
258 Charge (PIC), who ~~shall~~**must** be responsible for all pharmacy services provided to residents in Oregon,  
259 and to provide supervision and control in the pharmacy. To qualify for this designation, the person must:

260

261 (a) Hold a license to practice pharmacy in the resident state;

262

263 (b) Be normally present in the pharmacy for a minimum of 20 hours per week;

264

265 (c) Complete the annual non-resident PIC self-inspection report prior to February 1 each year; and

266

267 (d) Provide the PIC self-inspection report as requested by the Board.

268

269 (5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within  
270 four months of initial licensure of the pharmacy.

271

272 (6) When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the  
273 Board within ten business days and identify a contact person. The pharmacy will have an Oregon  
274 licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the  
275 pharmacy's state of residence and is responsible for the following:

276

277 (a) Supervision of pharmacy staff and ensuring compliance with laws and rules; and

278

279 (b) Responding to Board correspondence and inquiries.

280

281 (7) A new Pharmacist-in-Charge must be appointed, and communication made to the Board within 90  
282 days, or the non-resident pharmacy will cease drug distribution and provision of pharmacy services in  
283 Oregon.

284

285 Statutory/Other Authority: ORS 689.205

286 Statutes/Other Implemented: ORS 689.151, **ORS** 689.155 & **ORS** 689.225

287

288

289

290 ~~855-041-3000~~  
291 ~~Central Fill and Remote Processing Outlet Designations and Consulting/Drugless Pharmacy Outlets–~~  
292 ~~Purpose and Scope~~  
293

294 (1) ~~The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of~~  
295 ~~operation for centralized prescription drug filling by a pharmacy.~~

296  
297 (2) ~~The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of~~  
298 ~~operation for remote prescription processing by a pharmacy.~~

299  
300 (3) ~~Prior to initiating one of the above drug outlet models, a description of how the model will be~~  
301 ~~utilized must be submitted to the Board.~~

302  
303 (4) ~~The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where~~  
304 ~~a consulting pharmacist can provide pharmaceutical care and store health protected information in a~~  
305 ~~consulting or drugless pharmacy. Prior to initiating this model, a description of how the model will be~~  
306 ~~utilized to improve patient safety must be submitted to the Board.~~

307  
308 ~~Statutory/Other Authority: ORS 689.205~~  
309 ~~Statutes/Other Implemented: ORS 689.155~~

310  
311 ~~855-041-3100~~  
312 ~~Remote Processing – Purpose and Scope~~  
313

314 ~~The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of~~  
315 ~~operation for remote prescription drug processing by a pharmacy. Any facility that processes drug~~  
316 ~~orders on behalf of an Oregon pharmacy shall be licensed in Oregon as a retail or institutional drug~~  
317 ~~outlet. An applicant must submit its policies and procedures to the Board of Pharmacy. An applicant~~  
318 ~~must submit to the Board for approval policies and procedures and a description of how using remote~~  
319 ~~processing will improve patient safety.~~

320  
321 ~~Statutory/Other Authority: ORS 689.205~~  
322 ~~Statutes/Other Implemented: ORS 689.155~~

323  
324 ~~855-041-3105~~  
325 ~~Remote Processing – Definitions~~  
326

327 ~~The following words and terms, when used in OAR 855-041-3100 through 855-041-3130, shall have the~~  
328 ~~following meanings, unless the context clearly indicates otherwise. Any term not defined in this section~~  
329 ~~shall have the definition set out in OAR chapter 855, division 006.~~

330  
331 (1) ~~“Remote Processing Pharmacy” means an Oregon licensed pharmacy operated under the direction of~~  
332 ~~a pharmacist in charge that processes information related to the practice of pharmacy and engages in~~  
333 ~~remote prescription processing, including central processing.~~

334  
335 (2) ~~“Remote Processing Functions” may include, but are not limited to, data entry, prospective drug~~  
336 ~~utilization reviews, refill authorizations and interventions. This does not include the filling process.~~

337



338 (3) "Primary Pharmacy" means an in-state Oregon licensed pharmacy that receives a patient's or a  
339 prescribing practitioner's request to fill a prescription or drug order and delivers the drug or device  
340 directly to the patient or patient's agent, and maintains ownership of the prescription or drug order.  
341

342 Statutory/Other Authority: ORS 689.205

343 Statutes/Other Implemented: ORS 689.155

344

345 **855-041-3110**

346 **Remote Processing – General Requirements**

347

348 An Oregon licensed pharmacy may outsource prescription drug processing to a remote processing  
349 pharmacy provided both pharmacies:

350

351 (1) Have the same owner; or

352

353 (2) Have a written shared pharmacy services contract or agreement that specifies:

354

355 (a) The services to be provided by each pharmacy;

356

357 (b) The responsibilities of each pharmacy; and

358

359 (c) The accountabilities of each pharmacy.

360

361 (3) Maintain a separate Oregon pharmacy license for each location involved in providing services;

362

363 (4) Share a common electronic file or have appropriate technology or interface to allow access to  
364 information required to process and fill a prescription drug order;

365

366 (5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3115;

367

368 (6) Ensure that each prescription has been properly processed, filled and counseling has been provided  
369 to the patient;

370

371 (7) Designate a pharmacist in charge. To qualify for this designation, the person must hold a license to  
372 practice pharmacy in the state of Oregon and in the pharmacy's resident state if the pharmacy is out-of-  
373 state. The pharmacist in charge must be in good standing with both licensing Boards;

374

375 (8) Allow prospective drug utilization reviews, refill authorizations, interventions, and patient counseling  
376 for an Oregon patient must be performed only by a licensed pharmacist in Oregon or in the state in  
377 which the pharmacy is located;

378

379 (9) Ensure that each technician processing an order for an Oregon patient is a Certified Oregon  
380 Pharmacy Technician and is supervised by a licensed pharmacist or is a licensed technician in the state in  
381 which the pharmacy is located and is supervised by a licensed pharmacist in the state in which the  
382 pharmacy is located;

383

384 (10) Comply with all applicable federal and state laws and rules;

385

386 (11) Conduct an annual review of the written policies and procedures and document such review.

387

388 Statutory/Other Authority: ORS 689.205

389 Statutes/Other Implemented: ORS 689.155

390

391 ~~855-041-3115~~

392 ~~Remote Processing—Policies and Procedures~~

393

394 (1) In addition to the requirements of OAR 855-041-1040, the primary and the remote processing  
395 pharmacy is each accountable for establishing, maintaining, and enforcing its own written policies and  
396 procedures manual. The policies and procedures manual must include, but need not be limited to the  
397 following:

398

399 (a) The responsibilities of each pharmacy;

400

401 (b) The policies and procedures that protect confidentiality and ensure the integrity of patient  
402 information;

403

404 (c) Compliance with all applicable federal and state laws and rules;

405

406 (d) Records sufficient to identify by name, initials, or unique identification code, the identity and the  
407 specific activities of each pharmacist or technician who performed any processing function, and the  
408 location where each activity was performed;

409

410 (e) A continuous quality improvement program for pharmacy services designed to objectively and  
411 systematically monitor and evaluate the quality and appropriateness of patient care, to pursue  
412 opportunities to improve patient care, and to resolve identified problems; and

413

414 (f) Documentation of any errors or irregularities identified by the quality improvement program.

415

416 (2) The written policies and procedures manual shall be maintained at all pharmacies involved in remote  
417 processing and must be available to the Board upon request.

418

419 Statutory/Other Authority: ORS 689.205

420 Statutes/Other Implemented: ORS 689.155

421

422 ~~855-041-3120~~

423 ~~Remote Processing—Records~~

424

425 (1) The recordkeeping requirements OAR 855-041-3100 through 855-041-3130 are in addition to the  
426 requirements of other recordkeeping rules of the Board.

427

428 (2) The remote processing pharmacy must maintain all required records unless these records are  
429 maintained in the primary pharmacy.

430

431 (3) Both recordkeeping systems must:

432

- 433 (a) List the name, address, telephone number, and all license and registration numbers of each  
434 pharmacy involved in remote prescription processing;  
435  
436 (A) Document verification of each license and registration;  
437  
438 (B) Document the name of the individual responsible for verification of licensure and registration status.  
439  
440 (b) Identify by name, initials, or unique identification code the identity and the specific activities of each  
441 pharmacist or technician who performed any part of the prescription process;  
442  
443 (c) Include quality improvement program documentation;  
444  
445 (d) Be able to produce an audit trail showing each prescription process.  
446  
447 (4) Unless otherwise specified, all records and documentation required by these rules, must be retained  
448 for three years and made available to the Board for inspection upon request. Records must be stored  
449 onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable  
450 within three business days. Records and documentation may be written, electronic or a combination of  
451 the two;  
452  
453 (5) The primary pharmacy shall maintain records that:  
454  
455 (a) Indicate the date the request for processing was transmitted to the remote processing pharmacy;  
456 and  
457  
458 (b) Indicate the date the prescription information was received by the primary pharmacy.  
459  
460 (6) The remote processing pharmacy shall maintain records that:  
461  
462 (a) Track the prescription drug order during each step in the order entry process;  
463  
464 (b) Identify the name, initials, or unique identification code and the specific activity of each pharmacist  
465 or pharmacy technician who performed any activity related to processing the prescription including  
466 receipt, transmission or delivery of information.

467  
468 Statutory/Other Authority: ORS 689.205  
469 Statutes/Other Implemented: ORS 689.155

470  
471 **~~855-041-3125~~**

472 **~~Remote Processing – Prescription or Drug Order Processing~~**

473  
474 A prescription or drug order for a controlled substance may be processed by a remote processing  
475 pharmacy when permitted by law and consistent with federal rules.  
476

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

479  
480

481 **~~855-041-3130~~**

482 **~~Remote Processing—Prohibited Practices~~**

483  
484 A remote processing pharmacy may not process a prescription on behalf of a primary pharmacy that is  
485 not registered with the Board, if required by the laws and rules of Oregon to be registered.  
486

487 Statutory/Other Authority: ORS 689.205

488 Statutes/Other Implemented: ORS 689.155

489

490

491 **855-041-3200**

492 **Telework: Purpose and Scope**

493

494 **The purpose of OAR 855-041-3200 through OAR 855-041-3250 is to provide minimum requirements**  
495 **for pharmacy services conducted via telework.**

496

497 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

498 **Statutes/Other Implemented: ORS 689.155**

499

500

501

502 **855-041-3205**

503 **Telework: Definitions**

504

505 **(1) “Telework” means the practice or assistance in the practice of pharmacy physically outside of a**  
506 **registered drug outlet in a telework site.**

507

508 **(2) “Telework Site” means a location that is not a registered drug outlet where an Oregon licensed**  
509 **Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist**  
510 **in the practice of pharmacy as employees of an Oregon registered drug outlet.**

511

512 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

513 **Statutes/Other Implemented: ORS 689.155**

514

515

516

517 **855-041-3210**

518 **Telework: Registration**

519

520 **The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of the Drug Outlet**  
521 **Pharmacy are responsible for all licensees engaging in the practice of pharmacy or assisting in the**  
522 **practice of pharmacy from Telework Sites.**

523

524 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

525 **Statutes/Other Implemented: ORS 689.155**

526

527

528

529 **855-041-3215**

530 **Telework: General Requirements**

531

532 **(1) Each Oregon registered Drug Outlet Pharmacy and Pharmacist-in-charge of a Drug Outlet**  
533 **Pharmacy must ensure that Interns and Certified Oregon Pharmacy Technicians working from a**  
534 **Telework Site work under the supervision, direction and control of an Oregon licensed Pharmacist.**

535

536 **(2) A Pharmacist that engages in the practice of pharmacy and an Intern or Certified Oregon Pharmacy**  
537 **Technician that assists in the practice of pharmacy from a Telework Site for any person or facility**  
538 **located in Oregon must:**

539

540 **(a) be licensed by the board; and**

541

542 **(b) comply with all applicable federal and state laws and rules.**

543

544 **(3) Drugs and devices may not be at a Telework Site.**

545

546 **(4) The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of a Drug Outlet**  
547 **Pharmacy must:**

548

549 **(a) Have a written agreement that includes all conditions, duties and policies governing the licensee**  
550 **engaged in telework activities;**

551

552 **(b) Maintain a continuously updated list of all licensees engaged in telework and the Telework Sites to**  
553 **include:**

554

555 **(A) Address, phone number and hours that telework is performed for each Telework Site;**

556

557 **(B) Functions being performed by licensees engaged in telework; and**

558

559 **(C) The Oregon licensed Pharmacist providing supervision, direction and control for each non-**  
560 **pharmacist licensee;**

561

562 **(c) Develop, implement and enforce a continuous quality improvement program for services provided**  
563 **from a Telework Site designed to objectively and systematically:**

564

565 **(A) Monitor, evaluate, document the quality and appropriateness of patient care;**

566

567 **(B) Improve patient care; and**

568

569 **(C) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their**  
570 **reoccurrence;**

571

572 **(d) Develop, implement and enforce a procedure for identifying the Oregon licensed Pharmacist,**  
573 **Intern and Certified Oregon Pharmacy Technician responsible for each telework function;**

574

575 **(e) Develop, implement and enforce a process for a virtual inspection of the Telework Site by an**  
576 **Oregon licensed Pharmacist at least once every 6 months or more frequently as deemed necessary by**  
577 **the Oregon licensed Pharmacist. The inspection must be documented and records retained; and**  
578

579 **(f) Utilize an Oregon licensed Pharmacist and real-time audio and visual communication to provide**  
580 **counseling or accept the refusal of counseling from the patient or the patient’s agent for each**  
581 **prescription being dispensed when counseling is required under OAR 855-019-0230 or when**  
582 **requested and document the interaction.**  
583

584 **POLICY DISCUSSION:** A/V Requirement  
585

586 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**  
587 **Statutes/Other Implemented: ORS 689.155**  
588

590  
591 **855-041-3220**

592 **Telework: Supervision Requirements**  
593

594 **The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the**  
595 **supervising Oregon licensed Pharmacist from the Drug Outlet must:**  
596

597 **(1) Utilize a continuous real-time audio and visual connection that is recorded, reviewed and stored**  
598 **and have appropriate technology or interface to allow access to information required to complete**  
599 **assigned duties;**  
600

601 **(2) Ensure all telephone audio is recorded, reviewed and stored;**  
602

603 **(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and**  
604 **Certified Oregon Pharmacy Technician and that the continuous audio/visual connection is fully**  
605 **operational;**  
606

607 **(4) Ensure that an Oregon licensed Pharmacist performs random “check-ins” via the real-time audio**  
608 **and visual connection at least once every 2 hours to ensure compliance with federal and state laws**  
609 **and patient safety and document the interaction;**  
610

611 **(5) Be readily available to answer questions and fully responsible for the practice and accuracy of the**  
612 **licensee; and**  
613

614 **(6) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon**  
615 **licensed Pharmacist who is providing supervision, direction and control at all times.**  
616

617 **(7) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy**  
618 **Technician at a Telework Site must:**  
619

620 **(a) Using professional judgment, determine the percentage of patient interactions for each licensee**  
621 **that must be reviewed to ensure public health and safety with a minimum of 25% of patient**  
622 **interactions reviewed;**

623  
624 **(b) Review patient interactions within 24 hours of the patient interaction to ensure that each licensee**  
625 **is acting within the authority permitted under their license and patients are connected with a**  
626 **pharmacist upon request;**

627  
628 **(c) Document the following within 24 hours of the review in (b):**

629  
630 **(A) Number of each licensee’s patient interactions;**

631  
632 **(B) Number of each licensee’s patient interactions pharmacist is reviewing;**

633  
634 **(C) Date and time of licensee patient interaction pharmacist is reviewing;**

635  
636 **(D) Date and time of pharmacist review of licensee’s patient interaction; and**

637  
638 **(E) Pharmacist notes of each interaction reviewed; and**

639  
640 **(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours**  
641 **and the board within 10 days.**

642  
643 **(8) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist’s determination in**  
644 **(7)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain**  
645 **records.**

646  
647 **POLICY DISCUSSION:** Frequency of review

648  
649 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

650 **Statutes/Other Implemented: ORS 689.155**

651  
652  
653  
654 **855-041-3225**

655 **Telework: Confidentiality**

656  
657 **The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet Pharmacy, and**  
658 **the Pharmacist, Intern and Certified Oregon Pharmacy Technician from the Drug Outlet Pharmacy**  
659 **must:**

660  
661 **(1) Ensure patient and prescription information is managed in compliance with OAR 855-019, OAR**  
662 **855-025, OAR 855-031, and OAR 855-041.**

663  
664 **(2) Ensure the security and confidentiality of patient information and pharmacy records.**

665  
666 **(3) Document and report any breach in the security of the system or breach of confidentiality. Report**  
667 **of the breach must be reported in writing to the board within ten days of the event.**

668  
669 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

670 **Statutes/Other Implemented: ORS 689.155**

671 **855-041-3230**  
672 **Telework: Technology**

673  
674 **The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the**  
675 **Pharmacist from the Drug Outlet must:**

676  
677 **(1) Use still image capture or store and forward for verification of prescriptions with a camera that is**  
678 **of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered**  
679 **Drug Outlet Pharmacy can visually identify each:**

680  
681 **(a) Source container including manufacturer, name, strength, lot, and expiration;**

682  
683 **(b) Dispensed product including the imprint and physical characteristics;**

684  
685 **(c) Completed prescription container including the label; and**

686  
687 **(d) Ancillary document provided to patient at the time of dispensing.**

688  
689 **POLICY DISCUSSION:** Remote Verification

690  
691 **(2) Test the continuous audio and visual connection and document that it operates properly before**  
692 **engaging in telework.**

693  
694 **(3) Develop, implement and enforce a plan for responding to and recovering from an interruption of**  
695 **service which prevents an Oregon licensed Pharmacist from supervising, directing and controlling the**  
696 **Intern and Certified Oregon Pharmacy Technician at the Telework Site.**

697  
698 **(4) Ensure access to:**

699  
700 **(a) Appropriate and current pharmaceutical references based on the services offered; and**

701  
702 **(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States**  
703 **Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services**  
704 **offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters.**

705  
706 **(5) Train the Oregon licensed Pharmacists, Interns and Certified Oregon Pharmacy Technicians in the**  
707 **operation of continuous audio and visual connection.**

708  
709 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

710 **Statutes/Other Implemented: ORS 689.155**

711  
712  
713 **855-041-3235**  
714 **Telework: Personnel**

715  
716 **(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all**  
717 **operations at Drug Outlet Pharmacy including responsibility for the continuous audio and visual**  
718 **connection and enforcing policies and procedures.**



719 **(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel at**  
720 **Telework Sites.**

721  
722 **(3) An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have**  
723 **at least one year experience performing similar services for an Oregon registered Drug Outlet**  
724 **Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy**  
725 **Technician begins working at the Remote Dispensing Site Pharmacy.**

726  
727 **POLICY DISCUSSION:** Experience

728  
729 **(4) The Oregon licensed Pharmacist from the Drug Outlet Pharmacy who is supervising a licensee at a**  
730 **Telework Site must determine and document how many licensed individuals the pharmacist is capable**  
731 **of supervising, directing and controlling based on the services being provided.**

732  
733 **(5) When supervising an Intern or Certified Oregon Pharmacy Technician working at a Telework Site**  
734 **and licensees at a Drug Outlet Pharmacy, the Oregon licensed Pharmacist may supervise no more than**  
735 **four licensees.**

736  
737 **(6) The Drug Outlet Pharmacy is required to comply with the pharmacist's determination in (4) and**  
738 **retain records.**

739  
740 **(7) Prior to working at a Telework Site, the Intern or Certified Oregon Pharmacy Technician and the**  
741 **Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on**  
742 **the use of all equipment necessary for secure operation of the Telework Site.**

743  
744 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**  
745 **Statutes/Other Implemented: ORS 689.155**

746  
747  
748  
749 **855-041-3240**

750 **Telework: Environment and Security**

751  
752 **(1) Telework Sites must be:**

753  
754 **(a) Located in a designated area where:**

755  
756 **(A) All equipment is stored;**

757  
758 **(B) All work is performed; and**

759  
760 **(C) Confidentiality is maintained such that patient information cannot be viewed or overheard by**  
761 **anyone other than the Pharmacist, Intern or Certified Oregon Pharmacy Technician.**

762  
763 **(2) The Pharmacist-in-charge of the Drug Outlet Pharmacy and each Oregon licensed Pharmacist**  
764 **supervising a Telework Site is responsible for ensuring the Telework Site has a designated work area**  
765 **that is secure and has been approved and documented by an Oregon licensed Pharmacist prior to**  
766 **utilization.**

- 767 **(3) All computer equipment used at the Telework Site must:**  
768  
769 **(a) Establish and maintain a secure connection to the pharmacy and patient information;**  
770  
771 **(b) Utilize equipment that prevents unauthorized access to the pharmacy and patient information;**  
772 **and**  
773  
774 **(c) Be configured so that the pharmacy and patient information is not accessible when:**  
775  
776 **(A) There is no Oregon licensed Pharmacist actively supervising the Intern or Certified Oregon**  
777 **Pharmacy Technician who is assisting in the practice of pharmacy from a Telework Site;or**  
778  
779 **(B) There is no Pharmacist, Intern or Certified Oregon Pharmacy Technician present at the Telework**  
780 **Site; or**  
781  
782 **(C) Any component of the real-time audio and visual connection is not functioning; and**  
783  
784 **(d) Comply with all security and confidentiality requirements.**  
785  
786 **(4) A record must be maintained with the date, time and identification of the licensee accessing**  
787 **patient or pharmacy records from a Telework Site.**  
788  
789 **(5) Interns and Certified Oregon Pharmacy Technicians may only work from a Telework Site when**  
790 **authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the**  
791 **Telework Site.**  
792  
793 **(6) All records must be stored in a secure manner that prevents access by unauthorized persons.**  
794  
795 **(7) Any breach in security or confidentiality must be documented and reported to the Board within**  
796 **ten days.**  
797  
798 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**  
799 **Statutes/Other Implemented: ORS 689.155**  
800  
801  
802  
803 **855-041-3245**  
804 **Telework: Policies and Procedures**  
805  
806 **(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the Drug Outlet Pharmacy and the**  
807 **Oregon licensed Pharmacist-in-charge is accountable for establishing, maintaining, and enforcing**  
808 **written policies and procedures for the licensees working from a Telework Site. The written policies**  
809 **and procedures must be maintained at the Drug Outlet Pharmacy and must be available to the board**  
810 **upon request.**  
811  
812 **(2) The written policies and procedures must include at a minimum the services, responsibilities and**  
813 **accountabilities of the licensee engaging in telework including;**  
814

- 815 **(a) Security;**  
816  
817 **(b) Operation, testing and maintenance of the audio and visual connection;**  
818  
819 **(c) Detailed description of work performed;**  
820  
821 **(d) Oregon licensed Pharmacist supervision, direction and control of Interns and Certified Oregon**  
822 **Pharmacy Technicians;**  
823  
824 **(e) Recordkeeping;**  
825  
826 **(f) Patient confidentiality;**  
827  
828 **(g) Continuous quality improvement;**  
829  
830 **(h) Plan for discontinuing and recovering services if audio and visual connection disruption occurs;**  
831  
832 **(i) Confirmation of dedicated, secure Telework Sites;**  
833  
834 **(j) Documenting the identity, function, location, date and time of the licensees engaging in telework;**  
835  
836 **(k) Written agreement with licensees engaging in telework outlining specific functions performed,**  
837 **conditions and policies governing the operation of the Telework Site; and**  
838  
839 **(l) Equipment.**

840  
841 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**  
842 **Statutes/Other Implemented: ORS 689.155**

843  
844  
845  
846 **855-041-3250**  
847 **Telework: Records**

848  
849 **(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the recordkeeping requirements OAR**  
850 **855-041-3205 through OAR 855-041-3250 are in addition to the requirements of other recordkeeping**  
851 **rules of the board. Unless otherwise specified, all records and documentation required by these rules**  
852 **must be retained for three years and made available to the board for inspection upon request.**  
853 **Records created at Telework Sites must be stored at the Drug Outlet for at least one year and may be**  
854 **stored, after one year, in a secured off-site location if retrievable within three business days. Records**  
855 **and documentation may be written, electronic or a combination of the two.**

856  
857 **(2) Records must be stored at the Telework site in a manner that prevents unauthorized access.**

858  
859 **(3) Records must include, but are not limited to:**

860  
861 **(a) Patient profiles and records;**  
862

863 **(b) Patient contact and services provided;**  
864  
865 **(c) Date, time and identification of the licensee accessing patient or pharmacy records from a**  
866 **Telework Site;**  
867  
868 **(d) If filling prescriptions, date, time and identification of the licensee and the specific activity or**  
869 **function of the person performing each step in the dispensing process;**  
870

871 **(e) List of employees working from Telework Sites that includes:**

872

873 **(A) Name;**

874

875 **(B) License number;**

876

877 **(C) Verification of each license;**

878

879 **(D) Address of Telework Site; and**

880

881 **(E) Name of the Oregon licensed Pharmacist who verified each licensure, approved licensee to**  
882 **telework and approved each Telework Site; Telework;**

883

884 **(f) Audio and visual connection testing and training;**

885

886 **(g) Data, telephone audio, audio and video, still image capture, store and forward images, security**  
887 **and surveillance data. This must be retained according to (1); and**

888

889 **(h) Any errors or irregularities identified by the quality improvement program.**

890

891 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

892 **Statutes/Other Implemented: ORS 689.155**

893

894

895

896 **~~855-041-5100~~**

897 **~~Definitions – Technician Checking Validation Program (TCVP)~~**

898

899 ~~(1) “Error” in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity,~~  
900 ~~or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item~~  
901 ~~counts as one error.~~

902

903 ~~(2) “Error” in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the~~  
904 ~~inclusion of any drug with an expired date. All errors in any single dose count as one error.~~

905

906 ~~(3) “Line Item” is a checking unit for ADC restocking (example: one specific drug and dose, regardless of~~  
907 ~~quantity).~~

908

909 ~~(4) “Technician Checker” is an Oregon certified technician who has completed the TCVP validation~~  
910 ~~process and is currently authorized to check another technician’s work.~~

911  
912 (5) "Technician Checking Validation Program (TCVP)" is a program that uses a technician checker to  
913 check functions completed by another technician.

914  
915 (6) "Unit Dose" is the physical quantity of a drug product designed to be administered to a patient  
916 specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The  
917 unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A  
918 drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a  
919 check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged,  
920 oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed  
921 IV products.

922  
923 NOTE: Technician Checking Validation Program (TCVP) The TCVP is a tool to allow the re-direction of a  
924 pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve  
925 patient safety by focusing on assessing the accuracy and <sup>[[1]]</sup>appropriateness of the medications ordered  
926 and on educating staff and patients. The development of individualized training programs is the  
927 responsibility of each pharmacy in order to tailor the program to the patient population and medication  
928 distribution system of the institution. Assessment questions must be tailored to the site and be changed  
929 periodically as appropriate. It is the responsibility of the pharmacist in charge to ensure that all training  
930 is completed and documented prior to a technician <sup>[[1]]</sup>performing as a technician checker.

931  
932 **Statutory/Other Authority:** ORS 689.205

933 **Statutes/Other Implemented:** ORS 689.155

934  
935 ~~855-041-5120~~

936 **Technician Checking Validation Program (TCVP) – Hospital and Pharmacist in Charge Requirements**

937  
938 (1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital  
939 pharmacy must meet the following requirements:

940  
941 (a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-  
942 risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be  
943 available in the pharmacy for board inspectors.

944  
945 (b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can  
946 be implemented;

947  
948 (c) The hospital pharmacy must have a drug distribution system that is structured to allow for one  
949 additional check of the distributed medications by a licensed nurse or other licensed health care  
950 professional with authority to administer medications after the delivery of checked medications; and

951  
952 (d) The Pharmacist in Charge is responsible for the TCVP and will document any error, or irregularity in  
953 the quality assurance documentation records.

954  
955 (2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of  
956 Pharmacy. To apply for approval, the hospital must submit the following to the Board:

957  
958 (a) Copies of written training material that will be used to train technicians as technician checkers;

959 (b) Copies of quality assurance documentation records and forms that will be used to evaluate the  
960 technician checkers and the proposed TCVP;

961  
962 (c) Copies of the policy and procedures for the proposed TCVP; and  
963

964 (d) A description of how the proposed TVCP will improve patient safety by focusing on assessing the  
965 accuracy and appropriateness of the medications ordered and on educating staff and patients.

966 (e) Other items as requested by the Board.  
967

968 ~~Statutory/Other Authority:~~ ORS 689.205

969 ~~Statutes/Other Implemented:~~ ORS 689.155

970

971 **855-041-5130**

972 **Technician Checking Validation Program (TCVP) – Technician Eligibility and Training**

973

974 (1) Only Oregon-certified technicians who undergo specific training may work as technician checkers.  
975 The training must include the following:

976

977 (a) A minimum of one year of drug distribution experience;

978

979 (b) Didactic lecture or equivalent training with a self-learning packet;

980

981 (c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a  
982 pharmacist; and

983

984 (d) Initial Validation Process as described in OAR 855-041-5140(1).

985

986 (2) The practical training sessions must include:

987

988 (a) The trainee observing a technician checker or pharmacist performing the checking process that the  
989 trainee is learning;

990

991 (b) The trainee performing the initial check with a pharmacist verifying all doses;

992

993 (c) The trainee completing the validation process with a pharmacist verifying all doses;

994

995 (d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the  
996 technician to catch errors. Artificial errors introduced into the live environment, which are not corrected  
997 by the technician, must be removed.

998

999 (e) The pharmacist must document and notify a technician checker of any errors found during training.

1000

1001 (3) If at any time a TCVP technician loses his or her validation the technician must be retrained and  
1002 revalidated before acting as a technician checker.

1003

1004 ~~Statutory/Other Authority:~~ ORS 689.205

1005 ~~Statutes/Other Implemented:~~ ORS 689.155

1006

1007 **855-041-5140**

1008 **Technician Checking Validation Program (TCVP) – Initial Validation Process and Quality Assurance**  
1009 **Process**

1010

1011 (1) Initial Validation Process: The initial process to validate a trainee’s ability to accurately check another  
1012 technician’s work must include:

1013

1014 (a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a  
1015 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who  
1016 makes more than three errors in 1500 doses fails the validation and may not work as a technician  
1017 checker until the checking process is repeated and until successfully completed.

1018

1019 (A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications  
1020 after the trainee has checked them. The pharmacist must document any errors in the unit of use cart  
1021 and discuss them with the trainee.

1022

1023 (B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist  
1024 coordinating the training check will keep a record of the introduced errors and will ensure that all  
1025 introduced errors are removed before medications are distributed.

1026

1027 (C) The pharmacist must document the results of each initial validation check and retain the results in  
1028 the quality assurance file.

1029

1030 (b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent  
1031 trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five  
1032 separate training checks. A trainee who makes more than one error in 500 line items fails the validation  
1033 and may not work as a technician checker until the checking process is repeated and until successfully  
1034 completed.

1035

1036 (A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent  
1037 tray or kit medications after the trainee has checked them. The pharmacist must document any errors  
1038 and discuss them with the trainee.

1039

1040 (B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The  
1041 pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are  
1042 removed before medications are distributed.

1043

1044 (C) The pharmacist must document the results of each initial validation check and retain the results in  
1045 the quality assurance file.

1046

1047 (2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of  
1048 technician checkers must include:

1049

1050 (a) Quality checks conducted in the same manner as the applicable initial validation process described in  
1051 section one of this rule, except that the quality check sample must consist of at least 300 doses for  
1052 technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-  
1053 emergent trays and kits.

1054

1055 (b) The quality checks must occur on random and unannounced dates and times.  
1056  
1057 (c) A technician checker who makes more than one error fails the quality check and may not work as a  
1058 technician checker unless the technician first passes a second quality check within 30 days of the failed  
1059 quality check. If the technician does not pass the second quality check within 30 days, the technician  
1060 must be retrained and revalidated before working as a technician checker.  
1061  
1062 (d) The results of each quality check must be documented, including the total number of doses or line  
1063 items checked, a description of each error, the total number of errors, and the percent error rate.  
1064 Documentation must be retained in the quality assurance file.  
1065  
1066 (3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least  
1067 monthly. A technician checker who has successfully completed three consecutive monthly quality checks  
1068 must be checked at least quarterly for at least one year. A technician checker who has successfully  
1069 completed four consecutive quarterly quality checks must be checked at least every six months.  
1070  
1071 (4) A technician checker who does not perform TCVP duties for more than six months must undergo  
1072 initial validation as described in section one of this rule.  
1073  
1074 (5) A description of the quality assurance process must be included in the hospital's and the pharmacy's  
1075 quality assurance program and error reporting system.  
1076  
1077 **Statutory/Other Authority:** ORS 689.205  
1078 **Statutes/Other Implemented:** ORS 689.155  
1079  
1080 **855-041-5150**  
1081 **Technician Checking Validation Program (TCVP) – Checking Procedure**  
1082 (1) A technician checker must use the following procedure when checking another technician's work:  
1083  
1084 (a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent  
1085 trays and kits.  
1086  
1087 (b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and  
1088 kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and  
1089 quantity and must review the expiration dates of medications.  
1090  
1091 (c) If the technician checker discovers a filling error the technician checker must record the error and  
1092 return the product to the technician who originally filled it, if available, or to another technician. The  
1093 filling technician must correct the error and the technician checker must check the correction. A  
1094 pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or  
1095 kit, or medication corrections filled by a technician checker  
1096  
1097 (d) If a technician checker is not available, then all doses must be checked by a pharmacist.  
1098  
1099 (2) This checking process continues until all doses have been checked and determined to be correct.  
1100



1101 ~~Statutory/Other Authority: ORS 689.205~~  
1102 ~~Statutes/Other Implemented: ORS 689.155~~

1103  
1104 ~~855-041-5160~~

1105 ~~Technician Checking Validation Program (TCVP) – Eligible Specialized Functions~~

1106  
1107 (1) The following specialized functions are eligible for participation in the TCVP:

- 1108  
1109 (a) Cart fill;  
1110  
1111 (b) ADC batch replacement; and  
1112  
1113 (c) Non-Emergent kits and trays.

1114  
1115 (2) Upon written request, the Board may permit additional specialized functions if to do so will further  
1116 public health or safety. A waiver granted under this section shall be effective only when issued in writing  
1117 and approved by the Board.

1118  
1119 ~~Statutory/Other Authority: ORS 689.205~~  
1120 ~~Statutes/Other Implemented: ORS 689.155~~

1121  
1122 ~~855-041-5170~~

1123 ~~Technician Checking Validation Program (TCVP) – Records~~

1124  
1125 (1) Unless specified otherwise, all records and documentation required by these rules must be retained  
1126 for three years and made available to the Board for inspection upon request. Records must be stored  
1127 onsite for at least one year and may be stored in a secured off-site location if retrievable within three  
1128 business days. Records and documentation may be written, electronic or a combination of the two.

1129  
1130 (2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure  
1131 patient health, safety and welfare. Records must include:

- 1132  
1133 (a) Technician checker training documents;  
1134  
1135 (b) List of high risk medications;  
1136  
1137 (c) Documentation of any errors, irregularities and results of each initial validation check.  
1138  
1139 (d) Documentation of quality assurance and forms used to evaluate the technician checker including:  
1140  
1141 (A) Total number of doses or line item checks;  
1142  
1143 (B) Description of errors;  
1144  
1145 (C) Total number of errors; and  
1146  
1147 (D) Percent error rate.

1148

1149 (e) Documentation of the initial validation check.  
1150  
1151 ~~Statutory/Other Authority:~~ ORS 689.205  
1152 ~~Statutes/Other Implemented:~~ ORS 689.155

PROPOSED

**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 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.

2 Division 6  
3 DEFINITIONS

4  
5 **855-006-0005**  
6 **Definitions**

7  
8 As used in OAR chapter 855:

9  
10 **(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).**

11  
12 ~~(12)~~ "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the  
13 context.

14  
15 ~~(23)~~ "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy  
16 who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board and has  
17 completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for  
18 clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by  
19 the pharmacist are not considered pharmacy technicians.

20  
21 ~~(34)~~ "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a  
22 health care organization or a physician that permits the pharmacist to engage in the practice of clinical  
23 pharmacy for the benefit of the patients of the health care organization or physician.

24  
25 ~~(45)~~ "Collaborative Drug Therapy Management" means the participation by a pharmacist in the  
26 management of drug therapy pursuant to a written protocol that includes information specific to the  
27 dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and  
28 initiated upon a prescription order for an individual patient and:

29  
30 (a) Is agreed to by one pharmacist and one practitioner; or

31  
32 (b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or  
33 more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group  
34 practice, including but not limited to organized medical groups using a pharmacy and therapeutics  
35 committee.

36  
37 ~~(56)~~ "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or  
38 device:

39  
40 (a) As the result of a practitioner's prescription drug order, or initiative based on the relationship  
41 between the practitioner, the pharmacist and the patient, in the course of professional practice; or

42  
43 (b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or  
44 dispensing; or

45  
46 (c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine,  
47 regularly observed prescribing patterns.

48  
49 ~~(67)~~ "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

50  
51 ~~(78)~~ "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient  
52 medication, therapy management, drug storage and management, security, education, or any other  
53 pharmaceutical service.

54  
55 ~~(89)~~ The "Container" is the device that holds the drug and that is or may be in direct contact with the  
56 drug.

57  
58 ~~(910)~~ "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a  
59 lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration  
60 to or use by a patient or other individual entitled to receive the prescription drug.

61  
62 ~~(1011)~~ "Interpretation and evaluation of prescription orders" means the review of the order for  
63 therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug  
64 ordered, its applicability and its relationship to the other known medications used by the patient and  
65 determination of whether or not the dose and time interval of administration are within accepted limits  
66 of safety. The legal review for correctness of the prescription order includes a determination that the  
67 order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose,  
68 contains all information required by federal and state law, and is within the practitioner's scope of  
69 practice.

70  
71 ~~(1112)~~ "Labeling" means the process of preparing and affixing of a label to any drug container exclusive,  
72 however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or  
73 commercially packaged legend drug or device.

74  
75 **(13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).**

76  
77 ~~(1214)~~ "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of  
78 the therapeutic or adverse effect of medication upon a patient, including direct consultation with the  
79 patient or his agent and review of patient records, as to result and side effect, and the analysis of  
80 possible interactions with other medications that may be in the medication regimen of the patient. This  
81 section shall not be construed to prohibit monitoring by practitioners or their agents.

82  
83 ~~(1315)~~ "Medication Therapy Management (MTM)" means a distinct service or group of services that is  
84 intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management  
85 services are independent of, but can occur in conjunction with, the provision of a medication product.

86  
87 ~~(1416)~~ "Nationally Certified Exam" means an exam that is approved by the Board which demonstrates  
88 successful completion of a Specialized Education Program. The exam must be reliable, psychometrically  
89 sound, legally defensible and valid.

90  
91 ~~(1517)~~ "Non-legend drug" means a drug which does not require dispensing by prescription and which is  
92 not restricted to use by practitioners only.

93  
94 ~~(1618)~~ "Offering or performing of those acts, services, operations or transactions necessary in the  
95 conduct, operation, management and control of pharmacy" means, among other things:

96  
97 (a) The creation and retention of accurate and complete patient records;

98  
99 (b) Assuming authority and responsibility for product selection of drugs and devices;  
100  
101 (c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the  
102 general public;  
103  
104 (d) Maintaining confidentiality of patient information.  
105  
106 **(19) "Official compendium" means the official United States Pharmacopeia <USP>, official National**  
107 **Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States**  
108 **<HPUS> (v.2021), or any supplement to any of these.**

109  
110 (~~1720~~) "Oral Counseling" means an oral communication process between a pharmacist and a patient or  
111 a patient's agent in which the pharmacist obtains information from the patient (or agent) and the  
112 patient's pharmacy records, assesses that information and provides the patient (or agent) with  
113 professional advice regarding the safe and effective use of the prescription drug for the purpose of  
114 assuring therapeutic appropriateness.

115  
116 (~~1821~~) Participation in Drug Selection and Drug Utilization Review:

117  
118 (a) "Participation in drug selection" means the consultation with the practitioner in the selection of the  
119 best possible drug for a particular patient.

120  
121 (b) "Drug utilization review" means evaluating prescription drug order in light of the information  
122 currently provided to the pharmacist by the patient or the patient's agent and in light of the information  
123 contained in the patient's record for the purpose of promoting therapeutic appropriateness by  
124 identifying potential problems and consulting with the prescriber, when appropriate. Problems subject  
125 to identification during drug utilization review include, but are not limited to:

126  
127 (A) Over-utilization or under-utilization;

128  
129 (B) Therapeutic duplication;

130  
131 (C) Drug-disease contraindications;

132  
133 (D) Drug-drug interactions;

134  
135 (E) Incorrect drug dosage;

136  
137 (F) Incorrect duration of treatment;

138  
139 (G) Drug-allergy interactions; and

140  
141 (H) Clinical drug abuse or misuse.

142  
143 (~~1922~~) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of  
144 achieving definite outcomes that improve a patient's quality of life. These outcomes include:

145

- 146 (a) Cure of a disease;  
147  
148 (b) Elimination or reduction of a patient's symptomatology;  
149  
150 (c) Arrest or slowing of a disease process; or  
151  
152 (d) Prevention of a disease or symptomatology.  
153  
154 ~~(2023)~~ "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the  
155 pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the  
156 specialized education program pursuant to OAR 855-025-0012.  
157  
158 ~~(2124)~~ "Practice of clinical pharmacy" means:  
159  
160 (a) The health science discipline in which, in conjunction with the patient's other practitioners, a  
161 pharmacist provides patient care to optimize medication therapy and to promote disease prevention  
162 and the patient's health and wellness;  
163  
164 (b) The provision of patient care services, including but not limited to post-diagnostic disease state  
165 management services; and  
166  
167 (c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.  
168  
169 ~~(2225)~~ "Practice of pharmacy" is as defined in ORS 689.005.  
170  
171 ~~(2326)~~ "Prescription released by the pharmacist" means, a prescription which has been reviewed by the  
172 pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.  
173  
174 ~~(2427)~~ "Prohibited conduct" means conduct by a licensee that:  
175  
176 (a) Constitutes a criminal act against a patient or client; or  
177  
178 (b) Constitutes a criminal act that creates a risk of harm to a patient or client.  
179  
180 ~~(2528)~~ "Proper and safe storage of drugs and devices and maintenance of proper records therefore"  
181 means housing drugs and devices under conditions and circumstances that:  
182  
183 (a) Assure retention of their purity and potency;  
184  
185 (b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;  
186  
187 (c) Assure security and minimize the risk of their loss through accident or theft;  
188  
189 (d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;  
190  
191 (e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from  
192 harmful exposure to hazardous substances.  
193

194 ~~(2629)~~ "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned  
195 and systematic process for the monitoring and evaluation of the quality and appropriateness of  
196 pharmacy services and for identifying and resolving problems.

197  
198 ~~(2730)~~ "Responsibility for advising, when necessary or when regulated, of therapeutic values, content,  
199 hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing  
200 as required by these rules or federal regulation, of the possible therapeutic response to the medication,  
201 the names of the chemicals in the medication, the possible side effects of major importance, and the  
202 methods of use or administration of a medication.

203  
204 ~~(2831)~~ "Specialized Education Program" means;

205  
206 (a) A program providing education for persons desiring licensure as pharmacy technicians that is  
207 approved by the board and offered by an accredited college or university that grants a two-year degree  
208 upon successful completion of the program; or

209  
210 (b) A structured program approved by the board and designed to educate pharmacy technicians in one  
211 or more specific issues of patient health and safety that is offered by:

212  
213 (A) An organization recognized by the board as representing pharmacists or pharmacy technicians;

214  
215 (B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

216  
217 (C) A trade association recognized by the board as representing pharmacies.

218  
219 ~~(29)~~ "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy  
220 technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control  
221 and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action.  
222 During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic,  
223 "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being  
224 supervised, coupled with the ability to control and be responsible for the technician or interns actions  
225 and for the following remote processing functions only: prescription or order entry, other data entry,  
226 and insurance processing of prescriptions and medication orders.

227  
228 ~~(3032)~~ "Therapeutic substitution" means the act of dispensing a drug product with a different chemical  
229 structure for the drug product prescribed under circumstances where the prescriber has not given clear  
230 and conscious direction for substitution of the particular drug for the one which may later be ordered.

231  
232 ~~(3133)~~ "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy  
233 and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a  
234 certified Oregon pharmacy technician.

235  
236 Statutory/Other Authority: ORS 689.205

237 Statutes/Other Implemented: ORS 689.151 & ORS 689.155

238  
239  
240  
241



242 **855-041-1060**

243 **Non-Resident Pharmacies**

244

245 (1) For the purpose of these rules, a non-resident pharmacy **is any establishment located out of Oregon**  
246 **that engages in the dispensing, delivery or distribution of drugs to Oregon. A non-resident pharmacy**  
247 **also includes entities that provide pharmacy services to Oregon, such as drugless/consulting outlets,**  
248 **even if the entity is not dispensing, delivering or distributing drugs into Oregon.** ~~includes, but is not~~  
249 ~~limited to: Retail, Institutional, Remote Processing, Central Fill, and Drugless/Consulting Drug Outlets.~~

250

251 (2) Every non-resident pharmacy that provides drugs, devices or services to a resident in this state  
252 ~~shall~~**must** be registered with the Oregon Board of Pharmacy.

253

254 (3) To qualify for registration under these rules, every non-resident pharmacy ~~shall~~**must** be registered  
255 and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

256

257 (4) Every out-of-state non-resident pharmacy ~~shall~~**must** designate an Oregon licensed Pharmacist-in-  
258 Charge (PIC), who ~~shall~~**must** be responsible for all pharmacy services provided to residents in Oregon,  
259 and to provide supervision and control in the pharmacy. To qualify for this designation, the person must:

260

261 (a) Hold a license to practice pharmacy in the resident state;

262

263 (b) Be normally present in the pharmacy for a minimum of 20 hours per week;

264

265 (c) Complete the annual non-resident PIC self-inspection report prior to February 1 each year; and

266

267 (d) Provide the PIC self-inspection report as requested by the Board.

268

269 (5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within  
270 four months of initial licensure of the pharmacy.

271

272 (6) When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the  
273 Board within ten business days and identify a contact person. The pharmacy will have an Oregon  
274 licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the  
275 pharmacy's state of residence and is responsible for the following:

276

277 (a) Supervision of pharmacy staff and ensuring compliance with laws and rules; and

278

279 (b) Responding to Board correspondence and inquiries.

280

281 (7) A new Pharmacist-in-Charge must be appointed, and communication made to the Board within 90  
282 days, or the non-resident pharmacy will cease drug distribution and provision of pharmacy services in  
283 Oregon.

284

285 Statutory/Other Authority: ORS 689.205

286 Statutes/Other Implemented: ORS 689.151, **ORS** 689.155 & **ORS** 689.225

287

288

289

290 ~~855-041-3000~~  
291 ~~Central Fill and Remote Processing Outlet Designations and Consulting/Drugless Pharmacy Outlets–~~  
292 ~~Purpose and Scope~~  
293

294 (1) ~~The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of~~  
295 ~~operation for centralized prescription drug filling by a pharmacy.~~  
296

297 (2) ~~The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of~~  
298 ~~operation for remote prescription processing by a pharmacy.~~  
299

300 (3) ~~Prior to initiating one of the above drug outlet models, a description of how the model will be~~  
301 ~~utilized must be submitted to the Board.~~  
302

303 (4) ~~The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where~~  
304 ~~a consulting pharmacist can provide pharmaceutical care and store health protected information in a~~  
305 ~~consulting or drugless pharmacy. Prior to initiating this model, a description of how the model will be~~  
306 ~~utilized to improve patient safety must be submitted to the Board.~~  
307

308 ~~Statutory/Other Authority: ORS 689.205~~

309 ~~Statutes/Other Implemented: ORS 689.155~~  
310

311 ~~855-041-3100~~

312 ~~Remote Processing – Purpose and Scope~~  
313

314 ~~The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of~~  
315 ~~operation for remote prescription drug processing by a pharmacy. Any facility that processes drug~~  
316 ~~orders on behalf of an Oregon pharmacy shall be licensed in Oregon as a retail or institutional drug~~  
317 ~~outlet. An applicant must submit its policies and procedures to the Board of Pharmacy. An applicant~~  
318 ~~must submit to the Board for approval policies and procedures and a description of how using remote~~  
319 ~~processing will improve patient safety.~~  
320

321 ~~Statutory/Other Authority: ORS 689.205~~

322 ~~Statutes/Other Implemented: ORS 689.155~~  
323

324 ~~855-041-3105~~

325 ~~Remote Processing – Definitions~~  
326

327 ~~The following words and terms, when used in OAR 855-041-3100 through 855-041-3130, shall have the~~  
328 ~~following meanings, unless the context clearly indicates otherwise. Any term not defined in this section~~  
329 ~~shall have the definition set out in OAR chapter 855, division 006.~~  
330

331 (1) ~~“Remote Processing Pharmacy” means an Oregon licensed pharmacy operated under the direction of~~  
332 ~~a pharmacist in charge that processes information related to the practice of pharmacy and engages in~~  
333 ~~remote prescription processing, including central processing.~~  
334

335 (2) ~~“Remote Processing Functions” may include, but are not limited to, data entry, prospective drug~~  
336 ~~utilization reviews, refill authorizations and interventions. This does not include the filling process.~~  
337

338 (3) "Primary Pharmacy" means an in-state Oregon licensed pharmacy that receives a patient's or a  
339 prescribing practitioner's request to fill a prescription or drug order and delivers the drug or device  
340 directly to the patient or patient's agent, and maintains ownership of the prescription or drug order.  
341

342 Statutory/Other Authority: ORS 689.205

343 Statutes/Other Implemented: ORS 689.155

344

345 **855-041-3110**

346 **Remote Processing – General Requirements**

347

348 An Oregon licensed pharmacy may outsource prescription drug processing to a remote processing  
349 pharmacy provided both pharmacies:

350

351 (1) Have the same owner; or

352

353 (2) Have a written shared pharmacy services contract or agreement that specifies:

354

355 (a) The services to be provided by each pharmacy;

356

357 (b) The responsibilities of each pharmacy; and

358

359 (c) The accountabilities of each pharmacy.

360

361 (3) Maintain a separate Oregon pharmacy license for each location involved in providing services;

362

363 (4) Share a common electronic file or have appropriate technology or interface to allow access to  
364 information required to process and fill a prescription drug order;

365

366 (5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3115;

367

368 (6) Ensure that each prescription has been properly processed, filled and counseling has been provided  
369 to the patient;

370

371 (7) Designate a pharmacist in charge. To qualify for this designation, the person must hold a license to  
372 practice pharmacy in the state of Oregon and in the pharmacy's resident state if the pharmacy is out-of-  
373 state. The pharmacist in charge must be in good standing with both licensing Boards;

374

375 (8) Allow prospective drug utilization reviews, refill authorizations, interventions, and patient counseling  
376 for an Oregon patient must be performed only by a licensed pharmacist in Oregon or in the state in  
377 which the pharmacy is located;

378

379 (9) Ensure that each technician processing an order for an Oregon patient is a Certified Oregon  
380 Pharmacy Technician and is supervised by a licensed pharmacist or is a licensed technician in the state in  
381 which the pharmacy is located and is supervised by a licensed pharmacist in the state in which the  
382 pharmacy is located;

383

384 (10) Comply with all applicable federal and state laws and rules;

385

386 (11) Conduct an annual review of the written policies and procedures and document such review.

387

388 Statutory/Other Authority: ORS 689.205

389 Statutes/Other Implemented: ORS 689.155

390

391 ~~855-041-3115~~

392 ~~Remote Processing—Policies and Procedures~~

393

394 (1) In addition to the requirements of OAR 855-041-1040, the primary and the remote processing  
395 pharmacy is each accountable for establishing, maintaining, and enforcing its own written policies and  
396 procedures manual. The policies and procedures manual must include, but need not be limited to the  
397 following:

398

399 (a) The responsibilities of each pharmacy;

400

401 (b) The policies and procedures that protect confidentiality and ensure the integrity of patient  
402 information;

403

404 (c) Compliance with all applicable federal and state laws and rules;

405

406 (d) Records sufficient to identify by name, initials, or unique identification code, the identity and the  
407 specific activities of each pharmacist or technician who performed any processing function, and the  
408 location where each activity was performed;

409

410 (e) A continuous quality improvement program for pharmacy services designed to objectively and  
411 systematically monitor and evaluate the quality and appropriateness of patient care, to pursue  
412 opportunities to improve patient care, and to resolve identified problems; and

413

414 (f) Documentation of any errors or irregularities identified by the quality improvement program.

415

416 (2) The written policies and procedures manual shall be maintained at all pharmacies involved in remote  
417 processing and must be available to the Board upon request.

418

419 Statutory/Other Authority: ORS 689.205

420 Statutes/Other Implemented: ORS 689.155

421

422 ~~855-041-3120~~

423 ~~Remote Processing—Records~~

424

425 (1) The recordkeeping requirements OAR 855-041-3100 through 855-041-3130 are in addition to the  
426 requirements of other recordkeeping rules of the Board.

427

428 (2) The remote processing pharmacy must maintain all required records unless these records are  
429 maintained in the primary pharmacy.

430

431 (3) Both recordkeeping systems must:

432

- 433 (a) List the name, address, telephone number, and all license and registration numbers of each  
434 pharmacy involved in remote prescription processing;  
435  
436 (A) Document verification of each license and registration;  
437  
438 (B) Document the name of the individual responsible for verification of licensure and registration status.  
439  
440 (b) Identify by name, initials, or unique identification code the identity and the specific activities of each  
441 pharmacist or technician who performed any part of the prescription process;  
442  
443 (c) Include quality improvement program documentation;  
444  
445 (d) Be able to produce an audit trail showing each prescription process.  
446  
447 (4) Unless otherwise specified, all records and documentation required by these rules, must be retained  
448 for three years and made available to the Board for inspection upon request. Records must be stored  
449 onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable  
450 within three business days. Records and documentation may be written, electronic or a combination of  
451 the two;  
452  
453 (5) The primary pharmacy shall maintain records that:  
454  
455 (a) Indicate the date the request for processing was transmitted to the remote processing pharmacy;  
456 and  
457  
458 (b) Indicate the date the prescription information was received by the primary pharmacy.  
459  
460 (6) The remote processing pharmacy shall maintain records that:  
461  
462 (a) Track the prescription drug order during each step in the order entry process;  
463  
464 (b) Identify the name, initials, or unique identification code and the specific activity of each pharmacist  
465 or pharmacy technician who performed any activity related to processing the prescription including  
466 receipt, transmission or delivery of information.  
467

468 Statutory/Other Authority: ORS 689.205

469 Statutes/Other Implemented: ORS 689.155

470  
471 **~~855-041-3125~~**

472 **~~Remote Processing – Prescription or Drug Order Processing~~**

473  
474 A prescription or drug order for a controlled substance may be processed by a remote processing  
475 pharmacy when permitted by law and consistent with federal rules.  
476

477 Statutory/Other Authority: ORS 689.205

478 Statutes/Other Implemented: ORS 689.155

479

480

481 **~~855-041-3130~~**

482 **~~Remote Processing—Prohibited Practices~~**

483

484 A remote processing pharmacy may not process a prescription on behalf of a primary pharmacy that is  
485 not registered with the Board, if required by the laws and rules of Oregon to be registered.

486

487 Statutory/Other Authority: ORS 689.205

488 Statutes/Other Implemented: ORS 689.155

489

490

491 **855-041-3200**

492 **Telework: Purpose and Scope**

493

494 **The purpose of OAR 855-041-3200 through OAR 855-041-3250 is to provide minimum requirements**  
495 **for pharmacy services conducted via telework.**

496

497 Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205

498 Statutes/Other Implemented: ORS 689.155

499

500

501

502 **855-041-3205**

503 **Telework: Definitions**

504

505 **(1) “Telework” means the practice or assistance in the practice of pharmacy physically outside of a**  
506 **registered drug outlet in a telework site.**

507

508 **(2) “Telework Site” means a location that is not a registered drug outlet where an Oregon licensed**  
509 **Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist**  
510 **in the practice of pharmacy as employees of an Oregon registered drug outlet.**

511

512 Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205

513 Statutes/Other Implemented: ORS 689.155

514

515

516

517 **855-041-3210**

518 **Telework: Registration**

519

520 **The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of the Drug Outlet**  
521 **Pharmacy are responsible for all licensees engaging in the practice of pharmacy or assisting in the**  
522 **practice of pharmacy from Telework Sites.**

523

524 Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205

525 Statutes/Other Implemented: ORS 689.155

526

527

528

529 **855-041-3215**

530 **Telework: General Requirements**

531

532 **(1) Each Oregon registered Drug Outlet Pharmacy and Pharmacist-in-charge of a Drug Outlet**  
533 **Pharmacy must ensure that Interns and Certified Oregon Pharmacy Technicians working from a**  
534 **Telework Site work under the supervision, direction and control of an Oregon licensed Pharmacist.**

535

536 **(2) A Pharmacist that engages in the practice of pharmacy and an Intern or Certified Oregon Pharmacy**  
537 **Technician that assists in the practice of pharmacy from a Telework Site for any person or facility**  
538 **located in Oregon must:**

539

540 **(a) Be licensed by the board; and**

541

542 **(b) Comply with all applicable federal and state laws and rules.**

543

544 **(3) Drugs and devices may not be at a Telework Site.**

545

546 **(4) The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of a Drug Outlet**  
547 **Pharmacy must:**

548

549 **(a) Have a written agreement that includes all conditions, duties and policies governing the licensee**  
550 **engaged in telework activities;**

551

552 **(b) Maintain a continuously updated list of all licensees engaged in telework and the Telework Sites to**  
553 **include:**

554

555 **(A) Address, phone number and hours that telework is performed for each Telework Site;**

556

557 **(B) Functions being performed by licensees engaged in telework; and**

558

559 **(C) The Oregon licensed Pharmacist providing supervision, direction and control for each non-**  
560 **pharmacist licensee;**

561

562 **(c) Develop, implement and enforce a continuous quality improvement program for services provided**  
563 **from a Telework Site designed to objectively and systematically:**

564

565 **(A) Monitor, evaluate, document the quality and appropriateness of patient care;**

566

567 **(B) Improve patient care; and**

568

569 **(C) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their**  
570 **reoccurrence;**

571

572 **(d) Develop, implement and enforce a procedure for identifying the Oregon licensed Pharmacist,**  
573 **Intern and Certified Oregon Pharmacy Technician responsible for each telework function;**

574

575 **(e) Develop, implement and enforce a process for a virtual inspection of the Telework Site by an**  
576 **Oregon licensed Pharmacist at least once every 6 months or more frequently as deemed necessary by**  
577 **the Oregon licensed Pharmacist. The inspection must be documented and records retained; and**  
578

579 **(f) Utilize an Oregon licensed Pharmacist and real-time audio and visual communication to provide**  
580 **counseling or accept the refusal of counseling from the patient or the patient’s agent for each**  
581 **prescription being dispensed when counseling is required under OAR 855-019-0230 or when**  
582 **requested and document the interaction.**  
583

584 **POLICY DISCUSSION:** A/V Requirement  
585

586 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**  
587 **Statutes/Other Implemented: ORS 689.155**  
588

591 **855-041-3220**

592 **Telework: Supervision Requirements**  
593

594 **The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the**  
595 **supervising Oregon licensed Pharmacist from the Drug Outlet must:**  
596

597 **(1) Utilize a continuous real-time audio and visual connection that is recorded, reviewed and stored**  
598 **and have appropriate technology or interface to allow access to information required to complete**  
599 **assigned duties;**  
600

601 **(2) Ensure all telephone audio is recorded, reviewed and stored;**  
602

603 **(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and**  
604 **Certified Oregon Pharmacy Technician and that the continuous audio/visual connection is fully**  
605 **operational;**  
606

607 **(4) Ensure that an Oregon licensed Pharmacist performs random “check-ins” via the real-time audio**  
608 **and visual connection at least once every 2 hours to ensure compliance with federal and state laws**  
609 **and patient safety and document the interaction;**  
610

611 **(5) Be readily available to answer questions and fully responsible for the practice and accuracy of the**  
612 **licensee; and**  
613

614 **(6) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon**  
615 **licensed Pharmacist who is providing supervision, direction and control at all times.**  
616

617 **(7) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy**  
618 **Technician at a Telework Site must:**  
619

620 **(a) Using professional judgment, determine the percentage of patient interactions for each licensee**  
621 **that must be reviewed to ensure public health and safety with a minimum of 25% of patient**  
622 **interactions reviewed;**



623  
624 **(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee**  
625 **is acting within the authority permitted under their license and patients are connected with a**  
626 **pharmacist upon request;**

627  
628 **(c) Document the following within 24 hours of the review in (b):**

629  
630 **(A) Number of each licensee’s patient interactions;**

631  
632 **(B) Number of each licensee’s patient interactions pharmacist is reviewing;**

633  
634 **(C) Date and time of licensee patient interaction pharmacist is reviewing;**

635  
636 **(D) Date and time of pharmacist review of licensee’s patient interaction; and**

637  
638 **(E) Pharmacist notes of each interaction reviewed; and**

639  
640 **(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of**  
641 **discovery and to the board within 10 days.**

642  
643 **(8) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist’s determination in**  
644 **(7)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain**  
645 **records.**

646  
647 **POLICY DISCUSSION:** Frequency of review

648  
649 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

650 **Statutes/Other Implemented: ORS 689.155**

651  
652  
653  
654 **855-041-3225**

655 **Telework: Confidentiality**

656  
657 **The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet Pharmacy, and**  
658 **the Pharmacist, Intern and Certified Oregon Pharmacy Technician from the Drug Outlet Pharmacy**  
659 **must:**

660  
661 **(1) Ensure patient and prescription information is managed in compliance with OAR 855-019, OAR**  
662 **855-025, OAR 855-031, and OAR 855-041.**

663  
664 **(2) Ensure the security and confidentiality of patient information and pharmacy records.**

665  
666 **(3) Document and report any breach in the security of the system or breach of confidentiality. Report**  
667 **of the breach must be reported in writing to the board within ten days of the event.**

668  
669 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

670 **Statutes/Other Implemented: ORS 689.155**

671 **855-041-3230**  
672 **Telework: Technology**

673  
674 **The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the**  
675 **Pharmacist from the Drug Outlet must:**

676  
677 **(1) Use still image capture or store and forward for verification of prescriptions with a camera that is**  
678 **of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered**  
679 **Drug Outlet Pharmacy can visually identify each:**

680  
681 **(a) Source container including manufacturer, name, strength, lot, and expiration;**

682  
683 **(b) Dispensed product including the imprint and physical characteristics;**

684  
685 **(c) Completed prescription container including the label; and**

686  
687 **(d) Ancillary document provided to patient at the time of dispensing.**

688  
689 **POLICY DISCUSSION:** Remote Verification

690  
691 **(2) Test the continuous audio and visual connection and document that it operates properly before**  
692 **engaging in telework.**

693  
694 **(3) Develop, implement and enforce a plan for responding to and recovering from an interruption of**  
695 **service which prevents an Oregon licensed Pharmacist from supervising, directing and controlling the**  
696 **Intern and Certified Oregon Pharmacy Technician at the Telework Site.**

697  
698 **(4) Ensure access to:**

699  
700 **(a) Appropriate and current pharmaceutical references based on the services offered; and**

701  
702 **(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States**  
703 **Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services**  
704 **offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters.**

705  
706 **(5) Train the Oregon licensed Pharmacists, Interns and Certified Oregon Pharmacy Technicians in the**  
707 **operation of continuous audio and visual connection.**

708  
709 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

710 **Statutes/Other Implemented: ORS 689.155**

711  
712  
713 **855-041-3235**  
714 **Telework: Personnel**

715  
716 **(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all**  
717 **operations at Drug Outlet Pharmacy including responsibility for the continuous audio and visual**  
718 **connection and enforcing policies and procedures.**

719 **(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel at**  
720 **Telework Sites.**

721  
722 **(3) An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have**  
723 **at least one year experience performing similar services for an Oregon registered Drug Outlet**  
724 **Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy**  
725 **Technician begins working at the Remote Dispensing Site Pharmacy.**

726  
727 **POLICY DISCUSSION:** Experience

728  
729 **(4) The Oregon licensed Pharmacist from the Drug Outlet Pharmacy who is supervising a licensee at a**  
730 **Telework Site must determine and document how many licensed individuals the pharmacist is capable**  
731 **of supervising, directing and controlling based on the services being provided.**

732  
733 **(5) When supervising an Intern or Certified Oregon Pharmacy Technician working at a Telework Site,**  
734 **the Oregon licensed Pharmacist may supervise no more than four licensees among all locations,**  
735 **including the Drug Outlet Pharmacy.**

736  
737 **(6) The Drug Outlet Pharmacy is required to comply with the pharmacist's determination in (4) and**  
738 **retain records.**

739  
740 **(7) Prior to working at a Telework Site, the Intern or Certified Oregon Pharmacy Technician and the**  
741 **Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on**  
742 **the use of all equipment necessary for secure operation of the Telework Site.**

743  
744 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**  
745 **Statutes/Other Implemented: ORS 689.155**

746  
747  
748  
749 **855-041-3240**

750 **Telework: Environment and Security**

751  
752 **(1) Telework Sites must be:**

753  
754 **(a) Located in a designated area where:**

755  
756 **(A) All equipment is stored;**

757  
758 **(B) All work is performed; and**

759  
760 **(C) Confidentiality is maintained such that patient information cannot be viewed or overheard by**  
761 **anyone other than the Pharmacist, Intern or Certified Oregon Pharmacy Technician.**

762  
763 **(2) The Pharmacist-in-charge of the Drug Outlet Pharmacy and each Oregon licensed Pharmacist**  
764 **supervising a Telework Site is responsible for ensuring the Telework Site has a designated work area**  
765 **that is secure and has been approved and documented by an Oregon licensed Pharmacist prior to**  
766 **utilization.**

- 767 **(3) All computer equipment used at the Telework Site must:**  
768  
769 **(a) Establish and maintain a secure connection to the pharmacy and patient information;**  
770  
771 **(b) Utilize equipment that prevents unauthorized access to the pharmacy and patient information;**  
772 **and**  
773  
774 **(c) Be configured so that the pharmacy and patient information is not accessible when:**  
775  
776 **(A) There is no Oregon licensed Pharmacist actively supervising the Intern or Certified Oregon**  
777 **Pharmacy Technician who is assisting in the practice of pharmacy from a Telework Site; or**  
778  
779 **(B) There is no Pharmacist, Intern or Certified Oregon Pharmacy Technician present at the Telework**  
780 **Site; or**  
781  
782 **(C) Any component of the real-time audio and visual connection is not functioning; and**  
783  
784 **(d) Comply with all security and confidentiality requirements.**  
785  
786 **(4) A record must be maintained with the date, time and identification of the licensee accessing**  
787 **patient or pharmacy records from a Telework Site.**  
788  
789 **(5) Interns and Certified Oregon Pharmacy Technicians may only work from a Telework Site when**  
790 **authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the**  
791 **Telework Site.**  
792  
793 **(6) All records must be stored in a secure manner that prevents access by unauthorized persons.**  
794  
795 **(7) Any breach in security or confidentiality must be documented and reported to the Board within**  
796 **ten days.**  
797  
798 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**  
799 **Statutes/Other Implemented: ORS 689.155**  
800  
801  
802  
803 **855-041-3245**  
804 **Telework: Policies and Procedures**  
805  
806 **(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the Drug Outlet Pharmacy and the**  
807 **Oregon licensed Pharmacist-in-charge is accountable for establishing, maintaining, and enforcing**  
808 **written policies and procedures for the licensees working from a Telework Site. The written policies**  
809 **and procedures must be maintained at the Drug Outlet Pharmacy and must be available to the board**  
810 **upon request.**  
811  
812 **(2) The written policies and procedures must include at a minimum the services, responsibilities and**  
813 **accountabilities of the licensee engaging in telework including;**  
814

- 815 **(a) Security;**  
816  
817 **(b) Operation, testing and maintenance of the audio and visual connection;**  
818  
819 **(c) Detailed description of work performed;**  
820  
821 **(d) Oregon licensed Pharmacist supervision, direction and control of Interns and Certified Oregon**  
822 **Pharmacy Technicians;**  
823  
824 **(e) Recordkeeping;**  
825  
826 **(f) Patient confidentiality;**  
827  
828 **(g) Continuous quality improvement;**  
829  
830 **(h) Plan for discontinuing and recovering services if audio and visual connection disruption occurs;**  
831  
832 **(i) Confirmation of dedicated, secure Telework Sites;**  
833  
834 **(j) Documenting the identity, function, location, date and time of the licensees engaging in telework;**  
835  
836 **(k) Written agreement with licensees engaging in telework outlining specific functions performed,**  
837 **conditions and policies governing the operation of the Telework Site; and**  
838  
839 **(l) Equipment.**

840  
841 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**  
842 **Statutes/Other Implemented: ORS 689.155**

843  
844  
845  
846 **855-041-3250**  
847 **Telework: Records**

848  
849 **(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the recordkeeping requirements OAR**  
850 **855-041-3205 through OAR 855-041-3250 are in addition to the requirements of other recordkeeping**  
851 **rules of the board. Unless otherwise specified, all records and documentation required by these rules**  
852 **must be retained for three years and made available to the board for inspection upon request.**  
853 **Records created at Telework Sites must be stored at the Drug Outlet for at least one year and may be**  
854 **stored, after one year, in a secured off-site location if retrievable within three business days. Records**  
855 **and documentation may be written, electronic or a combination of the two.**

856  
857 **(2) Records must be stored at the Telework site in a manner that prevents unauthorized access.**

858  
859 **(3) Records must include, but are not limited to:**

860  
861 **(a) Patient profiles and records;**  
862

- 863 **(b) Patient contact and services provided;**  
864  
865 **(c) Date, time and identification of the licensee accessing patient or pharmacy records from a**  
866 **Telework Site;**  
867  
868 **(d) If filling prescriptions, date, time and identification of the licensee and the specific activity or**  
869 **function of the person performing each step in the dispensing process;**  
870  
871 **(e) List of employees working from Telework Sites that includes:**

872  
873 **(A) Name;**

874  
875 **(B) License number;**

876  
877 **(C) Verification of each license;**

878  
879 **(D) Address of Telework Site; and**

880  
881 **(E) Name of the Oregon licensed Pharmacist who verified each licensure, approved licensee to**  
882 **telework and approved each Telework Site; Telework;**

883  
884 **(f) Audio and visual connection testing and training;**

885  
886 **(g) Data, telephone audio, audio and video, still image capture, store and forward images, security**  
887 **and surveillance data. This must be retained according to (1); and**

888  
889 **(h) Any errors or irregularities identified by the quality improvement program.**

890  
891 **Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205**

892 **Statutes/Other Implemented: ORS 689.155**

893  
894  
895  
896 **~~855-041-5100~~**

897 **~~Definitions – Technician Checking Validation Program (TCVP)~~**

898  
899 ~~(1) “Error” in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity,~~  
900 ~~or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item~~  
901 ~~counts as one error.~~

902  
903 ~~(2) “Error” in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the~~  
904 ~~inclusion of any drug with an expired date. All errors in any single dose count as one error.~~

905  
906 ~~(3) “Line Item” is a checking unit for ADC restocking (example: one specific drug and dose, regardless of~~  
907 ~~quantity).~~

908  
909 ~~(4) “Technician Checker” is an Oregon certified technician who has completed the TCVP validation~~  
910 ~~process and is currently authorized to check another technician’s work.~~

911  
912 (5) "Technician Checking Validation Program (TCVP)" is a program that uses a technician checker to  
913 check functions completed by another technician.

914  
915 (6) "Unit Dose" is the physical quantity of a drug product designed to be administered to a patient  
916 specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The  
917 unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A  
918 drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a  
919 check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged,  
920 oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed  
921 IV products.

922  
923 NOTE: Technician Checking Validation Program (TCVP) The TCVP is a tool to allow the re-direction of a  
924 pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve  
925 patient safety by focusing on assessing the accuracy and <sup>[1]</sup>appropriateness of the medications ordered  
926 and on educating staff and patients. The development of individualized training programs is the  
927 responsibility of each pharmacy in order to tailor the program to the patient population and medication  
928 distribution system of the institution. Assessment questions must be tailored to the site and be changed  
929 periodically as appropriate. It is the responsibility of the pharmacist in charge to ensure that all training  
930 is completed and documented prior to a technician <sup>[1]</sup>performing as a technician checker.

931  
932 **Statutory/Other Authority:** ORS 689.205

933 **Statutes/Other Implemented:** ORS 689.155

934  
935 ~~855-041-5120~~

936 **Technician Checking Validation Program (TCVP) – Hospital and Pharmacist in Charge Requirements**

937  
938 (1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital  
939 pharmacy must meet the following requirements:

940  
941 (a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-  
942 risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be  
943 available in the pharmacy for board inspectors.

944  
945 (b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can  
946 be implemented;

947  
948 (c) The hospital pharmacy must have a drug distribution system that is structured to allow for one  
949 additional check of the distributed medications by a licensed nurse or other licensed health care  
950 professional with authority to administer medications after the delivery of checked medications; and

951  
952 (d) The Pharmacist in Charge is responsible for the TCVP and will document any error, or irregularity in  
953 the quality assurance documentation records.

954  
955 (2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of  
956 Pharmacy. To apply for approval, the hospital must submit the following to the Board:

957  
958 (a) Copies of written training material that will be used to train technicians as technician checkers;

959 (b) Copies of quality assurance documentation records and forms that will be used to evaluate the  
960 technician checkers and the proposed TCVP;

961  
962 (c) Copies of the policy and procedures for the proposed TCVP; and  
963

964 (d) A description of how the proposed TVCP will improve patient safety by focusing on assessing the  
965 accuracy and appropriateness of the medications ordered and on educating staff and patients.

966 (e) Other items as requested by the Board.  
967

968 ~~Statutory/Other Authority:~~ ORS 689.205

969 ~~Statutes/Other Implemented:~~ ORS 689.155

970

971 ~~855-041-5130~~

972 ~~Technician Checking Validation Program (TCVP) – Technician Eligibility and Training~~

973

974 (1) Only Oregon-certified technicians who undergo specific training may work as technician checkers.  
975 The training must include the following:

976

977 (a) A minimum of one year of drug distribution experience;

978

979 (b) Didactic lecture or equivalent training with a self-learning packet;

980

981 (c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a  
982 pharmacist; and

983

984 (d) Initial Validation Process as described in OAR 855-041-5140(1).

985

986 (2) The practical training sessions must include:

987

988 (a) The trainee observing a technician checker or pharmacist performing the checking process that the  
989 trainee is learning;

990

991 (b) The trainee performing the initial check with a pharmacist verifying all doses;

992

993 (c) The trainee completing the validation process with a pharmacist verifying all doses;

994

995 (d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the  
996 technician to catch errors. Artificial errors introduced into the live environment, which are not corrected  
997 by the technician, must be removed.

998

999 (e) The pharmacist must document and notify a technician checker of any errors found during training.

1000

1001 (3) If at any time a TCVP technician loses his or her validation the technician must be retrained and  
1002 revalidated before acting as a technician checker.

1003

1004 ~~Statutory/Other Authority:~~ ORS 689.205

1005 ~~Statutes/Other Implemented:~~ ORS 689.155

1006



1007 **855-041-5140**

1008 **Technician Checking Validation Program (TCVP) – Initial Validation Process and Quality Assurance**  
1009 **Process**

1010

1011 (1) Initial Validation Process: The initial process to validate a trainee’s ability to accurately check another  
1012 technician’s work must include:

1013

1014 (a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a  
1015 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who  
1016 makes more than three errors in 1500 doses fails the validation and may not work as a technician  
1017 checker until the checking process is repeated and until successfully completed.

1018

1019 (A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications  
1020 after the trainee has checked them. The pharmacist must document any errors in the unit of use cart  
1021 and discuss them with the trainee.

1022

1023 (B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist  
1024 coordinating the training check will keep a record of the introduced errors and will ensure that all  
1025 introduced errors are removed before medications are distributed.

1026

1027 (C) The pharmacist must document the results of each initial validation check and retain the results in  
1028 the quality assurance file.

1029

1030 (b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent  
1031 trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five  
1032 separate training checks. A trainee who makes more than one error in 500 line items fails the validation  
1033 and may not work as a technician checker until the checking process is repeated and until successfully  
1034 completed.

1035

1036 (A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent  
1037 tray or kit medications after the trainee has checked them. The pharmacist must document any errors  
1038 and discuss them with the trainee.

1039

1040 (B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The  
1041 pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are  
1042 removed before medications are distributed.

1043

1044 (C) The pharmacist must document the results of each initial validation check and retain the results in  
1045 the quality assurance file.

1046

1047 (2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of  
1048 technician checkers must include:

1049

1050 (a) Quality checks conducted in the same manner as the applicable initial validation process described in  
1051 section one of this rule, except that the quality check sample must consist of at least 300 doses for  
1052 technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-  
1053 emergent trays and kits.

1054

1055 (b) The quality checks must occur on random and unannounced dates and times.  
1056  
1057 (c) A technician checker who makes more than one error fails the quality check and may not work as a  
1058 technician checker unless the technician first passes a second quality check within 30 days of the failed  
1059 quality check. If the technician does not pass the second quality check within 30 days, the technician  
1060 must be retrained and revalidated before working as a technician checker.  
1061  
1062 (d) The results of each quality check must be documented, including the total number of doses or line  
1063 items checked, a description of each error, the total number of errors, and the percent error rate.  
1064 Documentation must be retained in the quality assurance file.  
1065  
1066 (3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least  
1067 monthly. A technician checker who has successfully completed three consecutive monthly quality checks  
1068 must be checked at least quarterly for at least one year. A technician checker who has successfully  
1069 completed four consecutive quarterly quality checks must be checked at least every six months.  
1070  
1071 (4) A technician checker who does not perform TCVP duties for more than six months must undergo  
1072 initial validation as described in section one of this rule.  
1073  
1074 (5) A description of the quality assurance process must be included in the hospital's and the pharmacy's  
1075 quality assurance program and error reporting system.  
1076  
1077 **Statutory/Other Authority:** ORS 689.205  
1078 **Statutes/Other Implemented:** ORS 689.155  
1079  
1080 **855-041-5150**  
1081 **Technician Checking Validation Program (TCVP) – Checking Procedure**  
1082 (1) A technician checker must use the following procedure when checking another technician's work:  
1083  
1084 (a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent  
1085 trays and kits.  
1086  
1087 (b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and  
1088 kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and  
1089 quantity and must review the expiration dates of medications.  
1090  
1091 (c) If the technician checker discovers a filling error the technician checker must record the error and  
1092 return the product to the technician who originally filled it, if available, or to another technician. The  
1093 filling technician must correct the error and the technician checker must check the correction. A  
1094 pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or  
1095 kit, or medication corrections filled by a technician checker  
1096  
1097 (d) If a technician checker is not available, then all doses must be checked by a pharmacist.  
1098  
1099 (2) This checking process continues until all doses have been checked and determined to be correct.  
1100

1101 ~~Statutory/Other Authority:~~ ORS 689.205  
1102 ~~Statutes/Other Implemented:~~ ORS 689.155

1103  
1104 ~~855-041-5160~~

1105 ~~Technician Checking Validation Program (TCVP) – Eligible Specialized Functions~~

1106  
1107 (1) The following specialized functions are eligible for participation in the TCVP:  
1108  
1109 (a) Cart fill;  
1110  
1111 (b) ADC batch replacement; and  
1112  
1113 (c) Non-Emergent kits and trays.  
1114  
1115 (2) Upon written request, the Board may permit additional specialized functions if to do so will further  
1116 public health or safety. A waiver granted under this section shall be effective only when issued in writing  
1117 and approved by the Board.

1118  
1119 ~~Statutory/Other Authority:~~ ORS 689.205  
1120 ~~Statutes/Other Implemented:~~ ORS 689.155

1121  
1122 ~~855-041-5170~~

1123 ~~Technician Checking Validation Program (TCVP) – Records~~

1124  
1125 (1) Unless specified otherwise, all records and documentation required by these rules must be retained  
1126 for three years and made available to the Board for inspection upon request. Records must be stored  
1127 onsite for at least one year and may be stored in a secured off-site location if retrievable within three  
1128 business days. Records and documentation may be written, electronic or a combination of the two.  
1129  
1130 (2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure  
1131 patient health, safety and welfare. Records must include:  
1132  
1133 (a) Technician checker training documents;  
1134  
1135 (b) List of high risk medications;  
1136  
1137 (c) Documentation of any errors, irregularities and results of each initial validation check.  
1138  
1139 (d) Documentation of quality assurance and forms used to evaluate the technician checker including:  
1140  
1141 (A) Total number of doses or line item checks;  
1142  
1143 (B) Description of errors;  
1144  
1145 (C) Total number of errors; and  
1146  
1147 (D) Percent error rate.  
1148

1149 (e) Documentation of the initial validation check.  
1150  
1151 ~~Statutory/Other Authority:~~ ORS 689.205  
1152 ~~Statutes/Other Implemented:~~ ORS 689.155

PROPOSED

## SBAR: Pharmacy Technician Licensure

S	<p>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.</p>
B	<p><a href="#">OAR 855-025-0012</a> requires an applicant to take and pass a national pharmacy technician certification exam and then apply for licensure as a COPT.</p> <p>Pharmacy Technician Certification Board (PTCB) requirements:</p> <ul style="list-style-type: none"> <li>• complete a PTCB-recognized education/training program, or;</li> <li>• complete at least 500 work hours and attest to fulfilling specified knowledge requirements</li> </ul> <p>National Healthcare Association (NHA) requires:</p> <ul style="list-style-type: none"> <li>• completion of a training program (employer-based or offered by national pharmacy association) that is recognized by the <a href="#">Board of Pharmacy</a>, or;</li> <li>• 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.</li> </ul> <p>With the new PTCB and existing NHA requirements:</p> <ul style="list-style-type: none"> <li>• A PT who has not recently completed the required training requirements is not eligible to take the exam</li> <li>• An individual who had a technician license that has been lapsed in the last 5 years: <ul style="list-style-type: none"> <li>○ Is not eligible for a COPT license</li> <li>○ Is not eligible to complete a training program as a PT or work in a pharmacy to obtain the required hours</li> </ul> </li> </ul> <p>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.</p> <p><a href="#">OAR 855-025-0060(2)</a> Reinstatement of a COPT License – states: A Certified Oregon Pharmacy Technician whose license <b>has been lapsed greater than five years must:</b></p> <p>(a) Re-take and pass a national pharmacy technician certification examination offered by:</p> <p>(A) The Pharmacy Technician Certification Board (PTCB); or</p> <p>(B) National Healthcareer Association (NHA).</p> <ul style="list-style-type: none"> <li>○ 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. <b>This represents a higher bar for reinstatement than for initial licensure.</b> (See above - <a href="#">OAR 855-025-0012</a>)</li> </ul> <p><a href="#">OAR 855-025-0005</a> (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.</p> <p>This means:</p> <ul style="list-style-type: none"> <li>• 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 <ul style="list-style-type: none"> <li>○ 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</li> <li>○ <a href="#">There is no waiver to the rules</a></li> </ul> </li> </ul>

[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”)

	<ul style="list-style-type: none"> <li>• National certification is not a “specialized education program”</li> <li>• Duties are not different for a PT vs COPT</li> </ul>
A	<ul style="list-style-type: none"> <li>• Pharmacy Technician rules require revision to remove barriers to licensure and clarify language. Current rules have affected pharmacy staffing in communities in Oregon.</li> </ul>
R	<ul style="list-style-type: none"> <li>• <i>Policy Discussion at October board meeting:</i></li> <li>• <i>Direct staff to draft rules that resolve barriers to PT licensure</i></li> <li>• <i>Provide broad policy direction (single license, education, certification, initial limitations on tasks for new technicians, specific duties vs. pharmacist discretion)</i></li> <li>• <i>Continue discussion at Strategic Planning meeting</i></li> </ul>



## **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





## OREGON BOARD OF PHARMACY DELEGATION OF AUTHORITY

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.



## OREGON BOARD OF PHARMACY DELEGATION OF AUTHORITY

- 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.



## OREGON BOARD OF PHARMACY DELEGATION OF AUTHORITY

- 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.
-

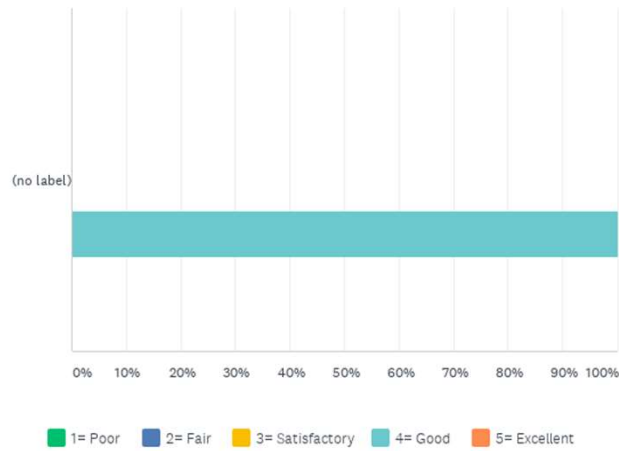


1



2

## Q1: This program provides a thorough review of women's reproductive health.



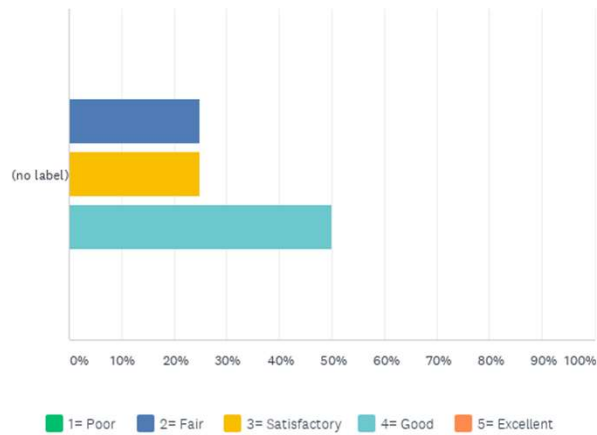
3

## 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.

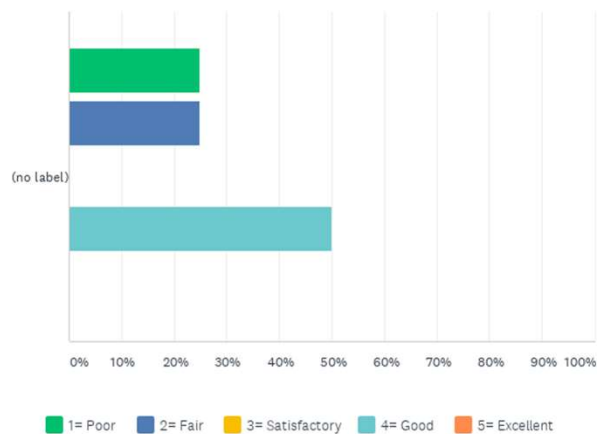
6

## 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 drospirinone 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 an 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

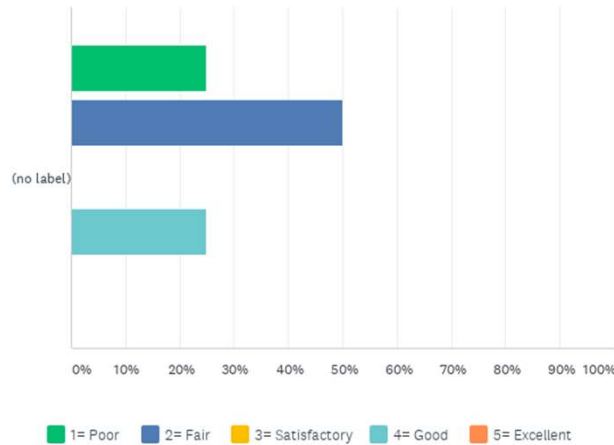
### Q3: This program comprehensively teaches the "art" of patient assessment, evaluation and contraceptive product selection.

- ▶ 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.



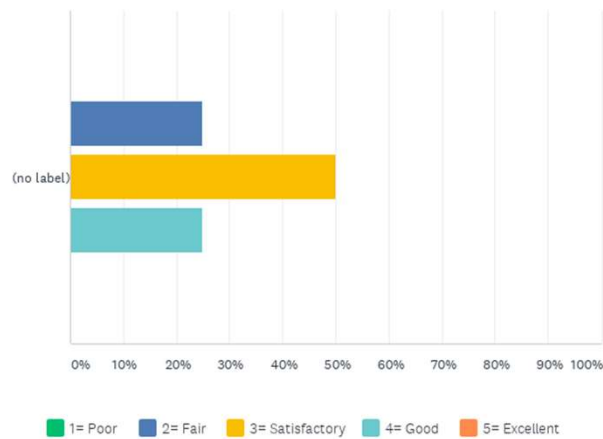
11

#### 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.

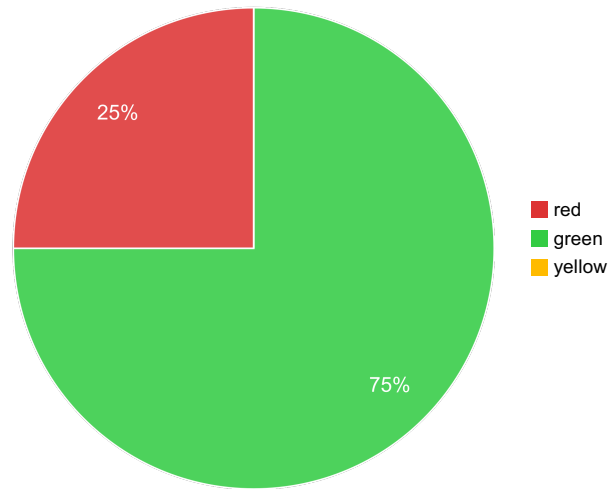
## **Pharmacy, Board of**

Annual Performance Progress Report

Reporting Year 2021

Published: 10/1/2021 12:46:26 PM

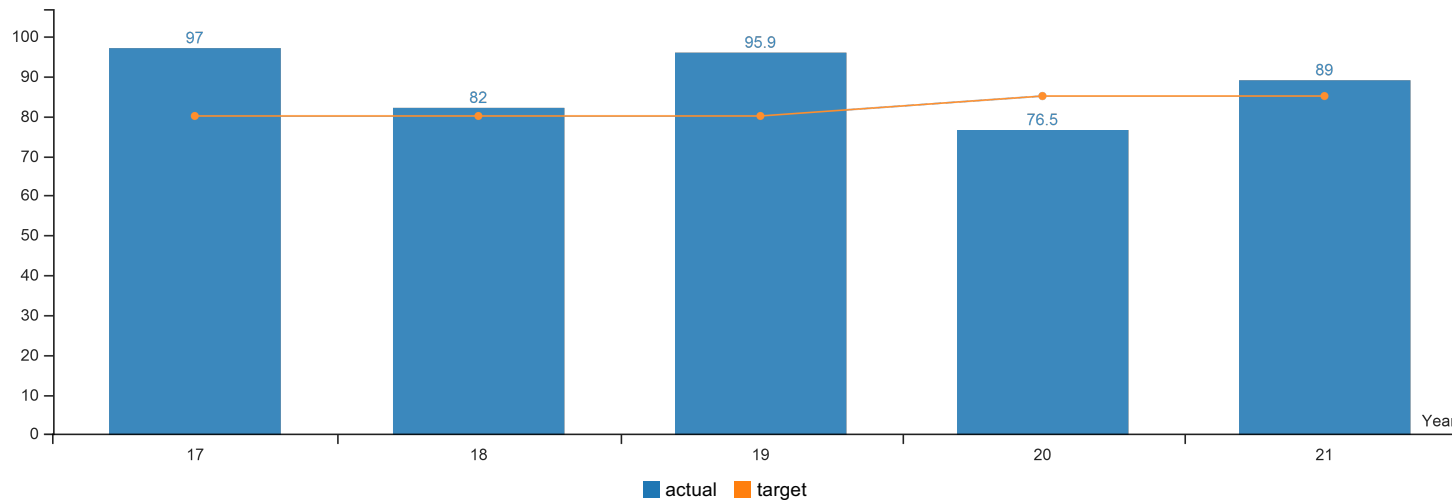
KPM #	Approved Key Performance Measures (KPMs)
1	Percent of inspected pharmacies that are in compliance annually. -
2	Percentage of individual and facility licenses that are issued within 30 days. -
3	Percent of pharmacies inspected every two years. -
4	Average number of days to complete an investigation 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
<b>Percentage of Pharmacies that are in compliance annually.</b>					
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.

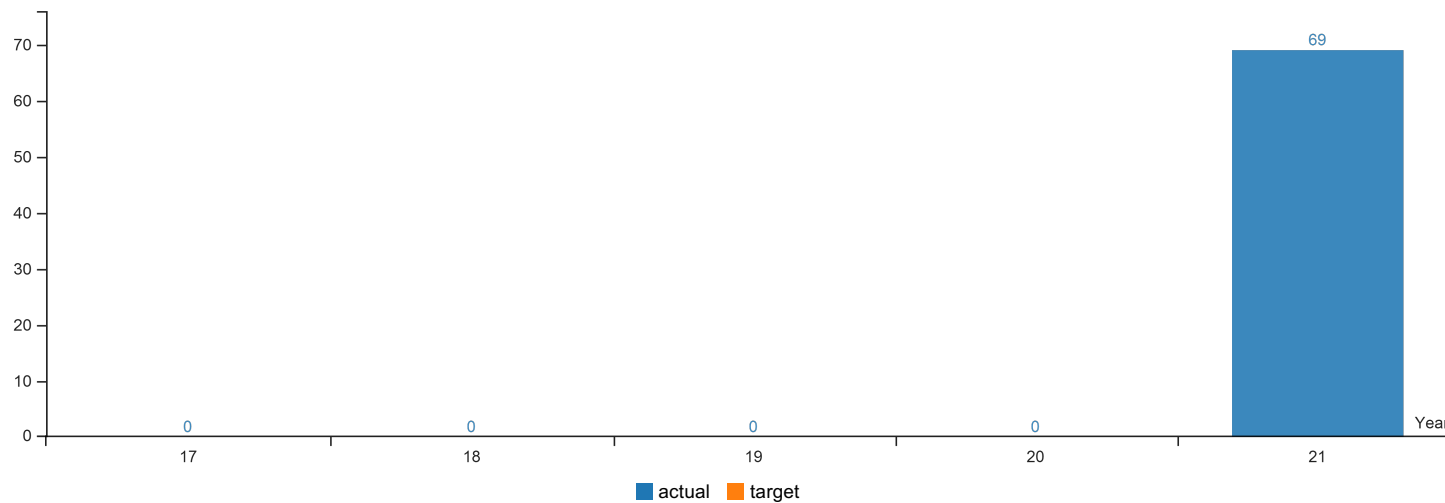
### Factors Affecting Results

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
<b>Percentage of individual and facility licenses that are issued within 30 days.</b>					
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.

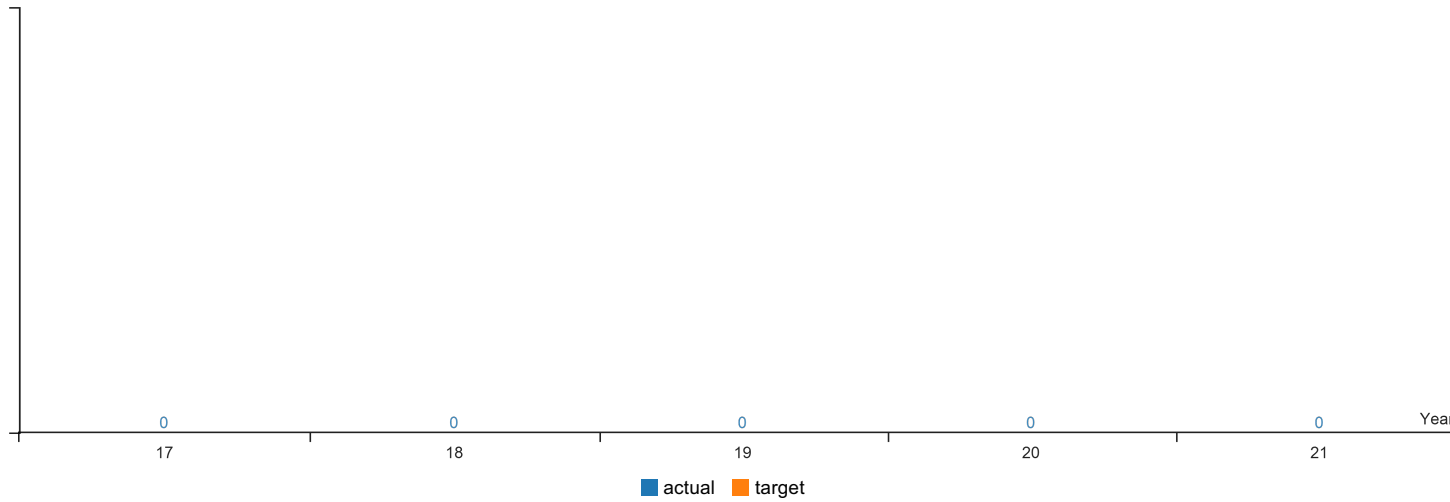
Applications that required Compliance Department and Board review were also impacted by the COVID-19 public health emergency. Much of the focus of the Compliance staff in 2020 was answering questions and following up with individuals to ensure the health, safety and welfare of patients, as well as pharmacy 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
<b>Percent of pharmacies inspected every 2 years.</b>					
Actual					
Target					

**How Are We Doing**

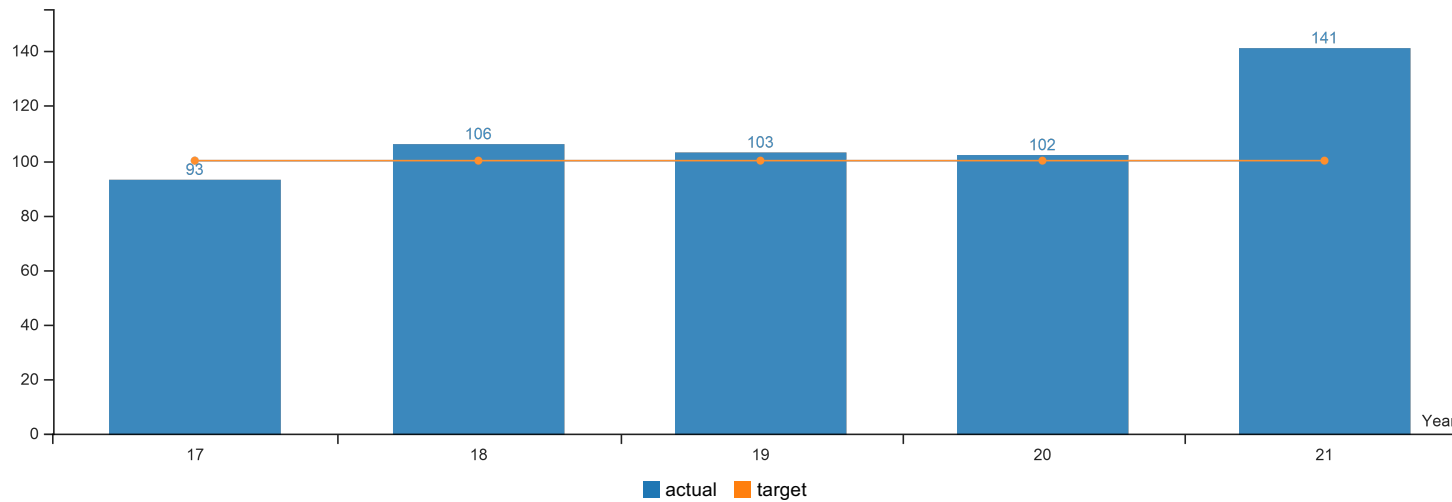
This measure was changed from annual to every two-year inspections effective 7/1/2021. Results for this measure will be reported in 2022 for calendar year 2021.

**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
<b>Number of days to process complete investigation from complaint to Board presentation.</b>					
Actual	93	106	103	102	141
Target	100	100	100	100	100

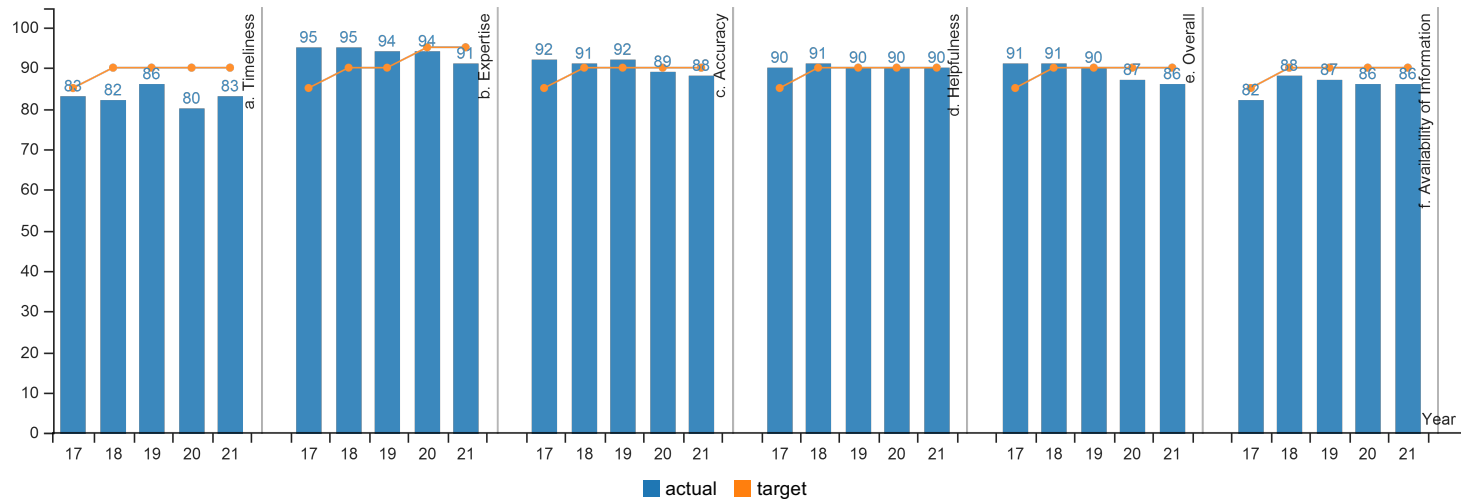
#### How Are We Doing

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
<b>a. Timeliness</b>					
Actual	83%	82%	86%	80%	83%
Target	85%	90%	90%	90%	90%
<b>b. Expertise</b>					
Actual	95%	95%	94%	94%	91%
Target	85%	90%	90%	95%	95%
<b>c. Accuracy</b>					
Actual	92%	91%	92%	89%	88%
Target	85%	90%	90%	90%	90%
<b>d. Helpfulness</b>					
Actual	90%	91%	90%	90%	90%
Target	85%	90%	90%	90%	90%
<b>e. Overall</b>					
Actual	91%	91%	90%	87%	86%
Target	85%	90%	90%	90%	90%
<b>f. Availability of Information</b>					
Actual	82%	88%	87%	86%	86%
Target	85%	90%	90%	90%	90%

How Are We Doing

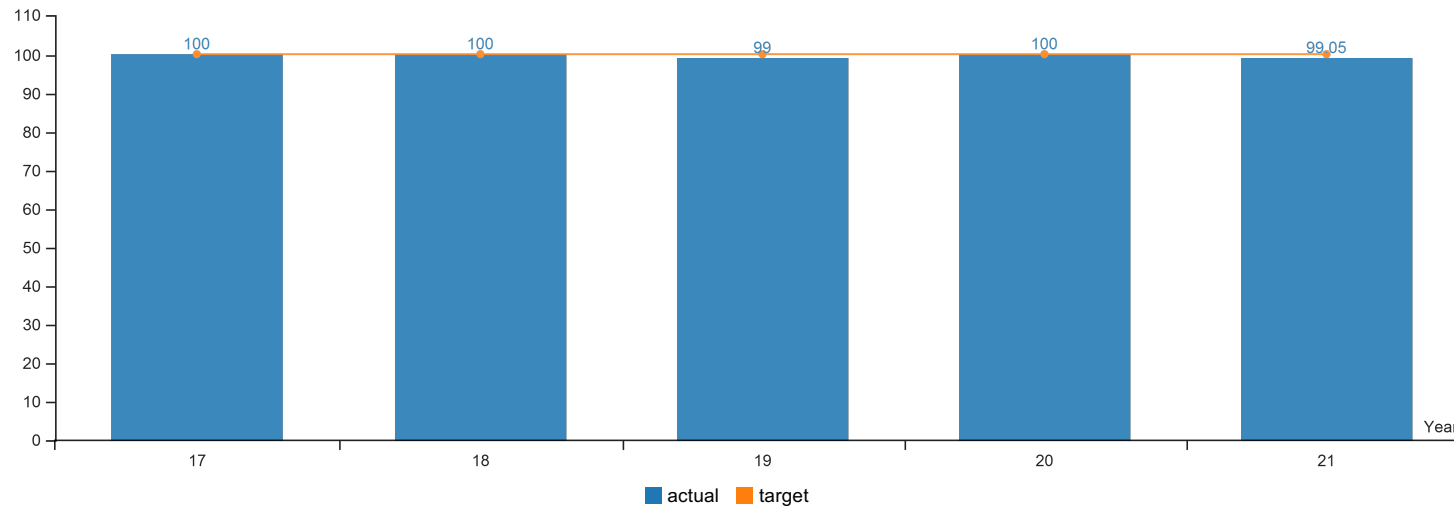
Our overall average of 87.5% is a decrease of .2% from 2019. The percentage results provided, represent the respondents who responded with a rating of either Excellent or Good. Those that responded "Don't Know" or "N/A" were not factored into these ratings.

**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
<b>Is the Board following Best Practices?</b>					
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

<p><b>S</b></p>	<p><b>Situation:</b> 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.</p>
<p><b>B</b></p>	<p><b>Background:</b></p> <ul style="list-style-type: none"> <li>• Regulations: <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ 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</li> </ul> </li> </ul> <p><b>Description:</b></p> <ul style="list-style-type: none"> <li>• In 2019, the Cancer Center registration changed from a drug room registration to a pharmacy registration, RP-0003512, prompting the need for this request.</li> <li>• 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.</li> <li>• 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.</li> </ul>
<p><b>A</b></p>	<p><b>Assessment:</b> Drug outlet registrations impacted are:</p> <ul style="list-style-type: none"> <li>• IP-0000616 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay) <ul style="list-style-type: none"> <li>○ Issue Date: 3/15/1974</li> </ul> </li> <li>• RP-0000822 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay) <ul style="list-style-type: none"> <li>○ Issue Date: 2/11/1981</li> </ul> </li> <li>• RP-0003512 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay) <ul style="list-style-type: none"> <li>○ Issue date: 9/5/19</li> </ul> </li> </ul>
<p><b>R</b></p>	<p><b>Recommendation:</b> 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)</p>

Inquiry Date: 10/7/2021

Board review: October 2021 meeting

**From:** [Schnebly, Eric](#)  
**To:** [HENNIGAN Chrysy \\* 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 Chrysy \* BOP <[Chrysy.HENNIGAN@bop.oregon.gov](mailto:Chrysy.HENNIGAN@bop.oregon.gov)>  
**Sent:** Wednesday, October 6, 2021 14:41  
**To:** Schnebly, Eric <[Eric.Schnebly@bayareahospital.org](mailto:Eric.Schnebly@bayareahospital.org)>  
**Subject:** RE: Request for PIC of Multiple Registrants

**CAUTION:** This email originated outside of Bay Area Hospital. Do not click links or open attachments unless you recognize the sender and know the content is safe.

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,

*Chrysy*

**Chrysy 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>



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---

**From:** Schnebly, Eric <[Eric.Schnebly@bayareahospital.org](mailto:Eric.Schnebly@bayareahospital.org)>  
**Sent:** Wednesday, October 6, 2021 2:38 PM  
**To:** HENNIGAN Chrysy \* BOP <[Chrysy.HENNIGAN@bop.oregon.gov](mailto:Chrysy.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](mailto:Chrisy.HENNIGAN@bop.oregon.gov)>

**Sent:** Wednesday, October 6, 2021 13:13

**To:** Schnebly, Eric <[Eric.Schnebly@bayareahospital.org](mailto:Eric.Schnebly@bayareahospital.org)>

**Subject:** RE: Request for PIC of Multiple Registrants

**CAUTION:** This email originated outside of Bay Area Hospital. Do not click links or open attachments unless you recognize the sender and know the content is safe.

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

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keep the contents confidential, and immediately delete the message and any attachments from your system.

---

**From:** Schnebly, Eric <[Eric.Schnebly@bayareahospital.org](mailto:Eric.Schnebly@bayareahospital.org)>  
**Sent:** Wednesday, October 6, 2021 12:58 PM  
**To:** HENNIGAN Chrissy \* BOP <[Chrissy.HENNIGAN@bop.oregon.gov](mailto:Chrissy.HENNIGAN@bop.oregon.gov)>  
**Cc:** [ericshnebly@gmail.com](mailto:ericshnebly@gmail.com); LOOSLI Tracy \* BOP <[Tracy.LOOSLI@bop.oregon.gov](mailto:Tracy.LOOSLI@bop.oregon.gov)>; HUNT Michael \*BOP <[Michael.HUNT@bop.oregon.gov](mailto: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 Chrissy \* BOP <[Chrissy.HENNIGAN@bop.oregon.gov](mailto:Chrissy.HENNIGAN@bop.oregon.gov)>  
**Sent:** Wednesday, October 6, 2021 12:44  
**To:** Schnebly, Eric <[Eric.Schnebly@bayareahospital.org](mailto:Eric.Schnebly@bayareahospital.org)>  
**Cc:** [ericshnebly@gmail.com](mailto:ericshnebly@gmail.com); LOOSLI Tracy \* BOP <[Tracy.LOOSLI@bop.oregon.gov](mailto:Tracy.LOOSLI@bop.oregon.gov)>; HUNT Michael \*BOP <[Michael.HUNT@bop.oregon.gov](mailto:Michael.HUNT@bop.oregon.gov)>  
**Subject:** RE: Request for PIC of Multiple Registrants

**CAUTION:** This email originated outside of Bay Area Hospital. Do not click links or open attachments unless you recognize the sender and know the content is safe.

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,

*Chrissy*

**Chrissy 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>



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---

**From:** Schnebly, Eric <[Eric.Schnebly@bayareahospital.org](mailto:Eric.Schnebly@bayareahospital.org)>  
**Sent:** Wednesday, October 6, 2021 8:39 AM  
**To:** PHARMACY BOARD \* BOP <[PHARMACY.BOARD@oregon.gov](mailto:PHARMACY.BOARD@oregon.gov)>  
**Cc:** [ericshnebly@gmail.com](mailto:ericshnebly@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 9<sup>th</sup>, 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**  
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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  
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

<p><b>S</b></p>	<p><b>Situation:</b>                  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.</p>						
<p><b>B</b></p>	<p><b>Background:</b></p> <ul style="list-style-type: none"> <li>• Regulations:                         <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ 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</li> </ul> </li> </ul> <p><b>Description:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• The Cancer Center registration change from a drug room registration to a pharmacy registration has been completed. The new license number is: RP-0003512.</li> <li>• 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.</li> <li>•Contact information:                         <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Heather Loudon-Howley, RPH-0017301</td> <td style="width: 50%;">Bay Area Hospital</td> </tr> <tr> <td>Directory of Pharmacy</td> <td>1775 Thompson Rd</td> </tr> <tr> <td>Phone: 541-269-8490</td> <td>Coos Bay, OR 97420</td> </tr> </table> </li> </ul>	Heather Loudon-Howley, RPH-0017301	Bay Area Hospital	Directory of Pharmacy	1775 Thompson Rd	Phone: 541-269-8490	Coos Bay, OR 97420
Heather Loudon-Howley, RPH-0017301	Bay Area Hospital						
Directory of Pharmacy	1775 Thompson Rd						
Phone: 541-269-8490	Coos Bay, OR 97420						
<p><b>A</b></p>	<p><b>Assessment:</b>                  Drug outlet registrations impacted are:</p> <ul style="list-style-type: none"> <li>• IP-0000616 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay)</li> <li>• RP-0000822 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay)</li> <li>• RP-0003512 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay)                         <ul style="list-style-type: none"> <li>○ Issue date: 9/5/19</li> </ul> </li> </ul>						
<p><b>R</b></p>	<p><b>Recommendation:</b>                  Staff recommendation for approval to replace Susanne McClelland as PIC with Heather Loudon-Howley for Bay Area Hospital waiver: Grant (5 year; traditional language)</p>						

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 both 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